NEWS RELEASE

BioVie to Host Conference Call to Discuss Topline Data from Phase 2 ADDRESS-LC Trial and the Potential of Bezisterim in Long Covid

2026-09-14

Conference call scheduled for Tuesday, September 15, 2026, at 8:30 a.m. Eastern Time (ET)

CARSON CITY, Nev., Sept. 14, 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 Company will host a conference call and webcast on Tuesday, September 15, 2026 at 8:30am ET to discuss topline results from its Phase 2 ADDRESS-LC trial (**NCT06847191**) evaluating its investigational drug candidate bezisterim, an oral drug that crosses the blood-brain barrier and is believed to reduce inflammation and improve insulin sensitivity, in Long COVID.

Michael Peluso, MD, MHS, Associate Professor of Medicine, University of California, San Francisco, and an investigator in the trial, and Ezra Spier, Long COVID patient advocate and a patient advisor on the ADDRESS-LC trial, will be guest speakers at the event. A live Q&A session with management will follow the presentation.

Registration Details

Date: September 15, 2026
Time: 8:30am ET
Registration: **Click here**

A replay will be available on the BioVie website following the event.

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 NFκB 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 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 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.

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