Statistical Analysis Plan (SAP)

Protocol Title:	An Open-label, Multi-center, Phase I/IIa Study of a Personalized Neoantigen DNA Vaccine (GNOS-PV02) and Plasmid encoded IL-12 (INO-9012) in Combination with Pembrolizumab (MK-3475) in Subjects with Advanced Hepatocellular Carcinoma
Protocol Version No./Date:	7.0/03-Feb-2023
CRF Version No./Date:	1.0/18-Dec-2020
SAP Version No./Date:	2.0/31-May-2023

1.0 Approvals

Geneos Therapeutics	
Representative/ Title:	Ildiko Csiki / Medical Monitor
Signature /Date:	Ildiko Csiki Ildiko Csiki 02 Jun 2023 16:07:00 UTC (Z) REASON: I approve this document a7fd9fe3-e4b6-43df-833e-91a09d8a1e0e
Representative/ Title:	Joann Peters/ Chief Operating Officer
Signature /Date:	Joann Peters Joann Peters 01 Jun 2023 13:24:55 UTC (Z) REASON: I approve this document 6149581f-d779-4a11-b8d0-68e63a448441
Representative/ Title:	Sarah Rochestie/ Clinical Project Manager
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PRA	
Biostatistician / Title:	Harshada Tamhankar / Principal Biostatistician
Signature /Date:	Harshada Tamhankar Harshada Tamhankar 02 Jun 2023 16:43:46 UTC (Z) REASON: I approve this document as author. 7e60cd23-01f8-40b0-963f-becaf9eeeebb

(NOTE: Electronic Signatures should only be used if all parties have the ability to eSign.)

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2.0 Change History

Version/Date	Change Log
0.1/11-Jun-2021	Created as new
0.2/09-Jul-2021	• The version and date is updated. • The name and designation of Geneos approvers is included. • Included details of study design in Section 8.0 • Included definition of screened subjects in Section 9.2.1 Enrolled Subjects • Included derivation of time sin ce last progression, time from end of last regimen and time from end of radiation. • Clarifications added to definition of prior and concomitant medication. • The Section 12.6.5.3 Electrocardiogram is moved to Section 12.2 and hence is renumbered as Section 12.2.6 Electrocardiogram. • The summary of Objective Response Rate at Week 12 is included. • The summary of Laboratory data by CTCAE grading is included.
0.3/24-Sep-2021	• The version and date is updated. • The definition of concomitant medications is updated to match protocol section 8.4. • The efficacy analysis based on per protocol analysis set is deleted. • The summary table for pregnancy tests is deleted. • The section of hypothesis testing is updated to consider no hypothesis testing needed for early phase study.
0.4/15-Nov-2021	• Formatting changes. • Remove the response assessment analysis at 12 weeks.
1.1/19-Apr-2023	• Updated protocol version to 7.0 and date to 03-Feb-2023. • Updated CRF version 1.0 date to 18-Dec-2020. • Section 8.0: Added language confirming: (1) subjects with CR, PR or SD who are still receiving treatment at the end of approx. 2 years (week 99) are eligible to continue with GNOS-PV02 treatment every 12 weeks until week 147. (2) Subjects who have disease progression with evidence of new lesions while receiving GNOS-PV02 treatment may have a new personalized vaccine manufactured and administered using a newly biopsied lesion, as per investigator's discretion and Sponsor's approval. • Section 8.1: Updated as per protocol version 7.0 this section is clarified for following: : (i) Removed language indicating ORR determination at 12 weeks since we can only determine PD rate (but not SD/PR/CR) based on first on-treatment scan at week 9 that is we can only determine (1-ORR) by week 12; and (ii) statistical testing will be only done once and only on the full cohort of approximately 36 subjects. • Section 10: Included definition of end of study. EOS date should equal DOD. • Section 10.12.1: The subjects who discontinued the study after baseline tumor assessments will be included in 'Not evaluable' category. • Section 10.12.1: Removed the text for confirmatory SD response.
1.2/18-May-2023	• No changes made in the document.
2.0/31-May-2023	• Update the version of the document to 2.0. • Update the date of the document. • Accepted all the changes and deleted all comments.

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4.0 Purpose

The Statistical Analysis Plan (SAP) describes the statistical methods to be used during the reporting and analyses of data collected under Geneos Therapeutics, Inc. Protocol GT-30.

5.0 Scope

The Statistical Analysis Plan outlines the following:

- Study Objectives
- Study Design
- Study Endpoints
- Applicable Study Definitions
- Statistical Methods

6.0 Introduction

This SAP should be read in conjunction with the study protocol and case report forms (CRF). Any further changes to the protocol or CRF may necessitate updates to this SAP.

Minor changes following this SAP will be tracked in the SAP Change Log and will be implemented in the final SAP before database lock.

6.1 Changes from Protocol

Change 1:

The imputation rule for prior and concomitant medications start and stop dates are clarified in SAP Section 10.13.2 and 10.13.3 .

Change 2:

The subject data listing for human immunodeficiency virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV) is considered in this SAP since collected at screening only, however the protocol section 11.9 mentions to summarize the same as well.

Change 3:

In the definition of per protocol (PP) analysis set 4 doses is updated to 3 doses as informed by Geneos.

Change 4:

The efficacy analysis based on PP analysis set is removed from this SAP as informed by Geneos.

7.0 Study Objectives

The study objectives are defined as below:

Primary Objectives

- To determine the safety and tolerability of GNOS-PV02 + INO-9012 delivered by intradermal (ID) injection followed by electroporation (EP) using the CELLECTRA® 2000 device in combination with pembrolizumab.
- To evaluate preliminary immune response to GNOS-PV02 + INO-9012 in combination with pembrolizumab in subjects with previously treated advanced hepatocellular carcinoma (HCC).

Secondary Objective

- To evaluate the anti-tumor activity of GNOS-PV02 + INO-9012 in combination with pembrolizumab in subjects with previously treated advanced HCC.

