

Protocol Clarification Letter Cover Page

NCT05169437

Title: A Single-Arm Phase-II Study of Niraparib in Locally Advanced or Metastatic Solid Tumor Patients with PALB2 Mutations

Date: 27July2022

Date: 27-July-2022

To: PAVO TMPS-101 (218046) Investigational Sites

Study: A Single-Arm Phase-II Study of Niraparib in Locally Advanced or Metastatic Solid Tumor Patients with PALB2 Mutations Who Have Received At Least One Line of Prior Therapy

From: [REDACTED], MD, Medical Director, Tempus

Re: Protocol Clarifications 1) Main Criteria for Inclusion #5 2) Main Criteria for Exclusion #14 3) Section 1.3, Schedule of Activities Windows

Dear PAVO TMPS-101 Study Investigators and Coordinators:

This memo is to clarify three items in the protocol:

(1) The PAVO TMPS-101 study team is clarifying Main Criteria for Inclusion #5 with the following statement in bold:

Participants must submit fresh or archived (collected within 24 months of enrollment) FFPE tumor sample to the central laboratory for post-enrollment confirmation of tPALB2 status, **where available/clinically feasible and based on sponsor approval.**

(2) Exclusion #14, outlining the 3 week pre dose washout period, omitted the term, “definitive”, in description of radiation therapy and is updated in bold below (please see section 6.5.1 as well for details regarding allowance for palliative RT):

Participants have received prior systemic cytotoxic chemotherapy, biological therapy, or hormonal therapy for cancer, or received **definitive** radiation therapy within 3 weeks of the first dose therapy preceding the study.

(3) Regarding Section 1.3, Schedule of Activities in the study protocol a window for protocol required procedures for C1D1 was omitted. It is acceptable for patient laboratory tests noted in the Schedule of Activities to be performed within a -1 day window of C1D1.

These clarifications will be added to a future amendment, if one is warranted in the future. Please do not hesitate to contact the PAVO TMPS-101 study team with any questions. Thank you very much for your continued efforts to make this study a success.

Sincerely,

[REDACTED]
Medical Director, TEMPUS

Signature:

DocuSigned by:

Date: 7/27/2022

Signer Name: [REDACTED]
Signing Reason: I approve this document
Signing Time: 7/27/2022 | 5:25:07 AM PDT

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