Title: Phase 1/2 Study of CORT125134 in Combination with Nab-paclitaxel in Patients with Solid Tumors

NCT Number: NCT02762981

Date: 14 October 2019

# STATISTICAL ANALYSIS PLAN

## Corcept Therapeutics

## CORT125134-550

| | |
|---|---|
| **Protocol Title:** | Phase 1/2 Study of CORT125134 in Combination with Nab-paclitaxel in Patients with Solid Tumors |
| **Protocol Version and Date:** | Amendment 5; 29 May 2018 |
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# 1 STATISTICAL ANALYSIS PLAN APPROVAL

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| **Sponsor:** | Corcept Therapeutics |
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# 3 LIST OF ABBREVIATIONS

**Table 1 List of Abbreviations**

| Abbreviation | Definition |
|---|---|
| ACTH | adrenocorticotropic hormone |
| AE | adverse event |
| ALP | alkaline phosphatase |
| ALT | alanine aminotransferase |
| AST | aspartate transaminase |
| ATC | Anatomical Therapeutic Chemical |
| BMI | body mass index |
| BUN | blood urea nitrogen |
| CAP | chest, abdomen & pelvis |
| CBR | clinical benefit rate |
| CR | complete response |
| CRF | case report form |
| CSR | clinical study report |
| CT | computed tomography |
| CTCAE | Common Terminology Criteria for Adverse Events |
| DHEA | dehydroepiandrosterone |
| DLT | dose-limiting toxicity |
| DOR | duration of response |
| DRC | Data Review Committee |
| ECG | electrocardiogram |
| eCRF | electronic case report form |
| ET | Early Termination |
| FSH | follicle-stimulating hormone |
| G-CSF | granulocyte colony-stimulating factor |
| GR | glucocorticoid receptor |
| ICH | International Conference on Harmonization |
| INR | internalized normalized ratio |
| LDH | lactate dehydrogenase |
| LH | luteinizing hormone |
| MCV | mean corpuscular volume |
| MedDRA | Medical Dictionary for Regulatory Activities |
| MTD | maximum tolerated dose |
| ORR | objective response rate |
| OS | overall survival |

| Abbreviation | Definition |
|---|---|
| PD | pharmacodynamic(s) |
| PE | physical examination |
| PFS | progression-free survival |
| PK | pharmacokinetic(s) |
| PR | partial response |
| RBC | red blood cell |
| RECIST | Response Evaluation Criteria in Solid Tumors |
| SAE | serious adverse event |
| SAP | statistical analysis plan |
| TA | tumor assessment |
| TEAE | treatment-emergent adverse event |
| TSH | thyroid stimulating hormone |
| WBC | white blood cell |
| WHO | World Health Organization |

# 4 INTRODUCTION

The purpose of this statistical analysis plan (SAP) is to provide comprehensive and detailed descriptions of the methods and presentation of data analyses proposed for Corcept Therapeutics Protocol CORT125134-550 (Phase 1/2 Study of CORT125134 in Combination with Nab-paclitaxel in Patients with Solid Tumors). Descriptions of planned analyses are provided in order to avoid post hoc decisions that may affect the interpretation of the statistical analysis. The statistical principles applied in the design and planned analyses of this study are consistent with the International Conference on Harmonisation (ICH) guideline E9 (Statistical Principles for Clinical Trials) (1).

This SAP will be finalized prior to data analysis and before database lock to provide full details, including templates for tables, listings, and figures, to be presented in the clinical study report (CSR). Any changes between the statistical methods provided in the clinical study protocol and this SAP will be explained herein; any changes or deviations from this SAP relative to the final analysis will be fully documented in the CSR. Minor changes or deviations from the templates for tables, figures, and listings need not be documented in the CSR.

# 5 STUDY OBJECTIVES

## 5.1 Primary Study Objective

The primary objective of this study is to determine the maximum tolerated dose (MTD) and the development regimen of the combination of CORT125134 and nab-paclitaxel in patients with solid tumors.

## 5.2 Secondary Study Objectives

The secondary objectives of this study are:

- To characterize the safety profile of the combination of CORT125134 and nab-paclitaxel;
- To characterize the preliminary anticancer activity (objective response rate [ORR], progression-free survival [PFS], and overall survival [OS]) of the combination of CORT125134 and nab-paclitaxel in patients with solid tumors in a dose-finding phase and in patients with specific tumor types;
- To characterize the preliminary anticancer activity (ORR, PFS, and OS) of the combination of CORT125134 and nab-paclitaxel in patients with glucocorticoid receptor (GR)-positive or GR-negative solid tumors enrolled in any part of the study;
- To characterize the pharmacokinetic (PK) and exposure-response of the combination of CORT125134 and nab-paclitaxel in patients with solid tumors in a dose-finding phase and in patients with specific tumor types; and

- To characterize the pharmacodynamic (PD) of the combination of CORT125134 and nab-paclitaxel indicative of modulation of GR function, including hormornal changes and FKBP5.

### 5.3 Exploratory Study Objectives

The exploratory objectives of this study are:

- To evaluate molecular, cellular, and soluable markers in peripheral blood and/or tumor tissue that may be relevant to the mechanism of action of or response/resistance to CORT125134 and

- To evaluate pharmacogenomic (PG) markers to assess genetic factors affecting drug metabolism and transporters.

# 6 INVESTIGATIONAL PLAN

### 6.1 Overall Study Design

This is a Phase 1/2 single-arm, open-label, multi-center study to determine the MTD and to assess safety, PK, PD, and preliminary anticancer activity of the combination of CORT125134 and nab-paclitaxel in patients with solid tumors.

The study will consist of two segments to evaluate alternative dosing schedules of CORT125134: Segment I will evaluate a continuous-dosing regimen and Segment II will evaluate a intermittent-dosing regimen. In Segment I, dose-escalation cohorts will be enrolled to determine the MTD and the development regimen for the continuous-dosing regimen; thereafter, dose-expansion cohorts will be enrolled and treated with the continuous-dosing development regimen to better characterize the antitumor activity in patients with specific tumor types and to better define the safety profile. In Segment II, dose-escalation cohorts will be enrolled to determine the MTD and the development regimen for the intermittent-dosing regimen; thereafter, dose-expansion cohorts will be enrolled and treated with the intermittent-dosing development regimen to better characterize the anticancer activity of that regimen in patients with specific tumor types and to better define the safety profile for that regimen. Enrollment in Segment I and Segment II will be mutually exclusive, and the two segments will enroll patiehnts concurrently.

#### *6.1.1 Segment I Continuous-Dosing Regimen*

- Part 1, Dose-Finding Phase:

    - Patients with any solid tumors for whom nab-paclitaxel is an appropriate therapy, in the opinion of the Investigator, will be enrolled according to a standard 3+3 cohort design.

- The starting dose level will be 100 mg CORT125134, administered once daily (QD), in combination with 80 mg/m$^2$ nab-paclitaxel administered on Days 1, 8, and 15 of a 28-day cycle.
- In Part I there will be a 1-week nab-paclitaxel lead-in (1 dose of nab-paclitaxel on Day 1) and a 1-week CORT125134 lead-in (CORT125134 daily for 7 days) before the start of Cycle 1, and then 28-day cycles consisting of CORT125134 daily for 28 days plus nab-paclitaxel weekly for 3 weeks.
- PK will be characterized after dosing with nab-paclitaxel alone, after 7 days of dosing with CORT125134 alone, and after dosing with the combination of nab-paclitaxel and CORT125134, in Cycle 1 only.
- After a minimum of two dose levels are observed in Part 1, the nab-paclitaxel lead-in may be discontinued per Data Review Committee (DRC) recommendataion if no meaningful drug-drug interactions are observed. If the nab-paclitaxel lead-in is discontinued, the first dose of study drug will be the CORT125134 dose on Day 1 of the CORT125134 lead-in.
- The DRC will review safety, laboratory, and any available PK data from each cohort prior to selecting the dose for the next cohort. Dosing will follow the dose-finding table (Table 3**Error! Reference source not found.**). Dose-limiting toxicities (DLTs) will be identified at each dose level. The MTD and development regimen to be used in Part 2 will be determined.
- A given dose level may be expanded to further evaluate safety, tolerability, PK, or preliminary efficacy at that dose level or in a more restricted patient population (ie see pancreatic cancer specific corhort).

- The Sponsor decided to end study enrollment after completion of Part 1, and plan for Part 2 portion of the study was not carried out.

During Segment 1, patients will have the following in-clinic visits: Screening; Baseline (if needed); Days 1 and 2 of a 1-week nab-paclitaxel lead-in and Days 1 and 7 of a 1-week CORT125134 lead-in before Cycle 1 (patients in Part 1); Cycle 1 Days 1, 8, and 15 (all patients) and Day 9 (patients in Part 1); Cycle ≥ 2 Days 1, 8, and 15; and a Posttreatment or Early Termination (ET) Visit. The Schedule of Visits and Procedures is provided in Section 6.2 (Table 2).

Patients will have safety assessments performed at all scheduled in-clinic visit, PK assessments during the 1-week lead-ins for patients in Part 1 only and during Cycle 1 for all patients, and PD assessments during Cycle 1. Serial PK sampling will be performed for patients.

Tumor assessments will occur at Screening (and Baseline if >28 days elapse between Screening and Cycle 1 Day 1), at the end of Cycle 2, and thereafter every 6–8 weeks and at time of suspicion of disease progression. Confirmation of response will be done as needed as per the Response Evaluation Criteria in Solid Tumors (RECIST). In patients with ovarian, fallopian tube, or primary peritoneal cancer, CA-125 will be assessed at the time of radiologic tumor assessments (baseline and every 6–8 weeks) and response reported per Gynecological Cancer Intergroup (GCIG) criteria in addition to RECIST v1.1.

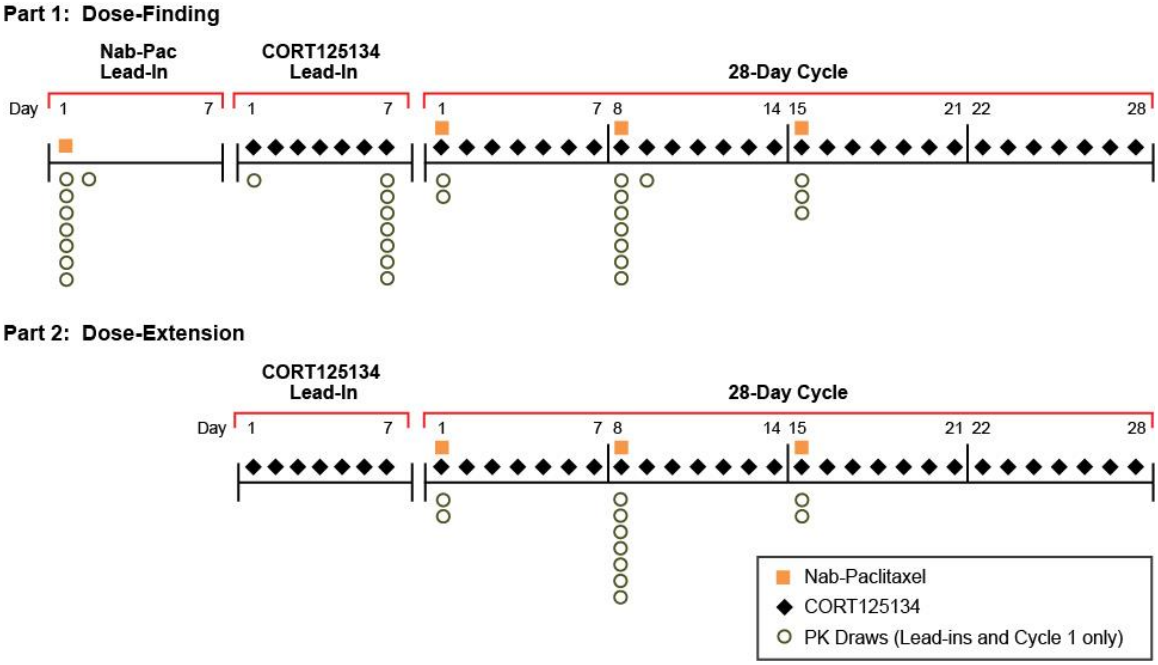
Patients will continue treatment in 28-day cycles until unacceptable toxicity, disease progression, or another withdrawal criterion is met. For patients with ovarian, fallopian tube, or primary peritoneal cancer, PFS will be based on RECIST 1.1 and progression should not be determined early based on increased CA-125 alone.

A Posttreatment Visit for safety will be scheduled within 28 ±7 days after the last dose of study drug. Tumor assessment will be done at this visit if ≥4 weeks have elapsed since the prior tumor assessment and progressive disease has not been documented.

Patients will be contacted by telephone to monitor for survival on a quarterly basis for 1 year after the last dose of study drug (CORT125134 or nab-paclitaxel, whichever is latest) in the last patient on treatment.

The study design scheme showing the dose schedule and planned PK sampling for patients in both parts of Segment I is shown in Figure 1.

**Figure 1 Segment I Continuous-Dosing Regimen: Schematic of Study Drug Dosing and Pharmacokintic Sampling Schedule**




Abbreviations: Nab-Pac, nab-paclitaxel; PK, pharmacokinetic

### *6.1.2 Segment II Intermittent-Dosing Regimen*

- Part 1, Dose-Finding Phase:
    - Patients with any solid tumor, for whom nab-paclitaxel is an appropriate therapy in the opinion of the Investigator, will be enrolled according to a standard 3+3 cohort design.
    - The starting dose level will be 200 mg CORT125134 in combination with 100 mg/m$^2$ nab-paclitaxel. CORT125134 will be administered once daily on the day before, the day of, and the day after the nab-paclitaxel infusions that will be administered on Days 1, 8, and 15 of the 28-day cycle.
    - PK will be characterized in Cycle 1 only, during treatment with combination nab-paclitasel and CORT125134.
    - The DRC will review safety, laboratory, and any available PK data from each cohort before selecting the dose for the next cohort. Dosing will follow the dose-finding table (Table 4**Error! Reference source not found.**). DLTs will be identified at each dose level. The MTD and development regimen to be used in further investigation will be determined.
- The Sponsor decided to end study enrollment after completion of Part 1, and plan for Part 2 portion of the study was not carried out.

During Segment II, patients will have the following in-clinic visits: Screening; Baseline/ CORT125134 Lead-in (Day −1); Cycle 1 Days 1, 2, 8, and 15 (all patients); Cycle ≥2 Days 1, 8, and 15; and a Posttreatment or Early Termination Visit. The Schedule of Visits and Procedures is provided in Section 6.2 (Table 3).

Patients in Segment II will follow the same schedule. After completing Screening assessments, patients will visit the clinic on Day −1 to complete their Baseline assessments then take their first dose of CORT125134. They will return to the clinic on Day 1 of Cycle 1 to receive their first infusion of nab-paclitaxel in combination with CORT125134, which is the start of the 28-day regimen of CORT125134 and nab-paclitaxel.

Patients will have safety assessments performed at all scheduled in-clinic visits, and serial PK assessments during the first 24 hours (ie, Day 1 predose through predose on Day 2) and on Day 15 of Cycle 1 only.

Tumor assessments will occur at Screening (and Baseline if >28 days elapse between Screening and Cycle 1 Day 1), at the end of Cycle 2, and thereafter every 6–8 weeks and at time of suspicion of disease progression. Confirmation of response will be done as needed as per RECIST. In patients with ovarian, fallopian tube, or primary peritoneal cancer, CA-125 will be assessed at the time of radiologic tumor assessments (baseline

and every 6–8 weeks) and response reported per GCIG criteria in addition to RECIST v1.1.

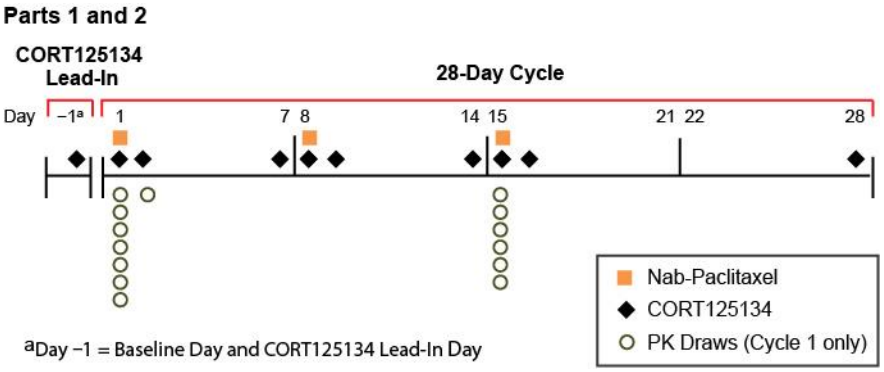
Patients will continue treatment in 28-day cycles until unacceptable toxicity, disease progression, or another withdrawal criterion is met. For patients with ovarian, fallopian tube, or primary peritoneal cancer, PFS will be based on RECIST 1.1 and progression should not be determined early based on increased CA-125 alone.

A Posttreatment Visit for safety will be scheduled within 28 ±7 days after the last dose of study drug. Tumor assessment will be done at this visit if ≥4 weeks have elapsed since the prior tumor assessment and progressive disease has not been documented.

Patients will be contacted by telephone to monitor for survival on a quarterly basis for 1 year after the last dose of study drug (CORT125134 or nab-paclitaxel, whichever is latest) in the last patient on treatment.

The study design scheme showing the dose schedule and planned PK sampling for patients in both parts of the Segment II is presented in Figure 2**Error! Reference source not found.**.

**Figure 2 Segment II Intermittent-Dosing Regimen: Schematic of Study Drug Dosing and Pharmacokinetic Sampling Schedule**




Abbreviation: NPK, pharmacokinetic

## 6.2 Schedule of Assessments

### Table 2 Segment I: Study Visits and Procedures

| Procedures/ Examinations [a] | Screening | Baseline [b] | 1-wk Nab-paclitaxel Lead-in [c] | | 1-wk CORT125134 Lead-in | | Cycle 1 (28-day cycle) | | | | Cycle 2+ (28-day cycles) | | | Post-Tx / ET |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Day -28 to -1 | Day -7 to -1 | Day 1 | Day 2 | Day 1 | Day 7 | Day 1 | Day 8 | Day 9 | Day 15 | Day 1 | Day 8 | Day 15 | |
| Informed consent [d] | X | | | | | | | | | | | | | |
| Inclusion/exclusion criteria [b] | X | X | | | | | X | | | | | | | |
| Medical/oncologic history [e] | X | | | | | | | | | | | | | |
| Physical examination (PE) [b,f] | X | X | | | | | X | X | | X | X | X | X | X |
| Vital signs [b,g] | X | X | X | | | | X | X | | X | X | X | X | X |
| ECOG performance status [b] | X | X | | | | | X | X | | X | X | X | X | X |
| ECG | X | | | | | X[h] | | | | | If clinically indicated | | | |
| Pregnancy test [i] | X | X | | | | | Every 12 wk (±7 d) | | | | | | | X |
| Hematology [b,j] | X | X | X | | X | | X | X | | X | X | X | X | X |
| Chemistry and INR [b,k] | X | X | | | | | X | X | | X | X | X | X | X |
| Fasting insulin | | X | | | | | | | | X [k] | | | | |
| Thyroid function test [l] | | X[l] | | | | | Every 12 weeks (±14 d) | | | | | | | |
| Hormone levels [m] | | X[m] | | | | | | | | X | | | | |
| Urinalysis (dipstick) [b,n] | X | X | | | | | X | | | | X [n] | | | X |
| Tumor assessment (RECIST v1.1) [o] | X | X | | | | | | | | | C3 D1 (±7 d) then every 6–8 wk | | | X[o] |
| PD/biomarker blood sample [p] | | X[p] | | | | | | | | X | Every 12 wk (±14 d) | | | X |
| Cytokine and T cell sample [q] | | | X | | | X | | X | | | | | | |
| Optional PG sample | | X | | | | | | | | | | | | |
| Tumor tissue for GR IHC: [r] archival or biopsy [s] | X | | | | | | | | | | | | | |
| Follow-up for survival [t] | | | | | | | | | | | | | | X[t] |
| Adverse events [u] | X | ← | — | — | — | — | — | — | — | — | — | — | → | X |
| Concomitant medications [v] | X | ← | — | — | — | — | — | — | — | — | — | — | → | X |
| PK/metabolites sample collection [w] | | | X | X | X | X | X | X | X | X | | | | |
| **Study treatment administration** | | | | | | | | | | | | | | |
| CORT125134 – oral [x,y] | | | | | ← | — | — | — | — | — | — | — | → | |

| | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Nab-paclitaxel – IV [x,y] | | | X | | | | X | X | | X | X | X | X | |

Note: The acceptable visit window is ± 3 days for Day 1 of each Cycle after Cycle 1. Nab-paclitaxel infusions must be no less than 7 days apart, and the recommended window for Day 8 and 15 is no more than +24 hours. No visit window is allowed for Nab-paclitaxel Lead-in Day 2, Cycle 1 Day 1, and Cycle 1 Day 9 due to the planned collection of the 24-hour PK samples. Posttreatment/Early Termination Visit to occur 28 (±7) days after the last dose of study drug.

a. All procedures and examinations should be performed before the administration of study treatment(s), unless specifically stated otherwise.
b. Inclusion/exclusion criteria and selected safety assessments (vital signs, ECOG, PE, and laboratory tests) are required to be repeated only for patients for whom screening assessments were performed >7 days before Day 1 of the 1-week lead-in (first dose of study treatment).
c. Patients in Part 1 will have a 1-week Nab-paclitaxel Lead-in before the 1-week CORT125134 Lead-in. After a minimum of two dose levels are observed, the nab-paclitaxel lead-in may be discontinued per the DRC recommendation.
d. The IRB-approved ICF must be signed before any study-specific procedures or examinations are performed.
e. Including prior cancer treatments. Any new or clinically significant changes in the patient's medical or oncologic history between signing of the IRB-approved ICF and the first dose of study treatment will be recorded on the AE CRF page.
f. Physical examinations at Screening/Baseline, at Day 1 of each cycle, and at the Posttreatment/Early Termination Visit should be complete assessments. Other weekly examinations may be focused, to identify changes from Screening/Baseline or evaluate changes based on the patient's clinical symptoms. Weight to be reported at each visit, height at Screening/Baseline Visit only.
g. On days of nab-paclitaxel IV administration, vital signs (heart rate, systolic and diastolic blood pressure, temperature, and respiration rate) should be collected pre-infusion and within 5 minutes after stopping the nab-paclitaxel infusion.
h. ECGs to be done at Screening (in triplicate) and at CORT125134 Lead-in Day 7 predose and 2.5 hours ±30 minutes postdose (in duplicate).
i. For women of childbearing potential, serum or urine pregnancy test is required at Screening/Baseline and at Posttreatment/Early Termination Visits. Serum or urine pregnancy test to be performed every 3 cycles (approximately every 12 weeks ±1 week). If treatment with CORT125134 is stopped for ≥7 days, patient should have a negative pregnancy test before restarting drug.
j. Hematology: Nab-paclitaxel Lead-in Day 1 hematology to be obtained if previous hematology done >7 days prior. If weekly hematology tests demonstrate CTCAE Grade 3/4 cytopenias, increase frequency as clinically appropriate. Hematology assessments scheduled for the day of study drug dosing must be available and assessed for toxicity before dosing. The sampling for hematology assessment may be drawn within 48 hours before dosing.
k. Chemistry: Baseline (Nab-paclitaxel Lead-in Day 1) and Cycle 1 Day 15 laboratory samples should be obtained in a fasting state to collect the fasting glucose and fasting insulin samples. Coagulation (INR) performed weekly for patients on warfarin. Samples for these assessments can be drawn within 48 hours before dosing.
l. TSH is to be measured at Baseline (Nab-paclitaxel Lead-in Day 1 [predose]) and every 12 weeks (±14 days) for the first year and then every 6 months thereafter. Post-Screening, testing can be on the same schedule as pregnancy testing. Free T4 and total T3 will be measured if TSH values are abnormal.
m. Estradiol, testosterone, FSH, LH, and DHEA-S. Draw predose at Baseline (Nab-paclitaxel Lead-in Day 1) and Cycle 1 Day 15. A fasting, early morning specimen (7–9 AM) is preferred.
n. Urinalysis at Screening, Baseline, Cycle 1 Day 1, Cycle 2 Day 1, Cycle 3 Day 1, then every 12 weeks (±14 days) thereafter and at the Posttreatment Visit. Microscopy is required only to follow-up clinically significant urine dipstick findings.
o. Tumor assessments (TAs): Screening—CAP CT scans done with contrast as standard of care ≤30 days of Screening may be used if they meet study quality criteria. Baseline—CAP CT scans with contrast done ≤28 days before the first dose of study drug will not need to be repeated for this time point. Subsequent TAs occur at Cycle 3 Day 1 (±7 days) and thereafter every 6–8 weeks (no more than 8 weeks between scans) and at time of clinical suspicion of disease progression. In patients with ovarian, fallopian tube, or primary peritoneal cancer, CA-125 levels will be assessed at the time of radiologic tumor assessments; levels of other biomarker collected as standard practice (such as CA15-3 and CA19-9, PSA, and CEA) will be documented in the case report form. At the Posttreatment/Early Termination Visit, TA will be done if ≥4 weeks have elapsed since the prior TA and progressive disease as not been documented.

p. Draw fasting, morning (7–9 AM) C-peptide, ACTH, morning cortisol, and FKBP5 at Baseline (Day 1 of Nab-paclitaxel Lead-in) and at Cycle 1 Day 15 before administration of any study treatment. FKBP5, morning cortisol, and ACTH will be repeated every 12 weeks (±14 days) for the first year and then approximately every 6 months thereafter and at the Posttreatment/End of Treatment Visit.
q. Cytokines and T cell samples for patients in Part 1 are drawn predose and at 4 hours (±30 minutes) postdose to coincide with the PK time points on Nab-paclitaxel Lead-in Day 1, on CORT125134 Lead-in Day 7, and Cycle 1 Day 8. For patients in Part 2, samples are drawn at Cycle 1 Day 8 before and at 4 hours (±30 minutes) after nab-paclitaxel infusion. Samples at all time points can be drawn with PK sample collections.
r. Tumor tissue for GR IHC (archival or biopsy) is mandatory for patients in the study. Optional tumor tissue biopsy at the time of disease progression.
s. Archival tumor tissue may consist of tumor block or 15 unstained formalin-fixed, paraffin-embedded slides (tissue block preferred). Tumor biopsy for screening GR IHC analysis is to be performed if archival tumor tissue is not available.
t. Patients will be followed for progression and survival via telephone on a quarterly basis for 1 year after the last dose of study drug in the last patient on treatment.
u. All AEs, including SAEs, will be recorded from the time of signing of the IRB-approved ICF until 28 days after the last dose of study treatment. An SAE related to study procedures or study conduct must be reported to the Sponsor if it occurs before first dose of study drugs. SAEs must be reported. Treatment-related AEs ongoing at the Posttreatment Visit should be followed to resolution or until the Investigator considers them “chronic” or “stable”. At the occurrence of a SAE or DLT, an additional ACTH, and cortisol blood sample and a PK sample will be drawn at the discretion of the Investigator, as close to the event as possible to help characterize any possible relationships between drug exposure and the clinical event.
v. All concomitant medications (including over-the-counter and herbal treatments) should be recorded from 28 days before the first dose until 28 (±7 days) after the last dose of study drug.
w. See PK sampling times.
x. CORT25134 will be dispensed to patients as blister packs of capsules to be self-administered orally once daily in the morning, starting with CORT125134-550 Lead-In Day 1. Patients should return all unused CORT125134 capsules and the dose diary during the patient visits, and patient adherence to treatment should be assessed. On visit days, CORT125134 should be taken in the clinical during the visit and after initial blood draws with time and dose administration documented in the clinic charts. On days when CORT125134 and nab-paclitaxel are administered in combination, CORT125134 is to be administered within 15 minutes before the start of nab-paclitaxel infusion.
y. All clinical laboratory results must be available and reviewed by the Investigator or Subinvestigator before each IV infusion of nab-paclitaxel and start of subsequent treatment cycles of CORT125134/nab-paclitaxel.

## Table 3 Segment II: Study Visits and Procedures

| Procedures/ Examinations[a] | Screening | Baseline/CORT125134 Lead-in [b] | Cycle 1 (28-day cycle) | | | Cycle 2+ (28-day cycles) | | Post-Tx / ET |
|---|---|---|---|---|---|---|---|---|
| | Day −28 to −2 | Day −1 | Day 1 | Day 2 | Day 8, 15 | Day 1 | Day 8, 15 | |
| Informed consent [c] | X | | | | | | | |
| Inclusion/exclusion criteria [b] | X | X | | | | | | |
| Medical/oncologic history [d] | X | | | | | | | |
| Physical examination (PE) [b,e] | X | X | | | X | X | X | X |
| Vital signs [b,f] | X | X | X | | X | X | X | X |
| ECOG performance status [b] | X | X | | | X | X | X | X |
| ECG [g] | X | | X[g] | | | If clinically indicated | | |
| Pregnancy test [h] | X | X | Every 12 weeks (±7 days) | | | | | X |
| Hematology [b,i] | X | X | X | | X | X | X | X |
| Chemistry and INR [b,j] | X | X | | | X | X | X | X |
| Fasting insulin | | X | | | X [i] | | | |
| Thyroid function test [k] | | X | Every 12 wk (±14 days) | | | | | |
| Hormone levels [l] | | X | | | X [l] | | | |
| Urinalysis (dipstick) [b,m] | X | X | | | | X | | X |
| Cytokine and T cell sample [n] | | X | X | | | | | |
| Optional PG sample | | X | | | | | | |
| Tumor assessment (RECIST v1.1) [o] | X | X | | | | Cycle 3 Day 1 (±7 days) then every 6–8 wk | | X[o] |
| PD/biomarker blood sample collection [p] | | X[p] | | | X | Every 12 wk (±14 d) | | X |
| Tumor tissue for GR IHC:[q] archival or biopsy [r] | X | | | | | | | |
| Follow-up for survival [s] | | | | | | | | X[s] |
| Adverse events [t] | X ← | | | | | | | → X |
| Concomitant medications [u] | X ← | | | | | | | → X |
| PK/metabolites sample collection [v] | | | X[v] | X[v] | X[v] | | | |
| Study treatment administration[w,x] | | | | | | | | |

Note: The acceptable visit window is ±3 days for Day 1 of each Cycle after Cycle 1. Nab-paclitaxel infusions must be no less than 7 days apart, and the recommended visit window for Day 8 and Day 15 is no more than +24 hours. On Cycle 1 Day 2 no visit window is allowed due to the planned collection of the 24-hour PK samples. Posttreatment/Early Termination Visit to occur 28 (±7) days after the last dose of study drug.

a. All procedures and examinations should be performed before the administration of study treatment(s), unless specifically stated otherwise.
b. Inclusion/exclusion criteria and selected safety assessments (vital signs, ECOG, PE, and laboratory tests) are required to be repeated only for patients for whom screening assessments were performed >7 days before Day −1 (first dose of CORT125134).
c. The IRB-approved ICF must be signed before any study-specific procedures or examinations are performed.
d. Including prior cancer treatments. Any new or clinically significant changes in the patient's medical or oncologic history between signing of the IRB-approved informed consent form and the first dose of study treatments will be recorded on the AE CRF page.
e. Physical examinations at Screening, at Day 1 of each cycle except Cycle 1 Day 1 when it is performed on Baseline/Day −1, and at the Posttreatment/Early Termination Visit should be complete assessments. Other weekly examinations may be focused, to identify changes from Screening/baseline or evaluate changes based on the patient's clinical symptoms. Weight to be reported at each visit, height at Screening/Baseline visit only.
f. On days of nab-paclitaxel IV administration, vital signs (heart rate, systolic and diastolic blood pressure, temperature, and respiration rate) should be collected pre-infusion and within 5 minutes after stopping the nab-paclitaxel infusion.
g. ECGs to be done at Screening (in triplicate) and at Cycle 1 Day 1 pre-CORT125134 dose and 2.5 hours ±30 minutes after start of nab-paclitaxel infusion (in duplicate).
h. For women of childbearing potential, serum or urine pregnancy test is required at Screening/Baseline and at Posttreatment/Early Termination Visits. Serum or urine pregnancy test to be performed every 3 cycles (approximately every 12 weeks ±1 week). If treatment with CORT125134 is stopped for ≥7 days, patient should have a negative pregnancy test prior to restarting drug.
i. Hematology: If weekly hematology tests demonstrate CTCAE Grade 3/4 cytopenias, increase frequency as clinically appropriate. Hematology assessments scheduled for the day of study drug dosing must be available and assessed for toxicity before dosing. The sampling for hematology assessment may be drawn within 48 hours prior to dosing.
j. Chemistry: Baseline/Day –1 and Cycle 1 Day 15 laboratory samples should be obtained in a fasting state to collect the fasting glucose and fasting insulin samples. Coagulation (INR) performed weekly for patients on warfarin. Samples for these assessments can be drawn within 48 hours before dosing.
k. TSH is to be measured at Baseline/Day–1 and every 12 weeks (±14 days) for the first year and then every 6 months thereafter. After Screening, testing can be on the same schedule as pregnancy testing. Free T4 and total T3 will be measured if TSH values are abnormal.
l. Estradiol, testosterone, FSH, LH, and DHEA-S. Draw predose at Baseline/Day −1 and Cycle 1 Day 15. A fasting, early morning specimen (7–9 AM) is preferred.
m. Urinalysis at Screening, Baseline/Day–1, Cycle 2 Day 1, Cycle 3 Day 1, then every 12 weeks (±14 days) thereafter and at the Posttreatment Visit. Microscopy is required only to follow-up clinically significant urine dipstick findings.
n. Cytokine and T cell samples are drawn at Baseline/Day -1 predose, and Cycle 1 Day 1 predose and at 4 hours (±30 minutes) after nab-paclitaxel infusion. All samples can be drawn with PK sample collections.
o. Tumor assessments (TAs): Screening—CAP CT scans done with contrast as standard of care ≤30 days of Screening may be used if they meet study quality criteria. Baseline—CAP CT scans with contrast done ≤28 days before the first dose of study drug will not need to be repeated for this time point. Subsequent TAs occur at Cycle 3 Day 1 (±7 days) and thereafter every 6–8 weeks (no more than 8 weeks between scans) and at time of clinical suspicion of disease progression. In patients with ovarian, fallopian tube, or primary peritoneal cancer, CA-125 levels will be assessed at the time of radiologic tumor assessments; levels of other biomarker collected as standard practice (such as CA15-3 and CA19-9, PSA, and CEA) will be documented in the case report form. At the Posttreatment/Early Termination Visit, TA will be done if ≥4 weeks have elapsed since the prior TA and progressive disease as not been documented.
p. Draw fasting, morning (7–9 AM) C-peptide, ACTH, cortisol, and FKBP5 at Baseline/Day −1 before administration of any study treatment and at Cycle 1 Day 15. FKBP5, morning cortisol, and ACTH will be repeated every 12 weeks (±14 days) for the first year and then approximately every 6 months thereafter and at the Posttreatment/End of Treatment assessment
q. Tumor tissue for GR IHC (archival or biopsy) is mandatory for patients in the study. Optional tumor tissue biopsy at the time of disease progression.

r. Archival tumor tissue may consist of tumor block or 15 unstained, formalin-fixed, paraffin-embedded slides(tissue block preferred). For patients enrolled in the study, tumor biopsy for screening GR IHC analysis is to be performed if archival tumor tissue is not available.
s. Patients will be followed for survival via telephone on a quarterly basis for 1 year after the last dose of study drug in the last patient on treatment.
t. All AEs, including SAEs, will be recorded from the time of signing of the IRB-approved ICF until 28 days after the last dose of study drug. An SAE related to study procedures or study conduct must be reported to Sponsor if it occurs prior to first dose of study drugs. SAEs must be reported as described in the protocol. Treatment-related AEs ongoing at the Posttreatment Visit should be followed to resolution or until the Investigator considers them "chronic" or "stable". At the occurrence of a SAE or DLT, an additional cortisol and ACTH sample and a PK sample will be drawn, at the discretion of the Investigator, as close to the event as possible to help characterize any possible relationships between drug exposure and the clinical event.
u. All concomitant medications (including over-the-counter and herbal treatments) should be recorded from 28 days before the first dose until 28 (±7 days) after the last dose of study drug.
v. See PK sampling times.
w. CORT25134 will be dispensed to patients as blister packs of capsules to be self-administered orally once daily in the morning, starting with CORT125134-550 Lead-In Day 1. Patients should return all unused CORT125134 capsules and the dose diary during the patient visits, and patient adherence to treatment should be assessed. On visit days, CORT125134 should be taken in the clinical during the visit and after initial blood draws with time and dose administration documented in the clinic charts. On days when CORT125134 and nab-paclitaxel are administered in combination, CORT125134 is to be administered within 15 minutes before the start of nab-paclitaxel infusion.
x. All clinical laboratory results must be available and reviewed by the Investigator or Subinvestigator before each IV infusion of nab-paclitaxel and start of subsequent treatment cycles of CORT125134/nab-paclitaxel.

## 6.3 Treatments

### *6.3.1 Treatments Administered*

Study treatments for Segment I, Continous-Dosing Regimen:

- CORT125134 is administered orally once daily in the morning for 7 days in a 1-week lead-in prior to Cycle 1 and once daily in the morning for 28 days during each 28-day cycle, preferably at the same time each day.
    - On the days nab-paclitaxel is administered, CORT125134 should be taken within 15 minutes before the start of nab-paclitaxel infusion.
    - On in-clinic visit days, CORT125134 should not be taken at home but brought to the clinic and taken after any scheduled predose PK samples are drawn.
- Nab-paclitaxel is administered by IV infusion over 30 minutes on Day 1 of a 1-week nab-paclitaxel lead-in for patients in Part 1 and on Days 1, 8, and 15 of each 28-day cycle for all patients. Nab-paclitaxel infusions must be no less than 7 days apart. After a minimum of two dose levels are observed, the nab-paclitaxel lead-in may be discontinued per the DRC recommendation.