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Exploratory Objectives

- To determine the feasibility of generating the personalized neoantigen Deoxyribonucleic acid (DNA) vaccine (GNOS-PV02) for subjects with advanced HCC.
- To evaluate tumor and immune biomarkers and their association with treatment outcome (antitumor activity and/or safety) in subjects with previously treated advanced HCC.

8.0 Study Design

This is a single-arm, open-label, multi-site Phase I/IIa study of a personalized neoantigen DNA vaccine (GNOS-PV02) and plasmid encoded IL-12 (INO-9012) delivered ID using the CELLECTRA® 2000 device in combination with pembrolizumab (MK-3475) in subjects with histologically or cytologically confirmed diagnosis of HCC based on pathology report.

Study participants will initially receive standard of care first-line treatment with lenvatinib or sorafenib. During first-line treatment, follow-up visits, blood work, and restaging scans will be scheduled at the discretion of the treating oncologist per standard of care. As this treatment is considered standard of care, no adverse events (AEs), will be collected and documented in the clinical database. Discontinuation of first-line standard of care therapy will occur at the discretion of the treating oncologist (i.e., objective radiographic progression on sorafenib, lenvatinib, or else intolerance to sorafenib or lenvatinib). Upon discontinuation of first-line therapy and guidance from the treating physician, subjects will begin receiving pembrolizumab every three weeks (Q3W) and, starting simultaneously, the personalized neoantigen DNA vaccine Q3W for 4 doses and then every nine weeks (Q9W) until week 99. Treatment will continue until progressive disease (PD), unacceptable AEs intercurrent illness that prevents further administration of treatment, investigator's decision to withdraw the subject, subject withdrawal of consent, pregnancy of the subject, noncompliance with study treatment or procedure requirements, subject receiving approx. 2 years of pembrolizumab or GNOS-PV02, or administrative reasons requiring cessation of treatment.

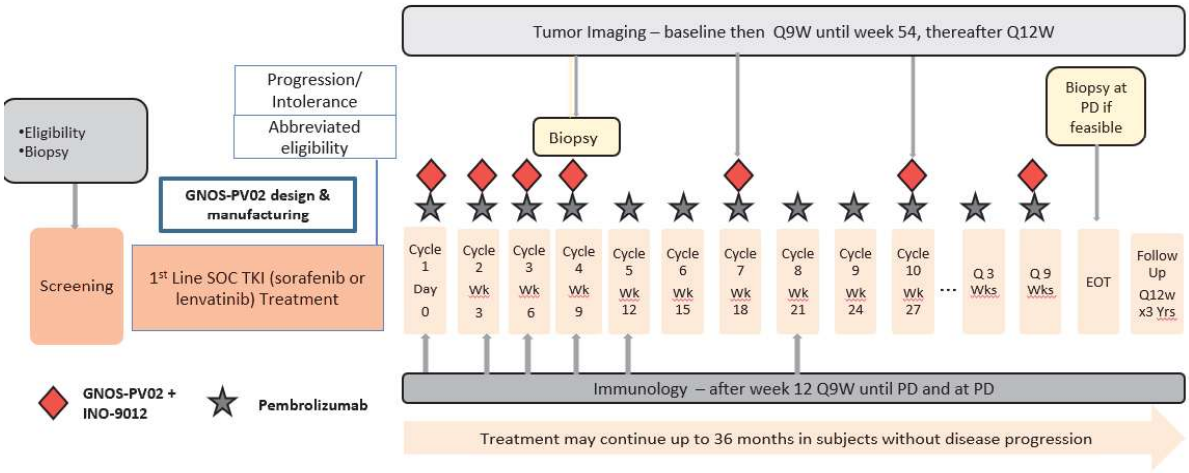
Subjects may continue to be treated with GNOS-PV02 and pembrolizumab post progression if in the opinion of the investigator, the subject is achieving a clinically meaningful benefit. Subjects who stop pembrolizumab or GNOS-PV02 as a result of obtaining a confirmed complete response (CR) by 2 tumor imaging assessments at least 4-6 weeks apart and who have received approximately 6 months of therapy with the personalized neoantigen vaccine and pembrolizumab, or those subjects who stop after receiving 2 years of study drug for reasons other than PD or intolerability, may be eligible to receive GNOS-PV02, at the discretion of the investigator, for an additional 1 year after radiographic PD, if they meet the criteria for re-treatment (Second Course Phase). Subjects with CR, PR or SD who continue to receive treatment at the end of approx. 2 years (week 99) are eligible to continue with GNOS-PV02 treatment every 12 weeks until week 147. Subjects who discontinue study treatment for reasons other than PD will have post-treatment follow-up visits for monitoring disease status until PD, initiating a non-study cancer treatment, withdrawing consent from study participation, or becoming lost to follow-up. All subjects will be followed (e.g., by telephone or visit) for overall survival (OS) until death, withdrawal of consent from study participation, loss to follow-up, or the end of the study, whichever comes first. After the last dose of study drug, each subject will be followed for 30 days for AE monitoring. Serious adverse events (SAEs) will be collected until the patient reaches the end of the study.

Subjects who have progressed with evidence of growth of existing target, non-target or development of new lesions while on GNOS-PV02 treatment may have another personalized vaccine manufactured and administered using a new tumor biopsy sample per investigator's discretion and Sponsor's approval. Once the subject receives their personalized vaccine, they will continue on study treatment until 2 years (W99) from the Day 0 visit.

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Figure 1. Schema of the Study of a Personalized Neoantigen DNA Vaccine (GNOS-PV02) and Plasmid Encoded IL-12 (INO-9012) in Combination with Pembrolizumab (MK-3475) in Subjects with Advanced Hepatocellular Carcinoma



8.1 Sample Size Considerations

AEs will be continuously monitored. Among the subjects enrolled in the study, for AEs that occur at an incidence of 20% the probability of observing at least one event is greater than 90%.

