

Doctor's Note — Clinical Trial Summary

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TRIAL

Study of RP2 Monotherapy and RP2 in Combination With Nivolumab in Patients With Solid Tumors

NCT ID: NCT04336241 Phase: PHASE1 Sponsor: Replimune Inc. Status: Active Not Recruiting

SUMMARY

RP2-001-18 is a Phase 1, multicenter, open label, single agent dose escalation and combination treatment study of RP2 in adult subjects with advanced solid tumors, to determine the maximum tolerated dose (MTD) and recommended Phase 2 dose (RP2D), as well as to evaluate preliminary efficacy.

KEY ELIGIBILITY CRITERIA

- * Willing and able to participate and comply with all trial requirements and able to provide signed and dated informed consent prior to initiation of any trial procedures
- * Male or Female e 18 years of age
- * Patients with advanced or metastatic non-neurological solid tumors, who have progressed on standard therapy or cannot tolerate standard therapy, or for which there is no standard therapy preferred to enrolment in a clinical trial
- * Consent to provide archival tumour biopsy samples within 6 months, or a fresh tumour biopsy is needed. Patients must also consent to provide on-treatment biopsies as per protocol
- * At least one measurable and injectable tumor of e 1 cm in longest diameter (or shorter diameter for lymph nodes).
- * Women of child-bearing potential (WOCBP) must have a negative urine pregnancy test at screening and a negative urine pregnancy test prior to administration of each dose of RP2 or nivolumab
- * WOCBP must agree to use adequate birth control throughout their participation and for 3 months after RP2 alone and 5 months after nivolumab last study treatment
- * Males with partners of child-bearing potential must agree to use adequate birth control throughout their participation and for 3 months for RP2 alone and 7 months after nivolumab last study treatment
- * Have laboratory values (obtained d 28 days prior to first infusion day) in accordance with the study protocol
- * Have an Eastern Cooperative Oncology Group (ECOG) performance status (PS) 0-1

Total sites: 6 | 0 currently recruiting