Study treatments for Segment II, Intermittent-Dosing Regimen:

- CORT125134 is administered orally once daily in the morning the day before, the day of, and the day after nab-paclitaxel infusion.
    - On the days nab-paclitaxel is administered, CORT125134 should be taken within 15 minutes before the start of nab-paclitaxel infusion.
    - On in-clinic visit days, CORT125134 should not be taken at home but brought to the clinic and taken after any scheduled predose PK samples are drawn.
- Nab-paclitaxel is administered by IV infusion over 30 minutes on Days 1, 8, and 15 of each 28-day cycle for all patients. Nab-paclitaxel infusions must be no less than 7 days apart.

#### *6.3.1.1 Dose Levels in Segment I*

In Segment I, the starting dose in Part 1 is 100 mg CORT125134 in combination with 80 mg/m$^2$ nab-paclitaxel. CORT125134 dose escalation will proceed by a maximum of 50 mg per dose level. Example target dose levels for evaluation in Segment I, Part 1 are shown in Table 4**Error! Reference source not found.**. The starting dose of 100 mg C ORT125134 is at the low end of the anticipated range of doses, yet retains the potential for PD effect. The starting dose of 80 mg/m$^2$ nab-paclitaxel is at the lower end of the

range for a standard dose of nab-paclitaxel. With the starting dose level set in a conservative manner, the plan is to escalate the investigational product, CORT125134, sequentially in 50 mg increments through the dose-finding phase of the study.

**Table 4 Segment I Continous Dosing: Example Dose-Finding Table of CORT125134 / Nab-paclitaxel Dose Levels for Part 1**

| Dose Level | CORT125134 Dose (mg) | Nab-paclitaxel Dose [a] ($mg/m^2$) |
|---|---|---|
| −1 | 50 | 80 |
| 1 Starting dose | 100 | 80 |
| 2 | 150 | 80 |
| 3 | 200 | 80 |
| 4 | 250 [b] | 80 |

[a] Taking the nab-paclitaxel exposure and safety data into account, the nab-paclitaxel dose may be increased to 100 mg/m2 or decreased to 60 $mg/m^2$. Nab-paclitaxel and CORT125134 will not be escalated simultaneously; therefore, a change in dose for nab-paclitaxel would constitute a separate dose level.

[b] Doses may exceed 250 mg CORT125134 based on safety and PK data and DRC recommendation.

### *6.3.1.2 Dose Levels in Segment II*

In Segment II, the starting dose level in Part 1 is 200 mg CORT125134 in combination with 100 $mg/m^2$ nab-paclitaxel. CORT125134 dose escalation is expected to proceed by 100 mg per dose level (Table 5). However, CORT125134 doses may be escalated in 50 mg increments if recommended by DRC. In Segment II, the DRC may recommend modifying the nab-paclitaxel dose to 80 $mg/m^2$ based on the nab-paclitaxel exposure and safety data. As noted above, enrollment in Segment I and Segment II will be mutually exclusive, and the two segments will enroll patients concurrently.

**Table 5 Segment II Intermittent-Dosing Regimen: Example Dose-Finding Table of CORT125134 / Nab-paclitaxel Dose Levels for Part 1**

| Dose Level | CORT125134 Dose (mg) | Nab-paclitaxel Dose ($mg/m^2$) |
|---|---|---|
| −1 | 150 | 100 |
| 1 – Starting dose | 200 | 100 |
| 2 | 300 | 100 |
| 3 | 400 [a] | 100 |

[a] Doses may exceed 400 mg CORT125134 based on DRC recommendation.

Nab-paclitaxel may be dose reduced or dosed increased based on PK and DDI findings.
CORT125134 doses may change in 50, or 100 mg increments based on DRC recommendations.

### *6.3.1.3 Dose Finding-Process*

Dose-finding decisions including selection of dose levels for cohorts, determination of the MTD and development regimen, and stopping enrollment, as applicable, will be performed by a DRC. The key principles guiding DRC recommendations for dose levels in dose-finding are to ensure that patients receive nab-paclitaxel at therapeutic exposures and to sequentially increase the dose of CORT125134 as tolerated.

Dose escalation or de-escalation will occur only after review of data from the first cohort by the DRC. If a lower dose level is explored and is well tolerated, the DRC may recommend re-escalating either CORT125134 or nab-paclitaxel.

During the Part 1 Dose-Escalation Phase, on review of safety, laboratory, and available PK data from each cohort, the DRC may recommend proceeding to the next dose level per Table 4 for Segment I and per Table 5 for Segment II. Alternatively, taking PK and safety data into account, the DRC could recommend modifying the nab-paclitaxel dose (eg, with an increase to 100 mg/m$^2$ or a decrease to 60 mg/m$^2$ in Segment I) for reasons including:

- Dose finding requires greater resolution to the titration of nab-paclitaxel exposure than may be induced by changes in dose of CORT125134 due to significant metabolic interaction (eg, increasing nab-paclitaxel dose by one step would increase nab-paclitaxel exposure to a lesser degree than increasing CORT125134 dose by one step).

- There is no significant metabolic interaction between CORT125134 and nab-paclitaxel.

- An AE profile is encountered that is not suggestive of a nab-paclitaxel effect and hence may be attributed to CORT125134.

For dose escalation, either CORT125134 or nab-paclitaxel, but not both, will be changed in the next dose level, based on recommendations by the DRC. If a lower dose level is explored and is well tolerated, the DRC may recommend re-escalating either CORT125134 or nab-paclitaxel.

All patients in the Part 1 Dose-Escalation cohorts in Segment I and Segment II will be treated with CORT125134 plus nab-paclitaxel and assessed for 1 cycle. Approximately 5 patients may be initially enrolled in a cohort, and non-DLT evaluable patients may be replaced to allow for a minimum of 3 evaluable patients for each cohort. Depending on the number of patients with DLTs, additional patients will be enrolled in the same cohort or additional cohorts will be enrolled following the criteria described in Table 6.

**Table 6 Rules for Dose-Finding to Define Maximum Tolerated Dose in Part 1 of Segment I and II**

| No. of Evaluable Patients with DLT at a Dose Level (cohort of <6 evaluable patients) | Dose-Escalation Decision Rule in Cycle 1 |
|---|---|
| 0 | • Enroll cohort at next higher dose level. |
| 1 | • Expand current dose level to 6 patients[a]<br>• If 1 of 6 patients (<33%) experiences DLT, enroll cohort at next higher dose level.<br>• If ≥2 of 6 patients (≥ 33%) experience DLT:<br>– Enroll cohort at next lower dose level, if available.<br>OR<br>– Declare next lower dose level as the MTD. |
| ≥2 | • If ≥2 patients experience DLT:<br>– Enroll cohort at next lower dose level, if available.<br>OR<br>– Declare next lower dose level as the MTD. |

Abbreviations: DLT, dose-limiting toxicity; MTD, maximum tolerated dose

[a] The DRC may make the recommendation to adjust the size of a cohort to more than 6 patients to further the evaluation of a given dose level, such as further evaluation of PK data or tolerability. If cohorts are >6 patients, the decision rule will be based on the percentage of patients experiencing DLT within that cohort.

The MTD is defined as the highest dose at which <33% (eg, 0 of 3 or 1 of 6 patients, with a minimum of 6 patients if 1 DLT is observed) experiences a DLT during Cycle 1. Alternatively, a different (lower) dose level may be declared the MTD depending on the nature, severity, and frequency of toxicities to date. Safety data that become available for patients remaining on-study after Cycle 1 will be taken into consideration when making decisions about dose escalation.

The dose level selected for the development regimen may be equal to or lower than the MTD and its selection will take into account other issues such as safety data occurring after the first cycle.

A sufficient number of patients will be enrolled in each cohort to ensure that there are DLT-evaluable patients available for determination of the MTD and identification of the development regimen. The number of DLT-evaluable patients may be inclusive of all cohorts at that dose level and schedule (such as advanced solid tumor and pancreatic cancer cohorts in Segment I) for determination of the MTD or dose-finding decisions, per DRC recommendation. If two distinct DLTs, such as events occurring in different MedDRA system organ classes, are observed within a dose level, the DRC may recommend expanding the cohort to >6 patients to further evaluate the tolerability of that dose level. DLT-evaluable patients will include those who complete one cycle of treatment or those who withdraw from the study due to toxicity during Cycle 1.

- DLT-evaluable patients will include those who complete one cycle of treatment or those who withdraw from the study due to toxicity during Cycle 1.

- Non-evaluable patients will include patients who withdraw from the study prior to completion of Cycle 1 for reasons other than toxicity (eg, lost to follow-up, withdrawal of consent, disease progression, or receipt of ≤80% of CORT125134 dosing due to reasons other than toxicity); these patients may be replaced.

- PK for patients with a history of GI resection or gastric bypass surgery will be considered separately from the remainder of the cohort. The safety data for these patients will be taken into consideration in the assessment of the overall tolerability of a given cohort. A minimum number of patients evaluable for DLT will be enrolled to a cohort to consider the tolerability at this dose level who don't have a history of GI resection/gastric bypass surgery.

Based on safety data from the initial dose-finding cohorts, the DRC may recommend following an alternative dose-finding strategy that evaluates any of the dose levels in the planned Part 1 phases with inclusion of granulocyte colony-stimulating factor (G-CSF).

- A given dose level may be expanded to further evaluate safety, tolerability, PK, or preliminary efficacy at that dose level or in a more restricted patient population.

- A dose of CORT125134 100 mg continuous dosing and nab-paclitaxel 60 mg/m2 with prophylactic G-CSF support will be explored in patients with pancreatic cancer. Initially, approximately 6–8 patients will be enrolled in this cohort. The DRC will review the safety and tolerability after 6 DLT-evaluable patients complete 1 cycle of therapy. If the dose-limiting toxicity (DLT) rate exceeds 33%, the dose will be declared non-tolerable for this population (tumor type and similar line of therapy) and no additional patients will be enrolled to that cohort. Alternatively, a higher or lower dose level may be evaluated, per the recommendation of the DRC based on safety and PK data. Once the dose level is declared tolerable, the cohort will be expanded to include approximately 12–15 additional patients to further assess the safety and efficacy of this dose level. Safety and efficacy data from all pancreatic cancer patients receiving this dose level will be summarized. The DRC will take into consideration the overall tolerability and toxicities observed in this cohort(s) to inform dose escalation decisions and the recommended Phase 2 dose.

### *6.3.2 Method of Assigning Patients to Treatment Groups*

This is an open-label study with approximately 146 patients planned; estimates are as follows:

- Segment I Continuous-Dosing Regimen—Part 1, approximately 62 patients;
  In addition to the standard dose finding process, approximately 6–8 patients with pancreatic cancer will be enrolled in Part 1 at a dose level of CORT125134 100 mg continuous dosing and nab-paclitaxel 60 mg/m2 with prophylactic G-CSF. The DRC will review the safety and tolerability after 6 DLT-evaluable patients complete 1 cycle of therapy. If the dose-limiting toxicity (DLT) rate exceeds 33%, the dose will be declared non-tolerable for this population (tumor type and similar

line of therapy) and no additional patients will be enrolled to that cohort. Alternatively, a higher or lower dose level may be evaluated, per the recommendation of the DRC based on safety and PK data. Once the dose level is declared tolerable, the cohort will be expanded to include approximately 12–15 additional patients to further assess the safety and efficacy of this dose level. Segment II Intermittent-Dosing Regimen—Part 1, approximately 24 patients.

## 6.4 Efficacy and Safety Variables

### *6.4.1 Efficacy Variables*

#### *6.4.1.1 Analysis of Anticancer Activity*

The efficacy objective of this study is to make a preliminary assessment of the anticancer activity of CORT125134 in combination with nab-paclitaxel in patients with the selected tumor types. The efficacy analyses will characterize anticancer activity for the following endpoints:

- ORR consisting of the percent of patients with an objective tumor response: measurable disease with partial response (PR) or complete response (CR) as defined by RECIST v1.1 and confirmed on a second, consecutive scan obtained no less than 4 weeks after the criteria for response are first met in cohorts of patients treated with the development regimen.

- Best response defined as the best response recorded from the date of the first dose of CORT125134 or nab-paclitaxel, whichever is earliest, across all time points during study observation period (including both confirmed and unconfirmed responses).

- Clinical benefit rate (CBR) defined as the percentage of patients who have achieved CR or PR, or SD for 16 weeks or greater.

- Progression-free survival will be defined as the time from the date the patient receives the first dose of CORT125134 or nab-paclitaxel, whichever is earliest, to the date the patient experiences unequivocal disease progression per RECIST v1.1 or death (all causes of mortality).

- Duration of response (DOR) as measured from the date that the criteria are met for complete response (CR) or partial response (PR) until the first date that progressive disease is objectively documented.

- Overall survival defined as the time from date of the first dose of CORT125134 or nab-paclitaxel, whichever is earliest, until the date of death from any cause.

Table 7 defines the RECIST v1.1 Response Criteria.

**Table 7 RECIST v1.1 Response Criteria**

| Response | Criteria |
|---|---|
| Complete Response (CR) | Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to < 10 mm. |
| Partial Response (PR) | At least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters. |
| Progressive Disease (PD) | At least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum on study (this includes the baseline sum if that is the smallest on study). In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm. (Note: the appearance of one or more new lesions is also considered progression). |
| Stable Disease (SD) | Neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for PD, taking as reference the smallest sum diameters while on study. |

Tumor tissue will be collected for GR IHC analysis throughout the study and summarized as part of the clinical study report; however, summarization of GR expression is outside the scope of this SAP.

#### *6.4.1.2 Gynecological Cancer Intergroup Definitions for Response and Progression in Ovarian Cancer*

Tumor response and assessment according to GCIG is described below. This description is not exhaustive and the source (5) should be referred to for further detail.

##### 6.4.1.2.1 Definition of Response

A CA-125 response is defined as at least a 50% reduction in CA-125 levels from a pretreatment sample. The response must be confirmed and maintained for at least 28 days. Patients can be evaluated according to CA-125 only if they have a pretreatment sample that is at least twice the upper limit of the reference range and within 2 weeks before starting the treatment.

To calculate CA-125 responses accurately, the following rules apply:

- Intervening samples and the 28-day confirmatory sample must be less than or equal to (within an assay variability of 10%) the previous sample.
- Variations within the reference range of CA-125 levels will not interfere with the response definition.
- For each patient, the same assay method must be used, and the assay must be tested in a quality control scheme.

- Patients are not evaluable by CA-125 if they have received mouse antibodies (unless the assay used has been shown not to be influenced by human antimouse antibody) or if there has been medical and/or surgical interference with their peritoneum or pleura during the previous 28 days (e.g., paracentesis). If assessing therapy that includes 2 treatment modalities for relapse (e.g., surgery and chemotherapy), any CA-125 response results from both treatment modalities. CA-125 cannot distinguish between the effects of the 2 treatments.

The date when the CA-125 level is first reduced by 50% is the date of the CA-125 response. To calculate response per GCIG criteria, an intent-to-treat analysis will be used that includes all patients with an initial CA-125 level of at least twice the upper limit of the reference range as eligible and evaluable. In addition, as a separate analysis, those patients who have a CA-125 response and whose CA-125 level falls to within the reference range can be classified as CA-125 complete responders. In Table 8 and Table 9 where CA-125 is stated as normalized or normal, means within the reference range. The reference range for CA-125 is 0 units/mL to 35 units/mL

#### 6.4.1.2.2 Evaluation of Best Overall Response in Patients without Initial Measurable Disease and Evaluable by CA-125 (GCIG)

CA-125 may be used to evaluate response in patients without initial measurable disease either because no measurable disease is evident on radiological imaging or because appropriate imaging has not been performed as demonstrated in Table 8.

**Table 8 Evaluation of Best Overall Response in Patients Without Initial Measurable Disease and Who are Evaluable by CA-125 (GCIG)**

| CA-125 | Nontarget Lesions [a] | New Lesions | Overall Response | Best Response for This Category Also Requires |
|---|---|---|---|---|
| Response and Normalized | CR | No | CR | Confirmed and maintained for at least 28 days |
| Response | Non-PD | No | PR | |
| Normalized but no response | Non-CR/Non-PD | No | SD | |
| Non-PR/non-PD | Non-PD | No | SD | |
| PD | Any | Yes or No | PD | |
| Any | PD [b] | Yes or No | PD | |
| Any | Any | Yes | PD | |

Abbreviations: CR, Complete response; PD, progressive disease; PR, partial response; SD, stable disease.
[a] Nontarget lesions include ascites and peritoneal thickening, which are not measurable according to RECIST.
[b] Unequivocal progression in nontarget lesions may be accepted as disease progression.

#### 6.4.1.2.3 Evaluation of Best Overall Response in Patients with Initial Measurable Disease and Who are Also Evaluable by CA-125 (GCIG)

A report that combines both CA-125 and RECIST v1.1 criteria is likely to include patients who are measurable by one or both of the criteria and who may have events at different time points. It should be determined according to Table 9. In patients who have measurable disease by both criteria, the date of response will be the date of the earlier of the two events if this approach to combined response reporting is to be used. In the combined assessment of CA-125 and RECIST v1.1 response, the following algorithm applies when determining the best overall response. If patients have progressive disease (PD) according to RECIST v1.1 within 28 days of CA-125 response, they are classified as having PD. If the PD according to RECIST v1.1 is longer than 28 days before or after the CA-125 response, they are classified as having partial response. Patients whose best response according to RECIST v1.1 is stable disease but who have a CA-125 response are classified as CA-125 responders.

**Table 9 Best Overall Response in Patients with Measurable Disease and Who are also Evaluable by CA-125 (GCIG)**

| Target Legion [a] | Nontarget [b] | New Lesion | CA-125 | Best Overall Response |
|---|---|---|---|---|
| CR | CR | No | Normal | CR |
| CR | Non-CR Non-PD | No | Not PD | PR |
| CR | CR | No | PR but not normal | PR |
| CR | NE | No | PR | PR |
| PR | Non-PD or NAE | No | Not PD | PR |
| NAE | Non-PD | No | PR | PR |
| PD or New >28 days from CA-125 PR [c] | | | PR | PR |
| SD | Non-PD | No | PR | PR |
| SD | Non-PD or NAE | No | Not PR and not PD | SD |
| PD or New ≤28 days From CA-125 PR [c] | | | PR | PD |
| PD | Any | Yes or No | Any | PD |
| Any | PD | Yes or No | Any | PD |
| Any | Any | Yes | Any | PD |
| Any | Any | Yes or No | PD | PD |

Abbreviations: CA-125, cell surface antigen 125; CR, Complete response; NE, Not evaluated; NAE, not all evaluated; PD, progressive disease; PR, partial response; SD, stable disease.

[a] Target lesions include up to 5 measurable lesions (2 per organ) as defined by RECIST v1.1.

[b] Nontarget lesions include ascites and peritoneal thickening which are not measurable according to RECIST v1.1.

[c] Patients who have a CA-125 response that occurs more than 28 days from PD according to RECIST v1.1 are considered a PR, according to best response, but PD if the RECIST v1.1 PD is within 28 days of CA-125 response.

#### 6.4.1.2.4 Reporting of Response According to both RECIST v1.1 and CA-125 (GCIG) Criteria

In this study, responses will be reported separately for both tumor response per RECIST v1.1 and CA-125 response per GCIG. A combined response endpoint based on both RECIST v1.1 and GCIG will also be reported. Tumor response will be assessed by the Investigator or local radiologist using RECIST v1.1. CA-125 response and the combined response will be derived based upon local CA-125 results.

### *6.4.2 Description of Safety Variables*

#### *6.4.2.1 Adverse Events*

An adverse event (AE) is any untoward medical occurrence in a study patient administered a pharmaceutical product, which does not necessarily have to have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended

sign (including an abnormal laboratory finding), symptom, or disease temporarily associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product that emerges or worsens relative to the patient's pretreatment baseline.

Illnesses present before the patient signs the ICF are considered pre-existing conditions and are documented on the medical history electronic case report form (eCRF). Pre-existing conditions that worsen during the study are entered on the AE eCRF.

#### *6.4.2.2 Laboratory Parameters*

Table 10 displays the Laboratory Parameters collected:

**Table 10 Clinical Laboratory Tests**

| Hematology | Serum Chemistry | Urinalysis (dipstick) |
|---|---|---|
| Red blood cell (RBC) count | Sodium | Bacteria |
| Hemoglobin | Potassium | Blood |
| Hematocrit | Calcium | Urobilinogen |
| Mean corpuscular volume (MCV) | Chloride | Nitrites |
| Platelet count | Phosphorus | Color |
| White blood cell (WBC) count | Magnesium | Clarity |
| WBC with 5-part differential: | Serum Creatinine | pH |
| Neutrophils | Total bilirubin | Specific gravity |
| Lymphocytes | Albumin | Ketones |
| Monocytes | Alkaline phosphatase (ALP) | Protein |
| Eosinophils | Lactate dehydrogenase (LDH) | Glucose |
| Basophils | Aspartate aminotransferase (AST) | Bilirubin |
| **Coagulation** | Alanine aminotransferase (ALT) | Leukocyte esterase |
| International normalized ratio (INR) (only for patients taking warfarin) | Glucose, fasting | **Other [a]** |
| | Blood urea nitrogen (BUN) | Serum or urine pregnancy test, if applicable |
| **Pharmacodynamic [a]** | Uric acid | Thyroid stimulating hormone (TSH) |
| C-peptide | Bicarbonate | Total T3 [b] |
| ACTH | Total protein | Free T4 [b] |
| Fasting morning cortisol [c] | | Estradiol |
| FKBP5 [c] | | Testosterone, total, free, and percent free |
| Insulin, fasting | | Follicle-stimulating hormone (FSH) |
| Cytokine and T cell profiles | | Luteinizing hormone (LH) |
| | | Dehydroepiandrosterone-sulfate (DHEA-S) |
| | | Optional pharmacogenomic sample |

[a] Pharmacodynamic and other laboratory test samples are to be drawn predose.
[b] Reflex testing only with abnormal TSH values.
[c] May represent a panel of mRNA expression/glucocorticoid-modulated pathways.

#### *6.4.2.3 Vital Signs*

Vital signs (heart rate, systolic and diastolic blood pressure, temperature, and respiration rate) will be assessed. On days of nab-paclitaxel IV administration, vital signs should be collected predose and within 5 minutes after stopping the nab-paclitaxel infusion.

Systolic and diastolic blood pressure will be measured after patients have been at rest (seated) for at least 3 minutes. Blood pressure will be recorded in mmHg. Heart rate will be measured in beats per minutes after the patient has been in a resting state (seated) for at least 3 minutes.

#### *6.4.2.4 ECOG Performance Status*

The ECOG scales and criteria are used by doctors and researchers to assess how a patient's disease is progressing, assess how the disease affects the daily living abilities of the patient, and determine appropriate treatment and prognosis.

If a patient's ECOG performance status declines to ≥2 between Screening/Baseline and Day 1, the patient will no longer be eligible and will be withdrawn from the study.

#### *6.4.2.5 Physical Examinations*

Weight will be reported at each visit and height will be recorded at screening only. Height (without shoes) will be measured in centimeters (cm) using an appropriate measuring device. Weight (without shoes) will be measured in kilograms (kg) using a scale. Historical patient information and/or patient reports should not be used for either measurement.

#### *6.4.2.6 ECG*

Electrocardiograms (ECGs) will be performed and read per ECG vendor specifications. The Investigator may do additional ECG measurements on a "for cause" basis as determined by clinical judgment. The Investigator or Subinvestigator (physician) will be responsible for review and interpretation of the safety ECG results on site and determining whether the ECG is normal, abnormal clinically insignificant, or abnormal clinically significant. The ECG report result should be initialed and dated.

### 6.5 Data Quality Assurance

Report summaries will be generated using validated Base SAS® software, version 9.4 or higher, on a PC or server-based platform. Additional validated software may be used to generate analyses, as needed.

All SAS programs that create outputs or supporting analysis datasets will be validated by a second statistical programmer or biostatistician. At a minimum, validation of programs will consist of a review of the program log, review of output or dataset format and structure, and independent confirmatory programming to verify output results or dataset content. Additionally, all outputs will undergo a review by a senior level team member before finalization.

The content of the source data will be reviewed on an ongoing basis by project statistical programmers and statisticians. Data will be checked for missing values, invalid records, and extreme outliers through defensive programming applications, analysis-based edit checks, and other programmatic testing procedures. All findings will be forwarded to the project data manager for appropriate action and resolution.

# 7 STATISTICAL METHODS

## 7.1 General Methodology

Data will be analyzed by Precision for Medicine, Oncology and Rare Disease ("Precision") personnel. Statistical analyses will be reported with tables, figures and patient data listings, presented in rich text format, and using recommended ICH numbering. Output specifications for all tables, listings and figures will be in conformance with guidelines specified by the ICH (2).

### *7.1.1 Reporting Conventions*

Efficacy tables and figures will be summarized by segment, tumor type, and for all patients combined. Safety tables and figures will be summarized by segment, dose level, and for all patients combined. Tables summarizing demographics and other baseline characteristics will include columns for segment, tumor type, and for all patients combined. In general, all data collected will be presented in patient data listings, for all enrolled patients. Listings will be ordered by segment, part, cohort, site, patient number, and assessment or event date.

In general, continuous variables will be summarized to indicate the population sample size (N), number of patients with available data (n), mean, SD, median, minimum, and maximum values. Categorical variables will be summarized by the population size (N), number of patients with available data (n), number of patients in each category, and the percentage of patients in each category. Unless otherwise noted, the denominator to determine the percentage of patients in each category will be based on the number of patients with available data. Select ordinal data may be summarized using both descriptive statistics and counts and percentages of patients in each category, as appropriate.

Non-zero percentages will be rounded to one decimal place. Rounding conventions for presentation of summary statistics will be based on the precision of the variable of summarization, as it is collected in its rawest form (ie, on the case report form [CRF] or as provided within an external file) and are outlined as follows:

- The mean and median will be rounded to one more decimal place than the precision of the variable of summarization;
- Measures of variability (eg, SD, SE) will be rounded to two more decimal places than the precision of the variable of summarization; and

- Minimum and maximum values will be presented using the same precision as the variable of summarization.

Other statistics (eg, CIs) will be presented using the same general rules outlined above, or assessed for the most appropriate presentation based on the underlying data.

### *7.1.2 Summarization by Visit*

Data summarized by study visit will be based on the nominal, scheduled visit as reported on the CRF. Data collected at unscheduled and early termination visits will not be included in tabular summaries by visit but will be presented in patient data listings.

### *7.1.3 Standard Calculations*

Where appropriate, the calculated study day of each assessment or event will be presented with the assessment or event date on patient data listings, where study day will be determined as:

- The assessment/event date minus the date of first dose, if the assessment/event date is prior to the date of first dose (resulting in a negative study day); and

- The assessment/event date minus the date of first dose, plus one, if the assessment/event date is on or after the date of first dose;

  where first dose is defined as the date the study treatment CORT125134 is first received.

Other variables requiring calculations will be derived using the following formulas:

- **Days:** A duration between two dates expressed in days will be calculated using the following conventions:

  - Later date – (earlier date + 1), if the earlier date is on or after the date of first dose of study treatment; or

  - Later date – earlier date, if the earlier date is prior to the date of first dose of study treatment.

- **Months:** A duration expressed in months will be calculated by dividing the duration in days by (365.25 / 12);

- **Years:** A duration expressed in years will be calculated by dividing the duration in days by 365.25.

## 7.2 Analysis Populations

The following populations will be defined for this study:

- The Safety population will include all patients who received at least one dose of CORT125134. Patients who received only nab-paclitaxel and never received CORT125134 will be separately described.

- Modified Intent-to-Treat (mITT) population will include all patients who received at least one dose of CORT125134. The mITT population concides with the Safety population.

- The DLT-evaluable population will include all patients in Part 1 (dose-finding phase) who complete 1 cycle of treatment and assessment or who receive at least one dose of CORT125134 and discontinue before completing the first cycle because of toxicity.

- The Response-evaluable population will be the subset of the Safety population with at least one post-baseline tumor assessment.

- The PK-evaluable population will be the subset of the Safety population with adequate PK data.

## 7.3 Study Patients

### *7.3.1 Disposition of Patients*

Patient disposition will be summarized for all enrolled patients by segment, tumor type, and dose level. Summaries will include the number and percentage of patients in each analysis population, primary reason for ending treatment, if the patient agreed to survival status monitoring, if the patient completed the survival follow-up period, and reason for study discontinuation. Patient disposition will also be summarized separately for each study center.

### *7.3.2 Protocol Deviations*

Deviations from the protocol and relevant details will be tracked throughout the study and summarized as part of the clinical study report; however, summarization is outside the scope of this SAP.

### *7.3.3 Demographic and Other Baseline Characteristics*

Demographic variables including age, sex, ethnicity and race, will be summarized by segment and tumor type for the safety, DLT-evaluable, and response-evaluable populations.

Age as reported on the CRF will be summarized using descriptive statistics. Sex, ethnicity, and race will be summarized with the number and percentage of patients in each parameter category.

Baseline characteristics include medical history, height, weight, and body mass index (BMI). BMI will be calculated as: weight (kg) / [height (cm) / 100]$^2$. Baseline characteristics will be summarized for the mITT Population by segment, tumor type, and for all patients combined. Height, weight, and BMI at baseline will be summarized using descriptive statistics.

Cancer type will be summarized by segment, tumor type, and for all patients combined for each analysis population. Summaries will include frequency counts and percentages or descriptive statistics for cancer type, prior lines of cancer therapy, and prior taxane.

Frequency counts and percentages summarize patients reporting abnormal medical history by system organ class for the safety population will be presented coded using the Medical Dictionary for Regulatory Activities (MedDRA), Version 19.0.

## 7.4 Efficacy

### *7.4.1 Datasets Analyzed*

All efficacy summaries will be based on the mITT population. A subset of the efficacy analyses will be performed on the Response-evaluable population as well. The mITT population concides with the Safety population.

### *7.4.2 Measurements of Treatment Compliance*

Compliance to the study treatment regimen will be determined separately for CORT125134 and nab-paclitaxel as the total dose received divided by the expected dose received, multiplied by 100. Dosing compliance will be summarized using descriptive statistics, by segment, tumor type, and for all patients combined based on the Safety Population. The number and percentages of patients who are < 80% compliant and ≥ 80% compliant within each group will be summarized.

### *7.4.3 Efficacy Endpoint Analysis Methods*

The analysis population is the mITT population. Analyses for ORR, BOR, and CBR will also be performed using the Response-Evaluable Population. The efficacy endpoints include best response, CBR, OS, PFS, DOR, ORR as defined by RECIST v1.1, and CA-125 response per GCIG criteria (patients with ovarian, fallopian tube, or primary peritoneal cancer only).

For OS, PFS, and DOR will be analized in the mITT population only using the Kaplan-Meier method to estimate the survival functions, using time to event and a censoring variable. The Kaplan-Meier curves will be plotted. Results will be presented by segment, tumor type, and for all patients combined. Counts and percentages for number of patients

who experienced the event of interest and those who are censored are presented along with minimum and maximum survival months. The median, 25th and 75th percentiles will be estimated and their corresponding Brookmeyer-Crowley 95% CIs using the Kaplan-Meier estimates. The survival estimates will be provided for 6 months, 12 months and 24 months survival time with their corresponding 95% CIs.

PFS is defined as time from date of first dose of CORT125134 or nab-paclitaxel, whichever is earlier, to the date of unequivocal disease progression per RECIST v1.1 or death from any cause, whichever occurs first. The censoring rules are described in Table 11.

**Table 11 Censoring Rules for the Analysis of PFS**

| Censoring Categories | Date of Censoring |
|---|---|
| Patients who did not have baseline or postbaseline tumor assessments and did not die on or before the data cutoff date | Date of first dose of CORT125134 or nab-paclitaxel, whichever is earliest +1 |
| Patients who did not have disease progression and did not die on or before the data cutoff date | Date of the last adequate tumor assessment on or before the data cutoff date |
| Patients who had 2 or more consecutive missed scheduled tumor assessments immediately prior to disease progression | Date of the last adequate tumor assessment without evidence of disease progression before the 2 missed tumor assessments and on or before the data cutoff date |

PFS, progression-free surivival.

Overall survival defined as the time from date of the first dose of CORT125134 or nab-paclitaxel, whichever is earliest, until the date of death from any cause. Patients who are not reported as having died before the data cutoff date will be analyzed as censored observations on the date they were last known to be alive.

Duration of response is measured from the date that the criteria are met for complete response (CR) or partial response (PR) until the first date that progressive disease is objectively documented. Patients who have not experienced disease progression or death before the data cutoff date will be censored at the last tumor assessment date.

Best response, CBR, and ORR will be summarized in the mITT and Response-evaluable populations, by segment, tumor type, and for all patients combined. Counts and percentages will be summarized according to the specified criteria with exact 95% bionomial CIs (Clopper-Pearson). The overall response rate (CR or PR) and the CBR (CR or PR or SD) will be presented for the RECIST criteria. Best response with percentage change from baseline will be displayed in a waterfall plot.

### *7.4.4 Statistical/Analytical Issues*

#### *7.4.4.1 Adjustments for Covariates*

There are no planned applications of covariate adjustments; all statistical results are descriptive in nature.

#### *7.4.4.2 Handling of Dropouts or Missing Data*

Detailed rules for imputation of missing/partially missing dates for adverse events and prior/concomitant medications/procedures are provided in Appendix A: Imputation of Missing/Partially Missing Dates. All other analyses will be based on observed data only.

#### *7.4.4.3 Interim Analyses and Data Monitoring*

A DRC will perform the safety monitoring of the study drug in accordance with procedures detailed in a DRC Charter. The DRC will monitor data throughout the course of dose-finding (Part 1), and make recommendations regarding dose escalation for each cohort.

No interim analyses are planned for the purposes of early stopping of the study or modifying the study design. However, data may be reviewed periodically by the Sponsor, as needed.

#### *7.4.4.4 Multicenter Studies*

This is a multicenter study, with approximately 8 sites expected to participate. Efficacy data collected from all study centers will be pooled for data analysis. The effect of study center on the efficacy analysis results may be explored post-hoc, as needed.

#### *7.4.4.5 Multiple Comparisons/Multiplicity*

There will be no adjustments for multiple comparisons in the efficacy analysis for this study. Results are descriptive in nature and there will be no formal comparisons made among treatment groups.

#### *7.4.4.6 Use of an "Efficacy Subset" of Patients*

All efficacy analysis will be performed on the mITT population. A subset of efficacy analyses will also be perfomerf on the Response-evaluable population since this population is the subset of the Safety population with at least one post-baseline tumor assessment.

#### *7.4.4.7 Active-Control Studies Intended to Show Equivalence*

This study does not include an active-control product and is not intended to demonstrate equivalence between any two drug products.

#### *7.4.4.8 Examination of Subgroups*

There are no planned analyses to assess efficacy results by subgroups.

### ***7.4.5 Pharmacokinetic Analysis***

Pharmacokinetic analysis will be summarized in a separate report and is outside the scope of this SAP.

### *7.4.6 Pharmacodynamic Analysis*

Pharmacodynamic analysis will be summarized in a separate report and is outside the scope of this SAP.

## 7.5 Safety Analysis

Safety analysis will be carried out for the Safety Population, to include all patients who receive at least one dose of nab-paclitaxel or CORT125134. Patients who do not complete the study, for whatever reason, will have all available data up until the time of termination included in the analysis.

### *7.5.1 Extent of Exposure*

Extent of exposure to nab-paclitaxel and CORT125134 will be summarized for the Safety Population by segment, dose level, and for all patients combined separately for each study drug.

- Number of Cycles of Treatment: The number of cycles for each study drug will be presented based on the last visit when the patient received treatment.

- Duration of Exposure: The duration of exposure for each study drug will be presented in days and calculated as the last dose of study drug minus the date of the first dose of study drug, plus one.

- Total Dose Received: The total dose received for each study drug will be the sum of the actual dose administered for the duration of exposure.

  For subjects where their dose received is either zero or missing, a received dose of zero is included in the total dose received derivation.

- Total Dose Expected: The total dose expected is calculated for each study drug. The expected study drug dosing schedule is as follows:

  - For Segment I patients CORT125134 is expected to be taken daily starting at the CORT125134 lead-in. Nab-paclitaxel is expected to be taken on nab-paclitaxel lead-in Day 1, and Day 1, 8, and 15 of each cycle.

  - For Segment II patients CORT125134 is expected to be taken on Day 1, 2, 7, 8, 9, 14, 15, 16, and 28 of each cycle. Nab-paclitaxel is expected to be taken on Day 1, 8, and 15 of each cycle.

  The expected drug dosing schedule is used in combination with the actual date and dose of study drug administration to calculate the total dose expected. A subject will have expected dose calculations based on all days within a cycle as determined by the earliest start date and the latest end date within a given cycle. For subjects where their dose received is either zero or missing, an associated expected dose is included in the toal dose expected derivation.

- Relative Dose Intensity: Relative dose intensity is calculated for each study drug as the total dose received divided by the total dose expected, multiplied by 100.

Number of cyles, duration of exposure, total dose received, total dose expected and relative dose intensity will be summarized using descriptive statistics for each study drug separately.

