NEWS RELEASE

BioVie Announces FDA Authorization to Initiate Phase 2 Trials Assessing NE3107's Pro-motoric Activity in Parkinson's Disease

2021-10-26

SANTA MONICA, Calif., Oct. 26, 2021 (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 FDA has authorized the company to initiate a Phase 2 study assessing NE3107’s potential pro-motoric impact in Parkinson’s disease patients.

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. 40 patients with a defined L-dopa “off state” will be randomized 1:1 placebo: active 20 mg twice daily for 28 days. Safety assessments will look at standard measures of patient health and potential for drug-drug interactions affecting L-dopa PK and activity. Efficacy assessments will use the Motor Disease Society Unified Parkinson’s Disease Rating (MDS-UPDRS) parts 1-4, Hauser ON/OFF Diary, and Non-Motor Symptom Scale.

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- and NFκB-stimulated inflammation. No major safety signals have been observed in nonclinical and clinical studies conducted to date.

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 has an active Phase 3 trial studying NE3107 in AD that is expected to have topline results by the end of 2022.

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.

The Company expects to initiate patient enrollment for the NM201 study before the end of 2021. Topline results are expected by the middle of 2022.

About BioVie

BioVie Inc. (NASDAQ: BIVI) is a clinical-stage company developing transformative therapies to overcome unmet medical needs in chronic debilitating conditions. 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 2 study for the treatment of refractory ascites with top-line results expected in mid-2022. The Company is also planning a pivotal Phase 3 study of BIV201 in the treatment of hepatorenal syndromeacute kidney injury (HRS-AKI) in 2022. 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. In neurodegenerative disease, BioVie acquired the assets of NeurMedix Inc., including NE3107 that inhibits inflammatory activation of ERK and NFB (e.g. TNF transcription) 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 subjects who have mild to moderate Alzheimer's disease (NCT04669028). An estimated six million Americans suffer from Alzheimer's. BioVie has initiated this study and is targeting primary completion in late 2022. A Phase 2a study of NE3107 in Parkinson's disease is planned to start later this year, and related compounds have additional potential to treat certain cancers. NE3107 is patented in the United States, Australia, Canada, Europe and South Korea. 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 clinical studies and to obtain approval for our product candidates, 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.

Contact:
Bruce Mackle
Managing Director
LifeSci Advisors, LLC
bmackle@lifesciadvisors.com