Seneca Therapeutics Announces the Dosing of the First Patient in the SVV-001 Phase I/II Trial

Trial to Demonstrate Safety and Preliminary Efficacy
with Poorly Differentiated Neuroendocrine Carcinomas or
High-Grade (Grade 3) Neuroendocrine Tumors

PHILADELPHIA, PA, UNITED STATES, May 27, 2025 /EINPresswire.com/ -- Seneca Therapeutics announced today the dosing of the first patient in the SVV-001 Phase I/II clinical trial in high grade neuroendocrine neoplasms.

The Phase I/II trial will assess the safety and preliminary efficacy of Seneca Valley Virus (SVV-001) in combination with the checkpoint inhibitors nivolumab and ipilimumab in the treatment of high-grade neuroendocrine neoplasms. The trial will be conducted at one of the leading NCI designated cancer centers in the United States. It will enroll 21-30 patients in three single ascending dose (SAD) cohorts and three multiple ascending dose (MAD) cohorts. The trial is anticipated to take 12-18 months to complete.

“We are very excited about the initiation of this trial,” said Dr. Paul Hallenbeck, President and Chief Scientific Officer at Seneca Therapeutics. “Unfortunately, this patient population has cancers that don’t respond well with checkpoint inhibitors as they are usually devoid of T cells within the tumor (referred to as cold tumors) that are necessary for effective therapy with checkpoint inhibitors. SVV-001 has shown the ability to turn these tumors ‘hot’ and increase the response to standard of care in preclinical studies. We believe that this trial’s combination of SVV-001 with nivolumab and ipilimumab should demonstrate higher response rates. The receptor of SVV-001, tumor endothelial marker 8 (TEM8), is a tumor-specific antigen that is expressed by many solid tumors, and studies have shown that high expression of TEM8 lowers survival across a number of solid tumor indications, including small cell lung cancer (a high-grade neuroendocrine neoplasm), bladder cancer, cervical cancer, breast cancer, and gastric cancer. High-grade neuroendocrine tumors and carcinomas are difficult to treat, and the objective response rates to treatment typically range from 5% to 20%.

SVV-001 selectively binds to TEM8 expressed by tumor cells, infects and kills these cells, and elicits a systemic anti-tumor immune response. A wealth of pre-clinical data, epidemiology studies, and all three prior clinical trials have shown that SVV-001 does not infect any normal human cells. SVV-001 is being developed as a TEM8 therapeutic with the aim of enhancing response rate and survival. In preclinical studies, SVV-001 administered in conjunction with

nivolumab and ipilimumab eradicated the tumors, induced a systemic anti-tumor immune response, and dramatically extended survival. This Phase I/II trial hopes to replicate the preclinical data in patients with high-grade neuroendocrine tumors and carcinomas.

About Seneca Therapeutics
Seneca Therapeutics is a clinical stage company developing SVV-001 for various tumor types. SVV-001 has been shown to selectively bind TEM8, and specifically infect and kill these cells. TEM8 is an important emerging cancer marker expressed by the majority of solid tumors. The presence of TEM8 has been shown to render tumors resistant to treatments and dramatically shorten survival. Three prior clinical trials observed no toxicities when patients were given a single dose of SVV-001 delivered via systemic intravenous administration. The company has initiated a Phase I/II to evaluate the safety and efficacy of multiple doses of SVV-001 in combination with standard of care to treat patients with high-grade neuroendocrine tumors and carcinomas. Additional indications are anticipated

Forward-Looking Statements
This press release contains “forward-looking statements” concerning the development of Seneca Therapeutics products, the potential benefits and attributes of those products, and the company’s expectations regarding its prospects. Forward-looking statements are subject to risks, assumptions and uncertainties that could cause actual future events or results to differ materially from such statements. These statements are made as of the date of this press release. Actual results may vary. Seneca Therapeutics undertakes no obligation to update any forward-looking statements for any reason.

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