Doctor's Note — Clinical Trial Summary

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TRIAL

Lenvatinib Plus Pembrolizumab In Patients With Immune Checkpoint Inhibitor Naïve Metastatic Uveal Melanoma

NCT ID: NCT05308901 Phase: PHASE2 Sponsor: Providence Health & Services Status: Active Not Recruiting

SUMMARY

The purpose of this study is to evaluate the efficacy of lenvatinib and pembrolizumab to treat metastatic uveal melanoma.

KEY ELIGIBILITY CRITERIA

- * Male/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.
- * Male participants must agree to use a contraception as detailed in Appendix 3 of this protocol during the treatment period and for at least 120 days after the last dose of Lenvatinib and refrain from donating sperm during this period.
- * Female participants are eligible to participate if she is not pregnant (see Appendix 3), not breastfeeding, and at least one of the following conditions applies:
- 1. Not a woman of childbearing potential (WOCBP) as defined in Appendix 3 OR
- 2. A WOCBP who agrees to follow the contraceptive guidance in Appendix 3 during the treatment period and for at least 120 days post pembrolizumab or post Lenvatinib whichever occurs last.
- * The participant (or legally acceptable representative if applicable) provides written informed consent for the trial.
- * Have measurable disease based on iRECIST. Lesions situated in a previously irradiated area are considered measurable if progression has been demonstrated in such lesions.
- * Have provided archival tumor tissue sample or newly obtained core or excisional biopsy of a tumor lesion not previously irradiated. Formalin-fixed, paraffin embedded (FFPE) tissue blocks are preferred to slides. If slides are only available, ten slides would be required. Newly obtained biopsies are preferred to archived tissue.
- * Have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1. Evaluation of ECOG is to be performed within 7 days prior to the first dose of study intervention.
- * Have adequate organ function as defined in the following table (Table 2). Specimens must be collected within 7 days prior to the start of study intervention.

Total sites: 1 | 0 currently recruiting