



## **Vigil Neuroscience Announces Update on its Small Molecule TREM2 Agonist Program**

Sep 08, 2023

- *Announced VG-3927 as lead candidate to enter clinical development for potential treatment of Alzheimer's Disease -*
- *IND for VG-3927 now open; Phase 1 clinical trial in healthy volunteers allowed to proceed with partial clinical hold related to maximum exposure limit -*
- *Phase 1 dosing expected to commence in October 2023; No anticipated delays in current clinical development plans -*
- *Company to host virtual R&D event highlighting its small molecule TREM2 agonist program on September 13, 2023 -*

**WATERTOWN, Mass., September 8, 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 it has received notification from the U.S. Food and Drug Administration (FDA) regarding its Investigational New Drug (IND) application to evaluate the Company's oral small molecule TREM2 agonist VG-3927. The IND for VG-3927 is now open and the Company's Phase 1 clinical trial in healthy volunteers is allowed to proceed with a partial clinical hold related to maximum exposure limit. At this time, the Company does not anticipate any delay in the current clinical development plans for VG-3927 and expects to commence dosing of the Phase 1 trial evaluating VG-3927 in healthy volunteers in October 2023.

Per the notification, the FDA has limited the maximum exposure of VG-3927 in healthy volunteers in the planned Phase 1 clinical trial. Based on preclinical studies, the Company believes that the maximum exposure limit exceeds the predicted efficacious dose of VG-3927. From the initial comments received from the FDA, the Company believes that the partial clinical hold was not a result of any preclinical toxicology findings or TREM2 pharmacology. The Company expects to receive additional details from the FDA within the next 30 days and will work closely with the FDA to address the partial clinical hold.

The Company also announced today that it will host a virtual R&D event highlighting its small molecule TREM2 agonist program for AD on Wednesday, September 13, 2023, from 7:30 a.m. to 9:00 a.m. ET.

The event will highlight new preclinical data for VG-3927, discuss current treatment approaches for AD, and Vigil's TREM2-focused clinical approach for treating AD guided by its precision medicine strategy. Vigil's management team will be joined by:

- Marco Colonna, M.D., Robert Rock Belliveau Professor of Pathology & Immunology, Washington University School of Medicine. Vigil Neuroscience Scientific Advisory Board Chairman; and,
- Samuel E. Gandy, Ph.D., M.D., Mount Sinai Professor of Alzheimer's Disease Research, Professor of Neurology & Psychiatry and Associate Director of Mount Sinai Alzheimer's Disease Research Center. Past Chairman, National Medical & Scientific Advisory Council of the Alzheimer's Association.

To access the live webcast of this event, please [register here](#) or visit “[Events & Presentations](#)” in the “Investors” section of the Vigil website at [www.vigilneuro.com](http://www.vigilneuro.com). An archived replay will be available for approximately 90 days following the presentation.

### **About VG-3927**

Vigil’s highly active, selective, and brain-penetrant small molecule TREM2 agonist, VG-3927, is designed to act as a molecular glue that potentiates the TREM2 signaling response to natural damage ligands. In preclinical studies, Vigil has established that VG-3927 demonstrated on-target TREM2 activation across both common and rare TREM2 variants. Additionally, VG-3927 demonstrated preclinically that it was able to deliver *in vivo* TREM2 responses within the central nervous system at a magnitude and specificity similar to VGL101.

### **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 timing for the commencement and dosing of patients in VG-3927’s Phase I trial; anticipated impact of the partial clinical hold on the Company’s clinical development plans; regulatory progress, clinical progress and clinical development plans for VG-3927; and expectations regarding the timing of additional regulatory information from the U.S. Food and Drug Administration (“FDA”). 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 risks and uncertainties related to the initiation and completion of clinical trials; Company’s ability to commence and recruit study subjects for clinical trials; the availability and timing of results and data from 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; 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.

### **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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