ARTACUS: AN OPEN-LABEL, MULTICENTER, PHASE 1B/2 STUDY OF RP1 IN SOLID ORGAN TRANSPLANT RECIPIENTS WITH ADVANCED CUTANEOUS MALIGNANCIES

1Jason Luke, 2Michael Miglen, 3Wanning Chi-Ho, 4Diana Bolotin, 5Trisha Wise-Daperer, 6Andrew Peklophovic, 7Douglas Lau, 8Meenal Khetepal, 9Claire Venslauregen, 10Frances Collichio, 11Jose Lutzky, 12Gregory Daniels, 13Katy Tsai, 14Susan Nivia, 15Henry Castro, 16Praveen Bommaraydy, 17Andrea Picklall, 18Robert Coffin, 19UPMC Hillman Cancer Center, Pittsburgh, PA, USA; 2University of Texas MD Anderson Cancer C, Houston, TX, USA; 3UCLA David Geffen School of Medicine, Los Angeles, USA; 4University of Chicago, Chicago, IL, USA; 5UC Vontz Center for Molecular Studies, Cincinnati, OH, USA; 6Virginia Commonwealth University, Richmond, MA, USA; 7University of Iowa Hospitals and Clinics, Iowa City, IA, USA; 8Duke University, Durham, NC, USA; 9Ohio State University Comprehensive Ctr, Columbus, OH, USA; 10UNC Chapel Hill, Chapel Hill, NC, USA; 11Sylvester Comprehensive Cancer Center, Miami, FL, USA; 12UC San Diego, La Jolla, CA, USA; 13University of California San Francisco, San Francisco, CA, USA; 14Replimune, Woburn, MA, USA

Background Solid organ transplantation (SOT) has emerged as an important lifesaving procedure for patients with a wide range of end-organ diseases characterized by dysfunction or specific organ function failure. SOT rejection is a major complication requiring patients to undergo lifelong immunosuppression to prevent allograft rejection. SKin cancers (SCs) including cutaneous squamous cell carcinoma (SCC) are common post transplant malignancies. SC in SOT pts is generally managed with surgical resection, radiation therapy and chemotherapy or targeted therapy. Use of immune checkpoint inhibitors in SOT recipients has improved outcomes but are associated with the high risk of allograft rejection. Thus, there is a high unmet need for a safe and effective treatment that also protects pts from allograft rejection. RP1 is an oncolytic virus (HSV-1) that expresses a fusogenic glycoprotein (GALV-GP R-) and granulocyte macrophage colony stimulating virus (HSV-1) that expresses a fusogenic glycoprotein.

Methods This study will enroll up to 65 evaluable allograft transplantation pts with locally advanced or metastatic SCs. Key inclusion criteria are pts with confirmed recurrent, locally advanced or metastatic CSCC and up to 10 pts with non-CSCC SC, stable allograft function and ECOG performance status of ≤1. Pts with prior systemic anti-cancer treatment are allowed. Key exclusion criteria are pts with oncology treatment, active herpetic infections or prior complications of HSV-1 infection and a history of organ graft rejection within 12 months. Pts will receive an initial dose of 1 x 10^6 plaque-forming units (PFU) of RP1. Two weeks later they will receive 1 x 10^7 PFU of RP1 and continue every two weeks until pre-specified study endpoints are met. RP1 will be administered by intra-tumoral injection including through imaging guidance as clinically appropriate. The primary objective of the trial is to assess efficacy determined by ORR and safety of single agent RP1. Additional secondary endpoints include DOR, CR, DCR, PFS and OS.

Trial Registration NCT04349436

REFERENCES

Ethics Approval The study was approved by institutional review board or the local ethics committee at each participating site. Informed consent was obtained from patients before participating in the trial.

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