



NEWS RELEASE

# BioVie Announces Treatment of First Patient in Phase 2 Clinical Trial of NE3107 for the Treatment of Parkinson's Disease

2022-01-20

RENO, Nev., Jan. 20, 2022 (GLOBE NEWSWIRE) -- BioVie Inc., (NASDAQ: BIVI) ("BioVie" or the "Company") a clinical-stage company developing innovative drug therapies for the treatment of advanced liver disease and neurological and neurodegenerative disorders today announced the treatment of the first patient in the Company's Phase 2 clinical trial assessing the potential pro-motoric impact of its NE3107 asset 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 will be treated with carbidopa/levodopa and NE3107 or placebo. Forty patients with a defined PD medication "off state" will be randomized 1:1 placebo to: active NE3107 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 pharmacokinetics and activity. Exploratory efficacy assessments will use the Motor Disease Society Unified Parkinson's Disease Rating (MDS-UPDRS) parts 1-3, ON/OFF Diary, and Non-Motor Symptom Scale. Topline results are expected for the NM201 trial in mid-2022.

"Our NM201 study is designed to be an efficient, cost-effective assessment of the safety and pharmacokinetics profile, as well as the potential efficacy of NE3017 for the treatment of PD," said Cuong V. Do, Chief Executive Officer of BioVie. "Enrollment of the first patient in our human development program is a significant milestone for BioVie, and we look forward to data readout for NM201 in mid-2022."

In preclinical studies, NE3107 was shown to improve motor symptoms as effectively as L-dopa. When NE3107 was administered in combination with L-dopa, the combination demonstrated greater pro-motoric activity than NE3107 or L-dopa given alone. Furthermore, NE3107 in combination with L-dopa reduced the severity of L-dopa induced dyskinesia (LID) without decreasing the beneficial effect of the drug on motor symptoms. NE3107 treatment in monkeys preserved roughly twice as many dopaminergic neurons as vehicle-treated animals, suggesting that



NE3107 may have neuroprotective properties.

Neuroinflammation, insulin resistance, and oxidative stress are common features in the major neurodegenerative diseases, including Parkinson's Disease (PD), Alzheimer's Disease (AD), frontotemporal dementia and ALS. NE3107 is an oral small molecule, blood-brain permeable, compound with 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 safety studies, and the NE3107 adverse event profile has not differed from that of placebo in 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 Alzheimer's Disease that is expected to have topline results by the end of 2022.

#### About BioVie

BioVie Inc. (NASDAQ: BIVI) is a clinical-stage company developing innovative 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 due to liver cirrhosis with top-line results anticipated in mid-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 NFκB (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 2 study of NE3107 in Parkinson's disease has been authorized by the FDA to start in early 2022, 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 [www.bioviepharma.com](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.

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