NEWS RELEASE

BioVie Announces First Patient Enrolled in Phase 3 Study of NE3107 in Alzheimer's Disease

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SANTA MONICA, Calif., Aug. 05, 2021 (GLOBE NEWSWIRE) -- BioVie Inc. (NASDAQ: BIVI) ("BioVie" or "Company"), a clinical-stage company developing innovative drug candidates for the treatment of neurological and neurodegenerative disorders, liver disease and certain cancers, today announced that the Company has enrolled the first patient into the NM101 Phase III clinical study testing NE3107 for the treatment of Alzheimer's Disease (AD).

The NM101 study (**NCT04669028**) is a potentially pivotal Phase 3, randomized, double blind, placebo-controlled, US multicenter study of NE3107 in 316 subjects with mild to moderate AD. In addition to conventional cognition, memory, functional, behavioral and imaging end points, NM101 will assess measures of glycemic control, brain glucose utilization and systems dysregulation. The mechanistic basis for the study design was recently published in a peer-reviewed article in Neurodegenerative Disease Management (**https://doi.org/10.2217/nmt-2021-0022**). This study design and pathophysiology and mechanism data were also presented as Poster 55458 entitled "Rationale for an Anti-inflammatory Insulin Sensitizer in a Phase 3 Alzheimer's Disease Trial" by Christopher L Reading, PhD, BioVie's Executive Vice President for Neuroscience Research & Development at the 2021 Alzheimer's Association International Conference (AAIC), July 28, 2021. The study aims to have data readout by the end of 2022.

"NM101 is the first randomized, double blind, placebo-controlled Phase 3 trial conducted by any company to test a potentially disease modifying anti-inflammatory insulin sensitizer compound in subjects with mild to moderate AD," said Cuong Do, Chief Executive Officer of BioVie. "In prior animal studies and Phase 1 and 2 human clinical studies, NE3107 generated data supporting reduced neuroinflammation and insulin resistance, both of which are recognized as important players in AD pathology."

Neuroinflammation and insulin resistance are associated with cognitive decline associated with Alzheimer's. NE3107's potential to inhibit neuroinflammation and insulin resistance forms the basis for the hypothesis that it may impact cognitive decline in Alzheimer's patients.

Inflammation is increasingly recognized as an important mechanism in AD. Inflammation drives activation of the Extracellular Signal-Regulated Kinase (ERK) signaling molecule and Nuclear Factor kappa-B (NFκB). NFκB is the central regulator of proinflammatory cytokines and chemokines important in neurodegeneration. Furthermore, NFκB activation in the brain is triggered by Amyloid Beta (Aβ) and phosphorylated tau (P-tau), and by the very proinflammatory mediators that NFκB stimulates, leading to perpetual low-grade chronic inflammation.

Inflammation also triggers inhibitory phosphorylation of Insulin Receptor Substrate 1/2, leading to insulin resistance (IR) and the inhibition of insulin signaling. As insulin is the master regulator of energy and metabolism, neuroinflammation's disruption of insulin signaling is believed to contribute to AD pathology. The Mayo Clinic estimates that up to 81% of AD subjects have impaired glucose tolerance or type 2 diabetes mellitus.

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 preclinical and clinical studies to date.

About BioVie

BioVie Inc. (NASDAQ: BIVI) is a clinical-stage company developing potentially 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 early 2022. The Company is also planning a Phase 3 study of BIV201 in the treatment of hepatorenal syndrome-acute 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 approved or available in the U.S. or Japan. In neuro-degenerative disease, BioVie recently 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 neuroinflammation and insulin resistance are thought to be drivers of Alzheimer's and Parkinson's diseases. The Company is conducting a 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 is planned for later this year, and related compounds have additional potential to treat certain cancers. NE3107 and related compounds are globally patented, potentially first-in-class molecules. For more information, visit **http://www.biovieinc.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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