NEWS RELEASE

Basis for BioVie's Phase 3 Clinical Trial of NE3107 in the Treatment of Alzheimer's Disease Published in Neurodegenerative Disease Management

2021-07-16

SANTA MONICA, Calif., July 16, 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 an article summarizing the scientific rationale for the Company's upcoming pivotal Phase 3 Trial of its NE3107 asset in Alzheimer's disease has been published in the medical journal Neurodegenerative Disease Management .

The article, NE3107 Alzheimer's Phase III Study Rationale, Design and Therapeutic Modulation of Neuroinflammation and Insulin Resistance, was authored by BioVie's Christopher L Reading, PhD, EVP Neuroscience R&D, Clarence N Ahlem, EVP Product Development, and Michael F Murphy, MD, PhD, CMO & CSO Worldwide Clinical Trials. In addition to presenting the design of the NM101 trial, this publication details the rationale for an anti-inflammatory insulin sensitizer in Alzheimer's disease, and elucidates the mechanism of NE3107 on the pathophysiology of Alzheimer's neurodegeneration and cognitive impairment. NE3107 has demonstrated a favorable safety profile based on chronic dosing safety studies in rats and dogs and in human clinical trials to date. NE3107 has shown a low potential for drug-drug interactions, is not immunosuppressive, and has a nonclinical profile that facilitates the evaluation of clinically relevant hypotheses in patients with Alzheimer's disease.

BioVie plans to launch a pivotal Phase 3 trial in Alzheimer's this summer to assess how treatment with NE3107 could slow cognitive decline and improve function and behavior compared to placebo as measured by Alzheimer's Disease Assessment Scale Cognitive Subscale 12 (ADAS-Cog12) and the Alzheimer's Disease Cooperative Study-Clinical Global Impression of Change (ADCS-CGIC). The study will have a number of secondary endpoints involving additional neuropsychological endpoints, glycemic control, and insulin sensitivity. The trial, a Phase 3, randomized, double-blind, placebo-controlled, parallel group, multicenter study of NE3107 in subjects who have mild to moderate Alzheimer's disease (**NCT04669028**) will be conducted at approximately thirty clinical sites in the U.S.

“NE3107 is one of the most exciting inhibitors of the pathological inflammatory cascade I have seen,” said Mr. Cuong Do, Chief Executive Officer of BioVie. “Research done to date indicates that this is a highly-targeted small molecule that crosses the blood-brain barrier with an excellent safety-profile. NE3107 blocks insulin resistance and neuroinflammation at the right time and place, without inhibiting homeostatic activity. As this manuscript illustrates, NE3107 has extremely broad potential, and we look forward to initiating the NM101 trial and validating this promise.”

NE3107, a new drug candidate in development for Alzheimer’s and Parkinson’s Diseases and other conditions, is an ERK inhibitor that selectively inhibits neuroinflammation and insulin resistance. The relationship between inflammation and insulin resistance is well established in type 2 diabetes. This relationship has been further advanced for Alzheimer’s disease, which is being referred in the scientific literature as “type 3 diabetes,” and is being intensively studied by diabetes and neurodegeneration experts. NE3107 is an anti-inflammatory insulin sensitizer that previously showed improvement in insulin sensitivity, and restoration of inflammation-driven systems dysregulation in clinical trials in both impaired glucose tolerance and advanced type 2 diabetic subjects.

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.

Contact:

INVESTOR RELATIONS:

Bruce Mackle

Managing Director

LifeSci Advisors, LLC

bmackle@lifesciadvisors.com