



NEWS RELEASE

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

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Last Patient Last On-Site Visit Completed with Topline Data Release Targeted September 2026

CARSON CITY, Nev., Aug. 31, 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 that the last on-treatment visit of its ADDRESS-LC Phase 2 trial evaluating bezisterim for the treatment of neurological symptoms of Long COVID has been completed. 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).

"With the last patient's treatment visit completed, and the one-month virtual follow-up nearly complete, we anticipate announcing topline results for ADDRESS-LC before the end of September 2026," said Cuong Do, President and CEO of BioVie. "The growing body of research surrounding Long COVID continues to reinforce the rationale for bezisterim's proposed mechanism, particularly its modulation of inflammatory pathways associated with symptoms relating to fatigue and 'brain fog.'"

"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."

An estimated 17-20 million U.S. adults reported to be living with Long COVID,¹ with 3.8 million experiencing significant limitation to their daily lives.² Almost 50 percent of those with Long COVID develop persistent or intermittent symptoms.³ The neurological and neuropsychiatric symptoms are among the most common and disabling manifestations of the condition and include fatigue, post-exertional malaise, sleep disturbance, and

persistent sense of difficulty with thinking and memory.⁴ Chronic innate inflammation accompanied by ongoing immune dysregulation is among the leading hypotheses proposed to explain the symptoms in Long COVID, with numerous investigators describing findings in Long COVID that appear to be supportive of the intended biological targets of bezisterim. Currently, there are no FDA-approved treatment options for Long-COVID.

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, proof-of-concept, 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. End points include assessing changes in overall clinical benefit, subjective and objective cognitive function, fatigue, sleep disturbance, Quality of Life and post-exertional malaise.

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 PD, BioVie completed the SUNRISE-PD trial, which enrolled 57 patients to establish proof of mechanism and proof of concept in individuals with early-stage disease who had not previously been treated with carbidopa/levodopa. Topline results showed that patients treated with bezisterim experienced improvements with blood-based markers of inflammation, as well as a broad range of biomarkers associated with cellular health and neuronal integrity. Clinically, patients treated with bezisterim demonstrated greater improvements than those receiving placebo across multiple measures of daily functioning, motor symptoms, and non-motor symptoms.

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).

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 U.S. Department of Health and Human Services (<https://www.hhs.gov/longcovid/index.html>)

² Bonuck et al. Commun Med. 2026;6:177. doi:10.1038/s43856-026-01516-7.

³ Thaweethai et al. Nat Commun. 2025;16(1):9557. doi:10.1038/s41467-025-65239-4.

⁴ Geng et al. JAMA. 2025 Feb 25;333(8):694-700. doi: 10.1001/jama.2024.24184.

Source: BioVie, Inc.