

Seneca Therapeutics Announces the Closing of \$3.9 million Series B Extension Round

Funding Provides 2+ Years Runway to Complete Phase I/II Trial of Seneca Vally Virus (SVV-001) Currently Underway in High-Grade Neuroendocrine Neoplasms

PHILADELPHIA, PA, UNITED STATES, August 28, 2025 /EINPresswire.com/ -- Seneca Therapeutics, Inc., announced today the closing of its \$3.9 million Series B Extension Round.

"We are excited about this raise, which provides the Company sufficient cash through 2027 and allows us to advance our goal of developing revolutionary treatments for solid tumors," said Cuong Do, Executive Chairman at Seneca Therapeutics. "This will provide funding to complete our currently enrolling Phase I/II trial of SVV-001 in high-grade neuroendocrine neoplasms."

The currently underway Phase I/II trial of SVV-001 (NCT06889493) will assess the safety and preliminary efficacy of SVV-001 in combination with the checkpoint inhibitors nivolumab and ipilimumab for the treatment of high-grade neuroendocrine neoplasms. The trial will enroll 21-30 patients in three single-ascending dose cohorts and two multiple-ascending dose cohorts. A 15-patient expansion cohort is also planned. The trial is anticipated to take 12-18 months to complete.

"Patients with high-grade neuroendocrine neoplasm don't respond well to checkpoint inhibitor immunotherapies as these cancers are usually devoid of T-cells within the tumor environment – referred to as cold tumors – that are necessary for effective treatment," said Dr. Paul Hallenbeck, President and Chief Scientific Officer at Seneca Therapeutics. "In pre-clinical studies, SVV-001 has shown the ability to draw in T-cells into the tumors thus making the cold tumors 'hot' and increase the response to checkpoint inhibitors and stimulating an anti-tumor immune response. We believe that by combining SVV-001 with dual checkpoint blockade of nivolumab and ipilimumab, we will enhance anti-tumor immunity and observe higher response rates."

The receptor of SVV-001, tumor endothelial marker 8 (TEM8), is a protein that is expressed by many solid tumors, and studies have shown that the high expression of TEM8 lowers survival rates 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 three prior clinical trials have shown that SVV-001 infection is highly specific to solid cancer 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 tumors, induced a systemic anti-tumor immune response, and dramatically extended survival. This Phase I/II trial aims to replicate the preclinical data in patients with high-grade neuroendocrine tumors and carcinomas.

About Seneca Therapeutics

Seneca Therapeutics was founded to capitalize on the profound tumor specificity of SVV-001 and its binding specificity to TEM8, an important emerging cancer marker expressed in the majority of solid tumors. A SVV-001 Phase I/II trial recently started to further the clinical development of SVV-001. We anticipate initial data read out from this clinical trial in the second half of 2026 or first half of 2027.

The Company has also developed an SVV-001 Companion Diagnostic that can identify patients whose tumor expresses TEM8 and may be susceptible to SVV-001 treatment. The Company is in the process of validating the diagnostic to be used in future clinical trials to identify patients that would benefit from SVV-001. Learn more at www.senecatherapeutics.com.

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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