NEWS RELEASE

BioVie Presents Protocol Design of Upcoming SUNRISE-PD Phase 2 Trial of Bezisterim in Patients with Early Parkinson's Disease at ATMRD 2024

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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

Additional presentation at congress highlighted data from earlier Phase 2a trial of bezisterim in Parkinson’s disease that helped inform SUNRISE-PD trial design

CARSON CITY, Nev., June 25, 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 data from two presentations at the Advanced Therapeutics in Movement and Related Disorders Congress® (ATMRD Congress) held June 21-25, 2024 in Washington, D.C.

Presentations include a first look at the protocol design of the upcoming SUNRISE-PD Phase 2 trial of bezisterim (NE3107) in patients with early Parkinson’s disease along with an encore presentation of detailed results from the Company’s Phase 2a trial of bezisterim adjunctive to carbidopa/levodopa (C/L) in patients with Parkinson’s disease.

"Promising preclinical data suggest bezisterim may address unmet needs in Parkinson's disease. Existing treatments offer variable success, and disease progression leads to worsening motor function, dyskinesias, and significant disability,” said Cuong Do, BioVie’s President and CEO. “Bezisterim's unique mechanism of action – targeting inflammation and insulin resistance – holds promise for mitigating these issues based on data from earlier-phase trials. SUNRISE-PD will allow us to further investigate bezisterim's safety and efficacy in a larger patient population who have minimal prior exposure to levodopa, with the goal of developing a treatment that can significantly improve the lives of people with Parkinson's disease."

Protocol Design of SUNRISE-PD: A Phase 2, Placebo-Controlled Study of Bezisterim in Early Parkinson's Disease

The presentation Assessment of Bezisterim (NE3107) in Patients with Early Parkinson's Disease: A Phase 2, Placebo-Controlled Study outlined the study protocol of the Company's upcoming SUNRISE-PD Phase 2 trial evaluating bezisterim in patients with Parkinson's disease who have had minimal exposure to C/L treatment but in need of symptomatic therapy for motor symptoms.

SUNRISE-PD will be 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 bezisterim 20 mg or placebo twice-daily.

Objectives and Endpoints:

Objective	Endpoint
Primary	
Evaluate the efficacy of bezisterim in the treatment of motor symptoms of PD	Change in MDS-UPDRS Part III score at week 12 (centralized ratings)
Secondary	
Evaluate the impact of bezisterim on non-motor symptoms of PD and on overall symptoms of PD as assessed by the clinician	• Change in the MDS-UPDRS Part I and Part II scores at week 12 • Percent of subjects with any improvement as measured by the CGI-I at week 12 • Percent of subjects with any improvement as measured by the CGI-S at week 1
Exploratory	
Assess the effects of bezisterim treatment on other aspects of PD	Change in MDS-UPDRS combined and sub-domain scores
Evaluate the effect of bezisterim on Patient Reported Outcomes	• Change in PDQ-39 response • Change in PDSS score
Evaluate the effect of bezisterim on discontinuation events for worsening of PD	• Proportion of subjects discontinuing from the study due to worsening of PD • Time to discontinuation due to worsening of PD
Assess the effect of bezisterim on epigenetics associated with biological age and alpha synuclein gene methylation	Change in DNA methylation up to week 12
Assess the effect of bezisterim on plasma biomarkers of inflammation and pharmacodynamics	Change in plasma biomarkers of inflammation up to week 12
Assess the effect of bezisterim on circulating biomarkers and correlations between biomarkers and clinical endpoint changes	Change and percent change from baseline in pre-specified exploratory biomarkers and the correlation between biomarkers and clinical endpoints at week 12
Assess population PK and E-R relationships for efficacy and safety of bezisterim	PK and E-R assessments for efficacy and safety where data permit
Safety	
Assess the safety and tolerability of bezisterim	• Treatment-emergent adverse events • Vital signs • Electrocardiograms • Clinical laboratory values • Physical exam • C-SSRS

PD = Parkinson's disease; MDS-UPDRS = Disorder Society Unified Parkinson's Disease Rating Scale; CGI-I = Clinical Global Impression-Improvement; CGI-S = Clinical Global Severity Scale; PDQ-39 = Parkinson's Disease Questionnaire-39; PDSS = Parkinson's Disease Sleep Scale; PK = pharmacokinetics; E-R = exposure response; C-SSRS

= Columbia-Suicide-Severity Rating Scale

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. If the results of the study are positive, then participants may be eligible to enter a longer-term, open-label safety study at a future date.

Phase 2a Data Reinforce Potential of Bezisterim to Improve Motor and Non-Motor Symptoms of Parkinson's Disease

An encore presentation, Improvement of Motor and Non-Motor Symptoms with Bezisterim (NE3107) Adjunctive to Carbidopa/Levodopa in Patients with Parkinson's Disease: A Phase 2a, Placebo-Controlled Study , suggested improvements in both motor and non-motor symptoms with bezisterim adjunctive to C/L. These findings were **presented** last month at the XXIX World Congress on Parkinson's Disease and Related Disorders hosted by the International Association of Parkinsonism and Related Disorders (IAPRD) in Lisbon, Portugal.

"The data from this comprehensive analysis of our Phase 2a trial strengthen the potential of bezisterim as an add-on therapy to levodopa for managing specific non-motor symptoms in Parkinson's disease, particularly sleep/fatigue and restless legs," said Joseph Palumbo, BioVie's Chief Medical Officer. "These findings built upon prior evidence of bezisterim's impact on motor symptoms and helped inform the direction of our Parkinson's disease program. We believe that our body of evidence to-date positions bezisterim well for further evaluation in our larger, late-stage SUNRISE-2 trial."

Patients treated with bezisterim and C/L experienced superior improvements on the Disorder Society Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Part III at 2- and 3-hour marks when compared to placebo. In patients younger than 70 years old (~50% of the total patient population) the advantage for bezisterim-treated patients was -4.7 points. Furthermore, 30% of bezisterim-treated patients experienced improvement in their ability to move, having Part III scores prior to their first morning dose of C/L that were equal to or better than Part III scores associated with their being in the "ON" state after C/L treatment at the start of the study, whereas none of the placebo patients had the similarly improved morning Part III scores. The difference was statistically significant (p=0.02).

Bezisterim-treated patients experienced a significant improvement of -2.4 points for the sleep/fatigue domain of the Non-Motor Symptom Scale (NMSS) in Parkinson's disease, whereas placebo patients experienced a worsening of +1.0 points (p=0.0159). Sleep/fatigue domain improvements correlated with motor score improvements (r=0.51; p=0.0259). More patients on bezisterim had improvements in the NMSS sleep/fatigue domain, while more patients on placebo worsened.

Bezisterim-treated patients experienced an improvement of -0.89 on the urge to move legs/restlessness in legs whereas placebo patients experienced a worsening of +0.99 (p=0.0321).

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 NFkB and the subsequent expression of inflammatory cytokines (IL-6, TNF, IFNg). Bezisterim has been shown to modulate the activation of NFkB 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 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:
Bruce Mackle
Managing Director
LifeSci Advisors, LLC
bmackle@lifesciadvisors.com

For Media Inquires
Melyssa Weible
Managing Partner, Elixir Health Public Relations
Ph: +1 201-723-5705
mweible@elixirhealthpr.com