To evaluate the secondary endpoint of objective response rate (ORR) per response evaluation criteria in solid tumors version 1.1 (RECIST v1.1) by investigator review with a null hypothesis of an ORR of 16.9% and an alternative hypothesis of an ORR of 33.1%, 36 subjects will be enrolled using an exact 1-sided binomial test of a single proportion. The overall power for this test with approximately 36 subjects is 80% assuming an one-sided alpha (α)=0.10. A statistically significant difference at the one-sided 5% level will be declared for an observed ORR of at least 30.5% for 36 subjects (11/36). The operating characteristics of this design are calculated using the exact binomial distribution.

8.2 Randomization

This is an open-label, single-arm study; there will be no randomization or blinding.

9.0 Study Endpoints

9.1 Endpoint

Objectives	Endpoints
Primary	Primary endpoints
• To determine the safety and tolerability of GNOS-PV02 + INO-9012 delivered by ID injection followed by EP using the CELLECTRA® 2000 device in combination with pembrolizumab.	• AEs as graded by common terminology criteria for adverse events (CTCAE) version 5.0.

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• To evaluate preliminary immune response to GNOS-PV02 +INO-9012 in combination with pembrolizumab in subjects with previously treated advanced HCC.	Neoantigen-specific cellular immune responses that may be assessed by but not limited to: • Interferon-γ secreting T lymphocytes in peripheral blood mononuclear cell (PBMCs) by ELI Spot. • T-cell activation and cytolytic cell phenotype in PBMCs by flow cytometry or secretion of immune molecules.
Secondary	Secondary endpoints
• To evaluate the anti-tumor activity of GNOS-PV02 + INO-9012 in combination with pembrolizumab in subjects with previously treated advanced HCC.	• ORR by RECIST v1.1 by investigator review. • ORR by immune response evaluation criteria in solid tumors (iRECIST) • Duration of response (DOR) • Disease control rate (DCR) • Progression free survival (PFS) by RECIST v1.1 and iRECIST • Overall survival (OS)
Exploratory	Exploratory endpoints
• To determine the feasibility of generating the personalized neoantigen DNA vaccine (GNOS-PV02) for subjects with advanced HCC.	The feasibility assessment will be based on: • Tumor-specific neoantigen identification. • Successful neoantigen-based DNA vaccine manufacturing. • The time period elapsed between tumor tissue collection and availability of the neoantigen vaccine for subject dosing.
• To evaluate tumor and immune biomarkers and their association with treatment outcome (antitumor activity and/or safety) in subjects with previously treated advanced hepatocellular carcinoma.	• Assessment of Myeloid derived suppressor cells (MDSC). • T-cell receptor (TCR) sequencing of PBMCs for diversity and putative antigen specificity. • Immune gene transcript profiling of PBMCs. • Assessment of pro-inflammatory and immunosuppressive elements in neoplastic and adjacent normal tissue, where feasible. • Pre- and post-treatment peripheral blood and tumor immune related gene expression -specific oncoproteins in tissue.

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9.2 Analysis Sets

The following analysis sets will be used for presentation of the data.

For each analysis set, the number and percentage of subjects eligible for inclusion will be summarized. A listing of reasons for exclusion from analysis sets will be provided by subject.

A subject data-listing of subject analysis set will be provided.

9.2.1 Enrolled Subjects

The subjects who have signed the informed consent form will be considered a screened subject. Screened subjects who meet all eligibility and abbreviated eligibility criteria and at least one dose of GNOS-PV02 + IL-12 will be considered an enrolled subject. The subject not meeting the eligibility criteria will be considered screen failure subjects.

9.2.2 Safety Analysis Set

The safety analysis will be based on the Safety Analysis Set, which comprises all enrolled subjects who receive at least 1 dose of the study treatment or component of the study treatment.

9.2.3 Modified Intention to Treat Set

The modified intention to treat (mITT) population includes all subjects who receive at least one dose of the study treatment and have evaluable baseline scan with measurable disease. The mITT population will be used for analysis of the immunogenicity and secondary efficacy endpoints.

9.2.4 Per-Protocol Set

The PP population is comprised of subjects who receive at least the first 3 doses of the trial treatment, have an evaluable baseline scan with measurable disease and who have no important protocol violations. Analyses on the PP population will be considered supportive of the corresponding mITT population for the analysis of efficacy. Subjects excluded from the PP population will be identified and documented prior to locking the trial database.

10.0 Conventions and Derivations

10.1 Study Treatment

10.2 Baseline

Unless otherwise specified, baseline measurement is defined as the last pre-treatment measurement obtained prior to the initial administration of study treatment, unless otherwise specified.

10.3 Change from Baseline

The change from baseline will be calculated by subtracting the baseline values from the individual post-baseline values. If either the baseline or post-baseline value is missing, the change from baseline is set to missing.

10.4 Study Day

Study days is defined as: date – date of first dose of study treatment.

10.5 Duration of the Disease

The duration of the disease (in years) will be derived as: Duration of disease (in years) = [(Informed consent date – Date of initial diagnosis) / 365.25]. If this produces a value that is negative, then duration of the cancer will be set to missing.

The imputation method for partial start and end dates is described in Section 10.14.1 of the SAP.

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10.6 Time since Last Disease Progression

The time since last disease progression (in years) will be derived as: ((date of first dose of study treatment - date of progression for last cancer history recorded) + 1) / 365.25.

No imputation of missing or partial dates will be performed.

10.7 Time from End of Last Regimen

The time from end of last regimen (in years) will be derived as: ((date of first dose of study treatment - date of last regimen) + 1) / 365.25.

No imputation of missing or partial dates will be performed.

10.8 Time from End of Last Radiation

The time from end of last radiation (in years) will be derived as: ((date of first dose of study treatment - date of last radiation) + 1) / 365.25.

No imputation of missing or partial dates will be performed.

