Doctor's Note — Clinical Trial Summary

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TRIAL

A Randomized, Phase 2/3 Study to Investigate the Efficacy and Safety of RP2 in Combination With Nivolumab in Immune Checkpoint Inhibitor-Naïve Adult Patients With Metastatic Uveal Melanoma

NCT ID: NCT06581406 Phase: PHASE2 / PHASE3 Sponsor: Replimune, Inc. Status: Recruiting

SUMMARY

The purpose of this study is to measure the clinical benefits of the combination of RP2 and nivolumab as compared with the combination of nivolumab and ipilimumab in patients with metastatic uveal melanoma who have not been treated with immune checkpoint inhibitor therapy.

KEY ELIGIBILITY CRITERIA

- * Patients who are 18 years of age or older at the time of signed informed consent.
- * Patients with confirmed diagnosis of metastatic Uveal melanoma not amenable to surgical resection.
- * Has at least 1 measurable and injectable tumor of e 1 cm in longest diameter (e 1.5 cm in the shortest axis for a lymph node \[LN\]) that is amenable to serial RP2 injections.
- * Must be willing to provide tumor biopsy samples.
- * LDH d 2 × upper limit of normal (ULN).
- * Has adequate hematologic, hepatic and renal function
- * Prothrombin time (PT) d 1.5 × ULN (or international normalization ratio \[INR\] d 1.3) and partial thromboplastin time (PTT) or activated partial thromboplastin time (aPTT) d 1.5 × ULN.
- * Eastern Cooperative Oncology Group (ECOG) performance status (PS) 0 or 1.
- * Life expectancy of \> 6 months as estimated by the Investigator.
- * Any exposure to immune checkpoint inhibitor (ICIs) since the time of first being diagnosed with uveal melanoma.

ENROLLMENT CONTACT

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Total sites: 33 | 33 currently recruiting