NEWS RELEASE

BioVie Invited to Present Data on Bezisterim in Parkinson’s Disease at the AD/PD2027 International Conference on Alzheimer's & Parkinson’s Diseases

2026-11-10

CARSON CITY, Nev., Nov. 10, 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 Company has been invited to present two oral presentations at the AD/PD2027 International Conference on Alzheimer's & Parkinson’s Diseases to be held in Barcelona, Spain from March 16-20, 2027.

The two presentations will be shared during the “AD, PD and Lewy Body Disorders: Novel Therapies” session being held on Saturday, March 20.

Presentation 1

- Title: Exploratory Analyses of a Phase II Trial (SUNRISE-PD) Suggest Positive Effects of Bezisterim on Markers of Parkinson’s Disease Progression
- Presenter: Joseph M. Palumbo, MD, BioVie Inc.
- Time: 9:10–9:25 a.m.

Presentation 2

- Title: Efficacy of Bezisterim in Early Parkinson's Disease: Clinical Outcomes and Biomarker-Based Patient Selection in the Phase 2 SUNRISE-PD Trial
- Presenter: Suzanne Hendrix, PhD, CEO of Pentara Corporation
- Time: 9:25–9:40 a.m.

The presentations will share additional findings from the 57-patient randomized, double-blind, placebo-controlled SUNRISE-PD trial (NCT06757010). Patients received bezisterim or placebo for 12 weeks. The study assessed motor symptoms, non-motor symptoms, activities of daily living, sleep, inflammatory biomarkers, and overall clinical benefit using a Composite Benefit Score (CBS), a fit-for purpose measure designed to capture changes across multiple domains of Parkinson's disease.

Patients with higher systemic inflammation at the start of the trial – defined as above-median platelet counts above 230 × 10^9/L – demonstrated the strongest response to bezisterim. In this prespecified subgroup, which represents approximately half of the trial population, bezisterim-treated patients experienced significant improvements in the Movement Disorder Society–Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Part I (non-motor) scores (-1.62 vs. +1.86 for placebo; Cohen's d = -1.33; p=0.0124), Part III (motor) scores (-1.32 vs. +1.26; Cohen's d = -0.92; p=0.0265), and Total Scores (-1.23 vs. +1.21; Cohen's d = -1.45; p=0.0006).

"These results provide evidence that an anti-inflammatory treatment can benefit both motor and, importantly, non-motor symptoms of Parkinson's disease," said Clarence Ahlem, BioVie's Senior Vice President and Program Lead for Parkinson's Disease. "Because non-motor symptoms remain a significant unmet need, the breadth of activity observed with bezisterim is particularly encouraging for its development as a treatment for early Parkinson's disease. In SUNRISE-PD we observed a consistent pattern of improvement across motor symptoms, non-motor symptoms, and daily functioning, with particularly encouraging results among patients with higher baseline platelet counts, a potential marker of systemic inflammation. We believe these findings provide an important foundation for future studies and support the development of bezisterim as a treatment with the potential not only to provide symptomatic benefit, but also to impact the underlying disease process and potentially slow disease progression."

In the overall modified intent-to-treat population, efficacy outcomes generally favored bezisterim across multiple measures. The CBS also demonstrated a large treatment effect favoring bezisterim (Cohen's d = -1.61; p=0.0004). Patients receiving bezisterim were 6.25-fold more likely to achieve clinically meaningful improvement on the CBS than patients receiving placebo (25% vs 4%), corresponding to a 525% relative increase and a 21-percentage-point absolute difference. Conversely, the risk of clinically meaningful worsening was approximately 70% lower with bezisterim than with placebo (14% vs 46%; relative risk 0.30), representing a 32-percentage-point absolute risk reduction.

About Parkinson's Disease

Parkinson's disease (PD) is the second most common neurodegenerative disorder worldwide, affecting more than 10 million people, including an estimated 1.1 million people in the United States, with nearly 90,000 new diagnoses each year.[1]

PD is best known for motor symptoms such as tremor, rigidity, slowed movement, and postural instability. However, PD involves neurodegeneration beyond the areas of the brain primarily associated with movement, giving rise to a broad range of non-motor symptoms, including sleep disturbances, cognitive changes, depression, anxiety, fatigue, and autonomic dysfunction.[2]

Some non-motor symptoms may emerge years before a diagnosis of PD[3] and can be more troublesome and disabling than movement symptoms.[4] Non-motor symptoms are strongly associated with reduced quality of life, yet they remain frequently under-recognized and undertreated.[5,6]

The economic burden of Parkinson's disease and atypical parkinsonism in the United States was estimated at $82.2 billion in 2024, including $58.4 billion in indirect and non-medical costs, and is projected to reach $112.4 billion annually by 2045. There remains a substantial need for treatments and care that address both the motor and non-motor manifestations of PD.

About the SUNRISE-PD trial

SUNRISE-PD (**NCT06757010**) was a Phase 2b, multicenter, randomized, double-blind, placebo-controlled trial designed to establish proof-of-mechanism and proof-of-concept in early-stage Parkinson's disease (PD) patients naïve to treatment with symptomatic dopaminergic therapy (carbidopa/levodopa). The study leveraged a hybrid decentralized design that lasted 20 weeks from the initial screening phase, a 12-week treatment period, through to the safety follow up.

Following a screening and prospective clinical stability assessment period, 57 eligible participants were randomized 1:1 to receive either 20 mg of bezisterim or matching placebo twice daily for 12 weeks.

The study prospectively evaluated a predefined battery of biologic, clinical, and quality of life assessments to assess a series of motor and non-motor endpoints and evaluate signals consistent with bezisterim's expected metabolic and anti-inflammatory actions. The trial endpoints and planned analyses were prespecified in the final Statistical Analysis Plan (SAP) submitted to the FDA prior to data unblinding.

The primary pharmacodynamic endpoint was to assess the effect of bezisterim on hematologic inflammatory biomarker indices (MLR, SIRI, NLR, SII, PLR, AISI) and a composite of those markers. Secondary and exploratory endpoints aimed to understand the pharmacodynamic, clinical, safety and tolerability, and to define the profile of bezisterim versus placebo in the study population to design a potentially pivotal registrational Phase 3 trial.

The study was designed to reduce common barriers to participation in PD research, including delayed diagnosis,

limited mobility, geographic constraints, and access to specialized care, and allowed patients to participate either from their home or at a clinical site. At-home participants were visited by study nurses who administered a modified MDS-UPDRS Part III and standard Part I and II examinations under the supervision of a physician and MDS-UPDRS expert attending through live video link. The Part III exam was recorded for review and scoring by a central rating committee with a final expert rater review and adjudication.

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.

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] Parkinson's Foundation. Statistics. Accessed July 16, 2026.
[2] Peña-Zelayeta et al. J Pers Med. 2025;15(5):172. doi:10.3390/jpm15050172.
[3] Castilla-Cortázar et al. J Transl Med (2020) 18:70. https://doi.org/10.1186/s12967-020-02223-0
[4] Parkinson's Foundation. Non-movement symptoms. Accessed July 16, 2026.
[5] van der Meer et al. Expert Rev Pharmacoecon Outcomes Res. 2025;25(1):17–27. doi:10.1080/14737167.2024.2390042.
[6] Chaudhuri et al. Parkinsonism Relat Disord. 2015;21(3):287–291. doi:10.1016/j.parkreldis.2014.12.031.

Source: BioVie, Inc.