Doctor's Note — Clinical Trial Summary

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TRIAL

Olaparib in Combination With Pembrolizumab for Advanced Uveal Melanoma

NCT ID: NCT05524935 Phase: PHASE2 Sponsor: H. Lee Moffitt Cancer Center and Research Institute Status: Recruiting

SUMMARY

This is a prospective phase II multi-center trial of the combination of the PARP inhibitor olaparib with the immune checkpoint inhibitor pembrolizumab in advanced uveal melanoma.

KEY ELIGIBILITY CRITERIA

- * Male or female participants who are at least 18 years of age on the day of signing informed consent with histologically confirmed diagnosis of metastatic uveal melanoma will be enrolled in this study. Prior hepatic directed therapy for metastatic uveal melanoma is permitted.
- * Male participants: A male participant must agree to use a contraception as detailed in Appendix 3 of this protocol during the treatment period and for at least 200 days after the last dose of study treatment and refrain from donating sperm during this period.
- * Female participants: A female participant is eligible to participate if she is not pregnant (see Appendix 3), not breastfeeding, and at least one of the following conditions applies: (a) Not a woman of childbearing potential (WOCBP) as defined in Appendix 3, OR (b) A WOCBP who agrees to follow the contraceptive guidance in Appendix 3 during the treatment period and for at least 120 days after the last dose of study treatment.
- * The participant (or legally acceptable representative if applicable) provides written informed consent for the trial.
- * Have measurable disease based on RECIST 1.1.49 Lesions situated in a previously irradiated area are considered measurable if progression has been demonstrated in such lesions.
- * Have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1.
- * Have the ability to swallow oral medications (olaparib).
- * Have adequate organ function as defined in the protocol.
- * A woman of childbearing potential (WOCBP) who has a positive urine or serum pregnancy test within 72 hours prior to start of study therapy. If the urine test is positive or cannot be confirmed as negative, a serum pregnancy test will be required.
- * Has received prior therapy with an anti-PD-1, anti-PD-L1, or anti-PD-L2 agent as monotherapy or as combination therapy for uveal melanoma. Note: these agents may have been used for the treatment of another malignancy as long as the therapy was completed more than 2 years ago (calculated from the date of signing the ICF).

ENROLLMENT CONTACT

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Total sites: 1 | 1 currently recruiting