NEWS RELEASE

BioVie Announces Full Enrollment of the ADDRESS-LC Trial of Bezisterim for the Treatment of Neurological Symptoms Associated with Long COVID

2026-05-26

-Topline Data Release Targeted Late Summer 2026-

CARSON CITY, Nev., May 26, 2026 (GLOBE NEWSWIRE) -- BioVie Inc. (NASDAQ: BIVI) ("BioVie" or the "Company"), a clinical-stage company developing innovative drug therapies for neurological and neurodegenerative diseases, today announced full enrollment of the Company's ADDRESS-LC Phase 2 trial evaluating its drug candidate bezisterim for the treatment of neurological symptoms of Long COVID. The Phase 2 study is fully funded by a grant from the U.S. Department of War (DoW, formerly the U.S. Department of Defense).

An estimated 15 million U.S. adults reported having long COVID between 2022 and 2023, with 3.8 million experiencing significant limitation to their daily lives.[1] Almost 50 percent of those with Long COVID develop persistent or intermittent symptoms.[2] The neurological and neuropsychiatric symptoms are among the most common and disabling manifestations of the condition and include fatigue, persistent cognitive dysfunction, post-exertional malaise and sleep disturbance.[3] Currently, there are no FDA-approved treatment options.

"The full enrollment of the ADDRESS-LC trial marks an important milestone for BioVie, and we look forward to reporting topline data later this summer," said Cuong Do, President and CEO of BioVie. "The evolving scientific understanding and growing body of research surrounding Long COVID continue to reinforce the rationale for bezisterim's proposed mechanism, particularly its modulation of inflammatory pathways associated with neurocognitive and neuropsychiatric symptoms." Chronic inflammation is among the leading hypotheses proposed to explain the persistence of symptoms in Long COVID, with recent evidence for ongoing neuroinflammation in individuals with Long COVID versus controls.[4]

"We thank the trial participants, clinical investigators, site staff and the broader Long COVID community for their

strong interest in and commitment to the ADDRESS-LC trial," said Penelope Markham, PhD, Senior Vice President of Liver Disease and Long COVID Programs at BioVie. "We are especially grateful to our advisors living with Long COVID, as well as advocacy partners **SolveME** and the **Patient-Led Research Collaborative** (PLRC), whose efforts to raise awareness and educate communities helped support enrollment and participation in the study."

Despite growing recognition of Long COVID as a serious and potentially debilitating condition, there are currently no FDA-approved therapies for treatment.

About the ADDRESS-LC trial

The Phase 2 ADDRESS-LC study, which is fully funded by a grant from the U.S. Department of War (DoW), is a randomized (1:1), placebo-controlled, multicenter trial evaluating the efficacy, safety and tolerability of bezisterim in adult participants with long COVID who have cognitive impairment sequelae and fatigue. The study is comparing bezisterim, administered as a 20 mg oral capsule twice daily, with a matching placebo to assess its effects on neurocognitive and fatigue-related symptoms.

The primary endpoint of the trial is change in performance on a bespoke Cogstate Cognitive Battery, an objective tool designed to assess bezisterim's potential to improve neurocognitive symptoms such as cognitive impairment associated with Long COVID. Other secondary end points include assessing changes in patient-reported outcomes, including PROMIS Cognitive Function, Fatigue, and Sleep Disturbance short forms, SF-12 physical and mental component scores, and the DePaul Symptom Questionnaire post-exertional malaise domain.

About Bezisterim

Bezisterim (NE3107) is an investigational oral drug that crosses the blood-brain barrier and works to reduce inflammation and improve insulin sensitivity without suppressing the immune system and with a low risk of drug-drug interactions. By modulating key pathways involved in neuroinflammation (ERK, NFκB, TNF-α), bezisterim may have therapeutic potential in several disease indications, including Parkinson's disease, Long COVID, and Alzheimer's disease.