### *7.5.2 Adverse Events*

Treatment-emergent adverse events (TEAEs) are defined as those adverse events (AEs) with onset after the first dose of CORT125134 or existing events that worsened after the first dose during the study through 28 days after the last dose of either study drug. TEAEs will be summarized by segment, dose level, and for all patients combined. Events reported with a partial onset date (eg, month and year are reported but the day is missing) will be considered to be treatment-emergent if it cannot be confirmed that the event onset was prior to the first dose of study drug based on the available date entries.

Verbatim terms on case report forms will be mapped to preferred terms and system organ classes using the Medical Dictionary for Regulatory Activities (MedDRA, version 19.0).

Summaries that are displayed by system organ class and preferred terms will be ordered by descending incidence of system organ class and preferred term within each system organ class. Summaries displayed by preferred term only will be ordered by descending incidence of preferred term. Summaries of the following types will be presented:

- Overall summary of number of unique TEAEs and treatment-emergent serious adverse events (SAEs) and patient incidence of TEAEs meeting various criteria will be presented for the Safety population.

- Patient incidence of TEAEs by MedDRA system organ class and preferred term;

- Patient incidence of TEAEs by MedDRA preferred term;

- Patient incidence of the most frequently-occurring TEAEs (ie, TEAEs occurring in ≥ 10% of the Safety population) by MedDRA preferred term;

- Patient incidence of the most frequently-occurring TEAEs (ie, TEAEs occurring in ≥ 10% of the Safety population) by CTCAE grade and MedDRA system organ class and preferred term;

- Patient incidence of the most frequently-occurring TEAEs (ie, TEAEs occurring in ≥ 10% of the Safety population) by CTCAE ≥ Grade 3 and MedDRA preferred term;

- Patient incidence of TEAEs by CTCAE grade and MedDRA system organ class and preferred term;

- Patient incidence of TEAEs related to CORT125134 by MedDRA system organ class and preferred term;
- Patient incidence of TEAEs related to CORT125134 by MedDRA preferred term;
- Patient incidence of the most frequently-occurring TEAEs related to CORT125134 (ie, related TEAEs occurring in ≥ 10% of the Safety population) by MedDRA preferred term;
- Patient incidence of TEAEs by CTCAE ≥ Grade 3 by MedDRA system organ class and preferred term;
- Patient incidence of TEAEs by CTCAE ≥ Grade 3 by MedDRA preferred term;
- Patient incidence of TEAE by CTCAE ≥ Grade 3 TEAEs related to study drugs (CORT125134 and nab-paclitaxel) by MedDRA system organ class and preferred term;
- Patient incidence of TEAEs leading to withdrawal of study drugs (any study drug, CORT125134, and nab-paclitaxel) by MedDRA system organ class and preferred term;
- Patient incidence of TEAEs leading to study drug interruption (any study drug, CORT125134, and nab-paclitaxel) by MedDRA system organ class and preferred term;
- Patient incidence of TEAEs leading to study drug reduction (any study drug, CORT125134, and nab-paclitaxel) by MedDRA system organ class and preferred term;
- Patient incidence of TEAEs leading to death by MedDRA system organ class and preferred term;
- Patient incidence of SAEs by MedDRA system organ class and preferred term;
- Patient incidence of Non-Hematolgical AEs

At each level of summarization (eg, any adverse event, system organ class, and preferred term), patients experiencing more than one TEAE will be counted only once. In the summary of TEAEs with TEAE ≥ Grade 3, patients will be counted once at the highest grade reported at each level of summarization; in the summary of TEAEs by relationship, patients will be counted once at the closest relationship to study drugs.

An overall summary of number of unique neutropenia TEAEs and treatment-emergent serious adverse events (SAEs) and patient incidence of TEAEs meeting various criteria will be presented for the Safety population. Neutropenia adverse events are those reporting a preferred term of “neutropenia,” “febrile neutropenia,” or “neutrophil count

decreased" using the Medical Dictionary for Regulatory Activities (MedDRA), version 19.0. The time to onset of first neutropenia TEAE and first neutropenia TEAE with CTCAE ≥ Grade 3 will be summarized for the Safety population.

Adverse event data will be presented in data listings by patient, segment, tumor type, dose level, and event. SAEs and adverse events leading to discontinuation of the study drugs will be presented in separate data listings.

### *7.5.3 Deaths, Other Serious Adverse Events, and Other Significant Adverse Events*

All deaths during the study, including the post treatment follow-up period, will be listed by patient, to include the primary cause of death and summarized in a table. Serious adverse events and other significant adverse events, including those that led to withdrawal, interruption, or dose reduction of the study drug, will be provided in separate patient data listings.

Primary cause of death as reported on the end of study case report form will be summarized by segment, dose level, and for all patients combined for the Safety population. The number of patients where death occurred within 28 days of last study drug dose and the number of patients where death did not occur within 28 days of last study drug dose will be presented. Primary cause of death will be summarized with the number and percentage of patients in each category.

### *7.5.4 Dose-Limiting Toxicity (DLTs)*

DLTs that occur during Cycle 1 of treatment will be presented in a data listing by segment and dose level for the DLT-evaluable population.

### *7.5.5 Clinical Laboratory Evaluation*

All descriptive summaries of laboratory results will be based on data analyzed by the central laboratory and presented in Système International units as suggested by the Center for Biologics Evaluation and Research and the Center for Drug Evaluation and Research (3). All data will be included in by-patient data listings. Laboratory measurements identified as abnormal (i.e., outside the normal range) will be listed separately by patient, laboratory test and unit.

Clinical laboratory measurements, including serum chemistry and hematology, will be summarized by segment, dose level, and for all patients combined. Descriptive statistics will be presented for observed values and changes from baseline at each visit where parameters were scheduled to be collected per the clinical study protocol.

Where applicable, laboratory results classified as "clinically significant" will be presented. Summary results will include the count and percentage of patients for each laboratory parameter within each part and group.

Where applicable, hematology and chemistry results for select parameters will be assigned a toxicity grade based on the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), version 4.03 (4). Five-by-five contingency tables will be presented for lab tests where toxicity grading can be applied to summarize the shift from the baseline grade to the worst post-baseline grade. Grades will be presented as none (Grade 0), mild (Grade 1), moderate (Grade 2), severe (Grade 3), or life-threatening (Grade 4). Death related to adverse event (ie, Grade 5) cannot be determined with available laboratory-based data collection and, thus, will not be summarized as a category. Summary results will include the count and percentage of patients within each shift category.

### *7.5.6 Vital Signs, Physical Findings, and Other Observations Related to Safety*

#### *7.5.6.1 Vital Signs*

Vital sign parameter measurements will be summarized by segment, dose level, and for all patients combined. Descriptive statistics will be presented for results and change from baseline at each visit where parameters were scheduled to be collected.

#### *7.5.6.2 12-Lead Electrocardiogram*

Twelve-Lead ECG interval parameters of QTc intervals calculated using Bazett's correction and Fridericia's correction, QTcB and QTcF, will be summarized by segment, dose level, and for all patients combined. Descriptive statistics will be presented for observed values and changes from baseline at each visit where parameters were scheduled to be collected.

Twelve-lead ECG will be classified by the investigator as normal or abnormal and will be presented to summarize the shift from the baseline to the worst post-baseline value. Summary results will include the number and percentage of patients within each shift category.

Prolonged QTc intervals will be summarized as QTcB and QTcF measurements (msec) categorized as >450, >470 and >500 at each visit. Change from baseline will also be summarized with a change of >30 or >60 from baseline value.

#### *7.5.6.3 ECOG Performance Status*

ECOG exams are to be performed at Screening/Baseline, at Day 1, 8, and 15 of each cycle, and at the Posttreatment/Early Termination Visit. ECOG performance status will be presented in patient data listings by patient and date.

#### *7.5.6.4 Physical Examination*

Complete physical examinations are to be performed at Screening/Baseline, at Day 1 of each cycle, and at the Posttreatment/Early Termination Visit. Results of the physical examination will be presented in patient data listings by patient, study visit, and body system.

#### *7.5.6.5 Prior and Concomitant Medications*

Medications will be coded using the World Health Organization (WHO Drug March 1, 2014 version, enhanced) dictionary. Medications entered on the case reports formats will be mapped to Anatomic Therapeutic Chemical (ATC) drug class (level 4) and drug name.

Prior and concomitant medications will be summarized separately by part and overall by segment and dose level. A prior medication is defined as any medication administered prior to the date of the first dose of study drug. A concomitant medication is defined as any medication administered on or after the date of first dose of study drug. A medication may be defined as both prior and concomitant. If it cannot be determined whether a medication was received prior to the start of study drug dosing due to partial or missing medication start and end dates, it will be considered a prior medication. Likewise, if it cannot be determined whether a medication was received after the start of study drug dosing, it will be considered concomitant. Detailed rules for imputation of missing/partially missing dates for adverse events and prior/concomitant medications/procedures are provided in Appendix A: Imputation of Missing/Partially Missing Dates.

For the summary of both prior medications and concomitant medications, the number and percentage of patients receiving any medication will be summarized, as will the number and percentage receiving any medication by ATC drug class and generic drug name. Patients reporting use of more than one medication at each level of summarization (any medication received, ATC class, and generic drug name) will be counted only once. ATC class terms will be displayed by descending order of incidence, as will generic drug names within each ATC class. The study phase during which each medication was received (eg, prior, concomitant, or both) will be presented on the listing of prior and concomitant medications.

## 7.6 Determination of Sample Size

There is no formal sample size calculation or hypothesis testing in this study. An adequate number of DLT-evaluable patients will be enrolled to determine the MTD and development regimen in Segment I, Part 1 (approximately 42 patients) and Segment II, Part 1 (approximately 24 patients).

## 7.7 Changes in the Conduct of the Study or Planned Analyses

The Sponsor decided to end study enrollment after completion of Part 1, and plan for Part 2 portion of the study was not carried out.

There were no changes to the study conduct or planned analyses identified within the development of this SAP, relative to the descriptions provided within the clinical study protocol.

# 8 REFERENCES

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2. M2 eCTD: Electronic Common Technical Document Specification Appendix 7, provided by the International Conference on Harmonization. Available from: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073240.pdf

3. Data Standards: Position on Use of SI Units for Lab Tests. U.S Food and Drug Administration; 25 October 2013. Available from: http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/ucm372553.htm

4. U.S. Department of Health and Human Services. Common Terminology Criteria for Adverse Events (CTCAE), Version 4.03. 14 June 2010. Available from: http://evs.nci.nih.gov/ftp1/CTCAE/CTCAE_4.03_2010-06-14_QuickReference_8.5x11.pdf.

5. Rustin, G. (2011). Definitions for Response and Progression in Ovarian Cancer Clinical Trials Incorporating RECIST 1.1 and CA 125 Agreed by the Gynecological Cancer Intergroup (GCIG). International Journal Of Gynecologic Cancer, 21(2), 419-423.

# APPENDIX A: IMPUTATION OF MISSING/PARTIALLY MISSING DATES

Missing data will not be imputed unless otherwise specified.

For safety analyses, incomplete date of last dose of study drug that is missing the day of the month, the 15th of the month will be used to impute the missing data. When imputing partial last dose dates, the last assessment date and death date will be taken into consideration. This imputation rule will be used to determine the treatment-emergent period.

Adverse Events and Concomitant Medications

The imputation rule for the safety analyses will be used to address the issues with partial dates. The imputed dates will be used to determine the treatment-emergent period. For adverse events with a partial date, available date parts (year, month, and day) of the partial date will be compared with the corresponding date components of the start date and end date of the treatment-emergent period to determine if the event is treatment emergent. When in doubt, the adverse event will be considered treatment emergent by default. The following rules will be applied to impute partial dates for adverse events:

If start date of an adverse event is partially missing, impute as follows:

- If both month and day are missing and year = year of treatment start date, then set to treatment start date
- If both month and day are missing and year ≠ year of treatment start date, then set to January 01
- If day is missing and month and year = month and year of treatment start date, then set to treatment start date
- If day is missing and month and year ≠ month and year of treatment start date, then set to first of the month
- If start date is completely missing, set to treatment start date as long as adverse event end date is not before treatment start date

If end date of an adverse event is partially missing, impute as follows:

- If both month and day are missing, then set to December 31
- If only day is missing, then set to last day of the month
- If end date is completely missing, do not impute

When the start date or end date of a medication is partially missing, the date will be imputed to determine whether the medication is prior or concomitant (or both). The following rules will be applied to impute partial dates for medications:

If start date of a medication is partially missing, impute as follows:

- If both month and day are missing, then set to January 01
- If only day is missing, then set to the first of the month

If end date of a medication is partially missing, impute as follows:

- If both month and day are missing, then set to December 31
- If only day is missing, then set to last day of the month

If start date or end date of a medication is completely missing, do not impute.

# APPENDIX B: LIST OF TABLES, FIGURES AND DATA LISTINGS

## List of Tables

| Number | Description | Analysis Set | Source Listing(s) |
|---|---|---|---|
| **14.1** | **Demographic Data Summaries** | | |
| 14.1.1.1 | Patient Disposition | All Enrolled Patients | 16.2.1 |
| 14.1.1.2 | Patient Disposition by Study Center | All Enrolled Patients | 16.2.1 |
| 14.1.2.1 | Demographic and Baseline Characteristics | mITT Population | 16.2.4.1 |
| 14.1.2.2 | Demographic and Baseline Characteristics | DLT-Evaluable Population | 16.2.4.1 |
| 14.1.2.3 | Demographic and Baseline Characteristics | Response-Evaluable Population | 16.2.4.1 |
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| Number | Description | Analysis Set | Source Listing(s) |
|---|---|---|---|
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*Narratives of deaths, other serious adverse events, and certain other significant adverse events will not be generated by analysis programming and are outside the scope of this analysis plan.

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# APPENDIX C: TABLE LAYOUTS

**Table 14.1.1.1**
**Patient Disposition**
**All Enrolled Patients**

| | Segment I: Continuous-Dosing Regimen | | | | Segment II: Intermittent-Dosing Regimen | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | PDAC[1] (N= ) | Ovarian Cancer[1] (N= ) | Other Solid Tumors[1] (N= ) | Total (N= ) | PDAC[1] (N= ) | Ovarian Cancer[1] (N= ) | Other Solid Tumors[1] (N= ) | Total (N= ) | Total (N= ) |
| Safety Population[2] | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| DLT-Evaluable Population[3] | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Response-Evaluable Population[4] | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Primary Reason for Ending Treatment | | | | | | | | | |
| Adverse Event | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Death | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Lost to Follow-Up | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Physician Decision | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Pregnancy | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Progressive Disease | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Study Terminated by Sponsor | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Withdrawl by Patient | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Agreed to Survival Status Monitoring | | | | | | | | | |
| Yes | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| No | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Completed Survival Follow-Up Period | | | | | | | | | |
| Yes | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| No | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |

Abbreviations: DLT=dose-limiting toxicity; PDAC=pancreatic ductal adenocarcinoma

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. Ovarian Cancer includes all ovarian cancer patients excluding juvenile granulosa subtype. Other Solid Tumors includes all patients not included in PDAC and ovarian cancer groups.
[2] Safety Population includes all patients who received at least one dose of study treatment.
[3] DLT-Evaluable population includes all patients in Part 1 who complete 1 cycle of treatment and assessment or who +inue before completing the first cycle because of toxicity.
[4] Response-Evaluable population is the subset of the Safety population with at least one post-baseline tumor assessment.

Reference: *Listing #(s)*
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**Table 14.1.1.1**
**Patient Disposition**
**All Enrolled Patients**

| | Segment I: Continuous-Dosing Regimen | | | | Segment II: Intermittent-Dosing Regimen | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | PDAC[1] (N= ) | Ovarian Cancer[1] (N= ) | Other Solid Tumors[1] (N= ) | Total (N= ) | PDAC[1] (N= ) | Ovarian Cancer[1] (N= ) | Other Solid Tumors[1] (N= ) | Total (N= ) | Total (N= ) |
| Reason for Study Discontinuation | | | | | | | | | |
| Death | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Lost to Follow-Up | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Study Terminated by Sponsor | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Withdrawl by Patient | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |

Abbreviations: DLT=dose-limiting toxicity; PDAC=pancreatic ductal adenocarcinoma

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. Ovarian Cancer includes all ovarian cancer patients excluding juvenile granulosa subtype. Other Solid Tumors includes all patients not included in PDAC and ovarian cancer groups.
[2] Safety Population includes all patients who received at least one dose of study treatment.
[3] DLT-Evaluable population includes all patients in Part 1 who complete 1 cycle of treatment and assessment or who discontinue before completing the first cycle because of toxicity.
[4] Response-Evaluable population is the subset of the Safety population with at least one post-baseline tumor assessment.

Reference: *Listing #(s)*
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**Table 14.1.1.2**
**Patient Disposition by Study Center**
**All Enrolled Patients**

| | | Segment I: Continuous-Dosing Regimen | | | | Segment II: Intermittent-Dosing Regimen | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Study Center | | PDAC[1] (N= ) | Ovarian Cancer[1] (N= ) | Other Solid Tumors[1] (N= ) | Total (N= ) | PDAC[1] (N= ) | Ovarian Cancer[1] (N= ) | Other Solid Tumors[1] (N= ) | Total (N= ) | Total (N= ) |
| Site 1 | Safety Population[2] | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | DLT-Evaluable Population[3] | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Response-Evaluable Population[4] | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Primary Reason for Ending Treatment | | | | | | | | | |
| | Adverse Event | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Death | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Lost to Follow-Up | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Physician Decision | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Pregnancy | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Progressive Disease | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Study Terminated by Sponsor | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Withdrawl by Patient | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Agreed to Survival Status Monitoring | | | | | | | | | |
| | Yes | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | No | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Completed Survival Follow-Up Period | | | | | | | | | |
| | Yes | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | No | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Site 2 | | | | | | | | | | |
| … | | | | | | | | | | |

Abbreviations: DLT=dose-limiting toxicity; PDAC=pancreatic ductal adenocarcinoma

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. Ovarian Cancer includes all ovarian cancer patients excluding juvenile granulosa subtype. Other Solid Tumors includes all patients not included in PDAC and ovarian cancer groups.
[2] Safety Population includes all patients who received at least one dose of study treatment.
[3] DLT-Evaluable population includes all patients in Part 1 who complete 1 cycle of treatment and assessment or who +inue before completing the first cycle because of toxicity.
[4] Response-Evaluable population is the subset of the Safety population with at least one post-baseline tumor assessment.

Reference: *Listing #(s)*
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**Table 14.1.1.2**
**Patient Disposition by Study Center**
**All Enrolled Patients**

| | | Segment I: Continuous-Dosing Regimen | | | | Segment II: Intermittent-Dosing Regimen | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Study Center | | PDAC[1] (N= ) | Ovarian Cancer[1] (N= ) | Other Solid Tumors[1] (N= ) | Total (N= ) | PDAC[1] (N= ) | Ovarian Cancer[1] (N= ) | Other Solid Tumors[1] (N= ) | Total (N= ) | Total (N= ) |
| Site 1 | Reason for Study Discontinuation | | | | | | | | | |
| | Death | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Lost to Follow-Up | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Study Terminated by Sponsor | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Withdrawl by Patient | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Site 2 | | | | | | | | | | |
| … | | | | | | | | | | |

Abbreviations: DLT=dose-limiting toxicity; PDAC=pancreatic ductal adenocarcinoma

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. Ovarian Cancer includes all ovarian cancer patients excluding juvenile granulosa subtype. Other Solid Tumors includes all patients not included in PDAC and ovarian cancer groups.
[2] Safety Population includes all patients who received at least one dose of study treatment.
[3] DLT-Evaluable population includes all patients in Part 1 who complete 1 cycle of treatment and assessment or who discontinue before completing the first cycle because of toxicity.
[4] Response-Evaluable population is the subset of the Safety population with at least one post-baseline tumor assessment.

Reference: *Listing #(s)*
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**Table 14.1.2.1**
**Demographic and Baseline Characteristics**
**mITT Population**

| | Segment I: Continuous-Dosing Regimen | | | | Segment II: Intermittent-Dosing Regimen | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | PDAC[1] (N= ) | Ovarian Cancer[1] (N= ) | Other Solid Tumors[1] (N= ) | Total (N= ) | PDAC[1] (N= ) | Ovarian Cancer[1] (N= ) | Other Solid Tumors[1] (N= ) | Total (N= ) | Total (N= ) |
| Age (years)[2] | | | | | | | | | |
| n | n | n | n | n | n | n | n | n | n |
| Mean (SD) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) |
| Median | x | x | x | x | x | x | x | x | x |
| Min, Max | x, x | x, x | x, x | x, x | x, x | x, x | x, x | x, x | x, x |
| Sex | | | | | | | | | |
| Male | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Female | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Ethnicity | | | | | | | | | |
| Hispanic or Latino | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Not Hispanic or Latino | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Race | | | | | | | | | |
| American Indian or Alaska Native | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Asian | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Black or African American | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Native Hawaiian or Other Pacific Islander | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| White | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |

Abbreviations: BMI=body mass index; PDAC=pancreatic ductal adenocarcinoma; TNBC=triple-negative breast cancer

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. Ovarian Cancer includes all ovarian cancer patients excluding juvenile granulosa subtype. Other Solid Tumors includes all patients not included in PDAC and ovarian cancer groups.
[2] Age as collected on the case report form.
[3] Cancer type as collected on the cancer history case report form. Patients may be included in more than one category.
[4] Number of distinct cancer therapy regimens.
[5] Number of patients with prior lines of cancer therapy that contain the text "taxo," "taxel," or "xane."

Reference: *Listing #(s)*
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**Table 14.1.2.1**
**Demographic and Baseline Characteristics**
**mITT Population**

| | Segment I: Continuous-Dosing Regimen | | | | Segment II: Intermittent-Dosing Regimen | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | PDAC[1] (N= ) | Ovarian Cancer[1] (N= ) | Other Solid Tumors[1] (N= ) | Total (N= ) | PDAC[1] (N= ) | Ovarian Cancer[1] (N= ) | Other Solid Tumors[1] (N= ) | Total (N= ) | Total (N= ) |
| Height (cm) | | | | | | | | | |
| n | n | n | n | n | n | n | n | n | n |
| Mean (SD) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) |
| Median | x.x | x.x | x.x | x.x | x.x | x.x | x.x | x.x | x.x |
| Min, Max | x.x, x.x | x.x, x.x | x.x, x.x | x.x, x.x | x.x, x.x | x.x, x.x | x.x, x.x | x.x, x.x | x.x, x.x |
| Weight (kg) | | | | | | | | | |
| n | n | n | n | n | n | n | n | n | n |
| Mean (SD) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) |
| Median | x.x | x.x | x.x | x.x | x.x | x.x | x.x | x.x | x.x |
| Min, Max | x.x, x.x | x.x, x.x | x.x, x.x | x.x, x.x | x.x, x.x | x.x, x.x | x.x, x.x | x.x, x.x | x.x, x.x |
| BMI (kg/m$^2$) | | | | | | | | | |
| n | n | n | n | n | n | n | n | n | n |
| Mean (SD) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) |
| Median | x.x | x.x | x.x | x.x | x.x | x.x | x.x | x.x | x.x |
| Min, Max | x.x, x.x | x.x, x.x | x.x, x.x | x.x, x.x | x.x, x.x | x.x, x.x | x.x, x.x | x.x, x.x | x.x, x.x |

Abbreviations: BMI=body mass index; PDAC=pancreatic ductal adenocarcinoma; TNBC=triple-negative breast cancer

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. Ovarian Cancer includes all ovarian cancer patients excluding juvenile granulosa subtype. Other Solid Tumors includes all patients not included in PDAC and ovarian cancer groups.
[2] Age as collected on the case report form.
[3] Cancer type as collected on the cancer history case report form. Patients may be included in more than one category.
[4] Number of distinct cancer therapy regimens.
[5] Number of patients with prior lines of cancer therapy that contain the text "taxo," "taxel," or "xane."

Reference: *Listing #(s)*
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**Table 14.1.2.1**
**Demographic and Baseline Characteristics**
**mITT Population**

| | Segment I: Continuous-Dosing Regimen | | | | Segment II: Intermittent-Dosing Regimen | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | PDAC[1] (N= ) | Ovarian Cancer[1] (N= ) | Other Solid Tumors[1] (N= ) | Total (N= ) | PDAC[1] (N= ) | Ovarian Cancer[1] (N= ) | Other Solid Tumors[1] (N= ) | Total (N= ) | Total (N= ) |
| Cancer Type[3] | | | | | | | | | |
| Pancreatic Ductal Adenocarcinoma | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Ovarian / Primary Peritoneal | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Sarcoma / Chondrosarcoma | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Head and Neck | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Melanoma / Uveal Melanoma | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Triple-negative Breast Cancer (TNBC) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Breast (Hormone Receptor Positive) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Cervical / Vulvar | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Rectal | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Other | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Prior lines of cancer therapy[4] | | | | | | | | | |
| n | n | n | n | n | n | n | n | n | n |
| Mean (SD) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) |
| Median | x.x | x.x | x.x | x.x | x.x | x.x | x.x | x.x | x.x |
| Min, Max | x.x, x.x | x.x, x.x | x.x, x.x | x.x, x.x | x.x, x.x | x.x, x.x | x.x, x.x | x.x, x.x | x.x, x.x |
| Prior taxane[5] | | | | | | | | | |
| Yes | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| No | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |

Abbreviations: BMI=body mass index; PDAC=pancreatic ductal adenocarcinoma; TNBC=triple-negative breast cancer

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. Ovarian Cancer includes all ovarian cancer patients excluding juvenile granulosa subtype. Other Solid Tumors includes all patients not included in PDAC and ovarian cancer groups.
[2] Age as collected on the case report form.
[3] Cancer type as collected on the cancer history case report form. Patients may be included in more than one category.
[4] Number of distinct cancer therapy regimens.
[5] Number of patients with prior lines of cancer therapy that contain the text "taxo," "taxel," or "xane."

Reference: *Listing #(s)*
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*See Programming Notes on next page*

*Repeat for the following:*

*Table 14.1.2.2 Demographic and Baseline Characteristics (DLT-Evaluable Population)*
*Table 14.1.2.3 Demographic and Baseline Characteristics (Response-Evaluable Population)*

**Table 14.1.4**
**Medical History**
**Safety Population**

| Body System / Preferred Term[2] | Segment I: Continuous-Dosing Regimen | | | | Segment II: Intermittent-Dosing Regimen | | | | Total |
|---|---|---|---|---|---|---|---|---|---|
| | PDAC[1] (N= ) | Ovarian Cancer[1] (N= ) | Other Solid Tumors[1] (N= ) | Total (N= ) | PDAC[1] (N= ) | Ovarian Cancer[1] (N= ) | Other Solid Tumors[1] (N= ) | Total (N= ) | (N= ) |
| Body System #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | | |
| Body System #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | | |
| … | | | | | | | | | |

Abbreviation: PDAC=pancreatic ductal adenocarcinoma

Note: At each level of summarization (any body system and preferred term), patients reporting more than one medical history event are counted only once.

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. Ovarian Cancer includes all ovarian cancer patients excluding juvenile granulosa subtype. Other Solid Tumors includes all patients not included in PDAC and ovarian cancer groups.
[2] Medical history terms are coded to body system and preferred term using the Medical Dictionary for Regulatory Activities (MedDRA), Version 19.0.

Reference: *Listing #(s)*
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**Table 14.1.5**
**Prior Medications**
**Safety Population**

| | Segment I: Continuous-Dosing Regimen | | | | Segment II: Intermittent-Dosing Regimen | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | PDAC[1] (N= ) | Ovarian Cancer[1] (N= ) | Other Solid Tumors[1] (N= ) | Total (N= ) | PDAC[1] (N= ) | Ovarian Cancer[1] (N= ) | Other Solid Tumors[1] (N= ) | Total (N= ) | Total (N= ) |
| Patients Receiving any Prior Medications | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| ATC Class #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Generic Drug Name #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Generic Drug Name #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | | |
| ATC Class #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Generic Drug Name #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Generic Drug Name #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | | |
| … | | | | | | | | | |

Abbreviations: ATC=anatomic therapeutic chemical; PDAC=pancreatic ductal adenocarcinoma; WHO=World Health Organization

Notes:
- Prior medications are those medications received prior to the first dose of study treatment.
- Medications are coded to ATC drug class (level 4) and generic drug names using the WHO Drug dictionary, March 1, 2014 Version.
- At each level of summarization (any medication, ATC class, generic drug name), patients reporting use of more than one medication are counted only once.

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. Ovarian Cancer includes all ovarian cancer patients excluding juvenile granulosa subtype. Other Solid Tumors includes all patients not included in PDAC and ovarian cancer groups.

Reference: *Listing #(s)*
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*Programming Notes:*
- *Sort medications by descending order of ATC class incidence and by descending order of drug name incidence within ATC class, based on the overall incidence (ie, sum over all treatment groups).*
- *When creating ATC level 4 drug class, utilize level 3 term if level 4 is missing in dataset and level 2 if both level 3 and level 4 are missing in the dataset*

**Table 14.2.1.1**
**Efficacy Analysis: Best Response Defined by RECIST v1.1**
**mITT Population**
**Part 1 of 2**

| | Segment I: Continuous-Dosing Regimen | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | PDAC[1] (N= ) | | Ovarian Cancer[1] (N= ) | | Other Solid Tumors[1] (N= ) | | Total (N= ) | |
| Best Response | n (%) | 95% CI[2] | n (%) | 95% CI[2] | n (%) | 95% CI[2] | n (%) | 95% CI[2] |
| Complete Response (CR) | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| Unconfirmed (CR) | n (x.x%) | | n (x.x%) | | n (x.x%) | | n (x.x%) | |
| Confirmed (CR) | n (x.x%) | | n (x.x%) | | n (x.x%) | | n (x.x%) | |
| Partial Response (PR) | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| Unconfirmed (PR) | n (x.x%) | | n (x.x%) | | n (x.x%) | | n (x.x%) | |
| Confirmed (PR) | n (x.x%) | | n (x.x%) | | n (x.x%) | | n (x.x%) | |
| Stable Disease (SD) | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| Progressive Disease (PD) | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| Missing or Not Evaluable (NE) | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| Objective Response Rate (CR or PR) | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| Unconfirmed (CR or PR) | n (x.x%) | | n (x.x%) | | n (x.x%) | | n (x.x%) | |
| Confirmed (CR or PR) | n (x.x%) | | n (x.x%) | | n (x.x%) | | n (x.x%) | |

Abbreviations: mITT=modified intent-to-treat; RECIST=response evaluation criteria in solid tumors v1.1

Notes:
- Best response is defined by RECIST v1.1 as the best response recorded from the date of the first dose of CORT125134 or nab-paclitaxel, whichever is earliest, across all time points during study observation period (including both confirmed and unconfirmed responses).
- Objective response rate is defined by RECIST v1.1 as best response of CR or PR from the start of CORT125134 or nab-paclitaxel, whichever is earliest, across all time points during study observation period (including both confirmed and unconfirmed responses).
- Clinical benefit rate is defined as the patients who have achieved CR or PR, or SD for 16 weeks or greater.

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. Ovarian Cancer includes all ovarian cancer patients excluding juvenile granulosa subtype. Other Solid Tumors includes all patients not included in PDAC and ovarian cancer groups.
[2] Exact binomial confidence intervals (Clopper-Pearson).

Reference: Listing #(s)
Path\filename.sas ddmmmyyyy hh:mm

**Table 14.2.1.1**
**Efficacy Analysis: Best Response Defined by RECIST v1.1**
**mITT Population**
**Part 1 of 2**

| | Segment I: Continuous-Dosing Regimen | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | PDAC[1] (N= ) | | Ovarian Cancer[1] (N= ) | | Other Solid Tumors[1] (N= ) | | Total (N= ) | |
| Best Response | n (%) | 95% CI[2] | n (%) | 95% CI[2] | n (%) | 95% CI[2] | n (%) | 95% CI[2] |
| Clinical Benefit Rate (CBR) | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| Unconfirmed CBR | n (x.x%) | | n (x.x%) | | n (x.x%) | | n (x.x%) | |
| Confirmed CBR | n (x.x%) | | n (x.x%) | | n (x.x%) | | n (x.x%) | |

Abbreviations: mITT=modified intent-to-treat; RECIST=response evaluation criteria in solid tumors v1.1

Notes:
- Best response is defined by RECIST v1.1 as the best response recorded from the date of the first dose of CORT125134 or nab-paclitaxel, whichever is earliest, across all time points during study observation period (including both confirmed and unconfirmed responses).
- Objective response rate is defined by RECIST v1.1 as best response of CR or PR from the start of CORT125134 or nab-paclitaxel, whichever is earliest, across all time points during study observation period (including both confirmed and unconfirmed responses).
- Clinical benefit rate is defined as the patients who have achieved CR or PR, or SD for 16 weeks or greater.

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. Ovarian Cancer includes all ovarian cancer patients excluding juvenile granulosa subtype. Other Solid Tumors includes all patients not included in PDAC and ovarian cancer groups.
[2] Exact binomial confidence intervals (Clopper-Pearson).

Reference: Listing #(s)
Path\filename.sas ddmmmyyyy hh:mm

**Table 14.2.1.1**
**Efficacy Analysis: Best Response Defined by RECIST v1.1**
**mITT Population**
**Part 2 of 2**

| | Segment II: Intermittent-Dosing Regimen | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | PDAC[1] (N= ) | | Ovarian Cancer[1] (N= ) | | Other Solid Tumors[1] (N= ) | | Total (N= ) | | Total (N= ) | |
| Best Response | n (%) | 95% CI[2] | n (%) | 95% CI[2] | n (%) | 95% CI[2] | n (%) | 95% CI[2] | n (%) | 95% CI[2] |
| Complete Response (CR) | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| Unconfirmed (CR) | n (x.x%) | | n (x.x%) | | n (x.x%) | | n (x.x%) | | n (x.x%) | |
| Confirmed (CR) | n (x.x%) | | n (x.x%) | | n (x.x%) | | n (x.x%) | | n (x.x%) | |
| Partial Response (PR) | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| Unconfirmed (PR) | n (x.x%) | | n (x.x%) | | n (x.x%) | | n (x.x%) | | n (x.x%) | |
| Confirmed (PR) | n (x.x%) | | n (x.x%) | | n (x.x%) | | n (x.x%) | | n (x.x%) | |
| Stable Disease (SD) | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| Progressive Disease (PD) | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| Missing or Not Evaluable (NE) | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| Objective Response Rate (CR or PR) | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| Unconfirmed (CR or PR) | n (x.x%) | | n (x.x%) | | n (x.x%) | | n (x.x%) | | n (x.x%) | |
| Confirmed (CR or PR) | n (x.x%) | | n (x.x%) | | n (x.x%) | | n (x.x%) | | n (x.x%) | |

Abbreviations: mITT=modified intent-to-treat; RECIST=response evaluation criteria in solid tumors v1.1

Notes:
- Best response is defined by RECIST v1.1 as the best response recorded from the date of the first dose of CORT125134 or nab-paclitaxel, whichever is earliest, across all time points during study observation period (including both confirmed and unconfirmed responses).
- Objective response rate is defined by RECIST v1.1 as best response of CR or PR from the start of CORT125134 or nab-paclitaxel, whichever is earliest, across all time points during study observation period (including both confirmed and unconfirmed responses).
- Clinical benefit rate is defined as the patients who have achieved CR or PR, or SD for 16 weeks or greater.

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. Ovarian Cancer includes all ovarian cancer patients excluding juvenile granulosa subtype. Other Solid Tumors includes all patients not included in PDAC and ovarian cancer groups.
[2] Exact binomial confidence intervals (Clopper-Pearson).

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**Corcept Therapeutics**
**CORT125134-550**

**Database Date/Analysis: DDMMMYYYY/Draft**
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**Table 14.2.1.1**
**Efficacy Analysis: Best Response Defined by RECIST v1.1**
**mITT Population**
**Part 2 of 2**

| | Segment II: Intermittent-Dosing Regimen | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | PDAC[1] (N= ) | | Ovarian Cancer[1] (N= ) | | Other Solid Tumors[1] (N= ) | | Total (N= ) | | Total (N= ) | |
| Best Response | n (%) | 95% CI[2] | n (%) | 95% CI[2] | n (%) | 95% CI[2] | n (%) | 95% CI[2] | n (%) | 95% CI[2] |
| Clinical Benefit Rate (CBR) | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| Unconfirmed CBR | n (x.x%) | | n (x.x%) | | n (x.x%) | | n (x.x%) | | n (x.x%) | |
| Confirmed CBR | n (x.x%) | | n (x.x%) | | n (x.x%) | | n (x.x%) | | n (x.x%) | |

Abbreviations: mITT=modified intent-to-treat; RECIST=response evaluation criteria in solid tumors v1.1

Notes:
- Best response is defined by RECIST v1.1 as the best response recorded from the date of the first dose of CORT125134 or nab-paclitaxel, whichever is earliest, across all time points during study observation period (including both confirmed and unconfirmed responses).
- Objective response rate is defined by RECIST v1.1 as best response of CR or PR from the start of CORT125134 or nab-paclitaxel, whichever is earliest, across all time points during study observation period (including both confirmed and unconfirmed responses).
- Clinical benefit rate is defined as the patients who have achieved CR or PR, or SD for 16 weeks or greater.

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. Ovarian Cancer includes all ovarian cancer patients excluding juvenile granulosa subtype. Other Solid Tumors includes all patients not included in PDAC and ovarian cancer groups.
[2] Exact binomial confidence intervals (Clopper-Pearson).

