**Vigil Neuroscience Receives Positive Opinion from European Medicines Agency on Orphan Drug Designation for VGL101 for the Treatment of ALSP**

Sep 26, 2023

WATERTOWN, Mass., Sept. 26, 2023 (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 announced that the Committee for Orphan Medicinal Products (COMP) of the European Medicines Agency (EMA) has issued a positive opinion on the Company’s application for orphan drug designation for VGL101 for the treatment of CSF1R-related leukoencephalopathy, which includes adult-onset leukoencephalopathy with axonal spheroids and pigmented glia (ALSP). The Company is currently evaluating VGL101 in a Phase 2 proof-of-concept trial in patients with ALSP. VGL101 was previously granted orphan drug designation by the U.S. Food and Drug Administration for ALSP in July 2022.

“Receiving a positive opinion for orphan drug designation for VGL101 in the EU is a tremendous achievement in our efforts to develop a therapy for individuals living with ALSP, which affects approximately 13,000 people in the EU,” said Ivana Magovčević-Liebisch, Ph.D., J.D., President and Chief Executive Officer of Vigil. “ALSP is a rare and rapidly progressive neurodegenerative disease with no approved treatment. We are committed to advancing our program through clinical development and bringing this potentially transformative therapy to these patients as quickly as possible.”

The EMA may grant orphan drug designation based on a positive opinion issued by the COMP. The EMAs orphan drug designation is available to sponsors developing therapies that aim to treat or prevent rare, life-threatening or chronically debilitating conditions that affect no more than five in 10,000 people in the EU, and for which no treatment is approved. Medicines that meet the EMAs orphan drug designation criteria qualify for certain benefits, such as reduced regulatory fees, protocol assistance, research grants, and, subject to obtaining and maintaining orphan medicine status, up to ten years of market exclusivity in the EU upon approval.

**About the Phase 2 IGNITE Trial**
The Company’s ongoing Phase 2 IGNITE trial is a global, open-label clinical trial evaluating VGL101 in approximately 15 patients with symptomatic ALSP who have a confirmed CSF1R gene mutation. As part of the protocol, patients will receive an intravenous (IV) infusion of VGL101 at 20 mg/kg or 40 mg/kg approximately every four weeks, for a treatment duration of one year. The primary objective of the IGNITE trial is to evaluate the safety and tolerability of VGL101. Secondary objectives include evaluating the impact of VGL101 on magnetic resonance imaging (MRI) and its pharmacodynamic effect on fluid biomarkers in patients with symptomatic ALSP. Clinical efficacy outcome measures are also being collected as exploratory endpoints. In the fourth quarter of 2023, the Company expects to report interim 6-month data from the IGNITE trial in the first 6 patients who have received 20 mg/kg of VGL101.

**About VGL101**
VGL101, Vigil’s lead product 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. VGL101 is in development for rare microglialopathies, 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 ALSP**
ALSP is a rare, inherited, autosomal dominant neurological disease with high penetrance. It is caused by a mutation to the CSF1R gene and affects an estimated 10,000 people in the US, with similar prevalence in Europe and Japan. The disease generally presents in adults in their forties, is diagnosed through genetic testing and established clinical/radiologic criteria and is characterized by cognitive dysfunction, neuropsychiatric symptoms, and motor impairment. These symptoms typically exhibit rapid progression with a life expectancy of approximately six to seven years on average after diagnosis, causing significant patient and caregiver burden. There are currently no approved therapies for the treatment of ALSP, underlining the high unmet need in this rare indication.

**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. We are utilizing the tools of modern neuroscience drug development across multiple therapeutic modalities in our efforts to develop precision-based therapies to improve the lives of patients and their families. VGL101, our 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. We are 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, Inc.’s ("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 progress and timing of the clinical development of Vigil’s programs, including VGL101 and the potential impact of the positive opinion of the Committee for Orphan Medicinal Products on such programs. 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 that are inherent in clinical stage therapeutic development; risks and uncertainties as to whether the Company will obtain and maintain orphan medicinal product designation in the E.U., the receipt of such designation may not speed the development or any potential marketing authorization of Vigil’s therapies, or determine if Vigil ultimately is able to obtain and maintain a period of E.U. orphan medicinal product market...
exclusivity; 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 June 30, 2023 and in any subsequent filings it may make 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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