



NEWS RELEASE

# BioVie Completes Enrollment in Phase 2 SUNRISE-PD Trial in Early Parkinson's Disease

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- Patient-centric trial aiming to evaluate whether bezisterim can help delay disease progression reaches enrollment milestone -

- Topline Results from the SUNRISE-PD Trial Expected in 1H 2026 -

CARSON CITY, Nev., Jan. 08, 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 it has completed enrollment of 60 patients in its Phase 2 SUNRISE-PD clinical trial evaluating the safety and efficacy of bezisterim (NE3107) on motor and non-motor symptoms in individuals with early-stage Parkinson's disease (PD) who have not been treated with carbidopa/levodopa.

SUNRISE-PD explores whether bezisterim can affect the progression of Parkinson's symptoms in patients diagnosed with PD within the past four years who need treatment for their symptoms. The trial uses a hybrid, decentralized Phase 2 trial designed to reduce common barriers to participation in PD research, including delayed diagnosis, limited mobility, geographic constraints, and access to specialized care. The study's flexible design allows participants to complete their study visits either at home or in a clinic, improving access and flexibility while maintaining rigorous data quality and centralized oversight. Completion of enrollment for SUNRISE-PD reflects strong engagement from the PD community and highlights the feasibility of patient-centric trial designs in PD research.

"We are looking to see how bezisterim treatment may affect symptomatic progression for Parkinson's disease patients needing treatment for the first time," said Cuong Do, President and CEO of BioVie Inc. "Completing enrollment in SUNRISE-PD is an important milestone for BioVie and a testament to the need for more accessible and inclusive clinical trials for people with Parkinson's disease. This milestone benefited from the strong engagement of the Parkinson's disease community, and we look forward to advancing SUNRISE-PD toward topline

data and continuing our mission to develop a potentially disease-modifying treatment for people living with Parkinson's disease."

Bezisterim is an anti-inflammatory and insulin-sensitizing agent being developed for PD and other neurodegenerative diseases including Alzheimer's disease (AD) and Long COVID (LC), all conditions where inflammation contributes to neurological damage. In previous clinical trials of PD, bezisterim was administered in combination with levodopa/carbidopa and demonstrated improvements in both motor and non-motor symptoms with a favorable safety profile. It is designed to target key biological processes believed to contribute to the progression of PD, with the goal of modifying the course of the condition over time.

SUNRISE-PD enrolled individuals ages 41 to 80 who were diagnosed with PD within the past four years and had not been treated with carbidopa/levodopa. BioVie supported enrollment through outreach and awareness efforts with the support of leading advocacy organizations in the PD field, including **The Michael J. Fox Foundation**, **Davis Phinney Foundation**, and the **Parkinson's Foundation**.

Now that participant enrollment is complete, the Company anticipates analyzing and reporting top-line results first half of 2026.

#### About Bezisterim

Bezisterim (NE3107) is an 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 already completed a Phase 2 study that showed patients with moderate- to severe Parkinson's taking bezisterim with levodopa had better motor control and fewer morning symptoms compared to those taking levodopa alone. Few drug-related side effects were observed. The current SUNRISE-PD just completed enrolling 60 patients to evaluate whether bezisterim alone can help improve motor and non-motor symptoms for Parkinson's patients who have not been treated with carbidopa/levodopa. Topline results are expected in mid-2026.

For Long COVID, the **ADDRESS-LC trial** is enrolling about 200 patient to evaluate if bezisterim can reduce brain fog, fatigue, and other lingering neurological symptoms associated with Long Covid, which are believed to 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 mid-2026.

In Alzheimer's disease, BioVie has conducted both Phase 2 and Phase 3 trials. Early results 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.

#### 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 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](http://www.bioviepharma.com)**.

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