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*Programming Note:*
- *Repeat for the following:*

*Table 14.2.1.2 Efficacy Analysis: Best Response Defined by RECIST v1.1 (Response-Evaluable Population)*

**Table 14.2.3**
**Survival Analysis: Overall Survival**
**mITT Population**

| | Segment I: Continuous-Dosing Regimen | | | | Segment II: Intermittent-Dosing Regimen | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Survival Estimates (Months) | PDAC[1] (N= ) | Ovarian Cancer[1] (N= ) | Other Solid Tumors[1] (N= ) | Total (N= ) | PDAC[1] (N= ) | Ovarian Cancer[1] (N= ) | Other Solid Tumors[1] (N= ) | Total (N= ) | Total (N= ) |
| Number (%) of Patients Who Died | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Number (%) of Patients Censored | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Quartiles (95% CI)[2] | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| 25th Percentile | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Median[3] | | | | | | | | | |
| 75th Percentile | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Range (Patients Who Died) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Range (All Patients) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |

Abbreviation: mITT=modified intent-to-treat

Note: Overall survival is defined as the time from date of the first dose of CORT125134 or nab-paclitaxel, whichever is earliest, to the date of death for any cause. Patients with no documentation of death on-study are censored at the date at which they are last known to be alive.

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. Ovarian Cancer includes all ovarian cancer patients excluding juvenile granulosa subtype. Other Solid Tumors includes all patients not included in PDAC and ovarian cancer groups.
[2] Kaplan-Meier product-limit estimates.
[3] Median is defined to be the smallest observed survival time for which the value of the estimated survival function is less than or equal to 0.5.

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**Table 14.2.4**
**Survival Analysis: Progression-Free Survival**
**mITT Population**

| | Segment I: Continuous-Dosing Regimen | | | | Segment II: Intermittent-Dosing Regimen | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Survival Estimates (Months) | PDAC[1] (N= ) | Ovarian Cancer[1] (N= ) | Other Solid Tumors[1] (N= ) | Total (N= ) | PDAC[1] (N= ) | Ovarian Cancer[1] (N= ) | Other Solid Tumors[1] (N= ) | Total (N= ) | Total (N= ) |
| Number (%) of Patients with Event | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Number (%) of Patients Censored | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Quartiles (95% CI)[3] | | | | | | | | | |
| 25th Percentile | x (x, x) | x (x, x) | x (x, x) | x (x, x) | x (x, x) | x (x, x) | x (x, x) | x (x, x) | x (x, x) |
| Median[4] | x (x, x) | x (x, x) | x (x, x) | x (x, x) | x (x, x) | x (x, x) | x (x, x) | x (x, x) | x (x, x) |
| 75th Percentile | x (x, x) | x (x, x) | x (x, x) | x (x, x) | x (x, x) | x (x, x) | x (x, x) | x (x, x) | x (x, x) |
| Range (Patients Who Died) | x, x | x, x | x, x | x, x | x, x | x, x | x, x | x, x | x, x |
| Range (All Patients) | x, x | x, x | x, x | x, x | x, x | x, x | x, x | x, x | x, x |
| Estimated Survival Distribution Function (# of Patients at Risk)[2] | | | | | | | | | |
| 6 Months | x.xxxx (n) | x.xxxx (n) | x.xxxx (n) | x.xxxx (n) | x.xxxx (n) | x.xxxx (n) | x.xxxx (n) | x.xxxx (n) | x.xxxx (n) |
| 12 Months | x.xxxx (n) | x.xxxx (n) | x.xxxx (n) | x.xxxx (n) | x.xxxx (n) | x.xxxx (n) | x.xxxx (n) | x.xxxx (n) | x.xxxx (n) |
| 24 Months | x.xxxx (n) | x.xxxx (n) | x.xxxx (n) | x.xxxx (n) | x.xxxx (n) | x.xxxx (n) | x.xxxx (n) | x.xxxx (n) | x.xxxx (n) |

Abbreviations: mITT=modified intent-to-treat; RECIST=response evaluation criteria in solid tumors v1.1

Note: Progression-free survival is defined as the time from date of first dose of CORT125134 or nab-paclitaxel, whichever is earliest, to the date of documented disease progression per RECIST v1.1 or death for any cause, whichever occurs first. Patients with no documentation of disease progression or death on-study are censored at the date of last available tumor assessment.

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. Ovarian Cancer includes all ovarian cancer patients excluding juvenile granulosa subtype. Other Solid Tumors includes all patients not included in PDAC and ovarian cancer groups.
[2] Kaplan-Meier product-limit estimates using the Brookmeyer-Crowley method.
[3] Median is defined to be the smallest observed survival time for which the value of the estimated survival function is less than or equal to 0.5.

Reference: *Listing #(s)*
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**Table 14.2.5**
**Survival Analysis: Duration of Response**
**mITT Population**

| | Segment I: Continuous-Dosing Regimen | | | | Segment II: Intermittent-Dosing Regimen | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Survival Estimates (Months) | PDAC[1] (N= ) | Ovarian Cancer[1] (N= ) | Other Solid Tumors[1] (N= ) | Total (N= ) | PDAC[1] (N= ) | Ovarian Cancer[1] (N= ) | Other Solid Tumors[1] (N= ) | Total (N= ) | Total (N= ) |
| Number of Patients with Response | n | n | n | n | n | n | n | n | n |
| Number (%) of Patients with Event | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Number (%) of Patients Censored | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Quartiles (95% CI)[2] | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| 25th Percentile | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Median[3] | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| 75th Percentile | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Range (Patients with Event) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Range (All Patients) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |

Abbreviations: CR=complete response; mITT=modified intent-to-treat; PR=partial response

Notes:

- Duration of response is defined as the date that criteria are met for CR or PR until the first date that progressive disease or death is objectively documented, whichever occurs first. Patients with no documentation of disease progression or death on-study are censored at the date of last available tumor assessment.
- Includes only patients who experience a response on-study.

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. Ovarian Cancer includes all ovarian cancer patients excluding juvenile granulosa subtype. Other Solid Tumors includes all patients not included in PDAC and ovarian cancer groups.
[2] Kaplan-Meier product-limit estimates.
[3] Median is defined to be the smallest observed survival time for which the value of the estimated survival function is less than or equal to 0.5.

Reference: *Listing #(s)*
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**Table 14.2.6.1**
**Efficacy Analysis: Best Response for CA-125 Defined by GCIG Criteria**
**mITT Population**
**Ovarian Cancer Patients**
**Part 1 of 2**

| | Segment I: Continuous-Dosing Regimen | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | PDAC[1] (N= ) | | Ovarian Cancer[1] (N= ) | | Other Solid Tumors[1] (N= ) | | Total (N= ) | |
| Best Response | n (%) | 95% CI[2] | n (%) | 95% CI[2] | n (%) | 95% CI[2] | n (%) | 95% CI[2] |
| Complete Response (CR) | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| Partial Response (PR) | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| Stable Disease (SD) | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| Progressive Disease (PD) | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| Missing or Not Evaluable (NE) | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |

Abbreviations: GCIG=Gynecological Cancer Intergroup; mITT=modified intent-to-treat

Note: A CA-125 response is defined as at least a 50% reduction in CA-125 levels from a pretreatment sample. Patients whose CA-125 levels fall within the reference range are classified as complete responders.

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. Ovarian Cancer includes all ovarian cancer patients excluding juvenile granulosa subtype. Other Solid Tumors includes all patients not included in PDAC and ovarian cancer groups.
[2] Exact binomial confidence intervals (Clopper-Pearson).

Reference: Listing #(s)
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**Table 14.2.6.1**
**Efficacy Analysis: Best Response for CA-125 Defined by GCIG Criteria**
**mITT Population**
**Ovarian Cancer Patients**
**Part 2 of 2**

| | Segment II: Intermittent-Dosing Regimen | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | PDAC[1] (N= ) | | Ovarian Cancer[1] (N= ) | | Other Solid Tumors[1] (N= ) | | Total (N= ) | | Total (N= ) | |
| Best Response | n (%) | 95% CI[2] | n (%) | 95% CI[2] | n (%) | 95% CI[2] | n (%) | 95% CI[2] | n (%) | 95% CI[2] |
| Complete Response (CR) | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| Partial Response (PR) | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| Stable Disease (SD) | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| Progressive Disease (PD) | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| Missing or Not Evaluable (NE) | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |

Abbreviations: GCIG=Gynecological Cancer Intergroup; mITT=modified intent-to-treat

Note: A CA-125 response is defined by GCIG as at least a 50% reduction in CA-125 levels from a pretreatment sample. Patients whose CA-125 levels fall within the reference range are classified as complete responders.

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. Ovarian Cancer includes all ovarian cancer patients excluding juvenile granulosa subtype. Other Solid Tumors includes all patients not included in PDAC and ovarian cancer groups.
[2] Exact binomial confidence intervals (Clopper-Pearson).

Reference: *Listing #(s)*
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*Programming Note:*

- *Repeat for the following:*

  *Table 14.2.6.2 Efficacy Analysis: Best Response for CA-125 Defined by GCIG Criteria (Response-Evaluable Population)*

**Table 14.2.7.1**
**Efficacy Analysis: Best Response for CA-125 Defined by GCIG Criteria and RECIST v1.1**
**mITT Population**
**Ovarian Cancer Patients**
**Part 1 of 2**

| | Segment I: Continuous-Dosing Regimen | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Best Response by RECIST v1.1 | PDAC[1] (N= ) | | Ovarian Cancer[1] (N= ) | | Other Solid Tumors[1] (N= ) | | Total (N= ) | |
| Response for CA-125 by GCIG | n (%) | 95% CI[2] | n (%) | 95% CI[2] | n (%) | 95% CI[2] | n (%) | 95% CI[2] |
| Combined Overall Response Rate (RECIST Response or CA-125 Response) | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| Complete Response (CR) | | | | | | | | |
| Yes | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| No or PD | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| NE | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| Partial Response (PR) | | | | | | | | |
| Yes | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| No or PD | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| NE | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |

Abbreviations: GCIG=Gynecological Cancer Intergroup; mITT=modified intent-to-treat; NE=not evaluable; RECIST=response evaluation criteria in solid tumors v1.1

Notes:
- Best response is defined by RECIST v1.1 as the best response recorded from the date of the first dose of CORT125134 or nab-paclitaxel, whichever is earliest, across all time points during study observation period (including both confirmed and unconfirmed responses).
- A CA-125 response is defined by GCIG as at least a 50% reduction in CA-125 levels from a pretreatment sample. Patients whose CA-125 levels fall within the reference range are classified as complete responders.

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. Ovarian Cancer includes all ovarian cancer patients excluding juvenile granulosa subtype. Other Solid Tumors includes all patients not included in PDAC and ovarian cancer groups.
[2] Exact binomial confidence intervals (Clopper-Pearson).

Reference: Listing #(s)
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**Table 14.2.7.1**
**Efficacy Analysis: Best Response for CA-125 Defined by GCIG Criteria and RECIST v1.1**
**mITT Population**
**Ovarian Cancer Patients**
**Part 1 of 2**

| | Segment I: Continuous-Dosing Regimen | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Best Response by RECIST v1.1 | PDAC[1] (N= ) | | Ovarian Cancer[1] (N= ) | | Other Solid Tumors[1] (N= ) | | Total (N= ) | |
| Response for CA-125 by GCIG | n (%) | 95% CI[2] | n (%) | 95% CI[2] | n (%) | 95% CI[2] | n (%) | 95% CI[2] |
| Stable Disease (SD) | | | | | | | | |
| Yes | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| No or PD | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| NE | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| Progressive Disease (PD) | | | | | | | | |
| Yes | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| No or PD | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| NE | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| Missing or Not Evaluable (NE) | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| Yes | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| No or PD | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| NE | | | | | | | | |

Abbreviations: GCIG=Gynecological Cancer Intergroup; mITT=modified intent-to-treat; NE=not evaluable; RECIST=response evaluation criteria in solid tumors v1.1

Notes:
- Best response is defined by RECIST v1.1 as the best response recorded from the date of the first dose of CORT125134 or nab-paclitaxel, whichever is earliest, across all time points during study observation period (including both confirmed and unconfirmed responses).
- A CA-125 response is defined by GCIG as at least a 50% reduction in CA-125 levels from a pretreatment sample. Patients whose CA-125 levels fall within the reference range are classified as complete responders.

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. Ovarian Cancer includes all ovarian cancer patients excluding juvenile granulosa subtype. Other Solid Tumors includes all patients not included in PDAC and ovarian cancer groups.
[2] Exact binomial confidence intervals (Clopper-Pearson).

Reference: Listing #(s)
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**Table 14.2.7.1**
**Efficacy Analysis: Best Response for CA-125 Defined by GCIG Criteria and RECIST v1.1**
**mITT Population**
**Ovarian Cancer Patients**
**Part 2 of 2**

| | Segment II: Intermittent-Dosing Regimen | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | PDAC[1] (N= ) | | Ovarian Cancer[1] (N= ) | | Other Solid Tumors[1] (N= ) | | Total (N= ) | | Total (N= ) | |
| Best Response by RECIST v1.1<br>Response for CA-125 by GCIG | n (%) | 95% CI[2] | n (%) | 95% CI[2] | n (%) | 95% CI[2] | n (%) | 95% CI[2] | n (%) | 95% CI[2] |
| Combined Overall Response Rate<br>(RECIST Response or CA-125 Response) | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| Complete Response (CR) | | | | | | | | | | |
| Yes | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| No or PD | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| NE | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| Partial Response (PR) | | | | | | | | | | |
| Yes | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| No or PD | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| NE | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |

Abbreviations: GCIG=Gynecological Cancer Intergroup; mITT=modified intent-to-treat; NE=not evaluable; RECIST=response evaluation criteria in solid tumors v1.1

Notes:
- Best response is defined by RECIST v1.1 as the best response recorded from the date of the first dose of CORT125134 or nab-paclitaxel, whichever is earliest, across all time points during study observation period (including both confirmed and unconfirmed responses).
- A CA-125 response is defined by GCIG as at least a 50% reduction in CA-125 levels from a pretreatment sample. Patients whose CA-125 levels fall within the reference range are classified as complete responders.

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. Ovarian Cancer includes all ovarian cancer patients excluding juvenile granulosa subtype. Other Solid Tumors includes all patients not included in PDAC and ovarian cancer groups.
[2] Exact binomial confidence intervals (Clopper-Pearson).

Reference: Listing #(s)
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**Table 14.2.7.1**
**Efficacy Analysis: Best Response for CA-125 Defined by GCIG Criteria and RECIST v1.1**
**mITT Population**
**Ovarian Cancer Patients**
**Part 2 of 2**

| | Segment II: Intermittent-Dosing Regimen | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | PDAC[1] (N= ) | | Ovarian Cancer[1] (N= ) | | Other Solid Tumors[1] (N= ) | | Total (N= ) | | Total (N= ) | |
| Best Response by RECIST v1.1<br>Response for CA-125 by GCIG | n (%) | 95% CI[2] | n (%) | 95% CI[2] | n (%) | 95% CI[2] | n (%) | 95% CI[2] | n (%) | 95% CI[2] |
| Stable Disease (SD) | | | | | | | | | | |
| Yes | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| No or PD | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| NE | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| Progressive Disease (PD) | | | | | | | | | | |
| Yes | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| No or PD | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| NE | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| Missing or Not Evaluable (NE) | | | | | | | | | | |
| Yes | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| No or PD | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |
| NE | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% | n (x.x%) | xx.x%, xx.x% |

Abbreviations: GCIG=Gynecological Cancer Intergroup; mITT=modified intent-to-treat; NE=not evaluable; RECIST=response evaluation criteria in solid tumors v1.1

Notes:
- Best response is defined by RECIST v1.1 as the best response recorded from the date of the first dose of CORT125134 or nab-paclitaxel, whichever is earliest, across all time points during study observation period (including both confirmed and unconfirmed responses).
- A CA-125 response is defined by GCIG as at least a 50% reduction in CA-125 levels from a pretreatment sample. Patients whose CA-125 levels fall within the reference range are classified as complete responders.

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. Ovarian Cancer includes all ovarian cancer patients excluding juvenile granulosa subtype. Other Solid Tumors includes all patients not included in PDAC and ovarian cancer groups.
[2] Exact binomial confidence intervals (Clopper-Pearson).

Reference: Listing #(s)
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*See Programming Notes on next page*

*Programming Note:*

- *Repeat for the following:*

*Table 14.2.7.2 Efficacy Analysis: Best Response for CA-125 Defined by GCIG Criteria and RECIST v1.1 (Response-Evaluable Population)*

**Table 14.3.1.1**
**Overall Summary of Treatment-Emergent Adverse Events**
**Safety Population**

| | Segment I: Continuous-Dosing Regimen[1] | | | | Segment II: Intermittent-Dosing Regimen[1] | | | |
|---|---|---|---|---|---|---|---|---|
| | 100 mg / 60 mg/m$^2$ (N= ) | 100 mg / 80 mg/m$^2$ (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | Total (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | 200 mg / 100 mg/m$^2$ (N= ) | Total (N= ) | Total (N= ) |
| Total Number of TEAEs | xx | xx | xx | xx | xx | xx | xx | xx |
| Total Number of TESAEs | xx | xx | xx | xx | xx | xx | xx | xx |
| Number (%) of Patients Reporting at Least One: | | | | | | | | |
| TEAE | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| TEAE Related to CORT125134[2] | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| TEAE Related to Nab-paclitaxel[2] | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| TEAE ≥ Grade 3 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| TEAE ≥ Grade 3 Related to CORT125134[2] | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| TEAE ≥ Grade 3 Related to Nab-paclitaxel[2] | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| TEAE Leading to Discontinuation of: | | | | | | | | |
| Any Study Drug | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| CORT125134 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Nab-paclitaxel | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| TEAE Requiring Dose Interruption of: | | | | | | | | |
| Any Study Drug | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| CORT125134 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Nab-paclitaxel | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| TEAE Leading to Dose Reduction of: | | | | | | | | |
| Any Study Drug | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| CORT125134 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Nab-paclitaxel | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |

Abbreviations: TEAE=CORT125134 treatment-emergent adverse event; TESAE=CORT125134 treatment-emergent serious adverse event

Note: Treatment-emergent adverse events are those events that occur from the first dose of CORT125134 through 28 days after administration of the last dose of study drug.

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m2).
[2] Patients reporting more than one adverse event are counted only once using the closest relationship to study drug. Not related events includes those reported as "Not Related" to study drug; related events include those reported as "Possibly Related" or "Probably Related" to study drug.

Reference: *Listing #(s)*
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**Table 14.3.1.1**
**Overall Summary of Treatment-Emergent Adverse Events**
**Safety Population**

| | Segment I: Continuous-Dosing Regimen[1] | | | | Segment II: Intermittent-Dosing Regimen[1] | | | |
|---|---|---|---|---|---|---|---|---|
| | 100 mg / 60 mg/m$^2$ (N= ) | 100 mg / 80 mg/m$^2$ (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | Total (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | 200 mg / 100 mg/m$^2$ (N= ) | Total (N= ) | Total (N= ) |
| TEAE Causing Death | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| TESAE | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| TESAE Related to CORT125134[2] | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| TESAE Related to Nab-paclitaxel[2] | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |

Abbreviations: TEAE=CORT125134 treatment-emergent adverse event; TESAE=CORT125134 treatment-emergent serious adverse event

Note: Treatment-emergent adverse events are those events that occur from the first dose of CORT125134 through 28 days after administration of the last dose of study drug.

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Patients reporting more than one adverse event are counted only once using the closest relationship to study drug. Not related events includes those reported as "Not Related" to study drug; related events include those reported as "Possibly Related" or "Probably Related" to study drug.

Reference: *Listing #(s)*
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**Table 14.3.1.2**
**Treatment-Emergent Adverse Events by System Organ Class and Preferred Term**
**Safety Population**

| System Organ Class[2] / Preferred Term[2] | Segment I: Continuous-Dosing Regimen[1] 100 mg / 60 mg/m$^2$ (N= ) | 100 mg / 80 mg/m$^2$ (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | Total (N= ) | Segment II: Intermittent-Dosing Regimen[1] 150 mg / 80 mg/m$^2$ (N= ) | 200 mg / 100 mg/m$^2$ (N= ) | Total (N= ) | Total (N= ) |
|---|---|---|---|---|---|---|---|---|
| Patients Reporting at Least One Adverse Event | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| System Organ Class #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | |
| System Organ Class #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | |

Notes:

- At each level of summarization (any event, system organ class, and preferred term), patients reporting more than one adverse event are counted only once.
- Treatment-emergent adverse events are those events that occur from the first dose of CORT125134 through 28 days after administration of the last dose of study drug.

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Adverse events are coded to system organ class and preferred term using the Medical Dictionary for Regulatory Activities (MedDRA), version 19.0.

Reference: *Listing #(s)*
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*Programming Notes:*

- *Sort events by descending order of system organ class incidence and by descending order of preferred term incidence within system organ class, based on the overall incidence (ie, sum over all treatment groups).*
- *Exclude AEs which occur > 28 days after last dose of study drug (any study drug)*

**Table 14.3.1.3**
**Most Frequently-Occurring (≥ 10% Overall) Treatment-Emergent Adverse Events**
**Safety Population**

| | Segment I: Continuous-Dosing Regimen[1] | | | | Segment II: Intermittent-Dosing Regimen[1] | | | |
|---|---|---|---|---|---|---|---|---|
| Preferred Term[2] | 100 mg / 60 mg/m$^2$ (N= ) | 100 mg / 80 mg/m$^2$ (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | Total (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | 200 mg / 100 mg/m$^2$ (N= ) | Total (N= ) | Total (N= ) |
| Preferred Term #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | |

Note: Patients reporting more than one adverse event are counted only once. Summary includes all events reported by ≥ 10% of patients in the Safety Population.

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m2).
[2] Adverse events are coded to preferred term using the Medical Dictionary for Regulatory Activities (MedDRA), version 19.0.

Reference: *Listing #(s)*
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*Programming Note: Sort events by descending order of preferred term incidence, based on the overall incidence (ie, sum over all treatment groups).*

**Corcept Therapeutics**
**CORT125134-550**

**Database Date/Analysis: DDMMMYYYY/Draft**
**Page x of y**

**14.3.1.4**
**Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and CTCAE Grade**
**Safety Population**

| System Organ Class[2] / Preferred Term[2] | CTCAE Grade | Segment I: Continuous-Dosing Regimen[1] 100 mg / 60 mg/m$^2$ (N= ) | 100 mg / 80 mg/m$^2$ (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | Total (N= ) | Segment II: Intermittent-Dosing Regimen[1] 150 mg / 80 mg/m$^2$ (N= ) | 200 mg / 100 mg/m$^2$ (N= ) | Total (N= ) | Total (N= ) |
|---|---|---|---|---|---|---|---|---|---|
| Patients Reporting at Least One Adverse Event | Grade 1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Grade 2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Grade 3 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Grade 4 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Grade 5 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| System Organ Class #1 | Grade 1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Grade 2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Grade 3 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Grade 4 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Grade 5 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #1 | Grade 1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Grade 2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Grade 3 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Grade 4 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Grade 5 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | … | | | | | | | | |

Abbreviation: CTCAE=Common Terminology Criteria for Adverse Events v4.03

Notes:

- At each level of summarization (any event, system organ class, and preferred term), patients reporting more than one adverse event are counted using the highest CTCAE grade, v4.03.
- Treatment-emergent adverse events are those events that occur from the first dose of CORT125134 through 28 days after administration of the last dose of study drug.

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Adverse events are coded to system organ class and preferred term using the Medical Dictionary for Regulatory Activities (MedDRA), version 19.0.

Reference: *Listing #(s)*
Path\filename.sas ddmmmyyyy hh:mm

*See programming notes on the next page.*

*Programming Notes:*

- *Sort events by descending order of system organ class incidence and by descending order of preferred term incidence within system organ class, based on the overall incidence (ie, sum over all treatment groups).*
- *Exclude AEs which occur > 28 days after last dose of study drug (any study drug)*

**Table 14.3.1.5**
**Treatment-Emergent CORT125134 Related Adverse Events by System Organ Class and Preferred Term**
**Safety Population**

| System Organ Class[2] / Preferred Term[2] | Segment I: Continuous-Dosing Regimen[1] | | | | Segment II: Intermittent-Dosing Regimen[1] | | | |
|---|---|---|---|---|---|---|---|---|
| | 100 mg / 60 mg/m$^2$ (N= ) | 100 mg / 80 mg/m$^2$ (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | Total (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | 200 mg / 100 mg/m$^2$ (N= ) | Total (N= ) | Total (N= ) |
| Patients Reporting at Least One CORT125134 Related Adverse Event | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| System Organ Class #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | |
| System Organ Class #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | |

Notes:

- At each level of summarization (any event, system organ class, and preferred term), patients reporting more than one adverse event are counted only once. Related adverse events are those reported as "Possibly Related" or "Probably Related" to CORT125134.
- Treatment-emergent adverse events are those events that occur from the first dose of CORT125134 through 28 days after administration of the last dose of study drug.

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Adverse events are coded to system organ class and preferred term using the Medical Dictionary for Regulatory Activities (MedDRA), version 19.0.

Reference: *Listing #(s)*
Path\filename.sas ddmmmyyyy hh:mm

*Programming Notes:*

- *Sort events by descending order of system organ class incidence and by descending order of preferred term incidence within system organ class, based on the overall incidence (ie, sum over all treatment groups).*
- *Include all AEs related to CORT125134*
- *Exclude AEs which occur > 28 days after last dose of study drug (any study drug)*

**Table 14.3.1.6**
**Most Frequently-Occurring (≥ 10% Overall) Treatment-Emergent Adverse Events Related to CORT125134**
**Safety Population**

| | Segment I: Continuous-Dosing Regimen[1] | | | | Segment II: Intermittent-Dosing Regimen[1] | | | |
|---|---|---|---|---|---|---|---|---|
| Preferred Term[2] | 100 mg / 60 mg/m$^2$ (N= ) | 100 mg / 80 mg/m$^2$ (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | Total (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | 200 mg / 100 mg/m$^2$ (N= ) | Total (N= ) | Total (N= ) |
| Preferred Term #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | |

Note: Patients reporting more than one related adverse event are counted only once. Summary includes all related events (ie, “Possibly Related,” “Probably Related,” or “Definitely Related” to CORT125134) reported by ≥ 10% of patients in the Safety Population.

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m2).
[2] Adverse events are coded to preferred term using the Medical Dictionary for Regulatory Activities (MedDRA), version 19.0.

Reference: *Listing #(s)*
Path\filename.sas ddmmmyyyy hh:mm

*Programming Note: Sort events by descending order of preferred term incidence, based on the overall incidence (ie, sum over all treatment groups).*

**Table 14.3.1.7**
**Most Frequently-Occurring (≥ 10% Overall) Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and CTCAE Grade**
**Safety Population**

| | | Segment I: Continuous-Dosing Regimen[1] | | | | Segment II: Intermittent-Dosing Regimen[1] | | | |
|---|---|---|---|---|---|---|---|---|---|
| System Organ Class[2] / Preferred Term[2] | CTCAE Grade | 100 mg / 60 mg/m$^2$ (N= ) | 100 mg / 80 mg/m$^2$ (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | Total (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | 200 mg / 100 mg/m$^2$ (N= ) | Total (N= ) | Total (N= ) |
| Patients Reporting at Least One Most Frequently-Occurring (≥ 10% Overall) Adverse Event | Any Grade | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Grade 1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Grade 2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Grade 3 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Grade 4 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Grade 5 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| System Organ Class #1 | Any Grade | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Grade 1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Grade 2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Grade 3 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Grade 4 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Grade 5 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #1 | Any Grade | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Grade 1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Grade 2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Grade 3 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Grade 4 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Grade 5 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | … | | | | | | | | |

Abbreviation: CTCAE=Common Terminology Criteria for Adverse Events, v4.03

Notes:
- At each level of summarization (any event, system organ class, and preferred term) patients reporting more than one adverse event are counted only once using the highest CTCAE grade, v4.03.
- Treatment-emergent adverse events are those events that occur from the first dose of CORT125134 through 28 days after administration of the last dose of study drug.

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$),
[2] Adverse events are coded to preferred term using the Medical Dictionary for Regulatory Activities (MedDRA), version 19.0.

Reference: *Listing #(s)*
Path\filename.sas ddmmmyyyy hh:mm

*Programming Notes:*

- *Sort events by descending order of of system organ class incidence and by descending order of preferred term incidence, based on the overall incidence (ie, sum over all treatment groups).*
- *AEs with a missing CTCAE Grade are excluded from the table*
- *"Any Grade" Total is used to determine the ≥ 10% for each Segment*
- *Exclude AEs which occur > 28 days after last dose of study drug (any study drug)*

**Table 14.3.1.8**
**Treatment-Emergent Grade ≥ 3 Adverse Events by System Organ Class and Preferred Term**
**Safety Population**

| System Organ Class[2] / Preferred Term[2] | Segment I: Continuous-Dosing Regimen[1] | | | | Segment II: Intermittent-Dosing Regimen[1] | | | Total |
|---|---|---|---|---|---|---|---|---|
| | 100 mg / 60 mg/m$^2$ (N= ) | 100 mg / 80 mg/m$^2$ (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | Total (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | 200 mg / 100 mg/m$^2$ (N= ) | Total (N= ) | |
| Patients Reporting at Least One Grade ≥ 3 Adverse Event | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| System Organ Class #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | |
| System Organ Class #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | |

Notes:

- At each level of summarization (any event, system organ class, and preferred term), patients reporting more than one adverse event are counted only once.
- Treatment-emergent adverse events are those events that occur from the first dose of CORT125134 through 28 days after administration of the last dose of study drug.

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Adverse events are coded to system organ class and preferred term using the Medical Dictionary for Regulatory Activities (MedDRA), version 19.0.

Reference: *Listing #(s)*
Path\filename.sas ddmmmyyyy hh:mm

*Programming Notes:*

- *Sort events by descending order of system organ class incidence and by descending order of preferred term incidence within system organ class, based on the overall incidence (ie, sum over all treatment groups).*
- *Include all AEs with Grade ≥ 3*
- *Exclude AEs which occur > 28 days after last dose of study drug (any study drug)*

**Table 14.3.1.9**
**Treatment-Emergent Grade ≥ 3 Adverse Events Related to CORT125134 by System Organ Class and Preferred Term**
**Safety Population**

| System Organ Class[2] / Preferred Term[2] | Segment I: Continuous-Dosing Regimen[1] | | | | Segment II: Intermittent-Dosing Regimen[1] | | | |
|---|---|---|---|---|---|---|---|---|
| | 100 mg / 60 mg/m$^2$ (N= ) | 100 mg / 80 mg/m$^2$ (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | Total (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | 200 mg / 100 mg/m$^2$ (N= ) | Total (N= ) | Total (N= ) |
| Patients Reporting at Least One CORT125134 Related Grade ≥ 3 Adverse Event | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| System Organ Class #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | |
| System Organ Class #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | |

Notes:

- At each level of summarization (any event, system organ class, and preferred term), patients reporting more than one adverse event are counted only once. Related adverse events are those reported as "Possibly Related" or "Probably Related" to CORT125134.
- Treatment-emergent adverse events are those events that occur from the first dose of CORT125134 through 28 days after administration of the last dose of study drug.

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m2).
[2] Adverse events are coded to system organ class and preferred term using the Medical Dictionary for Regulatory Activities (MedDRA), version 19.0.

Reference: *Listing #(s)*
Path\filename.sas ddmmmyyyy hh:mm

*Programming Notes:*

- *Sort events by descending order of system organ class incidence and by descending order of preferred term incidence within system organ class, based on the overall incidence (ie, sum over all treatment groups).*
- *Include all AEs related to CORT125134 with grade ≥ 3*
- *Exclude AEs which occur > 28 days after last dose of study drug (any study drug)*

**Table 14.3.1.10**
**Treatment-Emergent Grade ≥ 3 Adverse Events Related to Nab-paclitaxel by System Organ Class and Preferred Term**
**Safety Population**

| System Organ Class[2] / Preferred Term[2] | Segment I: Continuous-Dosing Regimen[1] | | | | Segment II: Intermittent-Dosing Regimen[1] | | | |
|---|---|---|---|---|---|---|---|---|
| | 100 mg / 60 mg/m$^2$ (N= ) | 100 mg / 80 mg/m$^2$ (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | Total (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | 200 mg / 100 mg/m$^2$ (N= ) | Total (N= ) | Total (N= ) |
| Patients Reporting at Least One Nab-paclitaxel Related Grade ≥ 3 Adverse Event | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| System Organ Class #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | |
| System Organ Class #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | |

Note: At each level of summarization (any event, system organ class, and preferred term), patients reporting more than one related and severe adverse event are counted only once. Related adverse events are those reported as "Possibly Related," "Probably Related," or "Definitely Related" to Nab-paclitaxel.

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m2).
[2] Adverse events are coded to system organ class and preferred term using the Medical Dictionary for Regulatory Activities (MedDRA), version 19.0.

Reference: *Listing #(s)*
Path\filename.sas ddmmmyyyy hh:mm

**Table 14.3.1.11**
**Treatment-Emergent Adverse Events by System Organ Class and Preferred Term Leading to Withdrawal of Any Study Drug**
**Safety Population**

| System Organ Class[2] / Preferred Term[2] | Segment I: Continuous-Dosing Regimen[1] | | | | Segment II: Intermittent-Dosing Regimen[1] | | | |
|---|---|---|---|---|---|---|---|---|
| | 100 mg / 60 mg/m$^2$ (N= ) | 100 mg / 80 mg/m$^2$ (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | Total (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | 200 mg / 100 mg/m$^2$ (N= ) | Total (N= ) | Total (N= ) |
| Patients Reporting at Least One Adverse Event Leading to Withdrawal of Any Study Drug | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| System Organ Class #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | |
| System Organ Class #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | |

Notes:

- At each level of summarization (any event, system organ class, and preferred term), patients reporting more than one adverse event are counted only once.
- Treatment-emergent adverse events are those events that occur from the first dose of CORT125134 through 28 days after administration of the last dose of study drug.
- Includes events when action taken with CORT125134 or Nab-paclitaxel is "Drug Withdrawn."

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Adverse events are coded to system organ class and preferred term using the Medical Dictionary for Regulatory Activities (MedDRA), version 19.0.

Reference: *Listing #(s)*
Path\filename.sas ddmmmyyyy hh:mm

*Programming Notes:*

- *Sort events by descending order of system organ class incidence and by descending order of preferred term incidence within system organ class, based on the overall incidence (ie, sum over all treatment groups).*
- *Include all AEs with Action Taken with CORT125134 = 'Drug Withdrawn' or Action Taken with Nab-paclitaxel = 'Drug Withdrawn'*
- *Exclude AEs which occur > 28 days after last dose of study drug (any study drug)*

**Table 14.3.1.12**
**Treatment-Emergent Adverse Events by System Organ Class and Preferred Term Leading to Withdrawal of CORT125134**
**Safety Population**

| System Organ Class[2] / Preferred Term[2] | Segment I: Continuous-Dosing Regimen[1] | | | | Segment II: Intermittent-Dosing Regimen[1] | | | |
|---|---|---|---|---|---|---|---|---|
| | 100 mg / 60 mg/m$^2$ (N= ) | 100 mg / 80 mg/m$^2$ (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | Total (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | 200 mg / 100 mg/m$^2$ (N= ) | Total (N= ) | Total (N= ) |
| Patients Reporting at Least One Adverse Event Leading to Withdrawal of CORT125134 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| System Organ Class #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | |
| System Organ Class #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | |

Notes:

- At each level of summarization (any event, system organ class, and preferred term), patients reporting more than one adverse event are counted only once.
- Treatment-emergent adverse events are those events that occur from the first dose of CORT125134 through 28 days after administration of the last dose of study drug.
- Includes events when action taken with CORT125134 is "Drug Withdrawn."

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Adverse events are coded to system organ class and preferred term using the Medical Dictionary for Regulatory Activities (MedDRA), version 19.0.

Reference: *Listing #(s)*
Path\filename.sas ddmmmyyyy hh:mm

*Programming Notes:*

- *Sort events by descending order of system organ class incidence and by descending order of preferred term incidence within system organ class, based on the overall incidence (ie, sum over all treatment groups).*
- *Include all AEs with Action Taken with CORT125134 = 'Drug Withdrawn'*
- *Exclude AEs which occur > 28 days after last dose of study drug (any study drug)*

**Table 14.3.1.13**
**Treatment-Emergent Adverse Events by System Organ Class and Preferred Term Leading to Withdrawal of Nab-paclitaxel**
**Safety Population**

| | Segment I: Continuous-Dosing Regimen[1] | | | | Segment II: Intermittent-Dosing Regimen[1] | | | |
|---|---|---|---|---|---|---|---|---|
| System Organ Class[2] / Preferred Term[2] | 100 mg / 60 mg/m$^2$ (N= ) | 100 mg / 80 mg/m$^2$ (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | Total (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | 200 mg / 100 mg/m$^2$ (N= ) | Total (N= ) | Total (N= ) |
| Patients Reporting at Least One Adverse Event Leading to Withdrawal of Nab-paclitaxel | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| System Organ Class #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | |
| System Organ Class #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | |

Notes:

- At each level of summarization (any event, system organ class, and preferred term), patients reporting more than one adverse event are counted only once.
- Treatment-emergent adverse events are those events that occur from the first dose of CORT125134 through 28 days after administration of the last dose of study drug.
- Includes events when action taken with Nab-paclitaxel is "Drug Withdrawn."

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Adverse events are coded to system organ class and preferred term using the Medical Dictionary for Regulatory Activities (MedDRA), version 19.0.