10.9 Prior and Concomitant Medication

A prior medication is defined as any medication taken before the start of the trial (within 28 days prior to Day 0). The medications with end date earlier than 28 days prior to Day 0 will be included in subject data listing and will be flagged as pre-study.

A concomitant medication is defined as any medications used 7 days prior to screening (Day 0) and during study (on or after Day 0). The medication with start date prior to first dose of study treatment and ongoing in the study will be included in subject data listing and will be flagged as prior and concomitant.

The imputation method for partial start and end dates is described in Section 10.13.2 and 10.13.3 of the SAP.

10.10 End of Study

The subject will be considered as completed study if the subject has completed 3 years of follow-up visits or has expired during this time period .

For the purpose of analysis and reporting, the data collected on the 'End of Study' eCRF page will be considered for completion of 3 years follow-up visits. Subjects who have completed their 3-year follow up visits will be indicated by the reason of 'Subject Completed Follow-up' on this form. The End of Study page will also capture the patient's date of death.

10.11 Study Treatment Exposure

10.11.1 Duration of exposure

The duration of exposure (months) is defined as date of last of study treatment to date of first dose of study treatment plus 1 divided by 30.4375.

10.12 Efficacy Variables

10.12.1 Best Overall Response

Best overall response (BOR) is defined as the best result obtained among all tumor assessment visits from baseline until end of treatment or determination of PD.

Not Evaluable (NE) is not considered a valid measurement. Overall response of NE will be changed to PD if subsequent scan is a PD. As a consequence, a BOR of NE will only be assigned if NE is the only available for one radiographic assessment (for instance, a subject having assessments of NE and PD will be assigned BOR of PD).

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A subject will be considered NE in case the subject had baseline tumor assessment but discontinued the study prior to Week 9.

10.12.2 Objective Response Rate

The ORR according to RECIST v1.1 is defined as the proportion of subjects having achieved CR or partial response (PR) as the BOR according to radiological assessments from the date of first administration to end of study treatment. The response should be confirmed by a repeat radiographic assessment. The scan for confirmation of response will be performed no earlier than 4-6 weeks after the first indication of response, or at the next scheduled scan, whichever is clinically indicated to RECIST v1.1..

The ORR for iRECIST is defined as the proportion of subjects having achieved complete response (iCR) or partial response (iPR) by iRECIST.

10.12.3 Duration of Response

DOR based on RECIST v1.1 is defined, for subjects with objective response, as the time from the first documentation of objective response (CR or PR) to the date of first documentation of PD or death due to any cause. For iRECIST, the iCR, iPR and iCPD will be used for obtaining DOR. The censoring of DOR will be similar to PFS.

The DOR (in months) will be calculated using following formulae:

- DOR (months) = [date of event or censoring– first date of confirmed OR +1]/30.4375

10.12.4 Disease Control Rate

Disease Control is defined as BOR of CR, PR, or SD accordingly to RECIST v1.1. For iRECIST, the iCR, iPR and iSD will be used for obtaining DOR. Disease control rate (DCR) is the proportion of patients with DC.

10.12.5 Progression Free Survival

PFS is defined as the time interval from the date of first dose of study treatment administration to the date of disease progression as determined by the investigator using RECIST v1.1 or the date of on-study death due to any cause, whichever occurs first.

For analysis based on iRECIST, the PFS is defined as the time interval from the date of first dose of study treatment administration to the date of confirmed disease progression by the investigator using iRECIST or the date of on-study death due to any cause, whichever occurs first.

Patients who die after receiving the first dose of study treatment without post-baseline tumor assessments evaluable using RECIST v1.1, will be considered to have a PFS event on the date of death.

The PFS (in months) will be calculated using following formulae:

- PFS (months) = [date of event or censoring – date of first dose of study treatment +1]/30.4375

The censoring rules for the analyses of PFS are summarized in the following table. The earliest of the following censoring times will be used:

Scenario	Date of censoring
PD or death after 2 or more missing or inadequate post-baseline tumor assessments	Date of last tumor assessment documenting no PD before new anti-cancer therapy is given or missed tumor assessments
No PD and no death	Date of last tumor assessment documenting no PD before new anti-cancer therapy is given or missed tumor assessments

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New anti-cancer therapy given	Date of last tumor assessment documenting no PD before new anti-cancer therapy

10.12.6 Overall Survival

OS is defined as the time from the date of first dose of study treatment administration until the documented date of death from any cause. The OS (in months) will be calculated using following formulae:

- OS (months) = [date of death, due to any cause – date of first dose of study treatment +1]/30.4375

Subjects who are still alive at the time of the data cutoff or end of study, date will be censored on the last date known to be alive or at the data cutoff date, whichever occurs first.

10.13 Safety Variables

10.13.1 Treatment Emergent Adverse Events

The treatment emergent adverse events (TEAEs) are defined as any AEs that occur starting on or after the first dose of the study treatment (Day 0) until the patient reaches the end of the study. Toxicities due to first-line standard of care therapy while awaiting study therapy will not be collected or reported.

10.14 Date Imputation Guideline

10.14.1 Imputation of Missing Date of First Diagnosis

The incomplete date of first diagnosis will be imputed using following rules:

- If the day is missing, it will be imputed to the 15th day of the month.
- If both day and month are missing and the year is prior to the year of the first study treatment, the month and day will be imputed as December 31st .
- If both day and month are missing and the year is same as the year of the first study treatment, the month and day will be imputed as January 1st .
- If the date is completely missing, no imputation will be performed.

10.14.2 Impute Missing AE/Prior or Concomitant Medications Start Dates

If the stop date is non missing and the imputed start date is after the stop date, the start date will be imputed by the stop date.

Missing day and month

- If the year is same as the year of first day on study treatment, then the day and month of the start date of study treatment will be assigned to the missing fields.
- If the year is prior to the year of first day on study treatment, then December 31 will be assigned to the missing fields.
- If the year is after the year of first day on study treatment, then January 1 will be assigned to the missing fields.