In Parkinson's disease, BioVie has completed a Phase 2 study in which patients with moderate- to severe-stage Parkinson's disease taking bezisterim with levodopa had better motor control and reported fewer morning symptoms compared to those taking levodopa alone. Few drug-related side effects were observed. The current SUNRISE-PD study has completed enrollment of 60 patients to evaluate whether bezisterim alone may help improve motor and non-motor symptoms in Parkinson's patients who have not been treated with carbidopa/levodopa. Topline results are expected in calendar Q3-2026

For Long COVID, the ADDRESS-LC trial enrolled approximately 200 patients to evaluate whether bezisterim may help reduce brain fog, fatigue, and other lingering neurological symptoms associated with Long COVID. The hypothesis being studied is that these symptoms may be triggered by persistent circulation of spike protein fragments that trigger inflammation via NFκB activation (which bezisterim has been shown to modulate). Topline data is expected late summer 2026.

In Alzheimer's disease, BioVie has conducted Phase 2 and Phase 3 trials. Preliminary data from these trials suggest improvements in cognition and biomarkers, supporting further trials to evaluate its potential as a therapy for the six million Americans living with Alzheimer's.

Terms of the U.S. Department of War (DoW) Award

The work is supported by the Assistant Secretary of War for Health Affairs and endorsed by the DoW by a fully funded award in the amount of $13.13 million through the Peer-Reviewed Medical Research Program (PRMRP) under Award No. HT9425-24-1-0113. Opinions, interpretations, conclusions and recommendations in this press release are those of the author and are not necessarily endorsed by the Assistant Secretary of Defense for Health Affairs or the DoW.

About BioVie Inc.

BioVie Inc. (NASDAQ: BIVI) is a clinical-stage biopharmaceutical company focused on developing therapies for neurological disorders and advanced liver disease. Its lead investigational drug candidate, bezisterim (NE3107), targets neuroinflammation and insulin resistance, which are believed to be key drivers of Alzheimer's and Parkinson's disease. Bezisterim is also being studied for Long COVID, where persistent TLR-4 driven neuroinflammation is thought to underlie symptoms such as brain fog and fatigue.

In liver disease, BioVie is advancing BIV201, a continuous infusion of terlipressin treatment that has received FDA Orphan and Fast Track designations. The active agent is approved in the U.S. and in about 40 countries for related complications of advanced liver cirrhosis, and the Company plans to study BIV201 in a Phase 3 trial for the reduction of further decompensation in patients with cirrhosis and ascites. For more information, visit **www.bioviepharma.com**.

Forward-Looking Statements

This press release contains forward-looking statements, which may be identified by words such as "expect," "look forward to," "anticipate" "intend," "plan," "believe," "seek," "estimate," "will," "project," "potential," "may," or words of similar meaning. Although BioVie Inc. believes such forward-looking statements are based on reasonable

assumptions, it can give no assurance that its expectations will be attained. Actual results may vary materially from those expressed or implied by the statements herein due to risk related to the early stage of development of bezisterim and other product candidates, the Company's ability to successfully raise sufficient capital on reasonable terms or at all, available cash on hand and contractual and statutory limitations that could impair our ability to pay future dividends, our ability to complete our pre-clinical or clinical studies and to obtain approval for our product candidates, the possibility that clinical trial results may not be indicative of results in subsequent or larger trials, our ability to successfully defend potential future litigation, changes in local or national economic conditions as well as various additional risks, many of which are now unknown and generally out of the Company's control, and which are detailed from time to time in reports filed by the Company with the SEC, including quarterly reports on Form 10-Q, reports on Form 8-K and annual reports on Form 10-K. BioVie Inc. does not undertake any duty to update any statements contained herein (including any forward-looking statements), except as required by law.

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[1] Bonuck K, Gao Q, Congdon S, et al. Long COVID disability burden in US adults. Commun Med. 2026;6:177. doi:10.1038/s43856-026-01516-7.

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[3] Geng LN, et al. 2024 Update of the RECOVER-Adult Long COVID Research Index. JAMA. 2025 Feb 25;333(8):694-700. doi: 10.1001/jama.2024.24184.

[4] VanElzakker MB, Bues HF, Brusaferri L, et al. Neuroinflammation in post-acute sequelae of COVID-19 (PASC) as assessed by [11C]PBR28 PET correlates with vascular disease measures. Brain Behav Immun. 2024;119:713-723. doi:10.1016/j.bbi.2024.04.015.

Source: BioVie, Inc.