



NEWS RELEASE

# BioVie Presents Data Supporting use of NE3107 in the Treatment of Alzheimer's Disease at 2021 Alzheimer's Association International Conference

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SANTA MONICA, Calif., July 27, 2021 (GLOBE NEWSWIRE) -- BioVie Inc., a clinical-stage company developing innovative drug therapies for the treatment of liver disease, neurodegenerative disease and certain cancers, announced today that a poster by Christopher L Reading, PhD, BioVie's Executive Vice President for Neuroscience Research & Development was presented at the 2021 Alzheimer's Association International Conference (AAIC).

Poster 55458 entitled "Rationale for an anti-inflammatory insulin sensitizer in a phase 3 Alzheimer's Disease trial" highlighted the safety profile and broad mechanism of action against features of Alzheimer's Disease of NE3107—an oral small molecule, blood-brain permeable anti-inflammatory insulin sensitizer that binds ERK. NE3017 has also been shown to selectively inhibit inflammation-driven ERK- and NFκB-stimulated inflammation without inhibiting their homeostatic functions. In prior animal studies and Phase 1 and 2 human clinical trials, NE3107 has been demonstrated to be safe and effective at reducing neuroinflammation and insulin resistance, both of which are recognized as important players in Alzheimer's Disease pathology.

BioVie has obtained authorization from the U.S. Food & Drug Administration to initiate a pivotal Phase 3 trial of NE3107 in Alzheimer's Disease called the NM101 study ( **NCT04669028** ). NM101 is a randomized double blind, placebo-controlled, US multicenter study of NE3107 in 316 subjects with mild to moderate Alzheimer's Disease. 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 basis for this study design was recently published in a peer-reviewed article in Neurodegenerative Disease Management (<https://doi.org/10.2217/nmt-2021-0022>). The study is actively recruiting and screening patients and aims to have data readout by the end of 2022.

At the AAIC this year there are literally hundreds of presentations on inflammation and Alzheimer's disease and



dozens on insulin resistance and AD.

“NE3107 is the first potentially disease modifying, anti-inflammatory insulin sensitizer therapy in a phase 3 trial,” said Cuong Do, Chief Executive Officer of BioVie. “Additionally, our NM101 study is the first randomized, double blind, placebo-controlled Phase 3 trial conducted by any company to test a disease modifying anti-inflammatory insulin sensitizer therapy in subjects with mild to moderate Alzheimer’s. NE3107 has been shown to decrease the inflammatory signal transduction cascades that are known to inhibit insulin action in the brain, and to restore insulin action. NE3107 blocks the major inflammatory nodes of extracellular signal-regulated kinase (ERK) and nuclear factor kappa B (NFkB). In addition, examples were presented to show that NE3107 preserves both ERK and NFkB homeostatic functions. We are initiating this trial with the aim of reading out the end of 2022.”

The AAIC is being held virtually and in Denver, CO, July 26-30, 2021.

#### 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 early 2022. The Company is also planning a pivotal Phase 3 study of BIV201 in the treatment of hepatorenal syndrome-acute kidney injury (HRS-AKI). 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 recently acquired the assets of NeurMedix Inc., including NE3107, that binds to ERK and selectively reduces neuroinflammation and insulin resistance. Both are drivers of Alzheimer’s and Parkinson’s diseases. The FDA has authorized a 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 is planning to initiate this trial in mid-2021 and targeting primary completion in late 2022. A Phase 2 trial 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, 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 trials 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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