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

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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 (pts) to undergo lifelong immunosuppression to prevent allograft rejection. Skin cancers (SCs) including cutaneous squamous cell carcinoma (CSCC) 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 factor (HSV-1) that protects pts from allograft rejection. RP1 is an oncolytic therapy, 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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