Reference: *Listing #(s)*
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*Programming Notes:*

- *Sort events by descending order of system organ class incidence and by descending order of preferred term incidence within system organ class, based on the overall incidence (ie, sum over all treatment groups).*
- *Include all AEs with Action Taken with Nab-paclitaxel = 'Drug Withdrawn'*
- *Exclude AEs which occur > 28 days after last dose of study drug (any study drug)*

**Table 14.3.1.14**
**Treatment-Emergent Adverse Events by System Organ Class and Preferred Term Leading to Interruption of Any Study Drug**
**Safety Population**

| System Organ Class[2] / Preferred Term[2] | Segment I: Continuous-Dosing Regimen[1] 100 mg / 60 mg/m$^2$ (N= ) | 100 mg / 80 mg/m$^2$ (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | Total (N= ) | Segment II: Intermittent-Dosing Regimen[1] 150 mg / 80 mg/m$^2$ (N= ) | 200 mg / 100 mg/m$^2$ (N= ) | Total (N= ) | Total (N= ) |
|---|---|---|---|---|---|---|---|---|
| Patients Reporting at Least One Adverse Event Leading to Any Study Drug Interruption | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| System Organ Class #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | |
| System Organ Class #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | |

Notes:

- At each level of summarization (any event, system organ class, and preferred term), patients reporting more than one adverse event are counted only once.
- Treatment-emergent adverse events are those events that occur from the first dose of CORT125134 through 28 days after administration of the last dose of study drug.
- Includes events when action taken with CORT125134 or Nab-paclitaxel is "Dose Interrupted" or "Drug Interrupted and then Dose Reduced."

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Adverse events are coded to system organ class and preferred term using the Medical Dictionary for Regulatory Activities (MedDRA), version 19.0.

Reference: *Listing #(s)*
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*Programming Notes:*

- *Sort events by descending order of system organ class incidence and by descending order of preferred term incidence within system organ class, based on the overall incidence (ie, sum over all treatment groups).*
- *Include all AEs with Action Taken with CORT125134 = 'Drug Interrupted' or 'Drug Interrrupted and then Dose Reduced' or Action Taken with Nab-Paclitaxel = 'Drug Interrupted' or 'Drug Interrrupted and then Dose Reduced'*
- *Exclude AEs which occur > 28 days after last dose of study drug (any study drug)*

**Table 14.3.1.15**
**Treatment-Emergent Adverse Events by System Organ Class and Preferred Term Leading to Interruption of CORT125134**
**Safety Population**

| System Organ Class[2] / Preferred Term[2] | Segment I: Continuous-Dosing Regimen[1] | | | | Segment II: Intermittent-Dosing Regimen[1] | | | |
|---|---|---|---|---|---|---|---|---|
| | 100 mg / 60 mg/m$^2$ (N= ) | 100 mg / 80 mg/m$^2$ (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | Total (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | 200 mg / 100 mg/m$^2$ (N= ) | Total (N= ) | Total (N= ) |
| Patients Reporting at Least One Adverse Event Leading to CORT125134 Interruption | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| System Organ Class #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | |
| System Organ Class #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | |

Notes:

- At each level of summarization (any event, system organ class, and preferred term), patients reporting more than one adverse event are counted only once.
- Treatment-emergent adverse events are those events that occur from the first dose of CORT125134 through 28 days after administration of the last dose of study drug.
- Includes events when action taken with CORT125134 is "Dose Interrupted" or "Drug Interrupted and then Dose Reduced."

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Adverse events are coded to system organ class and preferred term using the Medical Dictionary for Regulatory Activities (MedDRA), version 19.0.

Reference: *Listing #(s)*
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*Programming Notes:*

- *Sort events by descending order of system organ class incidence and by descending order of preferred term incidence within system organ class, based on the overall incidence (ie, sum over all treatment groups).*
- *Include all AEs with Action Taken with CORT125134 = 'Drug Interrupted' or 'Drug Interrrupted and then Dose Reduced'*
- *Exclude AEs which occur > 28 days after last dose of study drug (any study drug)*

**Corcept Therapeutics**
**CORT125134-550**

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**Table 14.3.1.16**
**Treatment-Emergent Adverse Events by System Organ Class and Preferred Term Leading to Interruption of Nab-paclitaxel**
**Safety Population**

| System Organ Class[2] / Preferred Term[2] | Segment I: Continuous-Dosing Regimen[1] | | | | Segment II: Intermittent-Dosing Regimen[1] | | | |
|---|---|---|---|---|---|---|---|---|
| | 100 mg / 60 mg/m$^2$ (N= ) | 100 mg / 80 mg/m$^2$ (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | Total (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | 200 mg / 100 mg/m$^2$ (N= ) | Total (N= ) | Total (N= ) |
| Patients Reporting at Least One Adverse Event Leading to Nab-paclitaxel Interruption | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| System Organ Class #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | |
| System Organ Class #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | |

Notes:

- At each level of summarization (any event, system organ class, and preferred term), patients reporting more than one adverse event are counted only once.
- Treatment-emergent adverse events are those events that occur from the first dose of CORT125134 through 28 days after administration of the last dose of study drug.
- Includes events when action taken with Nab-paclitaxel is "Dose Interrupted" or "Drug Interrupted and then Dose Reduced."

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Adverse events are coded to system organ class and preferred term using the Medical Dictionary for Regulatory Activities (MedDRA), version 19.0.

Reference: *Listing #(s)*
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*Programming Notes:*

- *Sort events by descending order of system organ class incidence and by descending order of preferred term incidence within system organ class, based on the overall incidence (ie, sum over all treatment groups).*
- *Include all AEs with Action Taken with Nab-paclitaxel = 'Drug Interrupted' or 'Drug Interrupted and then Dose Reduced'*
- *Exclude AEs which occur > 28 days after last dose of study drug (any study drug)*

**Corcept Therapeutics**
**CORT125134-550**

**Database Date/Analysis: DDMMMYYYY/Draft**
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**Table 14.3.1.17**
**Treatment-Emergent Adverse Events by System Organ Class and Preferred Term Leading to Reduction of Any Study Drug**
**Safety Population**

| | Segment I: Continuous-Dosing Regimen[1] | | | | Segment II: Intermittent-Dosing Regimen[1] | | | |
|---|---|---|---|---|---|---|---|---|
| System Organ Class[2] / Preferred Term[2] | 100 mg / 60 mg/m$^2$ (N= ) | 100 mg / 80 mg/m$^2$ (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | Total (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | 200 mg / 100 mg/m$^2$ (N= ) | Total (N= ) | Total (N= ) |
| Patients Reporting at Least One Adverse Event Leading to Any Study Drug Reduction | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| System Organ Class #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | |
| System Organ Class #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | |

Notes:

- At each level of summarization (any event, system organ class, and preferred term), patients reporting more than one adverse event are counted only once.
- Treatment-emergent adverse events are those events that occur from the first dose of CORT125134 through 28 days after administration of the last dose of study drug.
- Includes events when action taken with CORT125134 or Nab-paclitaxel is "Dose Reduced" or "Drug Interrupted and then Dose Reduced."

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Adverse events are coded to system organ class and preferred term using the Medical Dictionary for Regulatory Activities (MedDRA), version 19.0.

Reference: *Listing #(s)*
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*Programming Notes:*

- *Sort events by descending order of system organ class incidence and by descending order of preferred term incidence within system organ class, based on the overall incidence (ie, sum over all treatment groups).*
- *Include all AEs with Action Taken with CORT125134 = 'Drug Reduced' or 'Drug Interrupted and then Dose Reduced' or Action Taken with Nab-paclitaxel = 'Drug Reduced' or 'Drug Interrupted and then Dose Reduced'*
- *Exclude AEs which occur > 28 days after last dose of study drug (any study drug)*

**Table 14.3.1.18**
**Treatment-Emergent Adverse Events by System Organ Class and Preferred Term Leading to Reduction of CORT125134**
**Safety Population**

| System Organ Class[2] / Preferred Term[2] | Segment I: Continuous-Dosing Regimen[1] | | | | Segment II: Intermittent-Dosing Regimen[1] | | | |
|---|---|---|---|---|---|---|---|---|
| | 100 mg / 60 mg/m$^2$ (N= ) | 100 mg / 80 mg/m$^2$ (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | Total (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | 200 mg / 100 mg/m$^2$ (N= ) | Total (N= ) | Total (N= ) |
| Patients Reporting at Least One Adverse Event Leading to CORT125134 Reduction | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| System Organ Class #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | |
| System Organ Class #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | |

Notes:

- At each level of summarization (any event, system organ class, and preferred term), patients reporting more than one adverse event are counted only once.
- Treatment-emergent adverse events are those events that occur from the first dose of CORT125134 through 28 days after administration of the last dose of study drug.
- Includes events when action taken with CORT125134 is "Dose Reduced" or "Drug Interrupted and then Dose Reduced."

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Adverse events are coded to system organ class and preferred term using the Medical Dictionary for Regulatory Activities (MedDRA), version 19.0.

Reference: *Listing #(s)*
Path\filename.sas ddmmmyyyy hh:mm

*Programming Notes:*

- *Sort events by descending order of system organ class incidence and by descending order of preferred term incidence within system organ class, based on the overall incidence (ie, sum over all treatment groups).*
- *Include all AEs with Action Taken with CORT125134 = 'Drug Reduced' or 'Drug Interrupted and then Dose Reduced'*
- *Exclude AEs which occur > 28 days after last dose of study drug (any study drug)*

**Table 14.3.1.19**
**Treatment-Emergent Adverse Events by System Organ Class and Preferred Term Leading to Reduction of Nab-paclitaxel**
**Safety Population**

| System Organ Class[2] / Preferred Term[2] | Segment I: Continuous-Dosing Regimen[1] | | | | Segment II: Intermittent-Dosing Regimen[1] | | | Total |
|---|---|---|---|---|---|---|---|---|
| | 100 mg / 60 mg/m$^2$ (N= ) | 100 mg / 80 mg/m$^2$ (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | Total (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | 200 mg / 100 mg/m$^2$ (N= ) | Total (N= ) | (N= ) |
| Patients Reporting at Least One Adverse Event Leading to Nab-paclitaxel Reduction | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| System Organ Class #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | |
| System Organ Class #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | |

Notes:

- At each level of summarization (any event, system organ class, and preferred term), patients reporting more than one adverse event are counted only once.
- Treatment-emergent adverse events are those events that occur from the first dose of CORT125134 through 28 days after administration of the last dose of study drug.
- Includes events when action taken with Nab-paclitaxel is "Dose Reduced" or "Drug Interrupted and then Dose Reduced."

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Adverse events are coded to system organ class and preferred term using the Medical Dictionary for Regulatory Activities (MedDRA), version 19.0.

Reference: *Listing #(s)*
Path\filename.sas ddmmmyyyy hh:mm

*Programming Notes:*

- *Sort events by descending order of system organ class incidence and by descending order of preferred term incidence within system organ class, based on the overall incidence (ie, sum over all treatment groups).*
- *Include all AEs with Action Taken with Nab-paclitaxel = 'Drug Interrupted' or 'Drug Interrupted and then Dose Reduced'*
- *Exclude AEs which occur > 28 days after last dose of study drug (any study drug)*

**Table 14.3.1.20**
**Treatment-Emergent Adverse Events by System Organ Class and Preferred Term Leading to Death**
**Safety Population**

| System Organ Class[2] / Preferred Term[2] | Segment I: Continuous-Dosing Regimen[1] | | | | Segment II: Intermittent-Dosing Regimen[1] | | | Total |
|---|---|---|---|---|---|---|---|---|
| | 100 mg / 60 mg/m$^2$ (N= ) | 100 mg / 80 mg/m$^2$ (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | Total (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | 200 mg / 100 mg/m$^2$ (N= ) | Total (N= ) | (N= ) |
| Patients Reporting at Least One Adverse Event Leading to Death | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| System Organ Class #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | |
| System Organ Class #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | |

Notes:

- At each level of summarization (any event, system organ class, and preferred term), patients reporting more than one adverse event are counted only once.
- Treatment-emergent adverse events are those events that occur from the first dose of CORT125134 through 28 days after administration of the last dose of study drug.

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Adverse events are coded to system organ class and preferred term using the Medical Dictionary for Regulatory Activities (MedDRA), version 19.0.

Reference: *Listing #(s)*
Path\filename.sas ddmmmyyyy hh:mm

*Programming Notes:*

- *Sort events by descending order of system organ class incidence and by descending order of preferred term incidence within system organ class, based on the overall incidence (ie, sum over all treatment groups).*
- *Include all AEs with Outcome = 'Fatal' or CTCAE Grade = 5*
- *Exclude AEs which occur > 28 days after last dose of study drug (any study drug)*

**Table 14.3.1.21**
**Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term**
**Safety Population**

| System Organ Class[2] / Preferred Term[2] | Segment I: Continuous-Dosing Regimen[1] | | | | Segment II: Intermittent-Dosing Regimen[1] | | | |
|---|---|---|---|---|---|---|---|---|
| | 100 mg / 60 mg/m$^2$ (N= ) | 100 mg / 80 mg/m$^2$ (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | Total (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | 200 mg / 100 mg/m$^2$ (N= ) | Total (N= ) | Total (N= ) |
| Patients Reporting at Least One Serious Adverse Event | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| System Organ Class #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | |
| System Organ Class #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | |

Notes:

- At each level of summarization (any event, system organ class, and preferred term), patients reporting more than one serious adverse event are counted only once.
- Treatment-emergent adverse events are those events that occur from the first dose of CORT125134 through 28 days after administration of the last dose of study drug.

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Adverse events are coded to system organ class and preferred term using the Medical Dictionary for Regulatory Activities (MedDRA), version 19.0.

Reference: *Listing #(s)*
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*Programming Notes:*

- *Sort events by descending order of system organ class incidence and by descending order of preferred term incidence within system organ class, based on the overall incidence (ie, sum over all treatment groups).*
- *Include all AEs with Serious = 'Yes'*
- *Exclude AEs which occur > 28 days after last dose of study drug (any study drug)*

**Table 14.3.1.22**
**Summary of Treatment-Emergent Neutropenia Adverse Events**
**Safety Population**

| | Segment I: Continuous-Dosing Regimen[1] | | | | | Segment II: Intermittent-Dosing Regimen[1] | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | 100 mg / 60 mg/m$^2$ (N= ) | 100 mg / 80 mg/m$^2$ - G-CSF[2] (N= ) | 100 mg / 80 mg/m$^2$ + G-CSF[2] (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | Total (N= ) | 150 mg / 80 mg/m$^2$ - G-CSF[2] (N= ) | 150 mg / 80 mg/m$^2$ + G-CSF[2] (N= ) | 200 mg / 100 mg/m$^2$ (N= ) | Total (N= ) | Total (N= ) |
| Total Number of Neutropenia TEAEs | xx | xx | xx | xx | xx | xx | xx | xx | xx | xx |
| Total Number of Neutropenia TESAEs | xx | xx | xx | xx | xx | xx | xx | xx | xx | xx |
| Number (%) of Patients Reporting at Least One Neutropenia Event: | | | | | | | | | | |
| TEAE | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| TEAE ≥ Grade 3 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| TEAE Leading to Discontinuation of Any Study Drug | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| TEAE Requiring Dose Interruption of Any Study Drug | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| TEAE Leading to Dose Reduction of Any Study Drug | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| TEAE Outcome as Recovering or Resolved[3] | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| TEAE Causing Death | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| TESAE | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |

Abbreviations: G-CSF=granulocyte colony-stimulating factor; TEAE=CORT125134 treatment-emergent adverse event; TESAE=CORT125134 treatment-emergent serious adverse event

Notes:

- Neutropenia adverse events are those reporting a preferred term of "neutropenia," "febrile neutropenia," or "neutrophil count decreased" using the Medical Dictionary for Regulatory Activities (MedDRA), version 19.0.
- Treatment-emergent adverse events are those events that occur from the first dose of CORT125134 through 28 days after administration of the last dose of study drug.

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Segment I – G-CSF is defined as Cohort 1 and 2 and + G-CSF is defined as Cohort 3, 4, 5 and Pancreatic Cancer Cohort. Segment II – G-CSF is defined as Cohort 1 and 2 and + G-CSF is defined as Cohort 3.
[3] Recovered or Resolved events include those reported as "Recovered/Resolved" or "Recovered/Resolved with Sequelae."

Reference: *Listing #(s)*
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*Programming Note: Exclude AEs which occur > 28 days after last dose of study drug (any study drug)*

**Table 14.3.1.23**
**Time to Onset of Treatment-Emergent Neutropenia Adverse Events**
**Safety Population**

| | Segment I: Continuous-Dosing Regimen[1] | | | | | Segment II: Intermittent-Dosing Regimen[1] | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | 100 mg / 60 mg/m$^2$ (N= ) | 100 mg / 80 mg/m$^2$ - G-CSF[2] (N= ) | 100 mg / 80 mg/m$^2$ + G-CSF[2] (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | Total (N= ) | 150 mg / 80 mg/m$^2$ - G-CSF[2] (N= ) | 150 mg / 80 mg/m$^2$ + G-CSF[2] (N= ) | 200 mg / 100 mg/m$^2$ (N= ) | Total (N= ) | Total (N= ) |
| Time to Onset of First Neutropenia TEAE (days)[3] | | | | | | | | | | |
| n | n | n | n | n | n | n | n | n | n | n |
| Mean (SD) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) |
| Median | x.x | x.x | x.x | x.x | x.x | x.x | x.x | x.x | x.x | x.x |
| Min, Max (Range) | x, x (x) | x, x (x) | x, x (x) | x, x (x) | x, x (x) | x, x (x) | x, x (x) | x, x (x) | x, x (x) | x, x (x) |
| Time to Onset of First Neutropenia TEAE ≥ Grade 3 (days)[3] | | | | | | | | | | |
| n | n | n | n | n | n | n | n | n | n | n |
| Mean (SD) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) |
| Median | x.x | x.x | x.x | x.x | x.x | x.x | x.x | x.x | x.x | x.x |
| Min, Max (Range) | x, x (x) | x, x (x) | x, x (x) | x, x (x) | x, x (x) | x, x (x) | x, x (x) | x, x (x) | x, x (x) | x, x (x) |

Abbreviations: G-CSF=granulocyte colony-stimulating factor; TEAE=CORT125134 treatment-emergent adverse event

Notes:

- Neutropenia adverse events are those reporting a preferred term of "neutropenia," "febrile neutropenia," or "neutrophil count decreased" using the Medical Dictionary for Regulatory Activities (MedDRA), version 19.0.
- Treatment-emergent adverse events are those events that occur from the first dose of CORT125134 through 28 days after administration of the last dose of study drug.

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Segment I – G-CSF is defined as Cohort 1 and 2 and + G-CSF is defined as Cohort 3, 4, 5 and Pancreatic Cancer Cohort. Segment II – G-CSF is defined as Cohort 1 and 2 and + G-CSF is defined as Cohort 3.
[3] Time to onset in days is calculated as the first neutropenia adverse event start date – the date of first dose of CORT125134 + 1.

Reference: *Listing #(s)*
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*Programming Note: Exclude AEs which occur > 28 days after last dose of study drug (any study drug)*

**Table 14.3.1.24**
**Treatment-Emergent Adverse Events by Preferred Term**
**Safety Population**

| Preferred Term[1] | Segment I: Continuous-Dosing Regimen (N= ) | Segment II: Intermittent-Dosing Regimen (N= ) | Total (N= ) |
|---|---|---|---|
| Patients Reporting at Least One Adverse Event | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #1 | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #2 | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | |

Notes:

- At each level of summarization (any event and preferred term), patients reporting more than one adverse event are counted only once.
- Treatment-emergent adverse events are those events that occur from the first dose of CORT125134 through 28 days after administration of the last dose of study drug.

[1] Adverse events are coded to preferred term using the Medical Dictionary for Regulatory Activities (MedDRA), version 19.0.

Reference: *Listing #(s)*
Path\filename.sas ddmmmyyyy hh:mm

*Programming Notes:*

- *Sort events by descending order of preferred term incidence based on the overall incidence (ie, sum over all treatment groups).*
- *Exclude AEs which occur > 28 days after last dose of study drug (any study drug)*

**Table 14.3.1.25**
**Treatment-Emergent CORT125134 Related Adverse Events by Preferred Term**
**Safety Population**

| Preferred Term[1] | Segment I: Continuous-Dosing Regimen (N= ) | Segment II: Intermittent-Dosing Regimen (N= ) | Total (N= ) |
|---|---|---|---|
| Patients Reporting at Least One CORT125134 Related Adverse Event | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #1 | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #2 | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | |

Notes:

- At each level of summarization (any event and preferred term), patients reporting more than one adverse event are counted only once. Related adverse events are those reported as "Possibly Related" or "Probably Related" to CORT125134.
- Treatment-emergent adverse events are those events that occur from the first dose of CORT125134 through 28 days after administration of the last dose of study drug.

[1] Adverse events are coded to preferred term using the Medical Dictionary for Regulatory Activities (MedDRA), version 19.0.

Reference: *Listing #(s)*
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*Programming Notes:*

- *Sort events by descending order of preferred term incidence based on the overall incidence (ie, sum over all treatment groups).*
- *Include all AEs related to CORT125134*
- *Exclude AEs which occur > 28 days after last dose of study drug (any study drug)*

**Table 14.3.1.26**
**Treatment-Emergent Grade ≥ 3 Adverse Events by Preferred Term**
**Safety Population**

| Preferred Term[1] | Segment I: Continuous-Dosing Regimen (N= ) | Segment II: Intermittent-Dosing Regimen (N= ) | Total (N= ) |
|---|---|---|---|
| Patients Reporting at Least One Grade ≥ 3 Adverse Event | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #1 | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #2 | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | |

Notes:

- At each level of summarization (any event and preferred term), patients reporting more than one adverse event are counted only once.
- Treatment-emergent adverse events are those events that occur from the first dose of CORT125134 through 28 days after administration of the last dose of study drug.

[1] Adverse events are coded to preferred term using the Medical Dictionary for Regulatory Activities (MedDRA), version 19.0.

Reference: *Listing #(s)*
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*Programming Notes:*

- *Sort events by descending order of preferred term incidence based on the overall incidence (ie, sum over all treatment groups).*
- *Include all AEs with Grade ≥ 3*
- *Exclude AEs which occur > 28 days after last dose of study drug (any study drug)*

**Table 14.3.1.27**
**Treatment-Emergent CORT125134 Related Grade ≥ 3 Adverse Events by Preferred Term**
**Safety Population**

| Preferred Term[1] | Segment I: Continuous-Dosing Regimen (N= ) | Segment II: Intermittent-Dosing Regimen (N= ) | Total (N= ) |
|---|---|---|---|
| Patients Reporting at Least One CORT125134 Related Grade ≥ 3 Adverse Event | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #1 | n (x.x%) | n (x.x%) | n (x.x%) |
| Preferred Term #2 | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | |

Notes:

- At each level of summarization (any event and preferred term), patients reporting more than one adverse event are counted only once. Related adverse events are those reported as "Possibly Related" or "Probably Related" to CORT125134.
- Treatment-emergent adverse events are those events that occur from the first dose of CORT125134 through 28 days after administration of the last dose of study drug.

[1] Adverse events are coded to preferred term using the Medical Dictionary for Regulatory Activities (MedDRA), version 19.0.

Reference: *Listing #(s)*
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*Programming Notes:*

- *Sort events by descending order of preferred term incidence based on the overall incidence (ie, sum over all treatment groups).*
- *Include all AEs related to CORT125134 with Grade ≥ 3*
- *Exclude AEs which occur > 28 days after last dose of study drug (any study drug)*

**Table 14.3.1.28**
**Non-Hematological Adverse Events**
**Safety Population**

| | Segment I: Continuous-Dosing Regimen[1] | | | | Segment II: Intermittent-Dosing Regimen[1] | | | |
|---|---|---|---|---|---|---|---|---|
| Criteria | 100 mg / 60 mg/m$^2$ (N= ) | 100 mg / 80 mg/m$^2$ (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | Total (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | 200 mg / 100 mg/m$^2$ (N= ) | Total (N= ) | Total (N= ) |
| ALT or AST > 10x ULN | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| ALT or AST > 20x ULN | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| ALT or AST > 3x ULN and Bilirubin > 2x ULN | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |

Abbreviations: ALT, alanine aminotransferase; AST, aspartate aminotransferase; ULN, upper limit of normal

Note: Percentages are based on the number of patients with at least one non-missing post-screening value. Patients are counted once within each category if they have at least one measurement collected post screening.

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).

Reference: *Listing #(s)*
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**Table 14.3.1.29**
**Primary Cause of Death**
**Safety Population**

| | Segment I: Continuous-Dosing Regimen[1] | | | | Segment II: Intermittent-Dosing Regimen[1] | | | |
|---|---|---|---|---|---|---|---|---|
| Primary Cause of Death | 100 mg / 60 mg/m$^2$ (N= ) | 100 mg / 80 mg/m$^2$ (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | Total (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | 200 mg / 100 mg/m$^2$ (N= ) | Total (N= ) | Total (N= ) |
| Death Occurred Within 28 days of Last Study Drug Dose | | | | | | | | |
| Progressive Disease | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Cancer | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Adverse Event | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Other | | | | | | | | |
| Death Did Not Occur Within 28 days of Last Study Drug Dose | | | | | | | | |
| Progressive Disease | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Cancer | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Adverse Event | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Other | | | | | | | | |

Note: Death occurring within 28 days of last study drug dose as collected on the End of Study Case Report Form.

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).

Reference: *Listing #(s)*
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**Corcept Therapeutics**
**CORT125134-550**

**Database Date/Analysis: DDMMMYYYY/Draft**
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**Table 14.3.2.1**
**Listing of Deaths**
**All Enrolled Patients**

| Segment | Cohort[1] | Patient ID | Date of Death (Study Day[2]) | Primary Cause of Death | Did Patient Death Occur Within 28 Days of Last Study Drug Dose? |
|---|---|---|---|---|---|
| 1 | 100/60 PDAC / 100/80 PDAC / 150/80 PDAC / 100/60 OVCA / 100/80 OVCA / 150/80 OVCA / 100/60 OT / 100/80 OT / 150/80 OT | xxx-xxxx | ddMMMyyyy (xx) | *Adverse event or cause of death from the end of study CRF* | Yes / No |
| 2 | 150/80 PDAC / 200/100 PDAC / 150/80 OVCA / 200/100 OVCA / 150/80 OT / 200/100 OT | | | | |

Abbreviations: OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Time (days) relative to date of first dose of CORT125134

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**Table 14.3.2.2**
**Listing of Serious Adverse Events**
**Safety Population**

| Segment | Cohort[1] | Patient ID | System Organ Class[2] / Preferred Term[2] / Event Name | Treatment-Emergent[3] | Start Date and Time (Study Day[4]) | End Date and Time (Study Day[4]) | CTCAE Grade | Serious Criteria | Relationship to[5] | Action Taken with[6] | Outcome |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 100/60 PDAC / 100/80 PDAC / 150/80 PDAC / 100/60 OVCA / 100/80 OVCA / 150/80 OVCA / 100/60 OT / 100/80 OT / 150/80 OT | xxx-xxxx | *System Organ Class / Preferred Term / Event Name* | Yes / No | ddMMMyyyy HH:MM (xx) | ddMMMyyyy HH:MM (xx) / Ongoing | Grade 1 / Grade 2 / Grade 3 / Grade 4 / Grade 5 | Congenital Anomaly or Birth Defect / Significant Disability / Death / Hospitalization / Life Threatening / Other Medically Important Event<br><br>*Display all that are reported, separated by a comma* | C: Not Related to Study Drug / C: Unlikely Related to Study Drug/ C: Possibly Related to Study Drug/ C: Related to Study Drug<br><br>N: Not Related to Study Drug / N: Unlikely Related to Study Drug/ N: Possibly Related to Study Drug/ N: Related to Study Drug<br>*Sepearate C and N Relationship with a comma* | C: Dose Not Changed / C: Dose Reduced / C: Drug Interrupted / C: Drug Interrupted and then Dose Reduced / C: Drug Withdrawn / C: Not Applicable / C: Unknown<br>N: Dose Not Changed / N: Dose Reduced / N: Drug Interrupted / N: Drug Interrupted and then Dose Reduced / N: Drug Withdrawn / N: Not Applicable / N: Unknown<br>*Sepearate C and N Relationship with a comma* | Fatal / Not Recovered/ Not Resolved/ Recovered/ Resolved/ Recovered/ Resolved with Sequelae / Recovering/ Resolving/ Unknown |
| 2 | 150/80 PDAC / 200/100 PDAC / 150/80 OVCA / 200/100 OVCA / 150/80 OT / 200/100 OT | | | | | | | | | | |

Abbreviations: CTCAE=Common Terminology Criteria for Adverse Events, v4.03; OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Adverse events are coded to system organ class and preferred term using the Medical Dictionary for Regulatory Activities (MedDRA), version 19.0.
[3] Treatment-emergent adverse events are those events that occur from the first dose of CORT125134 through 28 days after administration of the last dose of study drug.
[4] Time (days) relative to date of first dose of CORT125134
[5] C: reports answer to question on case report form regarding relationship to CORT125134; N: reports answer to question on case report form regarding relationship to Nab-paclitaxel
[6] C: reports answer to question on case report form regarding action taken with CORT125134; N: reports answer to question on case report form regarding action taken with Nab-paclitaxel

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*Programming Note: Include all AEs with Serious = 'Yes'*

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**Database Date/Analysis: DDMMMYYYY/Draft**
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**Table 14.3.4.1**
**Listing of Abnormal Hematology Values**
**Safety Population**

| Segment | Cohort[1] | Patient ID | Visit | Collection Date and Time (Study Day[2]) | Test | Unit | Normal Range | Result | Alert | Clinically Significant | Comment |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 100/60 PDAC / 100/80 PDAC / 150/80 PDAC / 100/60 OVCA / 100/80 OVCA / 150/80 OVCA / 100/60 OT / 100/80 OT / 150/80 OT | xxx-xxxx | Screening | ddMMMyyyy HH:MM (xx) | *Test #1* | *Unit* | xxx – xxx | xxx | Low / High | Yes / No | *Comments* |
| | | | | | *Test #2* | | | | | | |
| 2 | 150/80 PDAC / 200/100 PDAC / 150/80 OVCA / 200/100 OVCA / 150/80 OT / 200/100 OT | | | | | | | | | | |
| | | | | | ... | | | | | | |

Abbreviations: OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma

[1] CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$)
[2] Time (days) relative to date of first dose of CORT125134

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*Repeat for the following:*

*Table 14.3.4.2 Listing of Abnormal Chemistry Values (Safety Population)*

**Table 14.3.5.1**
**Extent of Exposure**
**Safety Population**

| Drug | Sampling | | Segment I: Continuous-Dosing Regimen[1] 100 mg / 60 mg/m$^2$ (N= ) | Segment I: Continuous-Dosing Regimen[1] 100 mg / 80 mg/m$^2$ (N= ) | Segment I: Continuous-Dosing Regimen[1] 150 mg / 80 mg/m$^2$ (N= ) | Segment I: Continuous-Dosing Regimen[1] Total (N= ) | Segment II: Intermittent-Dosing Regimen[1] 150 mg / 80 mg/m$^2$ (N= ) | Segment II: Intermittent-Dosing Regimen[1] 200 mg / 100 mg/m$^2$ (N= ) | Segment II: Intermittent-Dosing Regimen[1] Total (N= ) | Total (N= ) |
|---|---|---|---|---|---|---|---|---|---|---|
| CORT125134 | Number of Cycles of Treatment | Total | | | | | | | | |
| | | n | n | n | n | n | n | n | n | n |
| | | Mean (SD) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) |
| | | Median | x | x | x | x | x | x | x | x |
| | | Min, Max | x, x | x, x | x, x | x, x | x, x | x, x | x, x | x, x |
| | Duration of Exposure (days)[2] | Total | | | | | | | | |
| | | n | n | n | n | n | n | n | n | n |
| | | Mean (SD) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) |
| | | Median | x | x | x | x | x | x | x | x |
| | | Min, Max | x, x | x, x | x, x | x, x | x, x | x, x | x, x | x, x |
| | Total Dose Received (mg) | Lead-In | | | | | | | | |
| | | n | n | n | n | n | n | n | n | n |
| | | Mean (SD) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) |
| | | Median | x | x | x | x | x | x | x | x |
| | | Min, Max | x, x | x, x | x, x | x, x | x, x | x, x | x, x | x, x |
| | | Cycle 1 | | | | | | | | |
| | | … | | | | | | | | |
| | | Total | | | | | | | | |
| | | n | n | n | n | n | n | n | n | n |
| | | Mean (SD) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) |
| | | Median | x | x | x | x | x | x | x | x |
| | | Min, Max | x, x | x, x | x, x | x, x | x, x | x, x | x, x | x, x |

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Duration of exposure is calculated as the date of last dose of drug – the date of first dose of drug + 1.
[3] Relative dose intensity is calculated as the total dose received / total dose expected * 100.

Reference: *Listing #(s)*
Path\filename.sas ddmmmyyyy hh:mm

**Table 14.3.5.1**
**Extent of Exposure**
**Safety Population**

| Drug | Sampling | | Segment I: Continuous-Dosing Regimen[1] 100 mg / 60 mg/m$^2$ (N= ) | Segment I: Continuous-Dosing Regimen[1] 100 mg / 80 mg/m$^2$ (N= ) | Segment I: Continuous-Dosing Regimen[1] 150 mg / 80 mg/m$^2$ (N= ) | Segment I: Continuous-Dosing Regimen[1] Total (N= ) | Segment II: Intermittent-Dosing Regimen[1] 150 mg / 80 mg/m$^2$ (N= ) | Segment II: Intermittent-Dosing Regimen[1] 200 mg / 100 mg/m$^2$ (N= ) | Segment II: Intermittent-Dosing Regimen[1] Total (N= ) | Total (N= ) |
|---|---|---|---|---|---|---|---|---|---|---|
| CORT125134 | Total Dose Expected (mg) | Lead-In | | | | | | | | |
| | | n | n | n | n | n | n | n | n | n |
| | | Mean (SD) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) |
| | | Median | x | x | x | x | x | x | x | x |
| | | Min, Max | x, x | x, x | x, x | x, x | x, x | x, x | x, x | x, x |
| | | Cycle 1 | | | | | | | | |
| | | … | | | | | | | | |
| | | Total | | | | | | | | |
| | | n | n | n | n | n | n | n | n | n |
| | | Mean (SD) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) |
| | | Median | x | x | x | x | x | x | x | x |
| | | Min, Max | x, x | x, x | x, x | x, x | x, x | x, x | x, x | x, x |
| | Relative Dose Intensity (%)[3] | Lead-In | | | | | | | | |
| | | n | n | n | n | n | n | n | n | n |
| | | Mean (SD) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) |
| | | Median | x | x | x | x | x | x | x | x |
| | | Min, Max | x, x | x, x | x, x | x, x | x, x | x, x | x, x | x, x |
| | | Cycle 1 | | | | | | | | |
| | | … | | | | | | | | |
| | | Total | | | | | | | | |
| | | … | | | | | | | | |

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Duration of exposure is calculated as the date of last dose of drug – the date of first dose of drug + 1.
[3] Relative dose intensity is calculated as the total dose received / total dose expected * 100.

Reference: *Listing #(s)*
Path\filename.sas ddmmmyyyy hh:mm

**Corcept Therapeutics**
**CORT125134-550**

**Database Date/Analysis: DDMMMYYYY/Draft**
**Page x of y**

**Table 14.3.5.1**
**Extent of Exposure**
**Safety Population**

| Drug | Sampling | | Segment I: Continuous-Dosing Regimen[1] 100 mg / 60 mg/m$^2$ (N= ) | Segment I: Continuous-Dosing Regimen[1] 100 mg / 80 mg/m$^2$ (N= ) | Segment I: Continuous-Dosing Regimen[1] 150 mg / 80 mg/m$^2$ (N= ) | Segment I: Continuous-Dosing Regimen[1] Total (N= ) | Segment II: Intermittent-Dosing Regimen[1] 150 mg / 80 mg/m$^2$ (N= ) | Segment II: Intermittent-Dosing Regimen[1] 200 mg / 100 mg/m$^2$ (N= ) | Segment II: Intermittent-Dosing Regimen[1] Total (N= ) | Total (N= ) |
|---|---|---|---|---|---|---|---|---|---|---|
| Nab-paclitaxel | Number of Cycles of Treatment | Total | | | | | | | | |
| | | n | n | n | n | n | n | n | n | n |
| | | Mean (SD) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) |
| | | Median | x | x | x | x | x | x | x | x |
| | | Min, Max | x, x | x, x | x, x | x, x | x, x | x, x | x, x | x, x |
| | Duration of Exposure (days)[2] | Total | | | | | | | | |
| | | n | n | n | n | n | n | n | n | n |
| | | Mean (SD) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) |
| | | Median | x | x | x | x | x | x | x | x |
| | | Min, Max | x, x | x, x | x, x | x, x | x, x | x, x | x, x | x, x |
| | Total Dose Received (mg/m$^2$) | Lead-In | | | | | | | | |
| | | n | n | n | n | n | n | n | n | n |
| | | Mean (SD) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) |
| | | Median | x | x | x | x | x | x | x | x |
| | | Min, Max | x, x | x, x | x, x | x, x | x, x | x, x | x, x | x, x |
| | | Cycle 1 | | | | | | | | |
| | | … | | | | | | | | |
| | | Total | | | | | | | | |
| | | n | n | n | n | n | n | n | n | n |
| | | Mean (SD) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) |
| | | Median | x | x | x | x | x | x | x | x |
| | | Min, Max | x, x | x, x | x, x | x, x | x, x | x, x | x, x | x, x |

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Duration of exposure is calculated as the date of last dose of drug – the date of first dose of drug + 1.
[3] Relative dose intensity is calculated as the total dose received / total dose expected * 100.

