Vigil Neuroscience Announces FDA Has Removed Partial Clinical Hold on VG-3927

Sep 17, 2024

WATERTOWN, Mass., Sept. 17, 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 announced that the U.S. Food and Drug Administration (FDA) has removed the partial clinical hold on its ongoing Phase 1 clinical trial of VG-3927. The FDA's decision was based on a complete response submitted by the Company.

"We are pleased with the resolution of the partial clinical hold – a decision that was supported by non-clinical and clinical data from our ongoing Phase 1 trial," said Petra Kaufmann, M.D., F.A.A.N., Chief Medical Officer at Vigil. "While the partial clinical hold did not delay clinical development of VG-3927, the option to increase the exposure limit provides us the best opportunity to explore the full pharmacology of VG-3927 as a potentially novel, next generation therapy for those living with Alzheimer's disease."

In July 2024, the Company reported interim data from the ongoing Phase 1 single- and multiple-ascending dose clinical trial evaluating VG-3927 in healthy volunteers. These data showed that the safety and tolerability profile observed in individual doses in six SAD and two MAD cohorts supported continued clinical development of VG-3927. In addition, VG-3927 demonstrated a predictable PK profile supportive of once-daily dosing. Importantly, VG-3927 achieved a robust and sustained decrease of soluble TREM2 in the CSF demonstrating clinical proof-of-target engagement. VG-3927 also showed an increase in osteopontin/secreted phosphoprotein 1 (SPP1) after repeat dosing.

As part of the Phase 1 clinical trial, the Company has initiated dosing of a cohort of Alzheimer's disease (AD) patients, including some participants who carry TREM2 or other disease-related variants to explore the biomarker response of VG-3927 after a single dose. Vigil expects to use these data to inform the development strategy for subsequent and larger trials evaluating VG-3927 in AD. The Company plans to report the complete Phase 1 clinical data, including data from the AD patient cohort, in the first quarter of 2025.

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: Vigil's strategy, business plans and focus; the potential therapeutic benefit of our product candidates, including VG-3927, and the expected therapeutic benefits of such programs; the timing, availability and utility of the complete Phase 1 clinical data from VG-3927's Phase 1 clinical trial, and Vigil's plans for further evaluation of the pharmacology of VG-3927. 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 clinical trials; whether results from preclinical studies and clinical trials will be predictive of the results of later preclinical studies and clinical trials; whether interim data results and analysis will be predictive of complete data results and analysis; 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, 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.

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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