NEWS RELEASE

BioVie Presents Data Highlighting Baseline Characteristics of Study Population in Phase 3 Trial of NE3107 in Mild to Moderate Alzheimer's Disease

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Data from Phase 3 Trial of NE3107 Presented as Poster at the 148 th American Neurological Association Annual Meeting

CARSON CITY, Nev., Sept. 11, 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 preliminary baseline data from its multicenter, randomized, placebo-controlled Phase 3 study (**NCT04669028**) of NE3107 in patients with mild to moderate Alzheimer’s Disease (AD) was presented as a poster at the American Neurological Association (ANA) annual meeting, being held September 11-13, 2023 in Philadelphia, PA.

The poster, Metabolic Dysregulation in Probable Alzheimer’s Disease (Christopher Reading, et al), is being presented by Joseph Palumbo, Chief Medical Officer of BioVie, and highlights the preliminary baseline metabolic and inflammation characteristics from the Phase 3 study population (see Table 1).

“The poster presentation does not reveal new data readouts,” stated Dr. Palumbo. “Instead, it provides an understanding of the patient population at the start of the trial, as understood to date. When looking at this preliminary baseline data in its totality, we see that patients enrolled in the trial have underlying medical conditions that are known risk factors for dementia.” BioVie is targeting primary completion of this study in the fourth quarter of calendar year 2023. Following the completion of all patients’ participation in the study, the clinical team will enter final data into the electronic data system, resolve any outstanding queries, and begin the cleaning process leading to database lock.

At baseline, the majority of the study population are coded with abdominal obesity (85%), hypertension (61%), and

impaired glucose metabolism (IFG/T2D; 52%). Almost half of all patients (47%) are coded as having some degree of insulin resistance, 40% and 30% of patients are coded as having hypertriglyceridemia and hypercholesterolemia, respectively; and patients are coded as having elevated inflammatory markers. Since these are known dementia risk factors, we believe NE3107's potential ability to help patients improve on some of these factors, as shown in some prior clinical trials, suggests that it may help patients improve on cognitive metrics in this trial.

Both Aβ+ and Aβ− patients with dementia were enrolled in the study and had, at baseline, comparable CDR-SB scores indicative of mild dementia. At baseline, enrolled Aβ+ patients had worse ADAS-Cog12 and MMSE scores (indicating lower cognitive functioning), while the enrolled Aβ− patients had significantly higher inflammation, insulin resistance, IFG, and hypertension, compared to their Aβ+ counterparts.

Subgroup analysis reveal higher degrees of impaired glucose metabolism and insulin resistance among the APOE ε4− patients compared to their APOE ε4+ counterparts and comparable baseline MMSE scores, indicating that both groups had mild to moderate cognitive impairment. Investigators in this study concluded that in the absence of classical risk markers, such as Aβ+ and APOE ε4+, central obesity (high WHR) and age-related systems dysregulation, involving inflammation (elevated CRP, RANTES, and C1q), hyperglycemia, insulin resistance, dyslipidemia, and hypertension, may contribute to probable AD and disease progression.

Prior clinical results indicate that NE3107 may be capable of reducing inflammation in a manner that was in some cases significantly correlated with observed improvements in cognition. Specifically, in July 2023, the Company presented a poster detailing the epigenetic basis for how NE3107 may have the potential to regulate methylation of specific genes in a manner that significantly correlated with observed cognitive and biomarker improvements at the Alzheimer's Associate's International Conference (AAIC) held in Amsterdam from July 16 through July 20, 2023. The poster presentation titled Treatment-Induced Epigenetic Modifications in MCI and Probable Alzheimer's (Reading C, et al.), showed how patients with clinical dementia treated with NE3107 for three months saw significant reductions in the level of DNA methylation, and that such reductions were, in some cases, significantly correlated with observed improvements in various cognitive measures (e.g., ADAS-Cog11, CDR, ADCOMS, QDRS) and biomarkers (including TNFα, CSF p-Tau/Aβ 42 , precuneus glutathione). NE3107's potential ability to reduce inflammation and insulin resistance suggests that it may be of benefit to both Aβ+ and Aβ− patients as well as APOE ε4+ and APOE ε4− patients.

