NEWS RELEASE

BioVie's Phase 2 Trial Assessing NE3107's Pro-motoric Activity in Parkinson's Disease is Fully Enrolled

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CARSON CITY, Nev., Oct. 19, 2022 (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 the Company’s Phase 2 trial assessing NE3107’s potential pro-motoric impact in Parkinson’s disease has fully enrolled 44 patients. Topline data readout is expected in December 2022.

The NM201 study (NCT05083260) is a double-blind, placebo-controlled, safety, tolerability, and pharmacokinetics study in Parkinson's disease (PD) participants treated with carbidopa/levodopa and NE3107. 44 patients with a defined L-dopa “off state” were randomized 1:1 placebo:active 20 mg twice daily for 28 days. This trial was launched with two design objectives:

1. The primary objective is a drug-drug interaction study as requested by the FDA to demonstrate the absence of adverse interactions of NE3107 with levodopa in humans (no indications of adverse DDI were observed in prior animal studies). Safety assessments will evaluate standard measures of patient health and potential for drug-drug interactions affecting L-dopa PK and activity.
2. The secondary objective is to explore an efficacy signal and determine if preclinical indications of promotoric activity and apparent enhancement of levodopa activity in MPTP rodents and nonhuman primates is observed in humans. Efficacy assessments use the Motor Disease Society Unified Parkinson’s Disease Rating (MDS-UPDRS) parts 1-3, ON/OFF Diary, and Non-Motor Symptom Scale.

Commenting on the PD trial progress, Cuong Do, BioVie’s President and CEO, said “To date, we have seen no drug-related adverse events in reviews. Additionally, we are detecting what we believe to be an efficacy signal among patients who have completed 28 days of treatment, and we look forward to having the full data from the trial to quantify the full therapeutic impact.”

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 that is a blood-brain permeable compound with potential anti-inflammatory, insulin sensitizing, and ERK-binding properties that may allow it to selectively inhibit ERK- and NFκB-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. The company recently provided topline data from an exploratory biomarker Phase 2 trial studying NE3107 in AD and has an active Phase 3 trial in AD that is expected to have topline results by mid-2023.

Remarkable parallels exist between AD and PD, among them activated microglia driving inflammation, involvement of TNFα, oxidative stress, mitochondrial dysfunction, and insulin resistance. In nonclinical and clinical studies, NE3107 reduced inflammation and enhanced insulin sensitivity, both of which are important to PD pathology. Nonclinical 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 dismobility. 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 therapies to overcome unmet medical needs in chronic debilitating conditions. 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) and is targeting primary completion in mid-2023. An estimated six million Americans suffer from Alzheimer's. A Phase 2 study of NE3107 in Parkinson's disease (NCT05083260) is fully enrolled and expects to have topline data readout in December 2022. 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 with top-line results anticipated in mid-2023. BIV201 is administered as a patent-pending liquid formulation. The active agent is approved in about 40 countries for related complications of advanced liver cirrhosis but is not available in the US or Japan. For more information, visit 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, 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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