NEWS RELEASE

BioVie Presents Rationale for Potentially Pivotal Trial of NE3107 in the Treatment of Parkinson's Disease at 2023 International Association of Parkinsonism and Related Disorders World Congress

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CARSON CITY, Nev., May 16, 2023 (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 detailing the supporting data and rationale for a potentially pivotal clinical trial of NE3107 in the treatment of Parkison’s Disease was presented at the **2023 World Congress on Parkison’s Disease and Related Disorders (IAPRD)** , held in Chicago, IL May 13-16, 2023.

In a poster presentation titled Rationale for a Potentially Pivotal Study of NE3107 in Parkinson’s Disease (Osman N., Ahlem, C., et al), outcomes from two previously reported studies that assessed the potential of NE3107 in the treatment of Parkinson’s Disease (PD) and Alzheimer’s Disease (AD) were highlighted. The Company’s NM201 (**NCT05083260**) study was an exploratory, Phase 2, double-blind, placebo-controlled study, that assessed the safety, tolerability, and efficacy of NE3107 or placebo in combination with carbidopa/levodopa (C/L) in patients with Parkinson’s Disease over 27 days, and its exploratory phase 2, open label, single arm study (**NCT05227820**) that assessed the safety and efficacy of 20 mg oral NE3107 in 18 patients with mild cognitive impairment (MCI) or mild dementia and 5 patients with moderate dementia over 3 months.

Highlighted Results from the NM201 Study

- Patients treated with NE3107 + C/L experienced greater improvements in their Motor Disease Society- Unified Parkinson's Disease Rating Scale (MDS UPDRS) Part III score than patients treated with placebo + C/L at the 2- and 3-hour marks
- Patients <70 years old treated with NE3107 + C/L experienced improvements that were ~6 points better than

those who received placebo + C/L

- Five (26%) of the 19 patients treated with NE3107, compared to none of the 19 placebo treated patients, who had a baseline of morning OFF experienced a morning ON state prior to receiving their morning medications on day 28; this difference was statistically significant (p=0.046)
- The study met its endpoints; investigators concluded that NE3107 + C/L combination treatment was associated with clinically meaningful and superior improvements (3+ points) on the motor examination part (Part III) of the MDS UPDRS

Results from the AD Phase 2 Study

- NE3107 was associated with improvements in neurophysiological, neuropsychological, and biomarker status
- Plasma TNFα levels decreased from baseline in 61% (n=11) of all 18 patients analyzed and 64% (n=9) of 14 patients with MMSE ≥20 (MCI or mild dementia), suggesting lower inflammation
- NE3107 treatment was associated with several patient and study partner reported benefits, including improved mood and memory

Presenters noted that to date, no adverse safety signal has been observed in any clinical study of NE3107. Presenters concluded that data from the two studies form the basis of a future, potentially pivotal confirmatory study to demonstrate the safety and efficacy of NE3107 in Parkinson's Disease patients. Presenters further concluded that the highlighted findings "demonstrate the potential intrinsic and levodopa enhancing, pro motoric activity of NE3107 that is consistent with data from animal models and support further clinical investigation of NE3107 in late phase trials."

"Throughout the past several months, data reported or presented at major medical conferences have established a compelling rationale for further clinical evaluation of NE3107 in Parkinson's Disease," said Cuong Do, BioVie's President & CEO. "We were pleased to present these summarized findings at the IAPRD, and look forward to advancing our program to explore the unique mechanism of action of NE3107 in a potentially pivotal Phase 3 study."

About Inflammation and NE3107's Mechanism of Action

Neuroinflammation, insulin resistance, and oxidative stress are common features in the major neurodegenerative diseases, including Alzheimer's Disease (AD), Parkinson's Disease (PD), frontotemporal lobar dementia, and ALS. NE3107 is an oral small molecule, blood-brain permeable, compound with potential anti-inflammatory, insulin sensitizing, and ERK-binding properties that may allow it to selectively inhibit ERK-, NFκB- and TNF-stimulated inflammation. NE3107's potential to inhibit neuroinflammation and insulin resistance forms the basis for the Company's work testing the molecule in AD and PD patients.

Remarkable parallels exist between AD and PD, among them activated microglia driving inflammation, involvement of TNFα, oxidative stress, protein misfolding, mitochondrial dysfunction, and insulin resistance. In preclinical and clinical studies, NE3107 reduced inflammation and enhanced insulin sensitivity, both of which are important to PD pathology. Preclinical studies in marmoset monkeys have shown NE3107 administered alone to be as pro-motoric as levodopa, underscoring the apparently critical role of inflammation in expression of PD dysmobility. When NE3107 was administered with levodopa, the combination improved motor control better than either drug alone. Furthermore, in the marmoset study, NE3107 reduced the severity of levodopa induced dyskinesia (LID) concurrent with pro-motoric benefit and decreased neurodegeneration, preserving twice as many dopaminergic neurons compared to control.

About BioVie

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 NE3107 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 Alzheimer's and Parkinson's diseases. The Company is conducting a potentially pivotal Phase 3 randomized, double-blind, placebo-controlled, parallel-group, multicenter study to evaluate NE3107 in patients who have mild to moderate Alzheimer's disease (NCT04669028). Results of a Phase 2 investigator-initiated trial (NCT05227820) showing NE3107-treated patients experienced improved cognition and biomarker levels were presented at the Clinical Trial in Alzheimer's Disease (CTAD) annual conference in December 2022. An estimated six million Americans suffer from Alzheimer's. A Phase 2 study of NE3107 in Parkinson's disease (NCT05083260) has completed, and data presented at the International Conference on Alzheimer's and Parkinson's Disease and Related Neurological Disorders conference 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 NE3107 and levodopa vs. patients treated with levodopa alone, and no drug-related adverse events. In liver disease, the Company's Orphan drug candidate BIV201 (continuous infusion terlipressin), with FDA Fast Track status, is being evaluated in a US Phase 2b study for the treatment of refractory ascites due to liver cirrhosis. BIV201 is administered as a patent-pending liquid formulation. 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 **http://www.bioviepharma.com/** .

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding the Company's strategy, plans and objectives, such as statements regarding the Company's anticipated timeline for announcing results from

the NE3107 Phase 3 potential pivotal trials. Forward-looking statements may generally 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 risks associated with conducting and completing clinical trials, including our reliance on third parties to conduct our clinical trials, to successfully defend potential future litigation, our ability to raise capital when needed on reasonable terms, 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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