Missing day only

- If the month and year are same as the year and month of first day on study treatment, then the start date of study medication will be assigned to the missing day.
- If the month and year are before the year and month of first day on study treatment, then the last day of the month will be assigned to the missing day.
- If the month and year are after the year and month of first day on study treatment, then the first day of the month will be assigned to the missing day.

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10.14.3 Impute Missing AE/ Prior or Concomitant Medications Stop Dates

If the imputed stop date is before the start date, then the imputed stop date will be equal to the start date.

Missing day and month

- If the year of the incomplete stop date is the same as the year of the last dose date of study medication, then the day and month of the last dose date will be assigned to the missing fields.
- If the year of the incomplete stop date is prior to the year of the last dose date, then December 31 will be assigned to the missing fields.
- If the year of the incomplete stop date is after the year of the last dose date of study medication, then January 1 will be assigned to the missing fields.

Missing day only

- If the month and year of the incomplete stop date are the same as the month and year of the last dose date of study medication, then the day of the last dose date will be assigned to the missing day.
- If the month and year of the incomplete stop date are before the month and year of the last dose date of the study medication, then the last day of the month will be assigned to the missing day.
- If the month and year of the incomplete stop date are after the month and year of the last dose date of study medication, then the first day of the month will be assigned to the missing day.

11.0 Interim Analyses

There is no formal interim analysis built-in to the study. However, safety endpoints will be assessed on an ongoing basis in order to assess Dose Limiting Toxicities (DLT).

The Stopping rules for AEs will be employed for this study. The safety stopping rules will be determined following the proportion of subjects with a particular DLT resulting from study treatment that exceeds a Bayesian stopping guideline. A toxicity level 45% would be considered the upper boundary. We expect the actual toxicity level to be 25% (49). A Beta (2.5, 5.5) prior, representing a toxicity rate of 31% (slightly above our expected rate), will be used to be conservative. After the first 6 subjects have been treated, safety will be monitored continuously. If the probability that the proportion of unacceptable toxicities exceeds 45%, we will halt accrual and re-evaluate the trial. The following table shows the number of toxicities that would need to be observed in order to trigger the stopping guidelines throughout the course of the trial. The calculated number of subjects with DLT sufficient to trigger the stopping rule is the following:

Number of Subjects	Number of Toxicities Needed to Trigger Re-Evaluation
6	4
7-8	5
9-10	6
11-13	7
14-15	8

At any point during the course of this clinical study a higher number of subjects than expected by Bayesian analysis (as defined above) experience a dose-limiting toxicity as defined in Section 10.3.8 of the protocol deemed related to investigational trial drug(s), enrollment will stop, and the Sponsor Medical Monitor, in addition to the Principal Investigator and Investigator(s) at the study site(s) will discuss the safety profile of the trial drug(s), and a decision will be made whether to modify trial drug administration schedule or to

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cease further enrollment. If a change in the protocol is required, enrollment will only be reinitiated after amendment of the protocol and approval of the amended protocol by the institutional review boards (IRB).

To ensure subject safety during the study, a Safety Committee will be formed to monitor safety on a periodic basis. Members of the Safety Committee will include a Safety Expert, Principal Investigator(s) and the Sponsor Medical Monitor. The Safety Committee will meet approximately every 6 months to review safety data collected from the point of first patient in to review safety, or as needed. The safety data will include demographic data, AEs, SAEs, and relevant laboratory data. Following each data review, the Safety Committee will provide recommendations as to whether the study should continue, be amended, or whether the study should be stopped on the basis of safety (i.e., evidence of harm). The final decision will rest with the Sponsor. Any outcomes of these safety reviews that affect study conduct will be communicated in a timely manner to the investigators for notification of the IRB/independent ethics committees (IECs).

12.0 Statistical Methods

Statistical analyses and generation of tables, figures, subject data listings, and statistical outputs (if applicable) will be performed using Workbench or SAS Version 9.4 or higher.

Descriptive statistics will be displayed to provide an overview of the study results.

For categorical parameters, the number (n) and percentage (%) of subjects in each category will be presented. The denominator for percentages will be based on the number of subjects appropriate for the purpose of analyses. Unless otherwise noted, all percentages will be displayed to 1 decimal place. No percentage will be displayed for zero counts, and no decimal will be presented when the percentage is 100%.

For continuous parameters, descriptive statistics will include number of subjects (n), mean, standard deviation (STD), median, first quartile (Q1), third quartile (Q3), minimum, and maximum. When appropriate 2-sided 95% confidence intervals will be provided along with the point estimate. Decimal places for descriptive statistics will always apply the following rules:

- “n” will be an integer.
- Mean, median, Q1 and Q3 will use 1 additional decimal place compared to the original data.
- STD will use 2 additional decimal places compared to original data.
- Minimum and maximum will have the same number of decimal places as the original data.
- Confidence intervals (CIs) will be presented to 1 more decimal place than the original data.

12.1 Subject Disposition

A summary table will be provided including the number of subjects screened, continued the study after screening, screen failure subjects, reason of screen failure.

For summary table of the subject disposition on study treatment, the number and percentages of subjects who completed the study, discontinued the study along with the primary reason of study discontinuation and discontinued the treatment along with the primary reason for discontinuation of the treatment will be presented. The information study completion and discontinuation will be considered from “End of Study” CRF page, whereas study treatment discontinuation information will be considered from “Treatment Discontinuation” CRF page.

If reason for discontinuation is death, the date of death will be documented on the “End of Study” CRF page.

The listing of discontinuation of study and discontinuation of study treatment will be presented separately.

A separate listing of subject visits will be present all scheduled and unscheduled visits for all subjects in safety analysis set along with the date of visit.

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12.2 Demographic and Baseline Characteristics

All demographic and baseline characteristics will be presented on all subjects in the safety analysis set.