Table 1. Baseline characteristics

Characteristic	All N=378	Aβ+ [a] n=57	Aβ− [b] n=77	P	APOE ε4+ n=97	APOE ε4− n=259	P
Age, mean (SE) y	73 (0.3)	76 (0.8)	72 (0.6)	**	73 (0.6)	73 (0.4)	-
Female, %	55	53	67	-	64	64	-
High WHR [c], %	85	84	84	-	81	82	-
FPG, mean, mg/dL	112	100	112	*	106	115	*

IFG, %	32	18	35	#	25	36	-
T2D, %	20	14	22	-	17	25	
Fasting insulin, mean (SE), µIU/mL	16 (1.1)	10 (1.0)	15 (2.4)	*	12 (1.1)	17 (1.6)	*
High (>23), %	15	9	15	-	10	17	-
HOMA2-IR, mean (SE)	1.8 (0.1)	1.3 (0.2)	1.9 (0.2)	*	1.5 (0.1)	1.9 (0.1)	*
1.4-2.5, %	27	13	29	##	24	27	-
>2.5, %	20	15	21	-	15	22	-
MAGE, mean (SE), mg/dL	70 (2.5)	62 (3.4)	68 (4.6)	-	68 (4.2)	71 (3.1)	-
CRP, mean (SE), mg/L	4.1 (0.4)	1.8 (0.2)	6.3 (1.2)	**	3.6 (0.8)	4.3 (0.4)	
>3, %	67	13	28	#	20	32	-
>10, %	18	0	18	##	4	21	
C1q, mean (SE), mg/dL	22 (0.2)	21 (0.4)	44 (0.5)	-	21 (0.3)	22 (0.2)	-
High (>22), %	32	28	33	-	34	31	-
RANTES, mean (SE), pg/mL	28 (1.6)	23 (2.0)	33 (2.8)	**	26 (2.8)	29 (2.0)	-
Cholesterol, mean (SE), mg/dL	189 (4)	174 (5)	175 (5)	-	183 (4)	180 (3)	-
High (>199), %	30	22	26	-	30	30	-
Triglycerides, mean (SE), mg/dL	143 (4)	130 (9)	143 (8)	-	132 (5)	148 (5)	-
High (>149), %	40	27	36	-	36	41	-
High BP (>130/80), %	61	47	71	##	54	63	-
Low BP (<66 diastolic), %	13	12	2.5	##	15	4.1	##
CDR-SB, mean (SE)	6.3 (0.1)	6.6 (0.3)	6.2 (0.2)	-	6.6 (0.2)	6.1 (0.1)	**
MMSE, mean (SE)	20 (0.1)	20 (0.1)	21 (0.2)	**	20 (0.2)	20 (0.1)	-
ADAS-Cog12, mean (SE)	28 (0.4)	31 (1.4)	25 (0.7)	**	30 (0.9)	27 (0.5)	**
ADCS-ADL, mean (SE)	55 (0.6)	57 (1.4)	57 (1.2)	-	56 (1.0)	55 (0.5)	-
Aβ42/40 ratio, mean (SE)	0.095 (0.001)	0.085 (0.001)	0.107 (0.001)	**	0.089 (0.002)	0.098 (0.001)	**

[a] Positive Precivity test; [b] Negative Precivity test; [c] For females WHR>0.8 and for males WHR>0.95; Mann-Whitney * P <0.05, ** P <0.01; Fisher's Exact Test #<0.05, ## <0.01.

About NE3107

NE3107 is an oral small molecule, blood-brain permeable anti-inflammatory insulin sensitizer that binds extracellular signal-regulated kinase. BioVie's Phase 3 trial is the largest study to date to evaluate the safety and efficacy of NE3107 in patients with AD. NE3107 is the only anti-inflammatory agent currently in phase 3 development for AD. Consistent with the proposed anti-inflammatory and insulin-sensitizing properties of NE3107, this phase 3 study was designed to confirm the efficacy and safety of NE3107 treatment in patients with probable AD.

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 data presented at the International Conference on Alzheimer's and Parkinson's Disease and Related Neurological Disorders conference in Gothenburg, Sweden in March 2023 showed significant improvements in “morning on” symptoms and 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 the Company’s strategy, plans and objectives, such as statements regarding the Company’s anticipated timeline for announcing results from the NE3107 Phase 3 potential pivotal trials. 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 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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