Reference: *Listing #(s)*
Path\filename.sas ddmmmyyyy hh:mm

**Corcept Therapeutics**
**CORT125134-550**

**Database Date/Analysis: DDMMMYYYY/Draft**
**Page x of y**

**Table 14.3.5.1**
**Extent of Exposure**
**Safety Population**

| Drug | Sampling | | Segment I: Continuous-Dosing Regimen[1] 100 mg / 60 mg/m$^2$ (N= ) | Segment I: Continuous-Dosing Regimen[1] 100 mg / 80 mg/m$^2$ (N= ) | Segment I: Continuous-Dosing Regimen[1] 150 mg / 80 mg/m$^2$ (N= ) | Segment I: Continuous-Dosing Regimen[1] Total (N= ) | Segment II: Intermittent-Dosing Regimen[1] 150 mg / 80 mg/m$^2$ (N= ) | Segment II: Intermittent-Dosing Regimen[1] 200 mg / 100 mg/m$^2$ (N= ) | Segment II: Intermittent-Dosing Regimen[1] Total (N= ) | Total (N= ) |
|---|---|---|---|---|---|---|---|---|---|---|
| Nab-paclitaxel | Total Dose Expected (mg/m$^2$) | Lead-In | | | | | | | | |
| | | n | n | n | n | n | n | n | n | n |
| | | Mean (SD) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) |
| | | Median | x | x | x | x | x | x | x | x |
| | | Min, Max | x, x | x, x | x, x | x, x | x, x | x, x | x, x | x, x |
| | | Cycle 1 | | | | | | | | |
| | | … | | | | | | | | |
| | | Total | | | | | | | | |
| | | n | n | n | n | n | n | n | n | n |
| | | Mean (SD) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) |
| | | Median | x | x | x | x | x | x | x | x |
| | | Min, Max | x, x | x, x | x, x | x, x | x, x | x, x | x, x | x, x |
| | Relative Dose Intensity (%)[3] | Lead-In | | | | | | | | |
| | | n | n | n | n | n | n | n | n | n |
| | | Mean (SD) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) |
| | | Median | x | x | x | x | x | x | x | x |
| | | Min, Max | x, x | x, x | x, x | x, x | x, x | x, x | x, x | x, x |
| | | Cycle 1 | | | | | | | | |
| | | … | | | | | | | | |
| | | Total | | | | | | | | |
| | | … | | | | | | | | |

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Duration of exposure is calculated as the date of last dose of drug – the date of first dose of drug + 1.
[3] Relative dose intensity is calculated as the total dose received / total dose expected * 100.

Reference: *Listing #(s)*
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**Table 14.3.5.2**
**Study Drug Compliance**
**Safety Population**

| | | Segment I: Continuous-Dosing Regimen[1] | | | | Segment II: Intermittent-Dosing Regimen[1] | | | |
|---|---|---|---|---|---|---|---|---|---|
| Study Drug | Study Drug Compliance (%)[2] | 100 mg / 60 mg/m$^2$ (N= ) | 100 mg / 80 mg/m$^2$ (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | Total (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | 200 mg / 100 mg/m$^2$ (N= ) | Total (N= ) | Total (N= ) |
| CORT125134 | n | n | n | n | n | n | n | n | n |
| | Mean (SD) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) |
| | Median | x | x | x | x | x | x | x | x |
| | Min, Max | x, x | x, x | x, x | x, x | x, x | x, x | x, x | x, x |
| | < 80% Compliant | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | ≥ 80% Compliant | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Nab-paclitaxel | n | n | n | n | n | n | n | n | n |
| | Mean (SD) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) |
| | Median | x | x | x | x | x | x | x | x |
| | Min, Max | x, x | x, x | x, x | x, x | x, x | x, x | x, x | x, x |
| | < 80% Compliant | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | ≥ 80% Compliant | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Study drug compliance is calculated as the total dose received / the expected dose received x 100.

Reference: *Listing #(s)*
Path\filename.sas ddmmmyyyy hh:mm

**Table 14.3.6.1**
**Hematology – Univariate Summary by Parameter and Visit**
**Safety Population**
**Part 1 of 2**

| | | Segment I: Continuous-Dosing Regimen | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | 100 mg / 60 mg/m$^2$ (N= ) | | 100 mg / 80 mg/m$^2$ (N= ) | | 150 mg / 80 mg/m$^2$ (N= ) | | Total (N= ) | |
| Parameter | Visit | Observed Value | Change from Baseline | Observed Value | Change from Baseline | Observed Value | Change from Baseline | Observed Value | Change from Baseline |
| Hemoglobin (g/L) | Baseline[2] | | | | | | | | |
| | n | n | | n | | n | | n | |
| | Mean (SD) | x.x (x.xx) | | x.x (x.xx) | | x.x (x.xx) | | x.x (x.xx) | |
| | Median | x | | x | | x | | x | |
| | Min, Max | x, x | | x, x | | x, x | | x, x | |
| | Nab-paclitaxel Lead In: Day 1 | | | | | | | | |
| | n | n | n | n | n | n | n | n | n |
| | Mean (SD) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) |
| | Median | x | x | x | x | x | x | x | x |
| | Min, Max | x, x | x, x | x, x | x, x | x, x | x, x | x, x | x, x |
| | Cycle 1 Day 1 | | | | | | | | |
| | … | | | | | | | | |
| Platelet Count ($10^9$/L) | | | | | | | | | |
| … | | | | | | | | | |

Abbreviation: WBC=white blood cell

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Baseline is defined as the last available measurement taken prior to the first dose of CORT125134.

Reference: *Listing #(s)*
Path\filename.sas ddmmmyyyy hh:mm

**Corcept Therapeutics**
**CORT125134-550**

**Database Date/Analysis: DDMMMYYYY/Draft**
**Page x of y**

**Table 14.3.6.1**
**Hematology – Univariate Summary by Parameter and Visit**
**Safety Population**
**Part 2 of 2**

| | | Segment II: Intermittent-Dosing Regimen[1] | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | 150 mg / 80 mg/m$^2$ (N= ) | | 200 mg / 100 mg/m$^2$ (N= ) | | Total (N= ) | | Total (N= ) | |
| Parameter | Visit | Observed Value | Change from Baseline | Observed Value | Change from Baseline | Observed Value | Change from Baseline | Observed Value | Change from Baseline |
| Hemoglobin (g/L) | Baseline[2] | | | | | | | | |
| | n | n | | n | | n | | n | |
| | Mean (SD) | x.x (x.xx) | | x.x (x.xx) | | x.x (x.xx) | | x.x (x.xx) | |
| | Median | x | | x | | x | | x | |
| | Min, Max | x, x | | x, x | | x, x | | x, x | |
| | Nab-paclitaxel Lead In: Day 1 | | | | | | | | |
| | n | n | n | n | n | n | n | n | n |
| | Mean (SD) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) |
| | Median | x | x | x | x | x | x | x | x |
| | Min, Max | x, x | x, x | x, x | x, x | x, x | x, x | x, x | x, x |
| | Cycle 1 Day 1 | | | | | | | | |
| | … | | | | | | | | |
| Platelet Count ($10^9$/L) | | | | | | | | | |
| … | | | | | | | | | |

Abbreviation: WBC=white blood cell

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Baseline is defined as the last available measurement taken prior to the first dose of CORT125134.

Reference: *Listing #(s)*
Path\filename.sas ddmmmyyyy hh:mm

*Programming Notes:*

- *Continue for remaining regularly-scheduled visits (Cycle 1 Day 8, Cycle 1 Day 15, Cycle 2 Day 1, Cycle 2 Day 8, Cycle 2 Day 15,(continue on Days 1, 8, 15 for Cycles 2+), Posttreatment)*
- *Continue for regularly-collected hematology parameters (WBC ($10^9$/L), Absolute Neutrophils ($10^9$/L))*

**Table 14.3.6.2**
**Hematology – Summary of Post-Baseline Clinically Significant Values**
**Safety Population**

| | Segment I: Continuous-Dosing Regimen[1] | | | | Segment II: Intermittent-Dosing Regimen[1] | | | |
|---|---|---|---|---|---|---|---|---|
| | 100 mg / 60 mg/m$^2$ (N= ) | 100 mg / 80 mg/m$^2$ (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | Total (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | 200 mg / 100 mg/m$^2$ (N= ) | Total (N= ) | Total (N= ) |
| Hemoglobin | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Platelet Count | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| WBC | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Absolute Neutrophils | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |

Abbreviation: WBC=white blood cell

Notes:

- This table summarizes laboratory values that are deemed to be clinically significant by the investigator at any point post-baseline.
- At each level of summarization (parameter), patients reporting more than one clinically significant value are counted only once.

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).

Reference: *Listing #(s)*
Path\filename.sas ddmmmyyyy hh:mm

**Table 14.3.6.3**
**Chemistry – Univariate Summary by Parameter and Visit**
**Safety Population**
**Part 1 of 2**

| | | Segment I: Continuous-Dosing Regimen | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | 100 mg / 60 mg/m$^2$ (N= ) | | 100 mg / 80 mg/m$^2$ (N= ) | | 150 mg / 80 mg/m$^2$ (N= ) | | Total (N= ) | |
| Parameter | Visit | Observed Value | Change from Baseline | Observed Value | Change from Baseline | Observed Value | Change from Baseline | Observed Value | Change from Baseline |
| AST (SGOT) (U/L) | Baseline[2] | | | | | | | | |
| | n | n | | n | | n | | n | |
| | Mean (SD) | x.x (x.xx) | | x.x (x.xx) | | x.x (x.xx) | | x.x (x.xx) | |
| | Median | x | | x | | x | | x | |
| | Min, Max | x, x | | x, x | | x, x | | x, x | |
| | Nab-paclitaxel Lead In: Day 1 | | | | | | | | |
| | n | n | n | n | n | n | n | n | n |
| | Mean (SD) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) |
| | Median | x | x | x | x | x | x | x | x |
| | Min, Max | x, x | x, x | x, x | x, x | x, x | x, x | x, x | x, x |
| | Cycle 1 Day 1 | | | | | | | | |
| | … | | | | | | | | |
| ALT (SGPT) (U/L) | | | | | | | | | |
| … | | | | | | | | | |

Abbreviations: ALT (SGPT)=alanine aminotransferase; AST (SGOT)=aspartate aminotransferase

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Baseline is defined as the last available measurement taken prior to the first dose of CORT125134.

Reference: *Listing #(s)*
Path\filename.sas ddmmmyyyy hh:mm

**Table 14.3.6.3**
**Chemistry – Univariate Summary by Parameter and Visit**
**Safety Population**
**Part 2 of 2**

| | | Segment II: Intermittent-Dosing Regimen[1] | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | 150 mg / 80 mg/m$^2$ (N= ) | | 200 mg / 100 mg/m$^2$ (N= ) | | Total (N= ) | | Total (N= ) | |
| Parameter | Visit | Observed Value | Change from Baseline | Observed Value | Change from Baseline | Observed Value | Change from Baseline | Observed Value | Change from Baseline |
| AST (SGOT) (U/L) | Baseline[2] | | | | | | | | |
| | n | n | | n | | n | | n | |
| | Mean (SD) | x.x (x.xx) | | x.x (x.xx) | | x.x (x.xx) | | x.x (x.xx) | |
| | Median | x | | x | | x | | x | |
| | Min, Max | x, x | | x, x | | x, x | | x, x | |
| | Nab-paclitaxel Lead In: Day 1 | | | | | | | | |
| | n | n | n | n | n | n | n | n | n |
| | Mean (SD) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) |
| | Median | x | x | x | x | x | x | x | x |
| | Min, Max | x, x | x, x | x, x | x, x | x, x | x, x | x, x | x, x |
| | Cycle 1 Day 1 | | | | | | | | |
| | … | | | | | | | | |
| ALT (SGPT) (U/L) | | | | | | | | | |
| … | | | | | | | | | |

Abbreviations: ALT (SGPT)=alanine aminotransferase; AST (SGOT)=aspartate aminotransferase

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Baseline is defined as the last available measurement taken prior to the first dose of CORT125134.

Reference: *Listing #(s)*
Path\filename.sas ddmmmyyyy hh:mm

*See Programming Notes on next page*

*Programming Notes:*

- *Continue for remaining regularly-scheduled visits: (Cycle 1 Day 15, Cycle 2 Day 1, Cycle 2 Day 8, Cycle 2 Day 15,(continue on Days 1, 8, 15 for Cycles 2+), Posttreatment )*
- *Continue for regularly-collected chemistry parameters: (Total Bilirubin (µmol/L), Sodium (mmol/L), Potassium (mmol/L))*

**Table 14.3.6.4**
**Chemistry – Summary of Post-Baseline Clinically Significant Values**
**Safety Population**

| | Segment I: Continuous-Dosing Regimen[1] | | | | Segment II: Intermittent-Dosing Regimen[1] | | | |
|---|---|---|---|---|---|---|---|---|
| | 100 mg / 60 mg/m$^2$ (N= ) | 100 mg / 80 mg/m$^2$ (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | Total (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | 200 mg / 100 mg/m$^2$ (N= ) | Total (N= ) | Total (N= ) |
| AST (SGOT) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| ALT (SGPT) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | |

Abbreviations: ALT (SGPT)=alanine aminotransferase; AST (SGOT)=aspartate aminotransferase

Notes:

- This table summarizes laboratory values that are deemed to be clinically significant by the investigator at any point post-baseline.
- At each level of summarization (parameter), patients reporting more than one clinically significant value are counted only once.

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).

Reference: *Listing #(s)*
Path\filename.sas ddmmmyyyy hh:mm

*Programming Notes:*

- *Continue for regularly-collected chemistry parameters with incidence: (Total Bilirubin, Direct Bilirubin, Sodium, Potassium)*

**Table 14.3.6.5**
**Shift from Baseline to Worst Post-Baseline NCI CTCAE Toxicity Grade by Laboratory Parameter**
**Safety Population**

| | | Segment I: Continuous-Dosing Regimen[1] | | | | Segment II: Intermittent-Dosing Regimen[1] | | | |
|---|---|---|---|---|---|---|---|---|---|
| Parameter<br>Baseline Assessment[2] | Worst Post-Baseline Grade[3] | 100 mg / 60 mg/m$^2$<br>(N= ) | 100 mg / 80 mg/m$^2$<br>(N= ) | 150 mg / 80 mg/m$^2$<br>(N= ) | Total<br>(N= ) | 150 mg / 80 mg/m$^2$<br>(N= ) | 200 mg / 100 mg/m$^2$<br>(N= ) | Total<br>(N= ) | Total<br>(N= ) |
| Absolute Neutrophils | Grade 0 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Grade 0 | Grade 1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Grade 2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Grade 3 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Grade 4 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Grade 1 | Grade 0 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Grade 1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Grade 2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Grade 3 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Grade 4 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | | |
| Grade 4 | … | | | | | | | | |

Abbreviations: CTCAE=Common Terminology Criteria for Adverse Events v4.03; NCI=National Cancer Institute

Notes:
- Laboratory measurements are classified according to CTCAE, v4.03.
- Percentages are based on the number of patients with a non-missing baseline value and at least one non-missing post-baseline value.

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Baseline is defined as the last available measurement taken prior to the first dose of CORT125134.
[3] The worst post-baseline grade is defined as the highest NCI CTCAE grade reported after the first dose of CORT125134.

Reference: *Listing #(s)*
Path\filename.sas ddmmmyyyy hh:mm

*Programming Notes: Continue for regularly-collected hematology and chemistry tests with NCI CTCAE grading assigned: (WBC, Hemoglobin, Platelet Count, AST (SGOT), ALT (SGPT), Total Bilirubin, Sodium, Potassium)*

**Table 14.3.7.1**
**Vital Signs – Univariate Summary by Parameter and Visit**
**Safety Population**
**Part 1 of 2**

| | | Segment I: Continuous-Dosing Regimen | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | 100 mg / 60 mg/m$^2$ (N= ) | | 100 mg / 80 mg/m$^2$ (N= ) | | 150 mg / 80 mg/m$^2$ (N= ) | | Total (N= ) | |
| Vital Sign | Visit | Observed Value | Change from Baseline | Observed Value | Change from Baseline | Observed Value | Change from Baseline | Observed Value | Change from Baseline |
| Systolic Blood Pressure (mmHg) | Baseline[2] | | | | | | | | |
| | n | n | | n | | n | | n | |
| | Mean (SD) | x.x (x.xx) | | x.x (x.xx) | | x.x (x.xx) | | x.x (x.xx) | |
| | Median | x | | x | | x | | x | |
| | Min, Max | x, x | | x, x | | x, x | | x, x | |
| | Nab-Paclitaxel Lead In Day 1 | | | | | | | | |
| | n | n | n | n | n | n | n | n | n |
| | Mean (SD) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) |
| | Median | x | x | x | x | x | x | x | x |
| | Min, Max | x, x | x, x | x, x | x, x | x, x | x, x | x, x | x, x |
| | Cycle 1 Day 1 | | | | | | | | |
| | … | | | | | | | | |
| Diastolic Blood Pressure (mmHg) | | | | | | | | | |
| … | | | | | | | | | |

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Baseline is defined as the last available measurement taken prior to the first dose of CORT125134.

Reference: *Listing #(s)*
Path\filename.sas ddmmmyyyy hh:mm

**Corcept Therapeutics**
**CORT125134-550**

**Database Date/Analysis: DDMMMYYYY/Draft**
**Page x of y**

**Table 14.3.7.1**
**Vital Signs – Univariate Summary by Parameter and Visit**
**Safety Population**
**Part 2 of 2**

| | | Segment II: Intermittent-Dosing Regimen[1] | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | 150 mg / 80 mg/m$^2$ (N= ) | | 200 mg / 100 mg/m$^2$ (N= ) | | Total (N= ) | | Total (N= ) | |
| Parameter | Visit | Observed Value | Change from Baseline | Observed Value | Change from Baseline | Observed Value | Change from Baseline | Observed Value | Change from Baseline |
| Systolic Blood Pressure (mmHg) | Baseline[2] | | | | | | | | |
| | n | n | | n | | n | | n | n |
| | Mean (SD) | x.x (x.xx) | | x.x (x.xx) | | x.x (x.xx) | | x.x (x.xx) | x.x (x.xx) |
| | Median | x | | x | | x | | x | x |
| | Min, Max | x, x | | x, x | | x, x | | x, x | x, x |
| | Nab-paclitaxel Lead In: Day 1 | | | | | | | | |
| | n | n | n | n | n | n | n | n | |
| | Mean (SD) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | |
| | Median | x | x | x | x | x | x | x | |
| | Min, Max | x, x | x, x | x, x | x, x | x, x | x, x | x, x | |
| | Cycle 1 Day 1 | | | | | | | | |
| | … | | | | | | | | |
| Diastolic Blood Pressure (mmHg) | | | | | | | | | |
| … | | | | | | | | | |

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Baseline is defined as the last available measurement taken prior to the first dose of CORT125134.

Reference: *Listing #(s)*
Path\filename.sas ddmmmyyyy hh:mm

*Programming Notes:*

- *Continue for remaining regularly-scheduled visits (Cycle 1 Day 8, Cycle 1 Day 15, Cycle 2 Day 1, Cycle 2 Day 8, Cycle 2 Day 15, (continue on Days 1, 8, 15 for Cycles 2+), Posttreatment)*
- *Continue for regularly-collected vital signs (Respiratory Rate (breaths/min), Temperature (C), Heart Rate (beats/min))*

**Table 14.3.7.2**
**12-Lead Electrocardiogram – Univariate Summary by Parameter and Visit**
**Safety Population**
**Part 1 of 2**

| | | Segment I: Continuous-Dosing Regimen | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | 100 mg / 60 mg/m$^2$ (N= ) | | 100 mg / 80 mg/m$^2$ (N= ) | | 150 mg / 80 mg/m$^2$ (N= ) | | Total (N= ) | |
| ECG Parameter | Visit | Observed Value | Change from Baseline | Observed Value | Change from Baseline | Observed Value | Change from Baseline | Observed Value | Change from Baseline |
| Heart Rate (bpm) | Baseline[2] | | | | | | | | |
| | n | n | | n | | n | | n | |
| | Mean (SD) | x.x (x.xx) | | x.x (x.xx) | | x.x (x.xx) | | x.x (x.xx) | |
| | Median | x | | x | | x | | x | |
| | Min, Max | x, x | | x, x | | x, x | | x, x | |
| | CORT125134 Lead In Day 7 Pre-Dose | | | | | | | | |
| | n | n | n | n | n | n | n | n | n |
| | Mean (SD) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) |
| | Median | x | x | x | x | x | x | x | x |
| | Min, Max | x, x | x, x | x, x | x, x | x, x | x, x | x, x | x, x |
| | CORT125134 Lead In Day 7 Post-Dose | | | | | | | | |
| | … | | | | | | | | |
| RR Interval (msec) | | | | | | | | | |
| … | | | | | | | | | |

Abbreviations: ECG=electrocardiogram; QTc=Corrected QT interval

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Baseline is defined as the last available measurement taken prior to the first dose of CORT125134.

Reference: *Listing #(s)*
Path\filename.sas ddmmmyyyy hh:mm

**Corcept Therapeutics**
**CORT125134-550**

**Database Date/Analysis: DDMMMYYYY/Draft**
**Page x of y**

**Table 14.3.7.2**
**12-Lead Electrocardiogram – Univariate Summary by Parameter and Visit**
**Safety Population**
**Part 2 of 2**

| | | Segment II: Intermittent-Dosing Regimen[1] | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | 150 mg / 80 mg/m$^2$ (N= ) | | 200 mg / 100 mg/m$^2$ (N= ) | | Total (N= ) | | Total (N= ) | |
| ECG Parameter | Visit | Observed Value | Change from Baseline | Observed Value | Change from Baseline | Observed Value | Change from Baseline | Observed Value | Change from Baseline |
| Heart Rate (bpm) | Baseline[2] | | | | | | | | |
| | n | n | | n | | n | | n | |
| | Mean (SD) | x.x (x.xx) | | x.x (x.xx) | | x.x (x.xx) | | x.x (x.xx) | |
| | Median | x | | x | | x | | x | |
| | Min, Max | x, x | | x, x | | x, x | | x, x | |
| | CORT125134 Lead In Day 7 Pre-Dose | | | | | | | | |
| | n | n | n | n | n | n | n | n | n |
| | Mean (SD) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) |
| | Median | x | x | x | x | x | x | x | x |
| | Min, Max | x, x | x, x | x, x | x, x | x, x | x, x | x, x | x, x |
| | CORT125134 Lead In Day 7 Post-Dose | | | | | | | | |
| | … | | | | | | | | |
| RR Interval (msec) | | | | | | | | | |
| … | | | | | | | | | |

Abbreviations: ECG=electrocardiogram; QTc=Corrected QT interval

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Baseline is defined as the last available measurement taken prior to the first dose of CORT125134.

Reference: *Listing #(s)*
Path\filename.sas ddmmmyyyy hh:mm
*Programming Notes:*

- *Continue for regularly-collected ECG parameters (PR Interval (msec), QRS Duration (msec), QT Interval (msec), RR Interval (msec), Heart Rate (beats/min), QTcB (msec), QTcF (msec))*
- *Continue for regularly collected visits (Cycle 1 Day 8 Pre-Dose, Cycle 1 Day 8 Post-Dose)*

**Table 14.3.7.3**
**12-Lead Electrocardiogram Overall Interpretation – Shift from Baseline to Worst Post-Baseline Value**
**Safety Population**
**Part 1 of 2**

| | Segment I: Continuous-Dosing Regimen[1] | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 100 mg / 60 mg/m$^2$ (N= ) | | 100 mg / 80 mg/m$^2$ (N= ) | | 150 mg / 80 mg/m$^2$ (N= ) | | Total (N= ) | |
| | Baseline Assessment[2] | | Baseline Assessment[2] | | Baseline Assessment[2] | | Baseline Assessment[2] | |
| Overall Interpretation | Normal | Abnormal | Normal | Abnormal | Normal | Abnormal | Normal | Abnormal |
| Worst Post-Baseline Assessment | (n= ) | | (n= ) | | (n= ) | | (n= ) | |
| Normal | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Abnormal | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |

Note: Percentages are based on the number of patients with a non-missing baseline value and at least one non-missing post-baseline value.

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Baseline is defined as the last available measurement taken prior to the first dose of CORT125134.

Reference: *Listing #(s)*
Path\filename.sas ddmmmyyyy hh:mm

**Table 14.3.7.3**
**12-Lead Electrocardiogram Overall Interpretation – Shift from Baseline to Worst Post-Baseline Value**
**Safety Population**
**Part 2 of 2**

| | Segment II: Intermittent-Dosing Regimen[1] | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 150 mg / 80 mg/m$^2$ (N= ) | | 200 mg / 100 mg/m$^2$ (N= ) | | Total (N= ) | | Total (N= ) | |
| Overall Interpretation | Observed Value | Change from Baseline | Observed Value | Change from Baseline | Observed Value | Change from Baseline | Observed Value | Change from Baseline |
| Worst Post-Baseline Assessment | (n= ) | | (n= ) | | (n= ) | | (n= ) | |
| Normal | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Abnormal | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |

Note: Percentages are based on the number of patients with a non-missing baseline value and at least one non-missing post-baseline value.

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Baseline is defined as the last available measurement taken prior to the first dose of CORT125134.

Reference: *Listing #(s)*
Path\filename.sas ddmmmyyyy hh:mm

**Table 14.3.7.4**
**12-Lead Electrocardiogram – QT Interval Categories**
**Safety Population**

| | | Segment I: Continuous-Dosing Regimen[1] | | | | Segment II: Intermittent-Dosing Regimen[1] | | | |
|---|---|---|---|---|---|---|---|---|---|
| Visit[2] | QTc Category | 100 mg / 60 mg/m$^2$ (N= ) | 100 mg / 80 mg/m$^2$ (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | Total (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | 200 mg / 100 mg/m$^2$ (N= ) | Total (N= ) | Total (N= ) |
| Baseline | Number of Patients | n | n | n | n | n | n | n | n |
| | > 450 msec | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | > 470 msec | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | > 500 msec | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| CORT125134 Lead In Day 7 Pre-Dose | Number of Patients | n | n | n | n | n | n | n | n |
| | > 450 msec | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | > 470 msec | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | > 500 msec | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | Change from Baseline | | | | | | | | |
| | > 30 msec | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| | > 60 msec | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| CORT125134 Lead In Day 7 Post-Dose | … | | | | | | | | |
| … | | | | | | | | | |

Abbreviation: QTc=Corrected QT interval

Note: Denominators for percentages are based on the number of patients within each treatment group with non-missing data at each visit.

[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Baseline is defined as the last available measurement taken prior to the first dose of CORT125134.

Reference: *Listing #(s)*
Path\filename.sas ddmmmyyyy hh:mm

*Programming Note: Continue for regularly collected visits (Cycle 1 Day 8 Pre-Dose, Cycle 1 Day 8 Post-Dose)*

**Table 14.3.7.5**
**Concomitant Medications**
**Safety Population**

| ATC Class / Generic Drug Name | Segment I: Continuous-Dosing Regimen[1] | | | | Segment II: Intermittent-Dosing Regimen[1] | | | |
|---|---|---|---|---|---|---|---|---|
| | 100 mg / 60 mg/m$^2$ (N= ) | 100 mg / 80 mg/m$^2$ (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | Total (N= ) | 150 mg / 80 mg/m$^2$ (N= ) | 200 mg / 100 mg/m$^2$ (N= ) | Total (N= ) | Total (N= ) |
| Patients Receiving any Concomitant Medications | n | n | n | n | n | n | n | n |
| ATC Class #1 | | | | | | | | |
| Generic Drug Name #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Generic Drug Name #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| ATC Class #2 | | | | | | | | |
| Generic Drug Name #1 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| Generic Drug Name #2 | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) | n (x.x%) |
| … | | | | | | | | |

Abbreviations: ATC=anatomic therapeutic chemical; WHO=World Health Organization

Notes:
- Concomitant medications are those medications received after the first dose of study treatment.
- Medications are coded to ATC drug class (level 4) and generic drug names using the WHO Drug dictionary, March 1, 2014 Version.
- At each level of summarization (any medication, ATC class, generic drug name), patients reporting use of more than one medication are counted only once.

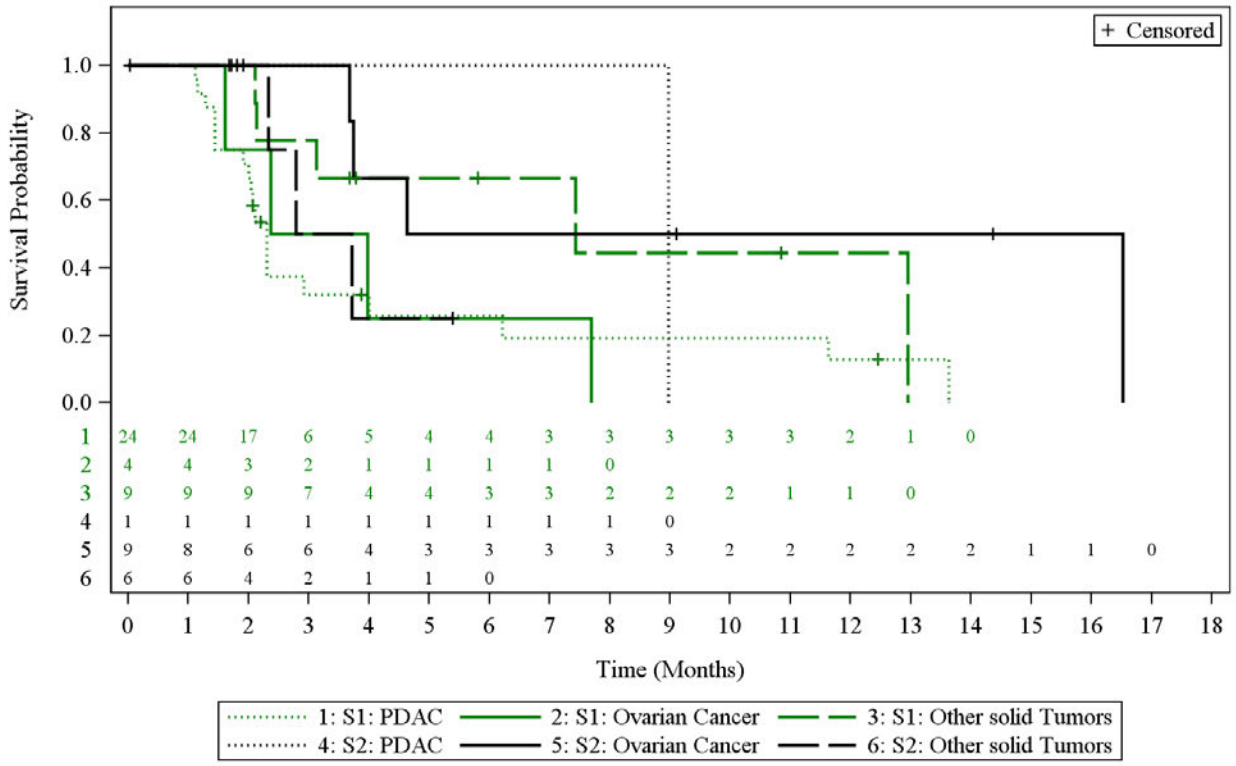
[1] Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).

Reference: *Listing #(s)*
Path\filename.sas ddmmmyyyy hh:mm

*Programming Notes:*
- *Sort medications by descending order of ATC class incidence and by descending order of drug name incidence within ATC class, based on the overall incidence (ie, sum over all treatment groups).*
- *When creating ATC level 4 drug class, utilize level 3 term if level 4 is missing in dataset and level 2 if both level 3 and level 4 are missing in the dataset*

# APPENDIX D: FIGURE LAYOUTS

**Figure 14.4.1.1**
**Kaplan-Meier Plot of Overall Survival**
**PDAC**
**mITT Population**




Abbreviation: PDAC=pancreatic ductal adenocarcinoma; S=segment

Notes:

- PDAC includes all pancreatic cancer patients excluding acinar subtype. Ovarian Cancer includes all ovarian cancer patients excluding juvenile granulosa subtype. Other Solid Tumors includes all patients not included in PDAC and ovarian cancer groups.
- Number of patients at risk are displayed by month along the x-axis.

Reference: *Table/Listing #(s)*
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*Programming Note: Continue for cancer types: Ovarian Cancer, Other Solid Tumors*

*Table 14.4.1.2 Kaplan-Meier Plot of Overall Survival by Tumor Type**
*Table 14.4.2.1 Kaplan-Meier Plot of Progression-Free Survival*
*Table 14.4.2.2 Kaplan-Meier Plot of Progression-Free Survival by Tumor Type**
*Table 14.4.3.1 Kaplan-Meier Plot of Duration of Response*
*Table 14.4.3.2 Kaplan-Meier Plot of Duration of Response by Tumor Type**
**Use above mock with a separate KM curve for each of the following Tumor Types: PDAC, Ovarian Cancer, Other Solid Tumors. Legend will have 1-3 for each tumor type*

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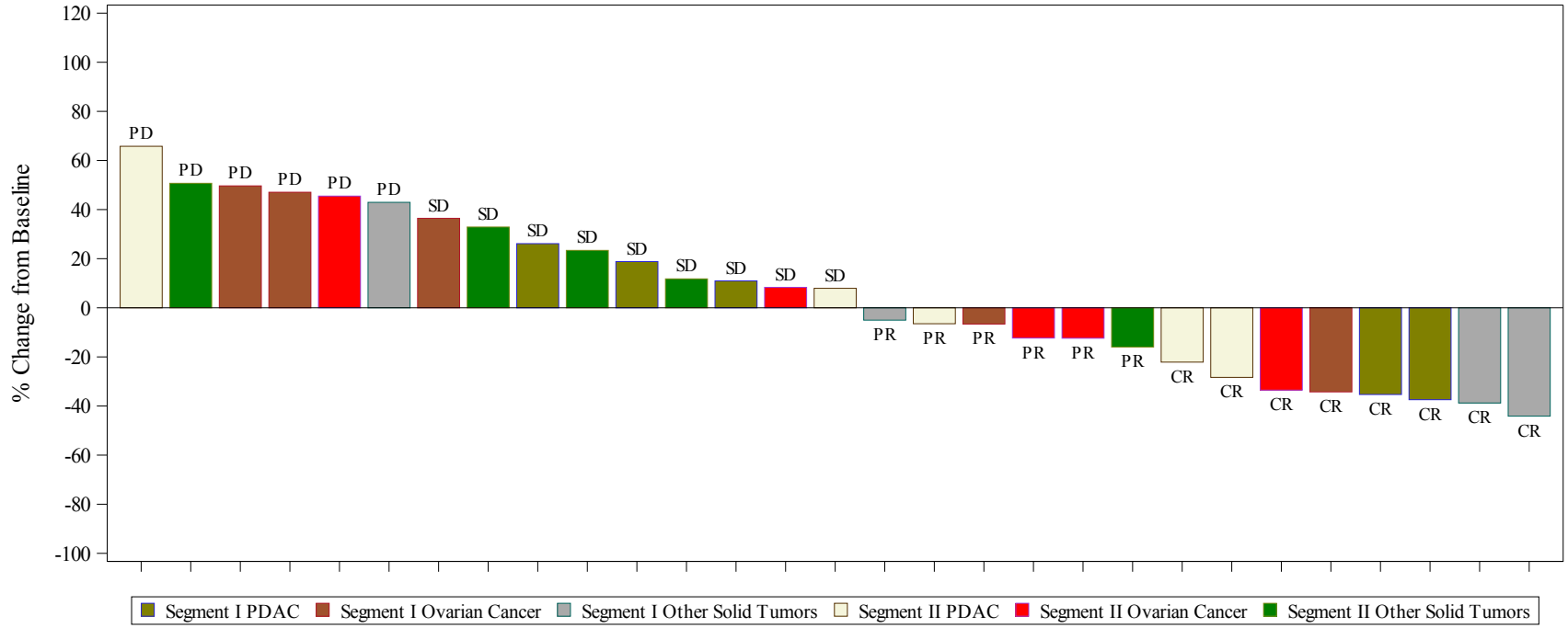
**Figure 14.4.4**
**Waterfall Plot of Best Response based on RECIST v1.1 Criteria**
**PDAC**
**mITT Population**




Abbreviations: CR=complete response; PD=progressive disease; PDAC=pancreatic ductal adenocarcinoma; PR=partial response; RECIST=response evaluation criteria in solid tumors v1.1; SD=stable disease

Notes:

- PDAC includes all pancreatic cancer patients excluding acinar subtype. Ovarian Cancer includes all ovarian cancer patients excluding juvenile granulosa subtype. Other Solid Tumors includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
- Best response is defined by RECIST v1.1 as the best response recorded from the date of the first dose of CORT125134 or nab-paclitaxel, whichever is earliest, across all time points during study observation period (including both confirmed and unconfirmed responses).
- The percentage change from baseline is the maximum percentage decrease (or minimum increase if no decrease) in the sum of the longest diameters of target lesions at a given visit relative to baseline.

