Vigil Neuroscience Highlights 2024 Corporate Achievements and Upcoming 2025 Milestones

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– On track to report data from Phase 1 clinical trial evaluating VG-3927 for the treatment of Alzheimer's disease in 1Q 2025 –

– Final analysis from IGNITE Phase 2 clinical trial evaluating iluzanebart in ALSP planned for 2Q 2025 –

– Company well-positioned for continued operational progress in 2025 –

WATERTOWN, Mass., Jan. 08, 2025 (GLOBE NEWSWIRE) -- Vigil Neuroscience, Inc. (Nasdaq: VIGL), a clinical-stage biotechnology company committed to harnessing the power of microglia for the treatment of neurodegenerative diseases, today highlighted 2024 corporate achievements and upcoming 2025 milestones.

"2024 was a year of strong operational execution, driven by the progress of our two TREM2 agonist programs, VG-3927 and iluzanebart, and a $40 million strategic investment from Sanofi," said Ivana Magovčević-Liebisch, Ph.D., J.D., President and Chief Executive Officer of Vigil. "Advancing these clinical programs requires both strong science and commitment, and we remain focused on delivering Phase 1 data on VG-3927 in the first quarter of 2025, and Phase 2 data on iluzanebart in the second quarter of 2025, both of which represent meaningful milestones for expanding our scientific insights and developing these programs into potential therapeutics."

2024 Key Achievements

Iluzanebart, Monoclonal Antibody TREM2 Agonist:

- Announced clinical development strategy update following Type C Meeting with U.S. Food and Drug Administration (FDA) where the Agency stated it was open to considering the accelerated approval pathway for iluzanebart in ALSP.
- Completed enrollment of 20 patients for IGNITE Phase 2 clinical trial, exceeding the initially planned 15 patients.
- Surpassed enrollment of 50 participants in ILLUMINATE natural history study of ALSP. Findings from ILLUMINATE have provided critical insights on MRI and NfL biomarkers and continue to improve the overall understanding of ALSP disease pathophysiology and progression.

VG-3927, Small Molecule TREM2 Agonist:

- Reported interim data from the ongoing Phase 1 clinical trial evaluating VG-3927 in healthy volunteers. These data demonstrated the safety, tolerability, pharmacokinetic, and pharmacodynamic profile supported continued clinical development. Initiated dosing of an Alzheimer's disease (AD) cohort in the ongoing Phase 1 clinical trial, including some participants who carry TREM2 or other disease-related variants, to explore the biomarker response of VG-3927 after a single dose.
- FDA removed the partial clinical hold on the Phase 1 clinical trial of VG-3927 based on a complete response submitted by the Company.
- Presented new preclinical data on the small molecule TREM2 agonist program at the Alzheimer's Association International Conference (AAIC) that highlighted its differentiated mechanism of action compared with antibody TREM2 agonists. These data demonstrated that Vigil's small molecules, including VG-3927, are fully brain penetrant, do not bind to sTREM2 resulting in more drug reaching the target, and also act as a positive allosteric modulator (PAM) which amplifies the functional response within sites of pathology leading to greater horsepower for superior neuroprotection.

Corporate:

- Secured a $40 million strategic investment from Sanofi to fund research and development activities. In connection with the equity investment, Vigil granted Sanofi the right of first negotiation (ROFN) for an exclusive license, grant or transfer of rights to research, develop, manufacture and commercialize the Company's small molecule TREM2 agonist program, including its clinical candidate, VG-3927.
- Appointed Petra Kaufmann, M.D., M.S., F.A.A.N, as Chief Medical Officer to lead the Company's clinical, regulatory, and patient advocacy efforts.

2025 Milestones

- On track to report data in the first quarter of 2025 from the Phase 1 clinical trial of VG-3927, including single-ascending and multiple-ascending dose data from healthy volunteers, data from a single cohort of AD patients and data from an elderly patient cohort. Vigil expects to use these data to inform the development strategy for subsequent and larger trials evaluating VG-3927 in AD.
- Final analysis from the IGNITE Phase 2 clinical trial, including all patients at 12 months dosed with either 20 mg/kg or 40 mg/kg of iluzanebart, is planned for the second quarter of 2025. The Company will pursue an accelerated approval pathway for iluzanebart in ALSP and expects to share an update on its progress when the final analysis is reported.

“Building on the momentum from 2024, we plan to report key data for both VG-3927 and iluzanebart in the first half of 2025. We expect these development milestones will further support our efforts to bring potentially transformative therapies to patients with ALSP and AD,” concluded Dr. Magovčević-Liebisch. “Looking ahead, we aim to leverage our deep expertise in microglial biology to explore additional targets to treat other rare and common neurodegenerative diseases.”

About Vigil Neuroscience

Vigil Neuroscience is a clinical-stage biotechnology company focused on developing treatments for both rare and common neurodegenerative diseases by restoring the vigilance of microglia, the sentinel immune cells of the brain. Vigil is utilizing the tools of modern neuroscience drug development across multiple therapeutic modalities in its efforts to develop precision-based therapies to improve the lives of patients and their families. Iluzanebart, Vigil’s lead clinical candidate, is a fully human monoclonal antibody agonist targeting human triggering receptor expressed on myeloid cells 2 (TREM2) in people with adult-onset leukoencephalopathy with axonal spheroids and pigmented glia (ALSP), a rare and fatal neurodegenerative disease. Vigil is also developing VG-3927, a novel small molecule TREM2 agonist, to treat common neurodegenerative diseases associated with microglial dysfunction, with an initial focus on Alzheimer’s disease (AD) patients, including some who carry TREM2 and other disease-associated variants.

Forward-Looking Statements

This press release includes certain disclosures that contain “forward-looking statements” of Vigil Neuroscience (“Vigil” or the “Company”) that are made pursuant to the safe harbor provisions of the federal securities laws, including, without limitation, express or implied statements regarding: the Company’s strategy, business plans and focus; the potential therapeutic benefit of the Company’s product candidates, including iluzanebart and VG-3927, and the expected therapeutic benefits of such programs as well as the ability to improve the lives of patients and their families; the progress and timing of the clinical development of Vigil’s programs, including the availability of, and expected timing for reporting, data from both the IGNITE Phase 2 clinical trial and the VG-3927 Phase 1 clinical trial; beliefs about observations made analyzing preclinical study and clinical trial data to date; and the timing and outcomes of the Company’s interactions with regulatory authorities, including with the FDA regarding the accelerated approval pathway. Forward-looking statements are based on Vigil’s current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict. Factors that could cause actual results to differ include, but are not limited to, risks and uncertainties related to uncertainties inherent in the development of product candidates, including the conduct of research activities and the conduct of clinical trials; uncertainties as to the availability and timing of results and data from clinical trials; whether results from prior preclinical studies and clinical trials will be predictive of the results of subsequent preclinical studies and clinical trials; and the timing and content of additional regulatory information from the FDA; as well as the risks and uncertainties identified in the Company’s filings with the Securities and Exchange Commission (SEC), including Vigil’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 and any subsequent filings Vigil makes with the SEC. Forward-looking statements contained in this announcement are made as of this date, and Vigil undertakes no duty to update such information except as required under applicable law. Readers should not rely upon the information on this page as current or accurate after its publication date.

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