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A Phase 1 Trial of the Oncolytic Virus SVV-001 with Nivolumab and Ipilimumab in Patients with High Grade Neuroendocrine Neoplasms.

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BACKGROUND

High-grade neuroendocrine neoplasms (NENs), including poorly differentiated neuroendocrine carcinomas (NECs) and well-differentiated grade 3 neuroendocrine tumors (NETs), are aggressive malignancies with limited effective treatment options. Immune checkpoint inhibitors (ICIs) have demonstrated limited clinical activity in these tumors. Seneca Valley Virus (SVV-001) is a novel oncolytic RNA virus that has shown synergistic activity with ICIs in preclinical models. Additionally, SVV-001 has been observed to reverse CPI resistance in vivo, supporting its evaluation in combination with nivolumab and ipilimumab.

METHODS

This is an investigator-initiated, phase 1, dose-escalation and cohort-expansion study evaluating intratumoral SVV-001 in combination with nivolumab and ipilimumab in patients with histologically confirmed poorly differentiated NEC or well-differentiated grade 3 NET. The trial was activated in March 2025, with patient enrollment currently ongoing and a target of up to 36 patients. A standard 3+3 dose-escalation design is being employed to determine the recommended phase 2 dose (RP2D). Following dose escalation, an expansion cohort will further evaluate safety and preliminary signals of activity. Tumor endothelial marker 8 (TEM8), a potential biomarker of SVV-001 sensitivity, will be assessed as part of correlative studies. NCT06889493

RESULTS

This Phase 1 trial is active at University of Miami and plans to expand the trial to other cancer centers in the US.

CONCLUSIONS

N/A

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