Reference: *Table/Listing #(s)*
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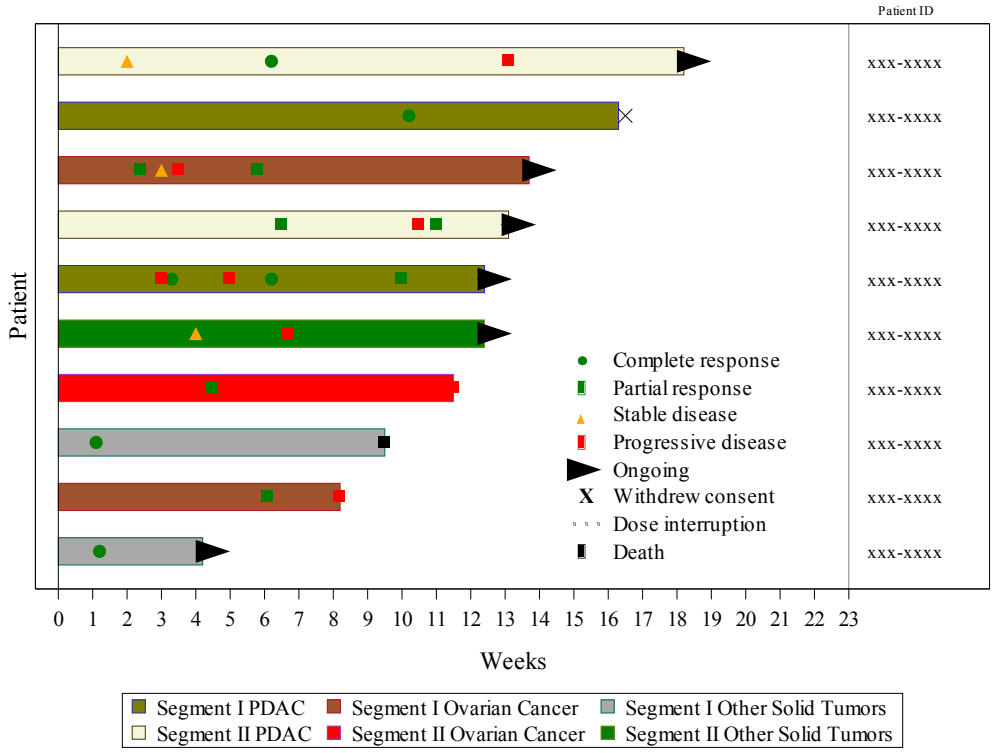
*See programming notes on the next page.*

*Programming Notes:*

- *Continue for cancer types: Ovarian Cancer, Other Solid Tumors*
- *X-axis to include Patient IDs along tick marks*

**Figure 14.4.5**
**Swim Plot of RECIST v1.1 Criteria**
**PDAC**
**mITT Population**




Abbreviations: PDAC=pancreatic ductal adenocarcinoma; RECIST=response evaluation criteria in solid tumors v1.1

Notes:

- PDAC includes all pancreatic cancer patients excluding acinar subtype. Ovarian Cancer includes all ovarian cancer patients excluding juvenile granulosa subtype. Other Solid Tumors includes all patients not included in PDAC and ovarian cancer groups.
- Time (weeks) from start of CORT125134 or nab-paclitaxel, whichever is earliest, until last dose of any study drug displayed
- Complete response, partial response, stable disease, and progressive disease are defined using RECIST v1.1.

Reference: *Table/Listing #(s)*
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*See Programming Notes on the next page*

*Programming Note: Continue for cancer types: Ovarian Cancer, Other Solid Tumors*

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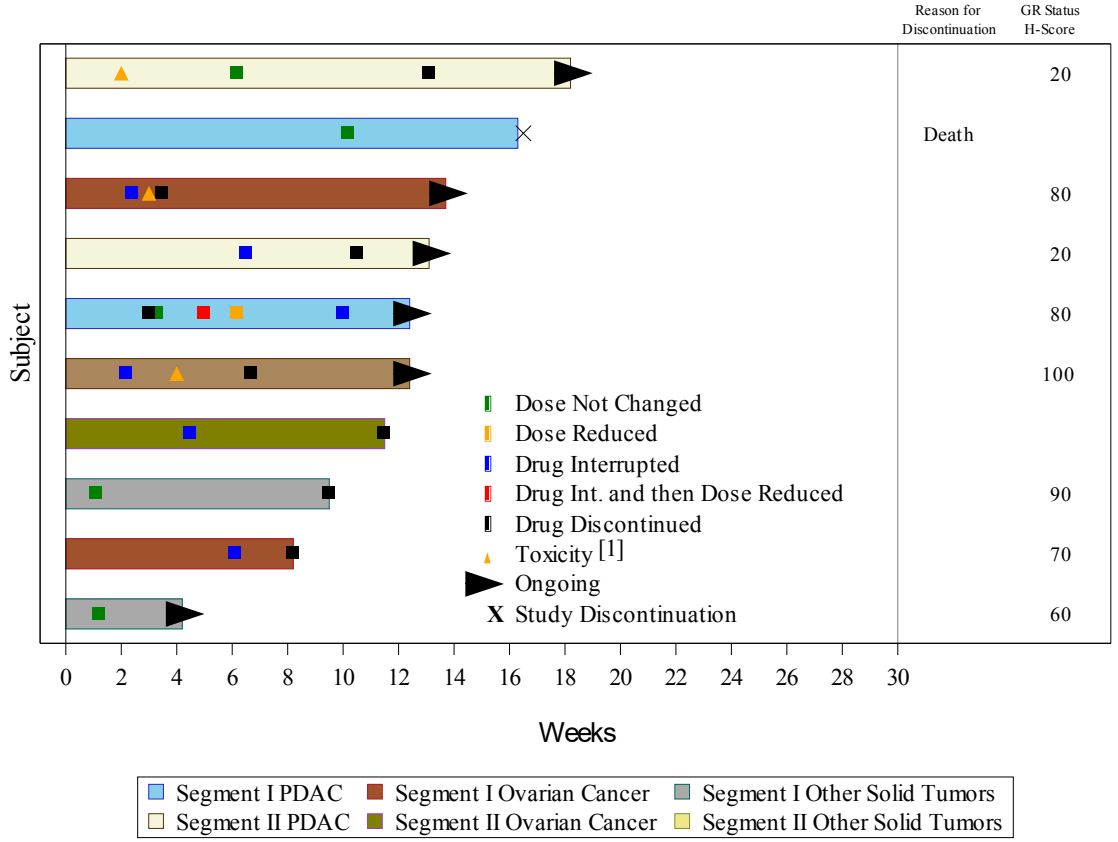
**Figure 14.4.6**
**Swim Plot of Nab-Paclitaxel Toxicity and Study Status**
**mITT Population**




Abbreviation: PDAC=pancreatic ductal adenocarcinoma

Reference: *Table/Listing #(s)*
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# APPENDIX E: LISTING LAYOUTS

**Listing 16.2.1**
**Patient Disposition**

| Segment | Cohort[1] | Patient ID | Completed Survival Follow-Up Period | Date of Study Completion or Discontinuation (Study Day[2]) | Reason for Discontinuation |
|---|---|---|---|---|---|
| 1 | 100/60 PDAC / 100/80 PDAC / 150/80 PDAC / 100/60 OVCA / 100/80 OVCA / 150/80 OVCA / 100/60 OT / 100/80 OT / 150/80 OT | xxx-xxxx | Yes / No | ddMMMyyyy (xx) | Death / Lost to Follow-Up / Study Terminated by Sponsor / Withdrawl by Patient: *Specify* / Other: *Specify* |
| 2 | 150/80 PDAC / 200/100 PDAC / 150/80 OVCA / 200/100 OVCA / 150/80 OT / 200/100 OT | | | | |
| | | … | | | |

Abbreviations: OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Time (days) relative to date of first dose of CORT125134

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**Listing 16.2.2**
**Informed Consent and Eligibility Criteria**

| | | | | | Inclusion/Exclusion Criteria Waivers | | | |
|---|---|---|---|---|---|---|---|---|
| Segment | Cohort[1] | Patient ID | Patient Sign Informed Consent? | Date Informed Consent Signed | Met All Eligability Criteria? | Criterion Identifier | Criterion | Inclusion/Exclusion Category |
| 1 | 100/60 PDAC / 100/80 PDAC / 150/80 PDAC / 100/60 OVCA / 100/80 OVCA / 150/80 OVCA / 100/60 OT / 100/80 OT / 150/80 OT | xxx-xxx | Yes / No | ddMMMyyyy | Yes / No | Inclusion # / Exclusion # | *Criteria* | Inclusion / Exclusion |
| 2 | 150/80 PDAC / 200/100 PDAC / 150/80 OVCA / 200/100 OVCA / 150/80 OT / 200/100 OT | | | | | | | |
| | | … | | | | | | |

Abbreviations: OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).

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**Listing 16.2.3**
**Patients Excluded from the Efficacy Analysis**

| Segment | Cohort[1] | Patient ID | Response-Evaluable Population[2] | Reason for Exclusion from the Efficacy Analysis |
|---|---|---|---|---|
| 1 | 100/60 PDAC /<br>100/80 PDAC /<br>150/80 PDAC /<br>100/60 OVCA /<br>100/80 OVCA /<br>150/80 OVCA /<br>100/60 OT /<br>100/80 OT /<br>150/80 OT | xxx-xxx | Yes /<br>No | *Reason (eg, screen failure, patient did not receive study drug, protocol violation, etc.), including any relevant specifications /*<br>*Did not have at least one post-baseline tumor response evaluation* |
| 2 | 150/80 PDAC /<br>200/100 PDAC /<br>150/80 OVCA /<br>200/100 OVCA /<br>150/80 OT /<br>200/100 OT | | | |
| | | … | | |

Abbreviations: OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/$m^2$).
[2] Response-Evaluable population is the subset of the Safety population with at least one post-baseline tumor assessment.

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**Listing 16.2.4.1**
**Demographics**

| Segment | Cohort[1] | Patient ID | Date of Birth | Age (years)[2] | Sex | Ethnicity | Race |
|---|---|---|---|---|---|---|---|
| 1 | 100/60 PDAC /<br>100/80 PDAC /<br>150/80 PDAC /<br>100/60 OVCA /<br>100/80 OVCA /<br>150/80 OVCA /<br>100/60 OT /<br>100/80 OT /<br>150/80 OT | xxx-xxxx | ddMMMyyyy | xx | Male /<br>Female | Hispanic or Latino /<br>Not Hispanic or Latino | Black or African American /<br>American Indian or Alaska Native /<br>Asian /<br>Native Hawaiian or Other Pacific Islander /<br>White |
| 2 | 150/80 PDAC /<br>200/100 PDAC /<br>150/80 OVCA /<br>200/100 OVCA /<br>150/80 OT /<br>200/100 OT | … | | | | | |

Abbreviations: CRF=case report form; OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/$m^2$).
[2] Age is listed as reported on the CRF.

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*Programming Notes:*

- *If multiple races are reported for a given patient, display all that are reported in the "Race" column, separated by a semicolon.*

**Listing 16.2.4.2**
**Cancer History**

| Segment | Cohort[1] | Patient ID | Date of Initial Diagnosis | Cancer Type | Histology | Molecular Typing | Stage at Initial Diagnosis | Stage at Screening | Triple Negative Breast Cancer (TNBC) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | ER (% cells positive) | PR (% cells positive) | HER2 | FISH HER2+ ≤ 1.8 | BRCA Result |
| 1 | 100/60 PDAC / 100/80 PDAC / 150/80 PDAC / 100/60 OVCA / 100/80 OVCA / 150/80 OVCA / 100/60 OT / 100/80 OT / 150/80 OT | xxx-xxxx | ddMMMyyyy | NSCLC / Pancreatic / Ovarian / Sarcoma / Head and Neck / Melanoma / TNBC)/ Other: *Specify* | *Histology* | *Typing* | *Stage* | *Stage* | xx | xx | HER2 IHC Score 0 / HER IHC Score 1 / FISH Ratio of HER2/CEN-17 | Yes / No | 1 / 2 / 1 and 2 / Wild Type / Unknown |
| 2 | 150/80 PDAC / 200/100 PDAC / 150/80 OVCA / 200/100 OVCA / 150/80 OT / 200/100 OT | | | | | | | | | | | | |
| | | … | | | | | | | | | | | |

Abbreviations: BRCA=breast caner 1 (gene); ER=estrogen receptor; FISH=fluorescence in situ hybridization; HER2=human epithelial receptor-2; NSCLC=non-small cell lung cancer; OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma; PR=progesterone receptor

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).

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*Programming Notes:*

- *Sort conditions based on initial diagnosis date. If partial onset dates are reported (eg, month and year only), separate out the portions of the date to sort separately by year, then month, then day.*

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**Listing 16.2.4.3**
**Prior Cancer Related Surgery**

| Segment | Cohort[1] | Patient ID | Prior Cancer Related Surgery? | Surgery Date | Surgical Procedure | Significant Details |
|---|---|---|---|---|---|---|
| 1 | 100/60 PDAC / 100/80 PDAC / 150/80 PDAC / 100/60 OVCA / 100/80 OVCA / 150/80 OVCA / 100/60 OT / 100/80 OT / 150/80 OT | xxx-xxxx | Yes / No | ddMMMyyyy | *Procedure* | *Details* |
| 2 | 150/80 PDAC / 200/100 PDAC / 150/80 OVCA / 200/100 OVCA / 150/80 OT / 200/100 OT | | | | | |
| | | … | | | | |

Abbreviations: OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).

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*Programming Notes:*

- *Sort conditions based on surgery date. If partial onset dates are reported (eg, month and year only), separate out the portions of the date to sort separately by year, then month, then day.*

**Listing 16.2.4.4**
**Prior Radiotherapy**

| Segment | Cohort[1] | Patient ID | Prior Radiation Therapy? | Site |
|---|---|---|---|---|
| 1 | 100/60 PDAC /<br>100/80 PDAC /<br>150/80 PDAC /<br>100/60 OVCA /<br>100/80 OVCA /<br>150/80 OVCA /<br>100/60 OT /<br>100/80 OT /<br>150/80 OT | xxx-xxxx | Yes /<br>No | Abdomen/Viscera /<br>Adrenals /<br>Bone /<br>Bone Marrow /<br>Bladder /<br>Chest Wall /<br>CNS/Brain<br>Kidney /<br>Liver /<br>Lung / |
| 2 | 150/80 PDAC /<br>200/100 PDAC /<br>150/80 OVCA /<br>200/100 OVCA /<br>150/80 OT /<br>200/100 OT | … | | Lymph Nodes /<br>Pancreas /<br>Peritoneum /<br>Pleura /<br>Prostate Gland /<br>Spleen /<br>Stomach /<br>Whole Body /<br>Other: *Specify* |

Abbreviations: OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).

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**Listing 16.2.4.5**
**Prior Systemic Therapy**

| Segment | Cohort[1] | Patient ID | Prior Cancer Therapy for Disease Indication? | Date of First Dose | Date of Last Dose | Agent Type | Agent Name | Reason for Administration | Best Response | Prior Line Response Duration | Reason for Discontinuation |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 100/60 PDAC / 100/80 PDAC / 150/80 PDAC / 100/60 OVCA / 100/80 OVCA / 150/80 OVCA / 100/60 OT / 100/80 OT / 150/80 OT | xxx-xxxx | Yes / No | ddMMMyyyy | ddMMMyyyy | Chemotherapy / Hormonal Therapy / Immunotherapy / Other: *Specify* | *Name* | Neoadjuvant / Adjuvant / Radio Sensitizing / Locally Advanced / Metastatic Disease / Other: *Specify*<br><br>*Display all that are reported, separated by a comma* | CR / PR / SD / PD / NE | Platinum refractory (progression during treatment) / Platinum resistance (reoccurance < 6 months) / Platinum sensitive (recurrence > 6 months) / Other: *Specify* | Relapse/Progressive Disease / Toxicity: *Specify* / Unknown / Other: *Specify* |
| 2 | 150/80 PDAC / 200/100 PDAC / 150/80 OVCA / 200/100 OVCA / 150/80 OT / 200/100 OT | | | | | | | | | | |
| | | … | | | | | | | | | |

Abbreviations: CR=complete response; NE=not evaluable; OT=other tumor; OVCA=ovarian tumor; PD=progressive disease; PDAC=pancreatic ductal adenocarcinoma; PR=partial response; SD=stable disease

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).

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*Programming Notes:*

- *Sort conditions based on date of first dose. If partial onset dates are reported (eg, month and year only), separate out the portions of the date to sort separately by year, then month, then day.*

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**Listing 16.2.4.6**
**Medical History**

| Segment | Cohort[1] | Patient ID | Body System | Diagnosis/Condition | Onset Date | Resolution Date |
|---|---|---|---|---|---|---|
| 1 | 100/60 PDAC /<br>100/80 PDAC /<br>150/80 PDAC /<br>100/60 OVCA /<br>100/80 OVCA /<br>150/80 OVCA /<br>100/60 OT /<br>100/80 OT /<br>150/80 OT | xxx-xxxx | *Body System* | *Diagnosis /Condition* | ddMMMyyyy | ddMMMyyyy /<br>Ongoing |
| 2 | 150/80 PDAC /<br>200/100 PDAC /<br>150/80 OVCA /<br>200/100 OVCA /<br>150/80 OT /<br>200/100 OT | | | | | |
| | | … | | | | |

Abbreviations: OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/$m^2$).

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*Programming Notes:*

- *Sort conditions based on onset date. If partial onset dates are reported (eg, month and year only), separate out the portions of the date to sort separately by year, then month, then day.*

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**Listing 16.2.5.1**
**Study Drug Administration: CORT125134**

| Segment | Cohort[1] | Patient ID | Visit | Dose Date and Time | Stop Date | Dose (mg) | Total Dose Expected (mg) | Total Dose Received (mg) |
|---|---|---|---|---|---|---|---|---|
| 1 | 100/60 PDAC / 100/80 PDAC / 150/80 PDAC / 100/60 OVCA / 100/80 OVCA / 150/80 OVCA / 100/60 OT / 100/80 OT / 150/80 OT | xxx-xxxx | CORT125134 Lead-In Day 1 … | ddMMMyyyy HH:MM | ddMMMyyyy | xx | xx | xx |
| 2 | 150/80 PDAC / 200/100 PDAC / 150/80 OVCA / 200/100 OVCA / 150/80 OT / 200/100 OT | … | | | | | | |

Abbreviations: OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/$m^2$).

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**Listing 16.2.5.2**
**Study Drug Administration: Nab-paclitaxel**

| Segment | Cohort[1] | Patient ID | Date Administered | Planned Dose ($mg/m^2$) | Total Prepared Dose (mg) | Infusion Start | Infusion Stop | Total Infusion Time | Total Dose Administered? | Total Dose Administered ($mg/m^2$) |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 100/60 PDAC /<br>100/80 PDAC /<br>150/80 PDAC /<br>100/60 OVCA /<br>100/80 OVCA /<br>150/80 OVCA /<br>100/60 OT /<br>100/80 OT /<br>150/80 OT | xxx-xxxx | ddMMMyyyy | xx | xx | hh:mm | hh:mm | hh:mm | Yes /<br>Drug Interupted /<br>Drug Withdrawn /<br>Dose Reduced: *Specify* /<br>Rate Changed: *Specify* /<br>Drug Delayed: *Specify* /<br>Dose Not Given: *Specify* /<br>Toxicity /<br>Infusion Related Reaction /<br>Other Adverse Event /<br>Venous Access Related /<br>Other: *Specify* | xx |
| 2 | 150/80 PDAC /<br>200/100 PDAC /<br>150/80 OVCA /<br>200/100 OVCA /<br>150/80 OT /<br>200/100 OT | … | | | | | | | | |

Abbreviations: OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose ($mg/m^2$).

Path\filename.sas ddmmmyyyy hh:mm

*Programming Notes:*

- *Sort based on date administered. If partial onset dates are reported (eg, month and year only), separate out the portions of the date to sort separately by year, then month, then day.*

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**Listing 16.2.5.3**
**Concentration Data: CORT125134**

| Segment | Cohort[1] | Patient ID | Visit | Date Collected (Study Day[2]) | Time Point | Time Collected | Actual Time Relative to Dose | Plasma Drug Concentration (mg) |
|---|---|---|---|---|---|---|---|---|
| 1 | 100/60 PDAC / 100/80 PDAC / 150/80 PDAC / 100/60 OVCA / 100/80 OVCA / 150/80 OVCA / 100/60 OT / 100/80 OT / 150/80 OT | xxx-xxxx | CORT125134 Lead-In Day 1 | ddMMMyyyy (xx) / Not Done | Pre-Dose | hh:mm | -hh:mm | xx |
| 2 | 150/80 PDAC / 200/100 PDAC / 150/80 OVCA / 200/100 OVCA / 150/80 OT / 200/100 OT | | | | | | | |
| | | | CORT124134 Lead-In Day 7 | ddMMMyyyy (xx) / Not Done | Pre-dose | hh:mm | hh:mm | xx |
| | | | | | 0.5 hour | hh:mm | hh:mm | xx |
| | | | | | … | | | |
| | | | … | | | | | |

Abbreviations: OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/$m^2$).
[2] Time (days) relative to date of first dose of CORT125134

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**Listing 16.2.6.1**
**RECIST Non-Target Lesions**

| Segment | Cohort[1] | Patient ID | Date of Scan (Study Day[2]) | Anatomical Site | Anatomical Description | Lesion Status | Method of Assessment | Scan Slice Thickness | Overall Evaluation of Non Target Lesions (RECIST 1.1) |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 100/60 PDAC / 100/80 PDAC / 150/80 PDAC / 100/60 OVCA / 100/80 OVCA / 150/80 OVCA / 100/60 OT / 100/80 OT / 150/80 OT | xxx-xxxx | ddMMMyyyy (xx) | Abdomen/Viscera / Adrenals / Bladder / Bone / Breast / Chest Wall / CNS/Brain / Kidney / Liver / Lymph Node / Lung / Pancreas / Peritoneium / Pleura / Prostate / Skin / Stomach / Spleen / Other: *Specify* | *Description* | Baseline Assessment / Stable Disease (Lesion present) / Complete Response (Disapperance of lesion) / Progressive Disease (Unequivocal progression and/or Clinical progression based on clinical signs/symptoms) / Unevaluable (Status unknown) / Not evaluated | Conventional CT / Spiral CT / MRI / PET/CT / X-ray / Other: *Specify* | 2.5 mm / 5 mm / 10 mm / Other: *Specify* | CR / PD / Non-CR/Non-PD / NE / Unequivocal Progression |
| 2 | 150/80 PDAC / 200/100 PDAC / 150/80 OVCA / 200/100 OVCA / 150/80 OT / 200/100 OT | | | | | | | | |
| | | … | | | | | | | |

Abbreviations: CR=complete response; NE=inevaluable; OT=other tumor; OVCA=ovarian tumor; PD=progressive disease; PDAC=pancreatic ductal adenocarcinoma; RECIST=response evaluation criteria in solid tumors

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Time (days) relative to date of first dose of CORT125134

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**Listing 16.2.6.2**
**RECIST Target Lesions**

| Segment | Cohort[1] | Patient ID | Date of Scan (Study Day[2]) | Anatomical Site | Anatomical Description | Lesion Status | Method of Assessment | Scan Slice Thickness | Axis (mm) | Sum of the Diameters | Overall Evaluation of Target Lesions (RECIST 1.1) | Overall Response (RECIST 1.1) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 100/60 PDAC / 100/80 PDAC / 150/80 PDAC / 100/60 OVCA / 100/80 OVCA / 150/80 OVCA / 100/60 OT / 100/80 OT / 150/80 OT | xxx-xxxx | ddMMMyyyy (xx) | Abdomen/Viscera / Adrenals / Bladder / Bone / Breast / Chest Wall / CNS/Brain / Kidney / Liver / Lymph Node / | *Description* | Baseline Assessment / Stable Disease (does not meet PR or PD criteria) / Partial Response (>= 30% decrease from baseline in sum of diameters) / Progressive Disease (>= 20% increase and >= 5 mm from nadir) / Too Small to Measure (default 5 mm per RECIST 1.1) / Complete Response (Disapperance of all non-nodal lesions; Any pathological LN must have SAD < 10 mm) / Not evaluated / Lesion Merged or Coalesced (LD of coalesced lesion is added to the sum) / Lesion split or Divided (LDs of the fragmented portions are added to the sum) | Conventional CT / Spiral CT / MRI / PET/CT / X-ray / Other: *Specify* | 2.5 mm / 5 mm / 10 mm / Other: *Specify* | xx | xx | CR / PR / PD / SD / NE | CR / PR / PD / SD / NE |
| 2 | 150/80 PDAC / 200/100 PDAC / 150/80 OVCA / 200/100 OVCA / 150/80 OT / 200/100 OT | | | Lung / Pancreas / Peritoneium / Pleura / Prostate / Skin / Stomach / Spleen / Other: *Specify* | | | | | | | | |

Abbreviations: LD=longest diameter; LN=lymph node; OT=other tumor; OVCA=ovarian tumor; PD=progressive disease; PDAC=pancreatic ductal adenocarcinoma; PR=partial response; RECIST=response evaluation criteria in solid tumors; SAD=short axis diameter

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Time (days) relative to date of first dose of CORT125134

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**Listing 16.2.6.3**
**Percentage Change of Target Lesions from Baseline**

| Segment | Cohort[1] | Patient ID | Cancer Type | Date of Scan (Study Day[2]) | Sum of Diameters (mm)[3] Result | % Change from Baseline | % Change from Nadir | Overall Evaluation of Target Lesions | Overall Evaluation of Non-Target Lesions | RECIST v1.1 Overall Response |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 100/60 PDAC / 100/80 PDAC / 150/80 PDAC / 100/60 OVCA / 100/80 OVCA / 150/80 OVCA / 100/60 OT / 100/80 OT / 150/80 OT | xxx-xxxx | NSCLC / Pancreatic / Ovarian / Sarcoma / Head and Neck / Melanoma / TNBC / Breast / Cervical / Rectal / Other: Specify | ddMMMyyyy (xx) | xx | xx | xx | CR / PR / SD / PD / NE | CR / PR / SD / PD / NE | CR / PR / SD / PD / NE |
| 2 | 150/80 PDAC / 200/100 PDAC / 150/80 OVCA / 200/100 OVCA / 150/80 OT / 200/100 OT | | *Display all that are reported, separated by a comma* | | | | | | | |

Abbreviations: CR=complete response; NE=not evaluable; NSCLC=non-small cell lung cancer; OT=other tumor; OVCA=ovarian tumor; PD=progressive disease; PDAC=pancreatic ductal adenocarcinoma; PR=partial response; RECIST=response evaluation criteria in solid tumors v1.1; SD=stable disease; TNBC=triple-negative breast cancer

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/$m^2$).
[2] Time (days) relative to date of first dose of study treatment
[3] Sum of Diameters (mm) percent change from baseline and percent change from nadir are used to assess a response criteria for RECIST v1.1. Percent change from nadir defines nadir as the smallest measurement up to and including the visit of interest.

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**Listing 16.2.6.4**
**Survival Status**

| Segment | Cohort[1] | Patient ID | Date of Survival Follow-Up (Study Day[2]) | Method of Contact | Patient Alive |
|---|---|---|---|---|---|
| 1 | 100/60 PDAC / 100/80 PDAC / 150/80 PDAC / 100/60 OVCA / 100/80 OVCA / 150/80 OVCA / 100/60 OT / 100/80 OT / 150/80 OT | xxx-xxxx | ddMMMyyyy (xx) | Telephone / Hospital/Clinic Visit / Hospital/Clinic Visit Note / Written communication / Other: *Specify* / Unable to contact | N / Y / U |
| 2 | 150/80 PDAC / 200/100 PDAC / 150/80 OVCA / 200/100 OVCA / 150/80 OT / 200/100 OT | | | | |
| | | … | | | |

Abbreviations: N=No; OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma; U=Unknown (lost to follow up); Y=Yes

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Time (days) relative to date of first dose of CORT125134

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**Listing 16.2.6.5**
**Tumor Tissue Collection**

| Segment | Cohort[1] | Patient ID | Date Biopsy Procedure Perfomed (Study Day[2]) | Sample Type | Biopsy Site | Sample Submitted for GR IHC Analysis |
|---|---|---|---|---|---|---|
| 1 | 100/60 PDAC /<br>100/80 PDAC /<br>150/80 PDAC /<br>100/60 OVCA /<br>100/80 OVCA /<br>150/80 OVCA /<br>100/60 OT /<br>100/80 OT /<br>150/80 OT | xxx-xxxx | ddMMMyyyy (xx) | Achival Tumor Tissue: *Specify* /<br>Fresh Tumor Biopsy | Abdomen/Viscera /<br>Adrenals /<br>Bone Marrow /<br>Bone /<br>Breast /<br>Chest Wall /<br>CNS/Brain /<br>Pancreas /<br>Bladder /<br>Kidney /<br>Liver /<br>Lymph Nodes /<br>Lung /<br>Peritoneum /<br>Pleura /<br>Stomach /<br>Spleen /<br>Prostate /<br>Other: *Specify* | Yes /<br>No |
| 2 | 150/80 PDAC /<br>200/100 PDAC /<br>150/80 OVCA /<br>200/100 OVCA /<br>150/80 OT /<br>200/100 OT | | | | | |
| | | … | | | | |

Abbreviations: OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Time (days) relative to date of first dose of CORT125134

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**Listing 16.2.6.6**
**Tumor Markers**

| Segment | Cohort[1] | Patient ID | Markers | Date of Collection (Study Day[2]) | Result | Units | % Change from Baseline[3] |
|---|---|---|---|---|---|---|---|
| 1 | 100/60 PDAC /<br>100/80 PDAC /<br>150/80 PDAC /<br>100/60 OVCA /<br>100/80 OVCA /<br>150/80 OVCA /<br>100/60 OT /<br>100/80 OT /<br>150/80 OT | xxx-xxxx | CA125 /<br>PSA /<br>Other: *specify* | ddMMMyyyy (xx) | xx | units/mL /<br>ng/mL /<br>Other: *specify* | xx% |
| 2 | 150/80 PDAC /<br>200/100 PDAC /<br>150/80 OVCA /<br>200/100 OVCA /<br>150/80 OT /<br>200/100 OT | | | | | | |
| | | … | | | | | |

Abbreviations: OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Time (days) relative to date of first dose of CORT125134
[3] Baseline defined as the last result measured prior to first dose of study treatment

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**Listing 16.2.6.7**
**Study Treatment and Prior Systemic Therapy Duration**

| Segment | Cohort[1] | Patient ID | Duration of Nab-Paclitaxel (months[2]) | Duration of CORT125134 (months[2]) | On Study Progressive Disease per RECIST | Agent Name | Agent Type | Duration of Prior Systemic Therapy (months[2]) | Prior Systemic Therapy Response Duration |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 100/60 PDAC / 100/80 PDAC / 150/80 PDAC / 100/60 OVCA / 100/80 OVCA / 150/80 OVCA / 100/60 OT / 100/80 OT / 150/80 OT | xxx-xxxx | xx | xx | Yes / No | *Agent* | Chemotherapy / Hormonal Therapy / Immonotherapy / Other: *specify* | xx | Progression During Treatment / Recurrence <6 Months / Recurrence >6 Months / > 1 Year / < 2 Years / > 2 Years / < 5 Years / > 5 Years / Other: *specify* |
| 2 | 150/80 PDAC / 200/100 PDAC / 150/80 OVCA / 200/100 OVCA / 150/80 OT / 200/100 OT | | | | | | | | |
| | | … | | | | | | | |

Abbreviations: CR=complete response; OT=other tumor; OVCA=ovarian tumor; PR=partial response; PD=progressive disease; PDAC=pancreatic ductal adenocarcinoma; NE=not evaluable; SD=stable disease

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] (Date of last dose – Date of first dose+1) / (365.25/12).

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*Programming Notes:*

- *Sort Agents based on duration of prior systemic therapy. If partial onset dates are reported (eg, month and year only), use the first of the month to perform the duration calculation. Prior therapies with the month and day missing should present a missing duration.*

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**Listing 16.2.7.1**
**Adverse Events**
**Safety Population**

| Segment | Cohort[1] | Patient ID | System Organ Class[2] / Preferred Term[2] / Event Name | Treatment-Emergent[3] | Start Date and Time (Study Day[4]) | End Date and Time (Study Day[4]) | CTCAE Grade | Serious | Relationship to[5] | Action Taken with[6] | Outcome |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 100/60 PDAC / 100/80 PDAC / 150/80 PDAC / 100/60 OVCA / 100/80 OVCA / 150/80 OVCA / 100/60 OT / 100/80 OT / 150/80 OT | xxx-xxxx | *System Organ Class / Preferred Term / Event Name* | Yes / No | ddMMMyyyy HH:MM (xx) | ddMMMyyyy HH:MM (xx) / Ongoing | Grade 1 / Grade 2 / Grade 3 / Grade 4 / Grade 5 | Yes / No | C: Not Related to Study Drug / C: Unlikely Related to Study Drug/ C: Possibly Related to Study Drug/ C: Related to Study Drug<br>N: Not Related to Study Drug / N: Unlikely Related to Study Drug/ N: Possibly Related to Study Drug/ N: Related to Study Drug<br>*Sepearate C and N Relationship with a comma* | C: Dose Not Changed / C: Dose Reduced / C: Drug Interrupted / C: Drug Interrupted and then Dose Reduced / C: Drug Withdrawn / C: Not Applicable / C: Unknown<br>N: Dose Not Changed / N: Dose Reduced / N: Drug Interrupted / N: Drug Interrupted and then Dose Reduced / N: Drug Withdrawn / N: Not Applicable / N: Unknown<br>*Sepearate C and N Relationship with a comma* | Fatal / Not Recovered/ Not Resolved/ Recovered/ Resolved/ Recovered/ Resolved with Sequelae / Recovering/ Resolving/ Unknown |
| 2 | 150/80 PDAC / 200/100 PDAC / 150/80 OVCA / 200/100 OVCA / 150/80 OT / 200/100 OT | | | | | | | | | | |

Abbreviations: CTCAE=Common Terminology Criteria for Adverse Events, v4.03; DLT=dose-limiting toxicity; OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Adverse events are coded to system organ class and preferred term using the Medical Dictionary for Regulatory Activities (MedDRA), version 19.0.
[3] Treatment-emergent adverse events are those events that occur from the first dose of CORT125134 through 28 days after administration of the last dose of study drug.
[4] Time (days) relative to date of first dose of study treatment
[5] C: reports answer to question on case report form regarding relationship to CORT125134; N: reports answer to question on case report form regarding relationship to Nab-paclitaxel
[6] C: reports answer to question on case report form regarding action taken with CORT125134; N: reports answer to question on case report form regarding action taken with Nab-paclitaxel

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*See Programming Notes on next page*

*Programming Note: Generate listing in XLS format as well with the following updates: 1. Population updated to use All Patients; 2. Add column for "Cycle 1 Day 1 Visit Date" prior to Start Date.*

**Listing 16.2.7.2**
**Grade ≥ 3 Adverse Events**
**Safety Population**

| Segment | Cohort[1] | Patient ID | System Organ Class[2] / Preferred Term[2] / Event Name | Treatment-Emergent[3] | Start Date and Time (Study Day[4]) | End Date and Time (Study Day[4]) | CTCAE Grade | Serious | Relationship to[5] | Action Taken with[6] | Outcome |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 100/60 PDAC / 100/80 PDAC / 150/80 PDAC / 100/60 OVCA / 100/80 OVCA / 150/80 OVCA / 100/60 OT / 100/80 OT / 150/80 OT | xxx-xxxx | *System Organ Class / Preferred Term / Event Name* | Yes / No | ddMMMyyyy HH:MM (xx) | ddMMMyyyy HH:MM (xx) / Ongoing | Grade 3 / Grade 4 / Grade 5 | Yes / No | C: Not Related to Study Drug / C: Unlikely Related to Study Drug/ C: Possibly Related to Study Drug/ C: Related to Study Drug<br><br>N: Not Related to Study Drug / N: Unlikely Related to Study Drug/ N: Possibly Related to Study Drug/ N: Related to Study Drug<br><br>*Sepearate C and N Relationship with a comma* | C: Dose Not Changed / C: Dose Reduced / C: Drug Interrupted / C: Drug Interrupted and then Dose Reduced / C: Drug Withdrawn / C: Not Applicable / C: Unknown<br><br>N: Dose Not Changed / N: Dose Reduced / N: Drug Interrupted / N: Drug Interrupted and then Dose Reduced / N: Drug Withdrawn / N: Not Applicable / N: Unknown<br>*Sepearate C and N Relationship with a comma* | Fatal / Not Recovered/ Not Resolved/ Recovered/ Resolved/ Recovered/ Resolved with Sequelae / Recovering/ Resolving/ Unknown |
| 2 | 150/80 PDAC / 200/100 PDAC / 150/80 OVCA / 200/100 OVCA / 150/80 OT / 200/100 OT | | | | | | | | | | |

Abbreviations: CTCAE=Common Terminology Criteria for Adverse Events, v4.03; OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Adverse events are coded to system organ class and preferred term using the Medical Dictionary for Regulatory Activities (MedDRA), version 19.0.
[3] Treatment-emergent adverse events are those events that occur from the first dose of CORT125134 through 28 days after administration of the last dose of study drug.
[4] Time (days) relative to date of first dose of CORT125134
[5] C: reports answer to question on case report form regarding relationship to CORT125134; N: reports answer to question on case report form regarding relationship to Nab-paclitaxel
[6] C: reports answer to question on case report form regarding action taken with CORT125134; N: reports answer to question on case report form regarding action taken with Nab-paclitaxel

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*Programming Note: Include all AEs with Grade ≥ 3*

**Listing 16.2.7.3**
**Listing of Adverse Events Leading to Withdrawal of CORT125134**
**Safety Population**

| Segment | Cohort[1] | Patient ID | System Organ Class[2] / Preferred Term[2] / Event Name | Treatment-Emergent[3] | Start Date and Time (Study Day[4]) | End Date and Time (Study Day[4]) | CTCAE Grade | Serious | Relationship to[5] | Action Taken with Nab-Paclitaxel | Outcome |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 100/60 PDAC / 100/80 PDAC / 150/80 PDAC / 100/60 OVCA / 100/80 OVCA / 150/80 OVCA / 100/60 OT / 100/80 OT / 150/80 OT | xxx-xxxx | *System Organ Class / Preferred Term / Event Name* | Yes / No | ddMMMyyyy HH:MM (xx) | ddMMMyyyy HH:MM (xx) / Ongoing | Grade 1 / Grade 2 / Grade 3 / Grade 4 / Grade 5 | Yes / No | C: Not Related to Study Drug / C: Unlikely Related to Study Drug/ C: Possibly Related to Study Drug/ C: Related to Study Drug<br><br>N: Not Related to Study Drug / N: Unlikely Related to Study Drug/ N: Possibly Related to Study Drug/ N: Related to Study Drug<br><br>*Sepearate C and N Relationship with a comma* | Dose Not Changed / Dose Reduced / Drug Interrupted / Drug Interrupted and then Dose Reduced / Drug Withdrawn / Not Applicable / Unknown | Fatal / Not Recovered/ Not Resolved/ Recovered/ Resolved/ Recovered/ Resolved with Sequelae / Recovering/ Resolving/ Unknown |
| 2 | 150/80 PDAC / 200/100 PDAC / 150/80 OVCA / 200/100 OVCA / 150/80 OT / 200/100 OT | | | | | | | | | | |

Abbreviations: CTCAE=Common Terminology Criteria for Adverse Events, v4.03; OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma

Note: Includes events where action taken with CORT125134 is "Drug Withdrawn."

