Vigil Neuroscience Provides Update on Clinical Development Strategy to Pursue Potential Accelerated Approval Pathway for Iluzanebart in ALSP

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WATERTOWN, Mass., July 18, 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, announced today an update following a Type C Meeting with the U.S. Food and Drug Administration (FDA) to its clinical development strategy for its IGNITE clinical trial evaluating iluzanebart in people with adult-onset leukoencephalopathy with axonal spheroids and pigmented glia (ALSP).

“We are updating our clinical development strategy to preserve the IGNITE dataset for a final analysis at 12 months, which we believe provides the best opportunity to leverage our biomarker strategy and to pursue the potential accelerated approval pathway. As part of this strategy, we will not conduct an interim analysis prior to the study completion,” said Ivana Magovčević-Liebisch, Ph.D., J.D., President and Chief Executive Officer of Vigil. “This follows a Type C meeting with the FDA where the Agency stated that it was open to considering the accelerated approval pathway and that we should provide additional data to support our proposed development plan. We look forward to continuing to engage with the FDA as we work to bring this potential therapy to patients in need as quickly as possible.”

The Company plans to report the final analysis from the IGNITE clinical trial, including all patients at 12 months dosed with either 20 mg/kg or 40 mg/kg of iluzanebart in the first half of 2025.

About IGNITE Clinical Trial

IGNITE is a global Phase 2 clinical trial to evaluate iluzanebart as a treatment for symptomatic ALSP patients who have a confirmed *CSF1R* gene mutation. Patients enrolled in the trial receive an intravenous (IV) infusion of iluzanebart at 20 mg/kg or 40 mg/kg approximately every four weeks for a treatment duration of one year. The trial is evaluating safety, biomarker endpoints, including magnetic resonance imaging (MRI) and neurofilament light chain (NfL), and clinical endpoints using standard cognitive, motor and functional assessments.

About Iluzanebart

Iluzanebart, Vigil’s lead clinical candidate, is a fully human monoclonal antibody targeting human triggering receptor expressed on myeloid cells 2 (TREM2), which is responsible for maintaining microglial cell function. TREM2 deficiency is believed to be a driver of certain neurodegenerative diseases. Iluzanebart is in development for rare microgliopathies, such as ALSP, as well as other neurodegenerative diseases for which TREM2 and/or microglia deficiency is believed to be a key driver of disease pathway.

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 potential therapeutic benefit of iluzanebart, beliefs about observations made analyzing preclinical study and clinical trial data to date; our ability to advance the clinical development of iluzanebart; the progress and timing of the clinical development of Vigil’s programs, including the availability of, and expected timing for reporting, final data from the IGNITE Phase 2 clinical trial; and the success and timing 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; 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; 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 March 31, 2024 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.

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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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