Background RP1 is an enhanced potency oncolytic HSV-1 which expresses a fusogenic glycoprotein (GALV-GP R-) and granulocyte macrophage colony stimulating factor (GM-CSF). In pre-clinical studies, RP1 demonstrated potent GALV-GP R-enhanced anti-tumor activity and immunogenic cell death. This Phase 1/2 (Ph 1/2) study was designed to evaluate the safety and efficacy of RP1 ± nivolumab (nivo) in patients (pts) with advanced solid tumors, including pts whose disease failed prior anti-PD-1/PD-L1 therapy and has reported promising interim data in a number of tumor types including cutaneous squamous cell carcinoma (CSCC) and anti-PD1 failed melanoma to date.

Methods This is a multi-center, first-in-human, open label, multi-cohort, non-randomized Ph1 study of RP1 alone and combined with nivo followed by Ph2 in combination with nivo in pts with recurrent advanced solid tumors including those that progressed after prior anti-PD-1/PD-L1 therapy. The Ph 1 monotherapy dose escalation (n=14) and RP-1 combination expansion (n=22) cohorts are fully enrolled. Approximately 260 pts are expected to be enrolled in the ongoing Ph 2 portion across five cohorts; melanoma (n=30, enrollment complete), non-melanoma skin cancer (n=45, to include 15 pts with anti-PD-1/PD-L1 failed disease), anti-PD-1 failed small-cell lung cancer (n=30) and a registration-directed multi-cohort, non-randomized Ph1 study of RP1 alone and combination with nivo followed by Ph2 in combination with nivo in patients (pts) with advanced solid tumors, including pts whose disease failed prior anti-PD-1/PD-L1 therapy and has reported promising interim data in a number of tumor types including cutaneous squamous cell carcinoma (CSCC) and anti-PD1 failed melanoma to date.2

Ethics Approval The study was approved by institutional review board or the local ethics committee at each site. Informed consent was obtained from patients prior to enrollment.