NEWS RELEASE

BioVie Announces Completion of Phase 2 SUNRISE-PD Trial in Early-Stage Parkinson's Disease

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Last Patient Evaluation Visit Completed with Topline Data Release Targeted Q3-2026

CARSON CITY, Nev., May 18, 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 last patient evaluation visit has been completed for the Company's SUNRISE-PD Phase 2 trial evaluating its drug candidate bezisterim in early-stage Parkinson's disease.

"With this last patient's treatment visit completed, our team will start the study closeout process, and the Company plans announce topline results in Q3," said Cuong Do, BioVie's President and CEO. "This trial was designed to assess bezisterim's magnitude of therapeutic impact on a series of motor and non-motor endpoints so that we can finalize the design for the Phase 3 registrational trials. We look forward to unblinding the data later this year to understand the molecule's true potential."

The company recently hosted a virtual key opinion leader (KOL) event featuring Suzanne de la Monte, MD, MPH, professor in Pathology and Laboratory Medicine, Neurology, & Neurosurgery at the Warren Alpert Medical School of Brown University, who joined company management to discuss the importance of insulin resistance in disease pathology and bezisterim's mechanism of action in relation to the pathology and progression of neurodegenerative conditions, including Parkinson's disease. The event also discussed the need to address Parkinson's non-motor symptoms, including sleep disorder, anxiety, depression and cognitive slowness. To view the replay, **click here**.

About the SUNRISE-PD trial

SUNRISE-PD is a Phase 2b, multicenter, randomized, double-blind, placebo-controlled trial in early-stage Parkinson's disease patients who have not been treated with carbidopa/levodopa. The study leveraged a hybrid decentralized design that lasted 20 weeks from the initial screening phase to the safety follow up. During the 12-week double-blind phase, 57 patients were randomized 1:1 to receive either 20 mg of bezisterim or placebo twice daily.

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 administrated a modified MDS-UPDRS[1] 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.

The study prospectively assessed a series of motor and non-motor endpoints using a predefined battery of biologic, clinical, and quality-of-life assessments to evaluate signals consistent with the expected metabolic and anti-inflammatory actions of bezisterim. Assessments include UPDRS Parts I, II, and III, the Parkinson's Disease Questionnaire (PDQ), the Parkinson's Disease Sleep Scale (PDSS), and Clinical Global Impression of improvement and severity (CGI-I and CGI-S). The study's endpoint selection was informed by the underlying biology of Parkinson's disease and the hypothesized mechanism of action of bezisterim. In parallel, the study evaluated plasma biomarkers of inflammation and neurodegeneration, including DNA methylation, to examine whether observed clinical findings are accompanied by biologic changes consistent with the proposed systems-level effects of bezisterim, and its potential to alter symptoms and progression in early-stage Parkinson's disease.

About the May 7th KOL event

The event featured Suzanne de la Monte, MD, MPH, who coined the term "Type 3 Diabetes" to describe the role of insulin resistance and metabolic imbalances in CNS conditions. Dr. de la Monte provided an understanding of how insulin resistance is an underlying driver of many CNS conditions, including Parkinson's, and Company speakers discussed how bezisterim could potentially modulate that impact. Dr. Joseph M. Palumbo, BioVie's Chief Medical Officer, led a discussion on the clinical journey in Parkinson's Disease, including its time course, current therapies, and the spectrum and impact of non-motor and motor symptoms associated with the Disease.

About Suzanne de la Monte, MD, MPH

Suzanne de la Monte, MD, MPH, is Professor in Pathology and Laboratory Medicine, Neurology, & Neurosurgery at the Warren Alpert Medical School of Brown University. Dr. de la Monte is also a medical staff member at the Rhode Island Hospital and Women and Infants Hospital of Rhode Island and formerly a research fellow at the National Institutes of Health. She received residency training in Anatomic and Pediatric Pathology at Johns Hopkins and fellowship training in Neuropathology at the Massachusetts General Hospital (MGH). Dr. de la Monte leads programs in basic, translational, and clinical research on mechanisms and consequences of brain insulin resistance and metabolic dysfunction and coined the term "Type 3 Diabetes". She has over 300 peer-reviewed articles published.

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, 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 completed a Phase 2 study in which patients with moderate- to severe-stage Parkinson's disease taking bezisterim with levodopa had better motor control and reported fewer morning symptoms compared to those taking levodopa alone. Few drug-related side effects were observed. The current SUNRISE-PD study has completed enrollment of 60 patients to evaluate whether bezisterim alone may help improve motor and non-motor symptoms in Parkinson's patients who have not been treated with carbidopa/levodopa. Topline results are expected in calendar Q3-2026.

For Long COVID, the ADDRESS-LC trial is enrolling approximately 200 patients to evaluate whether bezisterim may help reduce brain fog, fatigue, and other lingering neurological symptoms associated with Long COVID. The hypothesis being studied is that these symptoms may be triggered by persistent circulation of spike protein fragments that trigger inflammation via NFκBactivation (which bezisterim has been shown to modulate). Topline data is expected late summer 2026.

In Alzheimer's disease, 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 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 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. 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 risk related to the early stage of development of bezisterim and other product candidates, 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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[1] Movement Disorder Society-sponsored revision of the Unified Parkinson's Disease Rating Scale

Source: BioVie, Inc.