12.2.1 Demographic Information

Subject demographic variables such as age (years), weight (kg) at screening, height (cm) at screening and BMI (kg/m^2) will be presented descriptively. The number and percentage of subjects will be presented for Eastern Cooperative Oncology Group (ECOG) performance status at screening, gender, race, ethnicity, and age groups (<65 years, ≥65 years to < 75 years and ≥75 years).

The number and percentage of subjects will be provided by country.

A 12-lead electrocardiogram (ECG) will be performed at screening and parameters that include PR interval, QRS interval, QT interval, and QTc interval will be collected. The summary of overall assessment of 12-lead ECG will be presented in the demographic characteristics table.

All above demographic variables including ECG will be listed in by-subject.

A separate by-subject data listing will be provided for HIV, HCV, HBV and alcohol and tobacco history.

12.2.2 Medical History

General medical history will include details regarding the subjects overall medical and surgical history. Medical history data will be coded according to the Medical Dictionary for Regulatory Activities (MedDRA) version 26.0. The medical history data will be summarized with descriptive statistics by system organ class (SOC) and preferred term (PT). A comprehensive data listing will also be included.

12.2.3 Cancer History

The cancer history summary at the entry of study will summarized for following:

- Subjects with esophageal or gastric variceal bleeding in last 6 months, with clinically apparent ascites, subjects with portal vein invasion and subjects with encephalopathy.
- TNM classification and stage at the entry (The categories are as in CRF).
- BCLC Stage (The categories are as in CRF)
- Child-Pugh Score (The categories are as in CRF)
- Prior anti-tumor treatment (The categories are as in CRF)
- Time since first diagnosis of HCC (years)
- Time since last disease progression (years)

A subject data listing of cancer history will be provided.

12.2.4 Prior Systemic Therapy

The prior systemic therapy at the entry of study will summarized for following:

- Subjects with prior systemic therapy
- Number of regimens (0, 1, 2, 3, >3)
- Therapy type (Chemotherapy, Hormone therapy, Immunotherapy, Unknown and Other).
- Best response for the last regimen (CR, PR, SD, PD, Not applicable, Not evaluable. and Unknown)
- Time from end of last regimen and date of first dose of study treatment (months).

A subject data listing of prior systemic therapy will be provided.

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12.2.5 Prior Cancer Radiation

The prior systemic therapy at the entry of study will summarized for following:

- Subjects with prior radiation therapy
- Site of prior radiation therapy (categories depend on actual data)
- Best response for the last radiation therapy (CR, PR, SD, PD, Not applicable and Unknown)
- Time from end of last radiation therapy and date of first dose of study treatment (months).

A subject data listing of prior radiation therapy will be provided.

12.3 Treatments

The treatments to be used in this study is personalized neoantigen DNA vaccine (GNOS-PV02) and plasmid encoded IL-12 (INO-9012) in combination with pembrolizumab (MK-3475).

12.3.1 Extent of Study Drug Exposure

The summary of study treatment exposure will be based on all subjects in safety analysis set.

The summary of study treatment exposure will include following:

- Duration of exposure (in months) for the combination

Summary of GNOSPV02 + INO-9012 administration

- Descriptive summary of total number of GNOSPV02 + INO-9012 doses administered
- Number and percentage of subjects for whom GNOSPV02 + INO-9012 was not administered, along with the reason not administered, as per CRF page of “GNOSPV02 + INO-9012 Administration”.
- Number and percentage of subjects for whom total dose of GNOSPV02 + INO-9012 was not administered. This information collected on CRF of “GNOSPV02 + INO-9012 Administration” will be used. The reason for total dose not administered will be provided in subject data listing.

Summary of Pembrolizumab Administration

- Descriptive summary of total number of Pembrolizumab doses administered
- Number and percentage of subjects for whom Pembrolizumab was not administered, along with the reason not administered, as per CRF page of “Pembrolizumab Administration”.
- Number and percentage of subjects for whom entire infusion was administered, along with the reason not fully administered as per CRF page of “Pembrolizumab Administration”.

The subject data listing of administration of GNOSPV02 +INO-9012, and Pembrolizumab will be presented separately.

12.3.2 Concomitant Medications

Prior and concomitant medications received concomitantly with study treatment, categorized by medication group and subgroup according to WHODRUG 2019SEP01 Global B3, will be summarized. The summaries will include the number and percentage of subjects who had medications and will be presented by WHO Anatomic Therapeutic Classification (ATC) drug name and preferred term (PT).

All prior and concomitant medications will be listed.

12.4 Important Protocol Deviations

The study specific Protocol Deviation Guidance Document defines all important protocol deviations in this study.

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Per PRA processes, protocol deviations data will be entered into our system of record (PSO). The study team and the Sponsor will conduct ongoing reviews of the deviation data from PSO and classify those as important or non-important. The PP subjects set will be finalized at the data review meeting (or earlier), prior to database lock.

The number and percentage of subjects with important protocol deviations will be summarized along the protocol deviation category. The subjects may be counted in one or more protocol deviation category.

The by-subject data listing of all important and non-important deviations will be listed.

12.5 Efficacy Analyses

The efficacy analysis will be performed on all subjects in mITT analysis set.

12.5.1 Hypothesis Testing Strategy and Multiplicity

No hypothesis testing and multiplicity is not applicable.

12.5.2 Primary Immunogenicity Analyses

Neoantigen-specific cellular immune response assessed by, but not limited to, IFN-γ ELISpot will be summarized by visit using descriptive statistics and changes from baseline. Furthermore, Neoantigen-specific responses will be confirmed through intracellular cell staining of PBMCs stimulated with patient-specific neoepitope pools in *in vitro*. T-cell activation, proliferation and cytolytic cell phenotype in PBMCs by flow cytometry will be analyzed..

The primary immunogenicity analyses will be conducted on the mITT.

The immunogenicity data will be included in subject data listings.

12.5.3 Secondary Efficacy Analyses

The secondary endpoints will be summarized on subjects in mITT. The rules for censoring are defined in section 10.11 of this SAP.