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Adverse events are coded to system organ class and preferred term using the Medical Dictionary for Regulatory Activities (MedDRA), version 19.0.
[3] Treatment-emergent adverse events are those events that occur from the first dose of CORT125134 through 28 days after administration of the last dose of study drug.
[4] Time (days) relative to date of first dose of CORT125134
[5] C: reports answer to question on case report form regarding relationship to CORT125134; N: reports answer to question on case report form regarding relationship to Nab-paclitaxel

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*Programming Note: Include all AEs with Action Taken with CORT125134 = 'Drug Withdrawn'*

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**Listing 16.2.7.4**
**Listing of Adverse Events Leading to Withdrawal of Nab-paclitaxel**
**Safety Population**

| Segment | Cohort[1] | Patient ID | System Organ Class[2] / Preferred Term[2] / Event Name | Treatment-Emergent[3] | Start Date and Time (Study Day[4]) | End Date and Time (Study Day[4]) | CTCAE Grade | Serious | Relationship to[5] | Action Taken with CORT125134 | Outcome |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 100/60 PDAC / 100/80 PDAC / 150/80 PDAC / 100/60 OVCA / 100/80 OVCA / 150/80 OVCA / 100/60 OT / 100/80 OT / 150/80 OT | xxx-xxxx | *System Organ Class / Preferred Term / Event Name* | Yes / No | ddMMMyyyy HH:MM (xx) | ddMMMyyyy HH:MM (xx) / Ongoing | Grade 1 / Grade 2 / Grade 3 / Grade 4 / Grade 5 | Yes / No | C: Not Related to Study Drug / C: Unlikely Related to Study Drug/ C: Possibly Related to Study Drug/ C: Related to Study Drug<br><br>N: Not Related to Study Drug / N: Unlikely Related to Study Drug/ N: Possibly Related to Study Drug/ N: Related to Study Drug<br><br>*Sepearate C and N Relationship with a comma* | Dose Not Changed / Dose Reduced / Drug Interrupted / Drug Interrupted and then Dose Reduced / Drug Withdrawn / Not Applicable / Unknown | Fatal / Not Recovered/Not Resolved/ Recovered/Resolved/ Recovered/Resolved with Sequelae / Recovering/Resolving / Unknown |
| 2 | 150/80 PDAC / 200/100 PDAC / 150/80 OVCA / 200/100 OVCA / 150/80 OT / 200/100 OT | | | | | | | | | | |

Abbreviations: CTCAE=Common Terminology Criteria for Adverse Events, v4.03; OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma

Note: Includes events where action taken with Nab-paclitaxel is "Drug Withdrawn."

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/$m^2$).
[2] Adverse events are coded to system organ class and preferred term using the Medical Dictionary for Regulatory Activities (MedDRA), version 19.0.
[3] Treatment-emergent adverse events are those events that occur from the first dose of CORT125134 through 28 days after administration of the last dose of study drug.
[4] Time (days) relative to date of first dose of CORT125134
[5] C: reports answer to question on case report form regarding relationship to CORT125134; N: reports answer to question on case report form regarding relationship to Nab-paclitaxel

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*Programming Note: Include all AEs with Action Taken with Nab-paclitaxel = 'Drug Withdrawn'*

**Listing 16.2.7.5**
**Listing of Adverse Events Leading to CORT125134 Interruption**
**Safety Population**

| Segment | Cohort[1] | Patient ID | System Organ Class[2] / Preferred Term[2] / Event Name | Treatment-Emergent[3] | Start Date and Time (Study Day[4]) | End Date and Time (Study Day[4]) | CTCAE Grade | Serious | Relationship to[5] | Action Taken with[6] | Outcome |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 100/60 PDAC / 100/80 PDAC / 150/80 PDAC / 100/60 OVCA / 100/80 OVCA / 150/80 OVCA / 100/60 OT / 100/80 OT / 150/80 OT | xxx-xxxx | *System Organ Class / Preferred Term / Event Name* | Yes / No | ddMMMyyyy HH:MM (xx) | ddMMMyyyy HH:MM (xx) / Ongoing | Grade 1 / Grade 2 / Grade 3 / Grade 4 / Grade 5 | Yes / No | C: Not Related to Study Drug / C: Unlikely Related to Study Drug/ C: Possibly Related to Study Drug/ C: Related to Study Drug N: Not Related to Study Drug / N: Unlikely Related to Study Drug/ N: Possibly Related to Study Drug/ N: Related to Study Drug *Sepearate C and N Relationship with a comma* | C: Dose Not Changed / C: Dose Reduced / C: Drug Interrupted / C: Drug Interrupted and then Dose Reduced / C: Drug Withdrawn / C: Not Applicable / C: Unknown N: Dose Not Changed / N: Dose Reduced / N: Drug Interrupted / N: Drug Interrupted and then Dose Reduced / N: Drug Withdrawn / N: Not Applicable / N: Unknown *Sepearate C and N Relationship with a comma* | Fatal / Not Recovered/ Not Resolved/ Recovered/ Resolved/ Recovered/ Resolved with Sequelae / Recovering/ Resolving/ Unknown |
| 2 | 150/80 PDAC / 200/100 PDAC / 150/80 OVCA / 200/100 OVCA / 150/80 OT / 200/100 OT | | | | | | | | | | |

Abbreviations: CTCAE=Common Terminology Criteria for Adverse Events, v4.03; OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma

Note: Includes events where action taken with CORT125134 is "Dose Interrupted" or "Drug Interrupted and then Dose Reduced."

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Adverse events are coded to system organ class and preferred term using the Medical Dictionary for Regulatory Activities (MedDRA), version 19.0.
[3] Treatment-emergent adverse events are those events that occur from the first dose of CORT125134 through 28 days after administration of the last dose of study drug.
[4] Time (days) relative to date of first dose of CORT125134
[5] C: reports answer to question on case report form regarding relationship to CORT125134; N: reports answer to question on case report form regarding relationship to Nab-paclitaxel
[6] C: reports answer to question on case report form regarding action taken with CORT125134; N: reports answer to question on case report form regarding action taken with Nab-paclitaxel

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*Programming Note: Include all AEs with Action Taken with CORT125134 = 'Drug Interrupted' or 'Drug Interrupted and then Dose Reduced'*

**Listing 16.2.7.6**
**Listing of Adverse Events Leading to Nab-paclitaxel Interruption**
**Safety Population**

| Segment | Cohort[1] | Patient ID | System Organ Class[2] / Preferred Term[2] / Event Name | Treatment-Emergent[3] | Start Date and Time (Study Day[4]) | End Date and Time (Study Day[4]) | CTCAE Grade | Serious | Relationship to[5] | Action Taken with[6] | Outcome |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 100/60 PDAC / 100/80 PDAC / 150/80 PDAC / 100/60 OVCA / 100/80 OVCA / 150/80 OVCA / 100/60 OT / 100/80 OT / 150/80 OT | xxx-xxxx | *System Organ Class / Preferred Term / Event Name* | Yes / No | ddMMMyyyy HH:MM (xx) | ddMMMyyyy HH:MM (xx) / Ongoing | Grade 1 / Grade 2 / Grade 3 / Grade 4 / Grade 5 | Yes / No | C: Not Related to Study Drug / C: Unlikely Related to Study Drug/ C: Possibly Related to Study Drug/ C: Related to Study Drug N: Not Related to Study Drug / N: Unlikely Related to Study Drug/ N: Possibly Related to Study Drug/ N: Related to Study Drug *Sepearate C and N Relationship with a comma* | C: Dose Not Changed / C: Dose Reduced / C: Drug Interrupted / C: Drug Interrupted and then Dose Reduced / C: Drug Withdrawn / C: Not Applicable / C: Unknown N: Dose Not Changed / N: Dose Reduced / N: Drug Interrupted / N: Drug Interrupted and then Dose Reduced / N: Drug Withdrawn / N: Not Applicable / N: Unknown *Sepearate C and N Relationship with a comma* | Fatal / Not Recovered/ Not Resolved/ Recovered/ Resolved/ Recovered/ Resolved with Sequelae / Recovering/ Resolving/ Unknown |
| 2 | 150/80 PDAC / 200/100 PDAC / 150/80 OVCA / 200/100 OVCA / 150/80 OT / 200/100 OT | | | | | | | | | | |

Abbreviations: CTCAE=Common Terminology Criteria for Adverse Events, v4.03; OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma

Note: Includes events where action taken with Nab-paclitaxel is "Dose Interrupted" or "Drug Interrupted and then Dose Reduced."

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Adverse events are coded to system organ class and preferred term using the Medical Dictionary for Regulatory Activities (MedDRA), version 19.0.
[3] Treatment-emergent adverse events are those events that occur from the first dose of CORT125134 through 28 days after administration of the last dose of study drug.
[4] Time (days) relative to date of first dose of CORT125134
[5] C: reports answer to question on case report form regarding relationship to CORT125134; N: reports answer to question on case report form regarding relationship to Nab-paclitaxel
[6] C: reports answer to question on case report form regarding action taken with CORT125134; N: reports answer to question on case report form regarding action taken with Nab-paclitaxel
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*Programming Note: Include all AEs with Action Taken with Nab-paclitaxel = 'Drug Interrupted' or 'Drug Interruputed and then Dose Reduced'*

**Listing 16.2.7.7**
**Listing of Adverse Events Leading to CORT125134 Reduction**
**Safety Population**

| Segment | Cohort[1] | Patient ID | System Organ Class[2] / Preferred Term[2] / Event Name | Treatment-Emergent[3] | Start Date and Time (Study Day[4]) | End Date and Time (Study Day[4]) | CTCAE Grade | Serious | Relationship to[5] | Action Taken with[6] | Outcome |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 100/60 PDAC / 100/80 PDAC / 150/80 PDAC / 100/60 OVCA / 100/80 OVCA / 150/80 OVCA / 100/60 OT / 100/80 OT / 150/80 OT | xxx-xxxx | *System Organ Class / Preferred Term / Event Name* | Yes / No | ddMMMyyyy HH:MM (xx) | ddMMMyyyy HH:MM (xx) / Ongoing | Grade 1 / Grade 2 / Grade 3 / Grade 4 / Grade 5 | Yes / No | C: Not Related to Study Drug / C: Unlikely Related to Study Drug/ C: Possibly Related to Study Drug/ C: Related to Study Drug<br>N: Not Related to Study Drug / N: Unlikely Related to Study Drug/ N: Possibly Related to Study Drug/ N: Related to Study Drug<br>*Sepearate C and N Relationship with comma* | C: Dose Not Changed / C: Dose Reduced / C: Drug Interrupted / C: Drug Interrupted and then Dose Reduced / C: Drug Withdrawn / C: Not Applicable / C: Unknown<br>N: Dose Not Changed / N: Dose Reduced / N: Drug Interrupted / N: Drug Interrupted and then Dose Reduced / N: Drug Withdrawn / N: Not Applicable / N: Unknown<br>*Sepearate C and N Relationship with comma* | Fatal / Not Recovered/ Not Resolved/ Recovered/ Resolved/ Recovered/ Resolved with Sequelae / Recovering/ Resolving/ Unknown |
| 2 | 150/80 PDAC / 200/100 PDAC / 150/80 OVCA / 200/100 OVCA / 150/80 OT / 200/100 OT | | | | | | | | | | |

Abbreviations: CTCAE=Common Terminology Criteria for Adverse Events, v4.03; OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma

Note: Includes events where action taken with CORT125134 is "Dose Reduced" or "Drug Interrupted and then Dose Reduced."

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Adverse events are coded to system organ class and preferred term using the Medical Dictionary for Regulatory Activities (MedDRA), version 19.0.
[3] Treatment-emergent adverse events are those events that occur from the first dose of CORT125134 through 28 days after administration of the last dose of study drug.
[4] Time (days) relative to date of first dose of CORT125134
[5] C: reports answer to question on case report form regarding relationship to CORT125134; N: reports answer to question on case report form regarding relationship to Nab-paclitaxel
[6] C: reports answer to question on case report form regarding action taken with CORT125134; N: reports answer to question on case report form regarding action taken with Nab-paclitaxel

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*Programming Note: Include all AEs with Action Taken with CORT125134 = 'Dose Reduced' or 'Drug Interrupted and then Dose Reduced'*

**Listing 16.2.7.8**
**Listing of Adverse Events Leading to Nab-paclitaxel Reduction**
**Safety Population**

| Segment | Cohort[1] | Patient ID | System Organ Class[2] / Preferred Term[2] / Event Name | Treatment-Emergent[3] | Start Date and Time (Study Day[4]) | End Date and Time (Study Day[4]) | CTCAE Grade | Serious | Relationship to[5] | Action Taken with[6] | Outcome |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 100/60 PDAC / 100/80 PDAC / 150/80 PDAC / 100/60 OVCA / 100/80 OVCA / 150/80 OVCA / 100/60 OT / 100/80 OT / 150/80 OT | xxx-xxxx | *System Organ Class / Preferred Term / Event Name* | Yes / No | ddMMMyyyy HH:MM (xx) | ddMMMyyyy HH:MM (xx) / Ongoing | Grade 1 / Grade 2 / Grade 3 / Grade 4 / Grade 5 | Yes / No | C: Not Related to Study Drug / C: Unlikely Related to Study Drug/ C: Possibly Related to Study Drug/ C: Related to Study Drug N: Not Related to Study Drug / N: Unlikely Related to Study Drug/ N: Possibly Related to Study Drug/ N: Related to Study Drug *Sepearate C and N Relationship with a comma* | C: Dose Not Changed / C: Dose Reduced / C: Drug Interrupted / C: Drug Interrupted and then Dose Reduced / C: Drug Withdrawn / C: Not Applicable / C: Unknown N: Dose Not Changed / N: Dose Reduced / N: Drug Interrupted / N: Drug Interrupted and then Dose Reduced / N: Drug Withdrawn / N: Not Applicable / N: Unknown *Sepearate C and N Relationship with a comma* | Fatal / Not Recovered/ Not Resolved/ Recovered/ Resolved/ Recovered/ Resolved with Sequelae / Recovering/ Resolving/ Unknown |
| 2 | 150/80 PDAC / 200/100 PDAC / 150/80 OVCA / 200/100 OVCA / 150/80 OT / 200/100 OT | | | | | | | | | | |

Abbreviations: CTCAE=Common Terminology Criteria for Adverse Events, v4.03; OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma

Note: Includes events where action taken with Nab-paclitaxel is "Dose Reduced" or "Drug Interrupted and then Dose Reduced."

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Adverse events are coded to system organ class and preferred term using the Medical Dictionary for Regulatory Activities (MedDRA), version 19.0.
[3] Treatment-emergent adverse events are those events that occur from the first dose of CORT125134 through 28 days after administration of the last dose of study drug.
[4] Time (days) relative to date of first dose of CORT125134
[5] C: reports answer to question on case report form regarding relationship to CORT125134; N: reports answer to question on case report form regarding relationship to Nab-paclitaxel
[6] C: reports answer to question on case report form regarding action taken with CORT125134; N: reports answer to question on case report form regarding action taken with Nab-paclitaxel

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*Programming Note: Include all AEs with Action Taken with Nab-paclitaxel = 'Dose Reduced' or 'Drug Interrupted and then Dose Reduced'*

**Listing 16.2.7.9**
**Listing of Adverse Events Leading to Death**
**Safety Population**

| Segment | Cohort[1] | Patient ID | System Organ Class[2] / Preferred Term[2] / Event Name | Treatment-Emergent[3] | Start Date and Time (Study Day[4]) | End Date and Time (Study Day[4]) | CTCAE Grade | Serious | Relationship to[5] | Action Taken with[6] |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 100/60 PDAC / 100/80 PDAC / 150/80 PDAC / 100/60 OVCA / 100/80 OVCA / 150/80 OVCA / 100/60 OT / 100/80 OT / 150/80 OT | xxx-xxxx | *System Organ Class / Preferred Term / Event Name* | Yes / No | ddMMMyyyy HH:MM (xx) | ddMMMyyyy HH:MM (xx) / Ongoing | Grade 5 | Yes / No | C: Not Related to Study Drug / C: Unlikely Related to Study Drug/ C: Possibly Related to Study Drug/ C: Related to Study Drug | C: Dose Not Changed / C: Dose Reduced / C: Drug Interrupted / C: Drug Interrupted and then Dose Reduced / C: Drug Withdrawn / C: Not Applicable / C: Unknown |
| 2 | 150/80 PDAC / 200/100 PDAC / 150/80 OVCA / 200/100 OVCA / 150/80 OT / 200/100 OT | | | | | | | | N: Not Related to Study Drug / N: Unlikely Related to Study Drug/ N: Possibly Related to Study Drug/ N: Related to Study Drug *Sepearate C and N Relationship with a comma* | N: Dose Not Changed / N: Dose Reduced / N: Drug Interrupted / N: Drug Interrupted and then Dose Reduced / N: Drug Withdrawn / N: Not Applicable / N: Unknown *Sepearate C and N Relationship with a comma* |

Abbreviations: CTCAE=Common Terminology Criteria for Adverse Events, v4.03; OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Adverse events are coded to system organ class and preferred term using the Medical Dictionary for Regulatory Activities (MedDRA), version 19.0.
[3] Treatment-emergent adverse events are those events that occur from the first dose of CORT125134 through 28 days after administration of the last dose of study drug.
[4] Time (days) relative to date of first dose of CORT125134
[5] C: reports answer to question on case report form regarding relationship to CORT125134; N: reports answer to question on case report form regarding relationship to Nab-paclitaxel
[6] C: reports answer to question on case report form regarding action taken with CORT125134; N: reports answer to question on case report form regarding action taken with Nab-paclitaxel

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*Programming Notes:*

- *Include all AEs with Outcome = 'Fatal' or CTCAE Grade = 5*

**Listing 16.2.7.10**
**Dose-Limity Toxicities**
**DLT Evaluable Population**

| Segment | Cohort[1] | Patient ID | Pancreatic Cohort | DLT Evaluable | Experienced DLT |
|---|---|---|---|---|---|
| 1 | 100/60 PDAC /<br>100/80 PDAC /<br>150/80 PDAC /<br>100/60 OVCA /<br>100/80 OVCA /<br>150/80 OVCA /<br>100/60 OT /<br>100/80 OT /<br>150/80 OT | xxx-xxxx | Yes /<br>No | Yes /<br>No | Yes /<br>No |
| 2 | 150/80 PDAC /<br>200/100 PDAC /<br>150/80 OVCA /<br>200/100 OVCA /<br>150/80 OT /<br>200/100 OT | | | | |

Abbreviations: DLT=dose llimiting toxicity; OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma

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**Listing 16.2.8.1**
**Hematology**
**Part 1 of 2**

| Segment | Cohort[1] | Patient ID | Visit | Collection Date (Study Day[2]) | Collection Time | RBC Count ($10^{12}$/L) | Hematocrit (L/L) | Hemoglobin (g/L) | MCH (pg) | MCHC (g/L) | MCV (fL) | Platelet Count ($10^9$/L) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 100/60 PDAC / 100/80 PDAC / 150/80 PDAC / 100/60 OVCA / 100/80 OVCA / 150/80 OVCA / 100/60 OT / 100/80 OT / 150/80 OT | xxx-xxxx | Screening … | ddMMMyyyy (xx) | HH:MM | x.x *CS, H/L* | x.x *CS, H/L* | x.x *CS, H/L* | x.x *CS, H/L* | x.x *CS, H/L* | x.x *CS, H/L* | x.x *CS, H/L* |
| 2 | 150/80 PDAC / 200/100 PDAC / 150/80 OVCA / 200/100 OVCA / 150/80 OT / 200/100 OT | | | | | | | | | | | |

Abbreviations: CS=clinically significant; H=high; L=low; MCH=mean corpuscular hemoglobin; MCHC=mean corpuscular hemoglobin concentration; MCV=mean corpuscular volume; OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma; RBC=red blood cell

Note: H = high; L = low is displayed if result is outside the reference range

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Time (days) relative to date of first dose of CORT125134

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**Listing 16.2.8.1**
**Hematology**
**Part 2 of 2**

| Segment | Cohort[1] | Patient ID | Visit | Collection Date (Study Day[2]) | Collection Time | WBC Count ($10^9$/L) | Absolute Neutrophils ($10^9$/L) | Absolute Lymphocytes ($10^9$/L) | Absolute Monocytes ($10^9$/L) | Absolute Eosinophils ($10^9$/L) | Absolute Basophils ($10^9$/L) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 100/60 PDAC / 100/80 PDAC / 150/80 PDAC / 100/60 OVCA / 100/80 OVCA / 150/80 OVCA / 100/60 OT / 100/80 OT / 150/80 OT | xxx-xxxx | Screening | ddMMMyyyy (xx) | HH:MM | x.x *CS, H/L* | x.x *CS, H/L* | x.x *CS, H/L* | x.x *CS, H/L* | x.x *CS, H/L* | x.x *CS, H/L* |
| | | | … | | | | | | | | |
| 2 | 150/80 PDAC / 200/100 PDAC / 150/80 OVCA / 200/100 OVCA / 150/80 OT / 200/100 OT | | | | | | | | | | |
| | | … | | | | | | | | | |

Abbreviations: CS=clinically significant; H=high; L=low; OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma; WBC=white blood cell

Note: H = high; L = low is displayed if result is outside the reference range

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose ($mg/m^2$).
[2] Time (days) relative to date of first dose of CORT125134

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**Listing 16.2.8.2**
**Chemistry**
**Part 1 of 4**

| Segment | Cohort[1] | Patient ID | Visit | Collection Date (Study Day[2]) | Collection Time | AST (SGOT) (U/L) | ALT (SGPT) (U/L) | Alkaline Phosphatase (U/L) | Total Bilirubin (µmol/L) | Direct Bilirubin (µmol/L) | GGT (U/L) | Albumin (g/L) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 100/60 PDAC / 100/80 PDAC / 150/80 PDAC / 100/60 OVCA / 100/80 OVCA / 150/80 OVCA / 100/60 OT / 100/80 OT / 150/80 OT | xxx-xxxx | Screening … | ddMMMyyyy (xx) | HH:MM | x.x *CS, H/L* | x.x *CS, H/L* | x.x *CS, H/L* | x.x *CS, H/L* | x.x *CS, H/L* | x.x *CS, H/L* | x.x *CS, H/L* |
| 2 | 150/80 PDAC / 200/100 PDAC / 150/80 OVCA / 200/100 OVCA / 150/80 OT / 200/100 OT | | | | | | | | | | | |

Abbreviations: AST (SGOT)=aspartate aminotransferase; ALT (SGPT)=alanine aminotransferase; BUN=blood urea nitrogen; CS=clinically significant; H=high; L=low; OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma

Note: H = high; L = low is displayed if result is outside the reference range

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Time (days) relative to date of first dose of CORT125134

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**Listing 16.2.8.2**
**Chemistry**
**Part 2 of 4**

| Segment | Cohort[1] | Patient ID | Visit | Collection Date (Study Day[2]) | Collection Time | Total Protein (g/L) | BUN (mmol/L) | Creatinine (µmol/L) | Sodium (mmol/L) | Potassium (mmol/L) | Magnesium (mmol/L) | Chloride (mmol/L) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 100/60 PDAC / 100/80 PDAC / 150/80 PDAC / 100/60 OVCA / 100/80 OVCA / 150/80 OVCA / 100/60 OT / 100/80 OT / 150/80 OT | xxx-xxxx | Screening … | ddMMMyyyy (xx) | HH:MM | x.x *CS, H/L* | x.x *CS, H/L* | x.x *CS, H/L* | x.x *CS, H/L* | x.x *CS, H/L* | x.x *CS, H/L* | x.x *CS, H/L* |
| 2 | 150/80 PDAC / 200/100 PDAC / 150/80 OVCA / 200/100 OVCA / 150/80 OT / 200/100 OT | | | | | | | | | | | |

Abbreviations: $CO^2$=Carbon Dioxide; CS=clinically significant; H=high; L=low; OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma

Note: H = high; L = low is displayed if result is outside the reference range

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose ($mg/m^2$).
[2] Time (days) relative to date of first dose of CORT125134

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**Listing 16.2.8.2**
**Chemistry**
**Part 3 of 4**

| Segment | Cohort[1] | Patient ID | Visit | Collection Date (Study Day[2]) | Collection Time | Phosphorus (mmol/L) | Calcium (mmol/L) | $CO_2$ (mmol/L) | Glucose (mmol/L) | Cholesterol (mmol/L) | Triglycerides (mmol/L) | HDL Cholesterol (mmol/L) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 100/60 PDAC / 100/80 PDAC / 150/80 PDAC / 100/60 OVCA / 100/80 OVCA / 150/80 OVCA / 100/60 OT / 100/80 OT / 150/80 OT | xxx-xxxx | Screening … | ddMMMyyyy (xx) | HH:MM | x.x *CS, H/L* | x.x *CS, H/L* | x.x *CS, H/L* | x.x *CS, H/L* | x.x *CS, H/L* | x.x *CS, H/L* | x.x *CS, H/L* |
| 2 | 150/80 PDAC / 200/100 PDAC / 150/80 OVCA / 200/100 OVCA / 150/80 OT / 200/100 OT | | | | | | | | | | | |

Abbreviations: $CO^2$=Carbon Dioxide; CS=clinically significant; H=high; L=low; OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma

Note: H = high; L = low is displayed if result is outside the reference range

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose ($mg/m^2$).
[2] Time (days) relative to date of first dose of CORT125134

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**Listing 16.2.8.2**
**Chemistry**
**Part 4 of 4**

| Segment | Cohort[1] | Patient ID | Visit | Collection Date (Study Day[2]) | Collection Time | LDL Cholesterol (mmol/L) | Amylase (µkat/L) | Lipase (µkat/L) | Creatinine Kinase (U/L) | LDH (µkat/L) |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 100/60 PDAC / 100/80 PDAC / 150/80 PDAC / 100/60 OVCA / 100/80 OVCA / 150/80 OVCA / 100/60 OT / 100/80 OT / 150/80 OT | xxx-xxxx | Screening … | ddMMMyyyy (xx) | HH:MM | x.x *CS, H/L* | x.x *CS, H/L* | x.x *CS, H/L* | x.x *CS, H/L* | x.x *CS, H/L* |
| 2 | 150/80 PDAC / 200/100 PDAC / 150/80 OVCA / 200/100 OVCA / 150/80 OT / 200/100 OT | | | | | | | | | |

Abbreviations: $CO^2$=Carbon Dioxide; CS=clinically significant; H=high; L=low; OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma

Note: H = high; L = low is displayed if result is outside the reference range

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose ($mg/m^2$).
[2] Time (days) relative to date of first dose of CORT125134

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**Listing 16.2.8.3**
**Urinalysis**

| Segment | Cohort[1] | Patient ID | Visit | Collection Date (Study Day[2]) | Collection Time | Appearance | Bilirubin (mg/dL) | Color | Glucose (mg/dL) | Ketones | Nitrite | pH | Occult Blood | Specific Gravity |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 100/60 PDAC / 100/80 PDAC / 150/80 PDAC / 100/60 OVCA / 100/80 OVCA / 150/80 OVCA / 100/60 OT / 100/80 OT / 150/80 OT | xxx-xxxx | Screening … | ddMMMyyyy (xx) | HH:MM | *Result* | *Result* | *Result* | *Result* | *Result* | *Result* | x.x *CS, H/L* | *Result* | x.x *CS, H/L* |
| 2 | 150/80 PDAC / 200/100 PDAC / 150/80 OVCA / 200/100 OVCA / 150/80 OT / 200/100 OT | … | | | | | | | | | | | | |

Abbreviations: CS=clinically significant; H=high; L=low; OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma

Note: H = high; L = low is displayed if result is outside the reference range

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Time (days) relative to date of first dose of CORT125134

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**Listing 16.2.8.4**
**Urine/Serum Pregnancy Test**

| Segment | Cohort[1] | Patient ID | Visit | Collection Date (Study Day[2]) | Collection Time | Result |
|---|---|---|---|---|---|---|
| 1 | 100/60 PDAC / 100/80 PDAC / 150/80 PDAC / 100/60 OVCA / 100/80 OVCA / 150/80 OVCA / 100/60 OT / 100/80 OT / 150/80 OT | xxx-xxxx | Screening | ddMMMyyyy (xx) | HH:MM | Positive / Negative / N/A |
| | | | … | | | |
| 2 | 150/80 PDAC / 200/100 PDAC / 150/80 OVCA / 200/100 OVCA / 150/80 OT / 200/100 OT | | | | | |
| | | … | | | | |

Abbreviations: N/A=not applicable; OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Time (days) relative to date of first dose of CORT125134

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**Listing 16.2.9.1**
**Vital Signs**

| Segment | Cohort[1] | Patient ID | Visit | Visit Date (Study Day[2]) | Systolic Blood Pressure (mmHg) | Diastolic Blood Pressure (mmHg) | Respiratory Rate (breaths/min) | Temperature (°C) | Heart Rate (bpm) |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 100/60 PDAC / 100/80 PDAC / 150/80 PDAC / 100/60 OVCA / 100/80 OVCA / 150/80 OVCA / 100/60 OT / 100/80 OT / 150/80 OT | xxx-xxxx | Screening … | ddMMMyyyy (xx) | xxx | xxx | xxx | xx.x | xxx |
| 2 | 150/80 PDAC / 200/100 PDAC / 150/80 OVCA / 200/100 OVCA / 150/80 OT / 200/100 OT | | | | | | | | |

Abbreviations: BMI=body mass index; OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/$m^2$).
[2] Time (days) relative to date of first dose of CORT125134

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**Listing 16.2.9.2**
**ECOG Perfomance Status**

| Segment | Cohort[1] | Patient ID | Date of ECOG (Study Day[2]) | ECOG Performance Status |
|---|---|---|---|---|
| 1 | 100/60 PDAC / 100/80 PDAC / 150/80 PDAC / 100/60 OVCA / 100/80 OVCA / 150/80 OVCA / 100/60 OT / 100/80 OT / 150/80 OT | xxx-xxxx | ddMMMyyyy (xx) / Not Done | 0 – Fully active, able to carry on all pre-disease activities without restriction / 1 – Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, eg, light housework or office work / 2 – Ambulatory and capable of all self-care but unable to carry out any work activities; up and about more than 50% of waking hours / 3 – Capable of only limited self-care, confined to bed or chair more than 50% of waking hours / 4 – Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair / 5 - Dead |
| 2 | 150/80 PDAC / 200/100 PDAC / 150/80 OVCA / 200/100 OVCA / 150/80 OT / 200/100 OT | | | |

Abbreviations: ECOG=Eastern Cooperative Oncology Group; OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/$m^2$).
[2] Time (days) relative to date of first dose of CORT125134

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**Listing 16.2.9.3**
**Physical Examination**

| Segment | Cohort[1] | Patient ID | Visit | Assessment Date (Study Day[2]) | Body System | Condition | Clinically Significant |
|---|---|---|---|---|---|---|---|
| 1 | 100/60 PDAC / 100/80 PDAC / 150/80 PDAC / 100/60 OVCA / 100/80 OVCA / 150/80 OVCA / 100/60 OT / 100/80 OT / 150/80 OT | xxx-xxxx | Screening | ddMMMyyyy (xx) / Not Done | General Appearance / HEENT / Hematologic/Lymphatic / Respiratory / Cardiovascular / Gastrointestinal / Musculoskeletal/Extremity / Psychiatric / Neurological / Urogenital / Dermatological / Other: *Specify* | Normal / Abnormal: *Description of abnormalities* / Not Done: *Specify* | Yes / No |
| 2 | 150/80 PDAC / 200/100 PDAC / 150/80 OVCA / 200/100 OVCA / 150/80 OT / 200/100 OT | | | | | | |
| | | … | | | | | |

Abbreviations: HEENT=head, eyes, ears, nose and throat; N/A=not applicable; OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Time (days) relative to date of first dose of CORT125134
[3] Only collected during the brief physical examination collected at all visits after screening

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**Listing 16.2.9.4**
**12-Lead Electrocardiogram**

| Segment | Cohort[1] | Patient ID | Visit | Date of ECG (Study Day[2]) | Time of ECG | PR Interval (msec) | QRS Duration (msec) | QT Interval (msec) | RR Interval (msec) | Heart Rate (bpm) | QTCF Interval (msec) | QTCB Interval (msec) | Overall Interpretation |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 100/60 PDAC / 100/80 PDAC / 150/80 PDAC / 100/60 OVCA / 100/80 OVCA / 150/80 OVCA / 100/60 OT / 100/80 OT / 150/80 OT | xxx-xxxx | Screening | ddMMMyyyy (xx) / Not Done | HH:MM | xx | xx | xx | xx | xx | xx | xx | Normal / Abnormal, NCS: *Specify* / Abnormal, CS: *Specify* |
| 2 | 150/80 PDAC / 200/100 PDAC / 150/80 OVCA / 200/100 OVCA / 150/80 OT / 200/100 OT | … | | | | | | | | | | | |

Abbreviations: CS=clinically significant; ECG=electrocardiogram; NCS=not clinically significant; OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma; QTc=corrected QT interval

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Time (days) relative to date of first dose of CORT125134

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**Listing 16.2.9.5**
**Prior and Concomitant Medications**

| Segment | Cohort[1] | Patient ID | ATC Class[2] / Generic Drug Name[2] / Medication Name | Phase[3] | Start Date (Study Day[4]) | End Date (Study Day[4]) | Dose | Unit | Route | Frequency | Indication |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 100/60 PDAC / 100/80 PDAC / 150/80 PDAC / 100/60 OVCA / 100/80 OVCA / 150/80 OVCA / 100/60 OT / 100/80 OT / 150/80 OT | xxx-xxxx | *ATC Class / Generic Drug Name / Medication Name* | P / C / P, C | ddMMMyyyy (xx) | ddMMMyyyy (xx) / Ongoing | *Dose* | *Unit* | *Route* | *Frequency* | Medical History: *specify* / Adverse Event: *specify* / Prophylaxis / Other: *Specify* |
| 2 | 150/80 PDAC / 200/100 PDAC / 150/80 OVCA / 200/100 OVCA / 150/80 OT / 200/100 OT | | | | | | | | | | |

Abbreviations: ATC, anatomic therapeutic chemical; OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma; WHODDE, World Health Organization Drug Dictionary Enhanced

Note: Concomitant medications are those medications received after the first dose of study treatment.

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Medications are coded to ATC class (level 4) and drug names using the WHODDE, March 1, 2014 Version.
[3] The study phase during which each medication was received. P = prior (ie, received prior to the first dose of study drug); C = concomitant (ie, received on or after the first dose of study drug); P, C = both prior and concomitant
[4] Time (days) relative to date of first dose of CORT125134

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*Programming Note:*

- *If specifications for indications are reported as an AE or MH #, merge with AE/MH data to present the actual reported event as the specification.*
- *When creating ATC level 4 drug class, utilize level 3 term if level 4 is missing in dataset and level 2 if both level 3 and level 4 are missing in the dataset*

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**Listing 16.2.9.6**
**Granulocyte Colony-Simulating Factor**

| Segment | Cohort[1] | Patient ID | Cycle # | ATC Class[2] / Generic Drug Name[2] / Medication Name | Start Date (Study Day[3]) | End Date (Study Day[3]) | Granulocyte Colony-Stimulating Factor | Reason for Taking Growth Factor |
|---|---|---|---|---|---|---|---|---|
| 1 | 100/60 PDAC / 100/80 PDAC / 150/80 PDAC / 100/60 OVCA / 100/80 OVCA / 150/80 OVCA / 100/60 OT / 100/80 OT / 150/80 OT | xxx-xxxx | x | *ATC Class / Generic Drug Name / Medication Name* | ddMMMyyyy (xx) | ddMMMyyyy (xx) | *Factor* | Prophylactic (high risk such as elderly) / Nadir / Low ANC / Febrile neutropenia / Infection / Other: *specify* |
| 2 | 150/80 PDAC / 200/100 PDAC / 150/80 OVCA / 200/100 OVCA / 150/80 OT / 200/100 OT | | | | | | | |

Abbreviations: ATC, anatomic therapeutic chemical; OT=other tumor; OVCA=ovarian tumor; PDAC=pancreatic ductal adenocarcinoma

[1] PDAC includes all pancreatic cancer patients excluding acinar subtype. OVCA includes all ovarian cancer patients excluding juvenile granulosa subtype. OT includes all patients not included in PDAC and ovarian cancer groups. Dose levels represent: CORT125134 Dose (mg) / Nab-paclitaxel Dose (mg/m$^2$).
[2] Medications are coded to ATC class (level 4) and drug names using the WHODDE, March 1, 2014 Version.
[3] Time (days) relative to date of first dose of study treatment

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*Programming Note:*

- *When creating ATC level 4 drug class, utilize level 3 term if level 4 is missing in dataset and level 2 if both level 3 and level 4 are missing in the dataset*

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