Vigil Neuroscience Receives FDA Fast Track Designation for VGL101 for the Treatment of Patients with ALSP

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CAMBRIDGE, Mass., Nov. 01, 2022 (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 U.S. Food and Drug Administration (FDA) has granted Fast Track designation to VGL101 for the treatment of patients with adult-onset leukoencephalopathy with axonal spheroids and pigmented glia (ALSP). VGL101, Vigil’s lead product candidate, is a monoclonal antibody TREM2 agonist currently being evaluated in a Phase 1 trial in healthy volunteers.

“ALSP is a devastating disease that affects an estimated 10,000 people in the US with no approved treatments. We believe this Fast Track designation by the FDA recognizes the significant unmet need of ALSP patients and the therapeutic potential of VGL101,” said Ivana Magovčević-Liebisch, Ph.D., J.D., President and Chief Executive Officer of Vigil. “We are excited about the progress we’ve made in advancing VGL101 and we remain on track to report Phase 1 topline data and to initiate a Phase 2 proof-of-concept trial for VGL101 in ALSP this quarter.”

Fast Track designation is designed to facilitate development and expedite the review of therapies for serious conditions, such as ALSP, and fill an unmet medical need. Programs with Fast Track designation may benefit from early and frequent communications with the FDA as well as the potential for priority review and a rolling submission of the marketing application.

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 the treatment of 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, microglia-focused therapeutics 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.

Forward-Looking Statements
This press release includes certain disclosures that contain “forward-looking statements” of Vigil Neuroscience’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 addressable market for VGL101; the progress and timing of the preclinical and clinical development of Vigil’s programs, including the availability of data and expected timing for reporting data from the VGL101 Phase 1 trial, the initiation of its Phase 2 proof-of-concept trial in the fourth quarter of 2022; the belief that Fast Track designation recognizes the significant unmet need of ALSP patients and the therapeutic potential of VGL101; beliefs about the opportunity for early and frequent communications with the FDA as well as the potential for priority review and a rolling submission of the marketing application; and expectations regarding the development of VGL101 in ALSP and other indications. 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 initiation and completion of preclinical studies and clinical trials; uncertainties as to the availability and timing of results and data from preclinical and clinical studies; the timing of the Company’s ability to submit and obtain regulatory clearance for investigational new drug applications and initiate additional clinical trials; whether results from preclinical studies will be predictive of the results of later preclinical studies and clinical trials; the Company’s ability to initiate and complete its current and expected clinical trials and its ability to work with the FDA to successfully remove the partial clinical hold; whether Vigil’s cash resources will be sufficient to fund its foreseeable and unforeseeable operating expenses and capital expenditure requirements; uncertainties associated with the impact of the COVID-19 pandemic on its business and operations; as well as the risks and uncertainties identified in the Company’s filings with the Securities and Exchange Commission (SEC), including Vigil’s IPO registration statement, its Annual Report on Form 10-K for the year ended December 31, 2021, its Quarterly Report on Form 10-Q for the six months ended June 30, 2022 and in any subsequent filings it may make with the SEC, including its Quarterly Report on Form 10-Q for the nine months ended September 30, 2022. 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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