NEWS RELEASE

BioVie Announces Completion of Patient Enrollment in Phase 3 Trial Assessing NE3107 in Alzheimer's Disease

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CARSON CITY, Nev., March 02, 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 its NM101 trial evaluating NE3107 in the treatment of patients with Alzheimer’s Disease, has achieved its revised enrollment target of 400 patients. The Company anticipates announcing top line results from the study in October 2023.

The NM101 trial is 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). The study has co-primary endpoints looking at cognition using the Alzheimer’s Disease Assessment Scale-Cognitive Scale (ADAS-Cog 12) and function using the Alzheimer’s Disease Cooperative Study-Clinical Global Impression of Change (ADCS-CGIC).

The NM101 trial protocol originally specified enrolling at least 316 patients equally randomized to treatment and placebo arms. The protocol also pre-specified the potential for a review by the data safety monitoring board (DSMB), in a manner that is blinded to the Company, when roughly 50% of the 316 enrolled patients have completed the study to determine if increasing enrollment of up to 400 patients might be desirable for the purpose of enhancing the probability of achieving statistical significance. Due to an accelerating pace of enrollment as the trial progressed, the Company enrolled 316 patients before 50% of enrolled patients had completed the study. Consequently, the Company decided to proceed to 400 patients without the pre-specified interim analysis.

“We look forward to having topline data from this trial in October,” said Cuong Do, BioVie’s President and CEO. “We are optimistic that this trial will provide similar data to what was seen in the Phase 2 exploratory study, which showed that patients treated with NE3107 experienced enhanced cognition as measured by multiple assessment

tools, including a 2.1 points improvement on the modified ADAS-Cog12 scale."

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 topline data released in December 2022, showed 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 our strategy, plans and objectives, such as statements regarding our anticipated timeline for announcing top line results and our current expectations regarding the data from the NM101 trial. 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 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.

For Investor Relations Inquiries:

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