All secondary efficacy endpoints data will be included in subject data listings.

12.5.3.1 Objective Response Rate and Disease Control Rate

All RECIST assessments, whether scheduled or unscheduled, will be included in the calculations. At each scan visit, subjects will be assigned a RECIST v1.1 visit response of CR, PR, PD or SD and iRECIST response of iCR, iPR, iUPD, iCPD, or iSD depending on the status of their disease compared to baseline and previous assessments by the investigator.

The BOR will be summarized by number and percentage.

The number, percentage of subjects with confirmed ORR and DCR by RECIST v1.1 and iRECIST will be provided along with 95% CI based on exact binomial distribution (Clopper-Pearson exact method).

Tumor shrinkage per RECIST v1.1 will be summarized as the percent change from baseline in target lesions (sum of longest diameter for non-nodal lesion and short axis for nodal lesion) per time point. It will be derived as:

- ((Sum of target lesions at week XX – sum of target lesions at baseline)/sum of target lesions at baseline) × 100.

The maximum reduction per RECIST v1.1 in target lesions from baseline will be derived across all the postbaseline assessments until documented disease progression, excluding assessments after start of subsequent anti-cancer therapy, as:

- Minimum of ((sum of target lesions at week XX – sum of target lesions at baseline)/sum of target lesions at baseline) × 100.

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A waterfall plot of maximum percent reduction in the sum of longest diameter for non-nodal lesions and short axis for nodal lesions from baseline will be created by treatment group. These plots will display the best percentage change from baseline in the sum of the diameter of all target lesions for each subject in mITT.

12.5.3.2 Duration of Response

Kaplan-Meier estimates (product-limit estimates) will be presented together with a summary of associated statistics including the median DOR time with 2-sided 95% CIs. The CIs for the median will be calculated according to Brookmeyer and Crowley.

The censoring rules are similar to PFS censoring rules defined in SAP section 10.11.5.

DOR will be displayed graphically and analyzed using Kaplan-Meier methodology.

The DOR will be summarized by RECIST v1.1 and iRECIST.

12.5.3.3 Progression Free Survival

Kaplan-Meier estimates (product-limit estimates) will be presented together with a summary of associated statistics including the median PFS time with 2-sided 95% Cis. The Cis for the median will be calculated according to Brookmeyer and Crowley.

The censoring rules defined in SAP section 10.11.5.

PFS will be displayed graphically and analyzed using Kaplan-Meier methodology.

The PFS will be summarized by RECIST v1.1. and iRECIST.

12.5.3.4 Overall Survival

Kaplan-Meier estimates (product-limit estimates) will be presented together with a summary of associated statistics including the median PFS time with 2-sided 95% Cis. The Cis for the median will be calculated according to Brookmeyer and Crowley.

The censoring rules defined in SAP section 10.11.6.

OS will be displayed graphically and analyzed using Kaplan-Meier methodology.

12.5.4 Exploratory Analyses

Tumor and immune biomarkers, which include assessment of MDSC, T-cell receptor sequencing of PBMCs, immune gene transcript profiling of PBMCs, assessment of pro inflammatory and immunosuppressive elements in neoplastic and adjacent normal tissue, pre- and post-treatment peripheral blood tumor tissue, tumor-specific oncoproteins, microRNA, cytokine and chemokine profiles, and circulating tumor DNA, will be descriptively summarized by visit.

iORR, ORR, iPFS, PFS and OS will be modeled using logistic regression models and Cox PH models against the exploratory responses to examine associations. Baseline variables such as subject demographics, patient disease characteristics or immune responses will be included in the models as potential confounders.

All these exploratory analyses will be conducted on the mITT and/or Per Protocol populations as appropriate.

12.6 Safety Analyses

The safety analysis will include all subjects in safety analysis set, unless otherwise specified. Subjects will be grouped according to the study treatment they received.

12.6.1 Adverse Events

The AEs as graded by CTCAE version 5.0 is the primary endpoint of the study.

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All AEs will be coded to preferred term and system organ class using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0. The severity of all adverse events is to be evaluated by the Investigator based on the NCI CTCAE, version 5.0. Toxicities due to first-line standard of care therapy while awaiting study therapy will not be collected or reported.

The number and percentage of subjects with treatment emergent adverse events will be presented by MedDRA system organ class and preferred term, and NCI CTCAE grade. A subject reporting the same adverse event more than once is counted once and at the maximum CTCAE grade or worst relationship to study treatment, when calculating incidence.

For analysis, the missing relationship to GNOSPV02 + INO-9012, Investigational Device (ID) and Pembrolizumab will be as related respectively.

The AE of special interest and DLTs recorded on CRF will be summarized.

The 95% Clopper-Pearson CI will be presented in the overall summary of TEAEs for each category of AE. The following summaries will be presented:

- Overall summary of TEAE
- TEAEs by SOC and PT
- TEAEs by SOC, PT, and Maximum CTCAE grade
- CTCAE grade 3 or greater TEAE by SOC and PT
- TEAE related to GNOSPV02 + INO-9012 by SOC and PT
- TEAE related to GNOSPV02 + INO-9012 by SOC, PT, and Maximum CTCAE grade
- CTCAE grade 3 or greater TEAE related to GNOSPV02 + INO-9012 by SOC and PT
- TEAE related to CELLECTRA® 2000 by SOC and PT
- TEAE related to CELLECTRA® 2000 by SOC, PT, and Maximum CTCAE grade
- CTCAE grade 3 or greater TEAE related to CELLECTRA® 2000 by SOC and PT
- TEAE related to Pembrolizumab by SOC and PT
- TEAE related to Pembrolizumab by SOC, PT, and Maximum CTCAE grade
- CTCAE grade 3 or greater TEAE related to Pembrolizumab by SOC and PT
- TEAE related GNOSPV02 + INO-9012, CELLECTRA® 2000 or Pembrolizumab by SOC and PT
- TEAE related GNOSPV02 + INO-9012, CELLECTRA® 2000 or Pembrolizumab by SOC, PT, and Maximum CTCAE grade
- CTCAE grade 3 or greater TEAE related GNOSPV02 + INO-9012, CELLECTRA® 2000 or Pembrolizumab by SOC and PT
- TEAE Leading to study treatment discontinuation
- TEAE related to GNOSPV02 + INO-9012 Leading to study treatment discontinuation
- TEAE related to CELLECTRA® 2000 Leading to study treatment discontinuation
- TEAE related to Pembrolizumab Leading to study treatment discontinuation
- TEAE related of Special Interest by SOC and PT
- DLT by SOC and PT

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A TEAE and non TEAEs will be presented in separate listing. Additionally, a listing of subject with TEAEs of special interest, TEAEs leading to discontinuation of study treatment and subjects with DLTs will be presented separately.

