NEWS RELEASE

BioVie Announces Alignment with FDA on Clinical Trial to Assess Bezisterim in Parkinson's Disease

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SUNRISE-PD to evaluate the effect of bezisterim (NE3107) on motor and non-motor symptoms in ~60 patients with Parkinson’s disease who are naïve to carbidopa/levodopa

Company engaged in trial start-up activities and plans to initiate patient screening Q4 2024

CARSON CITY, Nev., Aug. 08, 2024 (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 it has achieved alignment with the Food and Drug Administration (FDA) on its upcoming SUNRISE-PD trial in Parkinson’s disease (“PD”). As a result, the Company is conducting trial start-up activities with a view to initiate patient screening in Q4 2024.

The Company submitted the SUNRISE-PD clinical trial protocol to the FDA for comments, and the agency provided a single, actionable comment recommending the inclusion of the Part II score from the Movement Disorder Society’s Unified Parkinson’s Disease Rating Scale (“MDS-UPDRS”) as a primary endpoint for potential future registrational filings. As this metric is already included as a secondary endpoint within the current trial design, BioVie believes it can proceed with the SUNRISE-PD trial as planned without protocol amendments.

"The SUNRISE-PD trial focuses on the second of two objectives we have in developing bezisterim for Parkinson’s disease, which is to improve upon the motor experiences in patients’ daily living,” said Cuong Do, BioVie’s President and CEO. “Our Phase 2a trial demonstrated that bezisterim in conjunction with levodopa may dramatically improved motor control for patients with moderate to severe symptoms of Parkinson’s disease. The Phase 2 SUNRISE-PD trial is designed to explore bezisterim’s impact on symptoms of Parkinson’s disease in patients who need medication for the first time. This Phase 2 study intends to address the newly diagnosed patient population, which in conjunction with our earlier trial, could establish bezisterim’s applicability for the total Parkinson’s patient population and provide a foundation for a disease progression study, which is the ultimate objective of the PD

program. We are currently engaged in trial start up preparations, and hope to initiate patient screening in Q4 of 2024."

About the SUNRISE-PD Trial in Early Parkinson's Disease

SUNRISE-PD is a Phase 2, 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. During the 12-week double-blind phase, around 60 patients will be randomized 1:1 to receive either 20 mg of bezisterim (NE3107), or placebo twice-daily.

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 Bezisterim

Bezisterim (NE3107) is an orally bioavailable, BBB-permeable, insulin-sensitizer that is also anti-inflammatory. In addition, it is not immunosuppressive and has a low risk of drug-to-drug interaction. Bezisterim has the potential to reduce symptoms of long COVID, including fatigue and cognitive dysfunction. Persistently circulating viral spike proteins are believed to trigger TLR-4 driven activation of NF-κB and the subsequent expression of inflammatory cytokines (IL-6, TNF, IFNg). Bezisterim has been shown to modulate the activation of NF-κB and thus modulate inflammation.

Bezisterim is being investigated for Alzheimer's disease (AD) and Parkinson's disease (PD). BioVie has 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 AD (NCT04669028). 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 AD. A Phase 2 study of bezisterim in PD (NCT05083260) has been completed, 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 vs. patients treated with levodopa alone, and no drug-related adverse events.

About BioVie Inc.

BioVie Inc. (NASDAQ: BIVI) is a clinical-stage company developing innovative drug therapies for the treatment of

neurological and neurodegenerative disorders and advanced liver disease. In neurodegenerative disease, the Company's drug candidate bezisterim inhibits inflammatory activation of ERK and NFkB (e.g., TNF signaling) that leads to neuroinflammation and insulin resistance, but not their homeostatic functions (e.g., insulin signaling and neuron growth and survival). Both are drivers of AD and PD. In liver disease, the Company's Orphan drug candidate BIV201 (continuous infusion terlipressin), with U.S. Food and Drug Administration ("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 treatment of ascites due to chronic liver cirrhosis. 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** .

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 conditionsas 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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