A Phase 1B/2 Study of RP1 in Solid Organ Transplant Patients With Advanced Cutaneous Malignancies

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Key

Inclusion Criteria:

1. Voluntary agreement to provide written informed consent prior to any study procedures and the willingness and ability to comply with all aspects of the protocol and understand the risk to their organ allograft. 2. Patients with histologically or cytologically confirmed recurrent, locally advanced or metastatic (to skin, soft tissue or lymph nodes) cutaneous malignancies, including CSCC, basal cell carcinoma, Merkel cell carcinoma, and melanoma 3. Patients must have progressed following local resection, prior radiation, topical or systemic therapies. 4. Documentation from the patient's transplant physician confirming that the patient's allograft is stable. 5. Patients for whom surgical or radiation treatment of lesions is contraindicated. 6. At least 1 lesion that is measurable and injectable by study criteria (tumor of ≥1cm in longest diameter or ≥1.5 cm in shortest diameter for lymph nodes). 7. Eastern Cooperative Oncology Group (ECOG) performance status ≤1. 8. Anticipated life expectancy \> 6 months 9. Baseline ECG without evidence of acute ischemia. 10. All patients must consent to provide archived or newly obtained tumor material (either formalin-fixed, paraffin-embedded \[FFPE\] block or 20 unstained slides). Key

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Exclusion Criteria:

1. Prior treatment with an oncolytic therapy. 2. Patients with visceral metastases. 3. Patients with active herpetic infections or prior complications of HSV-1 infection (e.g., herpetic keratitis or encephalitis). 4. Patients with a history of organ graft rejection within 12 months. 5. Had systemic infection requiring intravenous (IV) antibiotics or anti-virals, or other serious infection within 60 days prior to dosing. 6. Patients who require intermittent or chronic use of systemic (oral or intravenous) anti-virals with known anti-herpetic activity (e.g., acyclovir) unless for organ allograft preservation. 7. Patients requiring CTLA-4-Ig medications. 8. Ongoing or recent (within 5 years) evidence of significant autoimmune disease that required treatment with systemic immunosuppressive treatments beyond that required for maintenance allograft rejection prevention. The following are not exclusionary: vitiligo, childhood asthma that has resolved, type 1 diabetes, residual hypothyroidism that requires only hormone replacement, or psoriasis that does not require systemic treatment. 9. Active infection with hepatitis B virus (HBV), hepatitis C virus (HCV) or human immunodeficiency virus (HIV). 10. Any history of transplant-related viral infections, such as BKV, EBV or CMV, within 3 months of study entry. Patients with a history of hepatitis B or C virus must have undetectable viral load within 3 months of study entry. 11. Patients with a condition requiring an increase in the patient's usual immunosuppressive medications within 60 days of study treatment. 12. Known active CNS metastases and/or carcinomatous meningitis.

Conditions & Interventions

Interventions:

BIOLOGICAL: RP1, intra-tumoral injection, oncolytic virus

Conditions:

Cutaneous Squamous Cell Carcinoma, Merkel Cell Carcinoma, Basal Cell Carcinoma, Melanoma

More Information

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Phase: PHASE1

IRB

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