12.6.2 Deaths and Serious Adverse Events

TEAEs that lead to death and serious AEs (SAEs) will be summarized by SOC and PT. The following summaries will be presented:

- TEAE with an Outcome of Death by SOC and PT
- Serious TEAE by SOC and PT
- Serious TEAE related to GNOSPV02 + INO-9012 by SOC and PT
- Serious TEAE related to CELLECTRA 2000 by SOC and PT
- Serious TEAE related to Pembrolizumab by SOC and PT
- Serious TEAE related to GNOSPV02 + INO-9012, CELLECTRA® 2000 or Pembrolizumab by SOC and PT

A listing of subjects with TEAEs with outcome of death and serious TEAE will be presented separately.

12.6.3 Laboratory Data

The measurement and evaluation of serum chemistry, hematology, coagulation, thyroid, and pregnancy hormones (female subjects with childbearing potential) will be collected as described in protocol under schedule of assessments (Table 3 of protocol).

Local laboratory data collected during the study will be analyzed and summarized using both quantitative and qualitative methods. All laboratory data will be summarized in International System (SI) units as documented the Local Laboratory Conventions.

A descriptive summary of absolute value and change from baseline value for hematology, serum chemistry, coagulation, and thyroid will be presented. A subject data listing will be provided for all laboratory parameters.

A summary of investigator assessed clinically significant postbaseline hematology, serum chemistry, coagulation, and thyroid results will be presented by each postbaseline visit. The subjects with non-missing data at a visit and laboratory parameter will be considered for this summary. Laboratory values considered clinically significant will be presented in listings.

A separate listing will be provided for pregnancy test results.

12.6.3.1 NCI CTCAE Grading

CTCAE Version 5.0 will be used for assigning toxicity grades (0 to 4) to laboratory results for analysis. Grade 0 includes all values that do not meet the criteria for an abnormality of at least Grade 1. For laboratory tests with criteria for both increased and decreased levels; analyses for each direction (ie, increased, decreased) will be presented separately.

The grades will be applied based only on the numeric SI value of the parameter assessed; clinical signs and symptoms are not considered.

Shift summarizes for some hematology and chemistry tests will be presented by showing change in CTCAE grade from baseline to worst post-baseline grade including data from any unscheduled post-baseline visit.

The grading will be provided in subject data listings.

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12.6.4 Vital Signs

Vital signs (systolic blood pressure, diastolic blood pressure, body temperature, weight and heart rate, respiratory rate) absolute value and change from baseline value will be summarized descriptive. A subject data listing for all vital sign parameters will be provided.

12.6.5 Physical Examinations, and Other Observations Related to Safety

12.6.5.1 Physical Examinations

The number and percentage of subjects with abnormal physical examination findings at each time point will be descriptively summarized overall by body system. The subject data listing will also be provided.

12.6.5.2 Eastern Cooperative Oncology Group

The worst shift from baseline to post-baseline visits in ECOG performance status will be provided.

13.0 References

Brookmeyer, R., & Crowley, J. (1982). A confidence Interval for the Median Survival Time. Biometrics, 29-41.

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14.0 Glossary of Abbreviations

Glossary of Abbreviations:	
AE	Adverse event
ATC	Anatomic Therapeutic Classification
BCLC	Barcelona-Clinic Liver Cancer
BOR	Best Overall Response
CI	Confidence Interval
CR	Complete Response
CRF	Case Report Form
CTCAE	Common Terminology Criteria for Adverse Events
DCR	Disease Control Response
DLT	Dose Limiting Toxicities
DNA	Deoxyribonucleic acid
DOR	Duration of Response
ECG	Electrocardiogram
ECOG	Eastern Cooperative Oncology Group
EP	Electroporation
HCC	Hepatocellular Carcinoma
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HIV	Human Immunodeficiency Virus
iCPD	Confirmed progressive disease by iRECIST
iCR	Complete Response by iRECIST
ID	Intradermal
iPR	Partial Response by iRECIST
IRB	Institutional Review board
iRECIST	Immune Response Evaluation Criteria in Solid Tumors
iSD	Stable disease by iRECIST
iUPD	Unconfirmed progressive disease by iRECIST
MedDRA	Medical Dictionary for Regulatory Activities
MDSC	Myeloid derived suppressor cells
mITT	Modified Intention to Treat
NE	Not Evaluable
ORR	Objective Response Rate
OS	Overall Survival

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PBMC	Peripheral Blood Mononuclear Cell
PD	Progressive disease
PFS	Progression-Free Survival
PP	Per Protocol
PR	Partial Response
PT	Preferred Term
RECIST v1.1	Response Evaluation Criteria in Solid Tumors Version 1.1
SAE	Serious Adverse Events
SAP	Statistical Analysis Plan
SD	Stable Disease
SI	International Standard
SOC	System Organ Class
STD	Standard Deviation
SAE	Serious Adverse Event
TEAE	Treatment emergent adverse event
TCR	T-cell receptor
TFL	Tables, Listing, Figures
Q1	First Quartile
Q3	Third Quartile
Q3W	Every 3 weeks
Q9W	Every 9 weeks

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