Doctor's Note — Clinical Trial Summary

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TRIAL

Study of Cemiplimab Plus Ziv-Aflibercept for Subjects With Metastatic Uveal Melanoma

NCT ID: NCT06121180 Phase: PHASE2 Sponsor: H. Lee Moffitt Cancer Center and Research Institute Status: Recruiting

SUMMARY

The goal of this clinical research study is to find out if Cemiplimab plus Ziv-Aflibercept is safe and effective in treating your condition of metastatic (spread to other parts of your body) uveal melanoma. This research study will test the study drugs to see if the combination of Cemiplimab plus Ziv-Aflibercept can make tumors shrink or stop growing.

KEY ELIGIBILITY CRITERIA

- * Provision of signed and dated informed consent form.
- * Male or female, aged \>/= 18 years old.
- * Life expectancy of greater than 3 months in the opinion of the investigator.
- * Must be willing and able to provide informed consent signed by study patient or legally acceptable representative, as specified by health authorities and institutional guidelines.
- * Patients must have metastatic uveal melanoma, either initial presentation or recurrent, that is histologically diagnosed.
- * Patients with histologically or cytologically confirmed metastatic melanoma or cutaneous, mucosal or unknown primary origin are also eligible. This includes AJCC stage IV or advanced/inoperable stage III. This also includes patients with a history of lower stage melanoma and subsequent recurrent metastatic disease that is either locally/regionally advanced/inoperable disease or distant metastases. These patients must have previously received anti-PD1 immunotherapy (nivolumab or pembrolizumab) as monotherapy or in combination and later experienced disease progression. Patients with BRAF V600 mutant melanoma must have previously received BRAF targeted therapy for metastatic melanoma and later experienced disease progression. Patients who refuse or decline to receive BRAF targeted therapy or prefer to delay or were intolerant of BRAF targeted therapy are eligible
- * Patients must have ECOG performance status of 0-1.
- * Patients must have measurable disease, according to RECIST version 1.1.
- * Patients must have normal organ and marrow function as defined in protocol.
- * Urine protein should be screened by urinalysis for Urine Protein Creatinine Ratio (UPCR). For UPCR \> 1, a 24-hour urine protein should be obtained, and the level should be \<500 mg.

ENROLLMENT CONTACT

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Total sites: 4 | 4 currently recruiting

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