



NEWS RELEASE

BioVie Presents Data on Bezisterim in Long COVID at the 2026 American Neurological Association Annual Meeting

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Phase 2 data from the ADDRESS-LC trial of Bezisterim demonstrated statistically significant improvements versus placebo across fatigue, post-exertional malaise, and objective cognitive measures in Long COVID patients with higher baseline symptom burden

CARSON CITY, Nev., Oct. 19, 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 the presentation of results from the Phase 2 ADDRESS-LC study (NCT06847191) evaluating bezisterim (NE3107) in patients with Long COVID at the 151st Annual Meeting of the American Neurological Association (ANA), held October 17–20, 2026, in San Diego, California. The study's abstract was published in *Annals of Neurology* (Vol. 100, pp. S4–S375, <https://doi.org/10.1002%2Fana.78378>), in conjunction with the meeting.

The **poster**, "Results of a Double-Blind, Placebo-Controlled Study of the Efficacy and Safety of Bezisterim (NE3107) in Long COVID (ADDRESS-LC)," detailed findings from the randomized, double-blinded, placebo-controlled signal-finding ADDRESS-LC trial (**NCT06847191**). Patients (n=203) received bezisterim or placebo for 12 weeks to evaluate whether bezisterim could improve key neurological symptoms of Long COVID, including fatigue, brain fog, subjective and objective cognitive impairment, and post-exertional malaise (PEM), as well as safety and tolerability. The ADDRESS-LC trial explored 22 different measures to assess clinical outcomes to identify the clinical endpoints where bezisterim had the greatest effect and within which patient subpopulations, and no single endpoint was designated as primary. ADDRESS-LC also evaluated a series of biomarkers, and these data are pending analysis and will be presented at a future medical meeting.

In the intent-to-treat population, treatment with bezisterim showed a consistent trend toward improvement across most patient-reported and objective efficacy measures compared with placebo.

Importantly, analyses showed that patients with more severe baseline fatigue, post-exertional malaise (PEM), or objective cognitive impairment – symptoms affecting approximately 78% of trial participants in at least one domain – experienced the greatest benefits with bezisterim, including statistically significant improvements in multiple measures corresponding to their most pronounced symptoms.

“These results highlight the substantial heterogeneity of Long COVID and suggest that baseline disease burden may play an important role in identifying patients most likely to benefit from treatment with bezisterim,” said Penelope Markham, BioVie’s Senior Vice President and Program Lead for Long COVID. “We observed a consistent and clinically meaningful pattern of improvement across measures of fatigue, post-exertional malaise, clinician- and patient-reported outcomes, and objective measures of cognition function among patients with greater baseline symptom burden. We believe these findings provide an important foundation for the design of a confirmatory Phase 3 study.”

Among the most fatigued half of patients at baseline, defined as a PROMIS Fatigue T-score ≥ 65 , mean improvement in PROMIS Fatigue at Week 12 was 8.93 points with bezisterim compared with 5.30 points with placebo ($p=0.02$). In this subgroup, statistically significant treatment differences favoring bezisterim were also observed for PGI-Severity Fatigue, PGI-Change Fatigue, PGI-Change Overall, and CGI-Change Overall.

Among patients with high baseline PEM, defined as DSQ-PEM ≥ 67.5 , statistically significant differences favoring bezisterim were observed in objective global cognition, processing speed, and identification/attention, as well as CGI-Change Overall, DSQ-PEM, PGI-Change Overall, and PGI-Change Fatigue.

Patients with greater objective cognitive impairment at baseline, defined by a Cogstate Composite Global z-score of ≤ 0.130 , also demonstrated statistically significant treatment differences favoring bezisterim versus placebo in objective global cognition and three cognitive domains verbal learning, verbal memory, and processing speed, as assessed using a computerized cognitive assessment tool based on Cogstate.

Taken together, these findings indicate a consistent pattern in which greater baseline symptom burden was associated with larger treatment effects across multiple clinically relevant domains.

Safety and tolerability

Bezisterim demonstrated a safety and tolerability profile comparable to placebo. Treatment-emergent adverse events were reported in 41.6% of patients receiving bezisterim compared with 55.9% of those receiving placebo. Drug-related treatment-emergent adverse events occurred in 18.8% and 25.5% of patients, respectively. No serious treatment-emergent adverse events were reported in the bezisterim group, while one serious event was reported in the placebo group.

About Long COVID

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, PEM, 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 (**NCT06847191**), which is fully funded by a grant from the U.S. Department of War (DoW), is a randomized (1:1), placebo-controlled, signal-finding 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 compared 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 trial evaluated 22 clinical outcome measures, with no single endpoint pre-specified as the primary determinant of study success. Endpoints include assessing changes in overall clinical benefit, subjective and objective cognitive function, fatigue, sleep disturbance, Quality of Life and PEM. As a signal-finding study, the trial was designed to identify efficacy signals, measure treatment effect magnitude, and identify patient subgroups most likely to benefit, to inform the design of future Phase 3 trials.

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, TNFα), bezisterim may have therapeutic potential in several disease indications, including Parkinson's disease (PD), Long COVID (LC), and Alzheimer's disease (AD).

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 LC, 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 LC. The hypothesis being studied is that these symptoms may be triggered by persistent circulation of spike protein fragments that trigger inflammation via NFkB activation (which bezisterim has been shown to modulate).

In AD, 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 AD.

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

The Long COVID study 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 inflammation 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. Forward-looking statements in this release include, but are not limited to, statements regarding: the potential for bezisterim to address unmet clinical needs in Long COVID and Parkinson's disease; the design and conduct of future clinical trials, including a potentially pivotal Phase 3 trial; the potential clinical significance of subgroup analyses and biomarker observations; and the Company's ability to advance bezisterim through clinical development. The clinical endpoints reported in this release are exploratory in nature. The Phase 2 ADDRESS-LC trial did not achieve statistical significance on any endpoint in the overall intent-to-treat population; statistically significant results were observed only in pre-specified subgroup analyses. Subgroup analyses are hypothesis-generating and may not be replicated in future trials. Changes in biomarkers may not correlate with clinical benefit or support regulatory approval. The FDA has not validated these endpoints as surrogate endpoints for Long COVID. 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 risks related to the early stage of development of bezisterim and other product candidates, the possibility that results observed in this Phase 2 study of 203 patients may not be replicated in larger or longer-duration trials, the exploratory nature of subgroup analyses, 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.

For Investor Relations Inquiries:

Contact:

Chuck Padala

Managing Director, LifeSci Advisors, LLC

chuck@lifesciadvisors.com

For Media Inquiries:

Contact:

Melyssa Weible

Managing Partner, Elixir Health Public Relations

mweible@elixirhealthpr.com

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.