NEWS RELEASE

BioVie's Phase 3 Trial Assessing NE3107 in Alzheimer's Disease Has Fully Enrolled the Targeted 316 Patients

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CARSON CITY, Nev., Nov. 29, 2022 (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 more than 316 patients have enrolled in its Phase 3 trial, thereby achieving its trial enrollment target. Furthermore, the Company has opted to continue enrolling up to 400 patients without the pre-specified interim data analysis due to NE3107’s safety in this study to date and a faster than expected pace of study enrollment.

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 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. The pace of enrollment increased dramatically in recent months, creating a situation where the Company finished enrolling all 316 patients before 50% of enrolled patients had completed the study.

“We are pleased and encouraged by the dramatic increase in the pace of enrollment in recent months, and have decided that forgoing the interim analysis and continuing enrollment up to 400 patients is the best course for

obtaining the strongest possible data set," said Cuong Do, BioVie's President and CEO. "We believe all 400 patients can be enrolled in the coming months , and anticipate topline results will be available before the end of 3Q2023. By taking this step we believe we have enhanced our probability for success, and thus our ability to bring this hoped for innovation to the Alzheimer's patient community."

This decision to expand enrollment was informed by the following factors:

1. The Company monitors blinded study data daily and has not observed any serious adverse events that appear to be attributed to the administered study drug (NE3107 or placebo). In addition, the safety review committee has met in September and in November to review current safety of the trial. This safety profile is consistent with what was seen in prior clinical trials showing no statistical difference in the AE rates for the treated vs. placebo groups;
2. The recently released topline data from a Company-supported Phase 2 exploratory biomarker study showing that patients treated with NE3107 experienced improved cognition as measured by a modified ADAS-Cog12 score, reduced TNFα (i.e., inflammation) in a manner that's correlated to improvements in cognition, reduced CSF p-tau levels and the ratio of p-tau to $A\beta_{42}$, and imaging findings suggestive of improved neuronal health. Despite the open-label nature of the exploratory study, the emerging data and correlations provide encouraging signs of what we may see in the upcoming Phase 3 data reveal; and
3. The current pace of patient enrollment suggest that the additional 84 patients can be enrolled in approximately two months.

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 therapies to overcome unmet medical needs in chronic debilitating conditions. 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) and is targeting primary completion by 3Q2023. An estimated six million Americans suffer from Alzheimer's. A Phase 2 study of NE3107 in Parkinson's disease (NCT05083260) is fully enrolled and expects to have topline data readout in December 2022. 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 with top-line results anticipated in mid-2023. 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, 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 pre-clinical or clinical studies and to obtain approval for our product candidates, to successfully defend potential future litigation, 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.

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