



NEWS RELEASE

# BioVie to Present Rationale and Design of Phase 2 SUNRISE-PD Clinical Trial at the 30th World Congress on Parkinson's Disease and Related Disorders (IAPRD 2025)

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CARSON CITY, Nev., May 07, 2025 (GLOBE NEWSWIRE) -- BioVie Inc., (NASDAQ: BIVI) ("BioVie" or the "Company") a clinical-stage company developing innovative drug therapies for the treatment of neurological and neurodegenerative disorders and advanced liver disease, today announced that a poster on the rationale and design of its Phase 2 **SUNRISE-PD** clinical trial evaluating bezisterim (NE3107) in early Parkinson's disease will be presented in a Guided Poster Tour session at the 30th World Congress on Parkinson's Disease and Related Disorders (IAPRD 2025), being held May 7-10, 2025, in New York City.

Details for the presentation are as follows:

Title: Assessment of Bezisterim (NE3107) in Patients with Early Parkinson's Disease: A Phase 2, Placebo-Controlled, Hybrid Decentralized Study

Presentation date and time: Saturday, May 10

Presentation time: 8:00-9:00am EDT

Presenter: Joseph M. Palumbo, MD, Executive Vice President, Head of Research & Development and Chief Medical Officer, BioVie Inc.

SUNRISE-PD is a Phase 2b, multicenter, randomized, double-blind, placebo-controlled trial with a hybrid decentralized design that will last 20 weeks from the initial screening phase to the safety follow up.

As part of the trial, patients may participate either completely from their home or at a clinical site. At-home participants will be visited by study nurses who will complete study assessments with the assistance of a neurologist who will attend the visit remotely by video and supervise administration of a modified MDS-UPDRS Part



III examination, which will be recorded for review and scoring by a central rating committee. If the trial's results are positive, participants may be eligible to enter a longer-term, open-label safety study.

#### About Parkinson's Disease

Parkinson's disease (PD) is a progressive neurodegenerative disorder that primarily affects movement. It is characterized by the loss of dopamine-producing neurons in the substantia nigra, a region of the brain critical for motor control. Core symptoms include tremors, muscle rigidity, bradykinesia (slowness of movement), postural instability, and difficulties with speech.<sup>1-2</sup> Non-motor symptoms, such as cognitive impairment, mood disorders, and autonomic dysfunction, also significantly impact patients' quality of life.<sup>3</sup> In the early stages, symptoms are often mild and may include subtle tremors, slight movement difficulties, and changes in handwriting or facial expressions. As the disease progresses, motor symptoms become more pronounced, leading to difficulties with balance, speech, and daily activities, often requiring full-time care in later stages.<sup>4</sup>

Since the 1960s, when dopamine's critical role in Parkinson's disease was first identified, levodopa has remained the cornerstone of treatment, providing significant symptom relief by replenishing dopamine levels in the brain.<sup>5-6</sup> However, long-term use is associated with complications such as motor fluctuations—where symptom control becomes less stable—and dyskinesia, involuntary movements that can become debilitating.<sup>7-9</sup>

Emerging research highlights the role of chronic inflammation and insulin resistance in the onset and progression of Parkinson's disease. Neuroinflammation, driven by activated microglia and elevated levels of pro-inflammatory cytokines, contributes to oxidative stress and accelerates neuronal degeneration.<sup>10-12</sup> Additionally, insulin resistance, which impairs the brain's ability to regulate glucose metabolism, has been linked to increased neurodegeneration and worsening motor symptoms.<sup>13-14</sup> These metabolic dysfunctions create a harmful cycle that exacerbates disease progression, underscoring the potential of anti-inflammatory and insulin-sensitizing therapies as new avenues for treatment.

#### About Bezisterim

Bezisterim (NE3107) is an orally bioavailable, blood-brain barrier (BBB)-permeable modulator of inflammation and insulin-sensitizer. In addition, it is not immunosuppressive and has a low risk of drug-drug interaction. By binding to ERK and selectively modulating NFκB activation and TNF-α production, BioVie believes that bezisterim may offer clinical improvements in several disease indications, including Alzheimer's disease, Parkinson's disease and long COVID.

In Parkinson's disease, BioVie is currently enrolling patients in the Phase 2 **SUNRISE-PD** clinical trial evaluating the safety and efficacy of bezisterim on motor and non-motor symptoms in patients who have not been treated with carbidopa/levodopa, with topline data expected in late 2025 or early 2026. A previous Phase 2 study of bezisterim in Parkinson's disease (NCT05083260) completed in 2022, and data presented at the AD/PD™ 2023 International

Conference on Alzheimer's and Parkinson's Diseases and related neurological disorders in Gothenburg, Sweden in March 2023 showed significant improvements in "morning on" symptoms and clinically meaningful improvement in motor control in patients treated with a combination of bezisterim and levodopa versus patients treated with levodopa alone, and no drug-related adverse events.

In long COVID, bezisterim has the potential to reduce neurological symptoms including fatigue and cognitive dysfunction. Persistently circulating viral spike proteins are believed to trigger TLR-4 driven activation of NFκB and the subsequent expression of inflammatory cytokines (IL-6, TNF, IFNγ). BioVie's Phase 2 **ADDRESS-LC** study, is a randomized (1:1), placebo-controlled, multicenter trial in approximately 200 patients to evaluate the safety, tolerability and potential efficacy of 3 months of treatment with bezisterim to reduce the neurocognitive symptoms associated with long COVID, including difficulty concentrating or remembering things ("brain fog") and fatigue.

In Alzheimer's disease, BioVie conducted and reported efficacy data on its Phase 3 randomized, double-blind, placebo-controlled, parallel-group, multicenter study to evaluate bezisterim in patients who have mild-to-moderate Alzheimer's disease (NCT04669028) in 2023. Results of a Phase 2 investigator-initiated trial (NCT05227820) showing bezisterim-treated patients experienced improved cognition and biomarker levels were presented at the Clinical Trials on Alzheimer's Disease (CTAD) annual conference in December 2022. An estimated six million Americans suffer from Alzheimer's disease.

#### About BioVie Inc.

BioVie Inc. (NASDAQ: BIVI) is a clinical-stage company developing innovative drug therapies for the treatment of neurological and neurodegenerative disorders (Alzheimer's disease, Parkinson's disease and long COVID) and advanced liver disease. In neurodegenerative disease, the Company's drug candidate bezisterim inhibits inflammatory activation of extracellular signal-regulated kinase and the transcription factor nuclear factor-κB, and the associated neuroinflammation and insulin resistance but not ERK and NFκB homeostatic functions (e.g., insulin signaling and neuron growth and survival). Both neuroinflammation and insulin resistance are drivers of AD and PD. Persistent systematic inflammation and neuroinflammation are key features in patients with neurological symptoms of long COVID. In liver disease, the Company's Orphan drug candidate BIV201 (continuous infusion terlipressin), with FDA Fast Track status, is being evaluated and discussed with guidance received from the FDA regarding the design of Phase 3 clinical testing of BIV201 for the reduction of further decompensation in participants with liver cirrhosis and ascites. The active agent is approved in the U.S. and in about 40 countries for related complications of advanced liver cirrhosis. For more information, visit [www.bioviepharma.com](http://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" 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 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, 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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