Vigil Neuroscience Provides 2023 Year-in-Review and Highlights Upcoming 2024 Milestones

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- On track to report interim Phase 1 data for VG-3927 in healthy volunteers in mid-2024 and Phase 2 results from IGNITE clinical trial evaluating iluzanebart in ALSP in Q3 2024 -

- Extends projected cash runway into second half of 2025 -

- Company to present at J.P. Morgan Healthcare Conference on January 11, 2024 at 7:30 a.m. PT/10:30 a.m. ET -

WATERTOWN, Mass., Jan. 03, 2024 (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 provided a 2023 year-in-review and outlined key milestones anticipated in 2024. The Company also today announced that it has extended its projected cash runway into the second half of 2025.

“2023 marked a year of persistent advancement and landmark achievements for the Company,” said Ivana Magovčević-Liebisch, Ph.D., J.D., President and Chief Executive Officer of Vigil. “Most notably, we were the first company to demonstrate clinical data supporting TREM2 agonism as a potential therapeutic approach in neurodegenerative disease. We accomplished another first when we commenced dosing in our Phase 1 healthy volunteer clinical trial evaluating VG-3927, the only small molecule TREM2 agonist in the clinic for the potential treatment of Alzheimer’s disease.”

Key Clinical Program Highlights for 2023

Iluzanebart (VGL101): A fully human monoclonal antibody candidate targeting human triggering receptor expressed on myeloid cells 2 (TREM2)

- Completed Phase 1 clinical trial of iluzanebart and reported data from single and multiple ascending dose (SAD and MAD) cohorts in healthy volunteers, which demonstrated that iluzanebart continued to have a favorable safety and tolerability profile and showed proof-of-target engagement in SAD/MAD cohorts up to 60 mg/kg.
- Granted orphan drug designation for iluzanebart from the European Commission for the treatment of colony stimulating factor 1 receptor (CSF1R)-related leukoencephalopathy, which includes ALSP.
- Reported positive interim data from Phase 2 IGNITE proof-of-concept clinical trial of iluzanebart in ALSP. These data highlighted a favorable safety and tolerability profile and demonstrated clear CNS target engagement and downstream pharmacological activity and directionally supportive changes in individual patients at 6 months on magnetic resonance imaging (MRI) and neurofilament light chain (NfL) biomarkers.
- Reported findings from its ongoing natural history study, ILLUMINATE, which continued to provide critical insights on MRI and NfL biomarkers and support soluble CSF1R (sCSF1R) as a potential key biomarker of ALSP disease pathology.
- Based on the totality of the data reported in 2023 from the ILLUMINATE and IGNITE studies, the Company plans to engage with the U.S. Food and Drug Administration (FDA) in the first half of 2024 regarding a potential accelerated development pathway for iluzanebart in ALSP.

VG-3927: A highly active, selective, and brain-penetrant small molecule TREM2 agonist

- Received notification from the FDA that the Investigational New Drug (IND) application for VG-3927 was open and the Phase 1 clinical trial evaluating VG-3927 in healthy volunteers was allowed to proceed with a partial clinical hold related to maximum exposure limit. The Company is in the process of obtaining additional PK data and will work with the FDA to address the partial clinical hold. Based on preclinical studies, the Company believes that the maximum exposure limit exceeds the predicted efficacious dose of VG-3927.
- Dosed its first participant in the Phase 1 clinical trial of VG-3927 in healthy volunteers, making it the first and only small molecule TREM2 agonist in the clinic for the potential treatment of Alzheimer’s disease.

Key Corporate Highlights for 2023

- Launched ALSPAware, a new program providing no-cost genetic testing and counseling services for the diagnosis of ALSP.

Corporate Update & 2024 Anticipated Milestones

- The Company has extended its projected cash runway into the second half of 2025 by focusing its financial resources on

current business priorities, including its iluzanebart and VG-3927 clinical development programs. The Company's reallocation of capital is not expected to have any impact on employee headcount or anticipated development milestones.

- Vigil is on track to report interim data from the ongoing Phase 1 clinical trial of VG-3927 in healthy volunteers in mid-2024.
- The Company expects to report Phase 2 results from its IGNITE clinical trial evaluating iluzanebart in ALSP from all patients (n=15) at 6 months at both 20 mg/kg and 40 mg/kg doses in the third quarter of 2024.

"We enter 2024 well-positioned to achieve our planned value-driving milestones across our development pipeline," concluded Dr. Magovčević-Liebisch. "We are confident in our ability to continue executing on our precision medicine strategy while thoughtfully allocating financial resources to best support our current development programs and our commitment to our patient communities."

J.P. Morgan Healthcare Conference Details

The Company today announced that Dr. Magovčević-Liebisch will present at the 42nd Annual J.P. Morgan Healthcare Conference on Thursday, January 11, 2024, at 7:30 a.m. PT / 10:30 a.m. ET.

To register for the live event, please click here. The live webcast will also be available on the Company's website on the "Events & Presentations" page in the "Investors" section. An archived webcast will be available for approximately 90 days following the presentation.

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) in genetically defined subpopulations.

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 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; expectations regarding the VG-3927 partial clinical hold; beliefs that the maximum exposure limit for VG-3927 exceeds the predicted efficacious dose; the success and timing of the Company's interactions with regulatory authorities; beliefs about the ability of the Company to execute on strategy and efficiently allocate financial resources and extend the Company's cash runway into the second half of 2025. 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 identification and 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 preclinical studies and clinical trials will be predictive of the results of later preclinical studies and clinical trials; the timing and content of additional regulatory information from the FDA; the Company's ability to work with the FDA to successfully remove the partial clinical hold on VG-3927; whether Vigil's cash resources will be sufficient to fund its foreseeable and unforeseeable operating expenses and capital expenditure requirements; 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, 2023 and in 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.

Internet Posting of Information

Vigil Neuroscience routinely posts information that may be important to investors in the 'Investors' section of its website at https://www.vigilneuro.com. The company encourages investors and potential investors to consult our website regularly for important information about Vigil Neuroscience.

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