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 chemotheraphy 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 that also protects pts from allograft rejection. RP1 is an oncolytic immunotherapy platform based on herpes simplex virus type 1. RP1, an enhanced potency oncolytic HSV, combined with nivolumab: updated results from the skin cancer cohorts. J Immunother Cancer 2020;8(3): doi: http://dx.doi.org/10.1136/jitc-2020-SITC2020.0422

Methods This study will enroll up to 65 evaluable allograft recipients with advanced cutaneous malignant neoplasms. 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 prior systemic anti-cancer treatment. Analysis of HPV-1 infection and a history of organ graft rejection. 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 (GM-CSF). In preclinical studies, RP1 induced immunogenic cell death and potent antitumor activity and clinical data in combination with nivolumab has demonstrated a high rate of deep and durable response in patients with advanced SCs.

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.

http://dx.doi.org/10.1136/jitc-2021-SITC2021.550