



NEWS RELEASE

# BioVie Announces Pipeline Update and Near-Term Clinical Priorities

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Recently completed financing provides sufficient funds for near-term Parkinson's Disease priority

Plans for Phase 2b trial of NE3107 as first-line monotherapy for Parkinson's Disease being finalized with targeted launch late-summer 2024

Once-daily NE3107 formulation expected to be available early 2025 and will be used for Phase 3 trial in Alzheimer's Disease

Phase 3 trial for BIV201 in preparation following FDA feedback with guidance on development path; program delayed pending partnership funding

CARSON CITY, Nev., March 11, 2024 (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 its recently completed funding round provides opportunity to further the Company's clinical priorities in Parkinson's Disease (PD), Alzheimer's Disease (AD), and ascites/liver disease. The Company continues to explore longevity and aging in conjunction with external collaborators.

## Parkinson's Disease

As presented at the International Conference on Alzheimer's and Parkinson's Diseases 2024 (AD/PD™ 2024) this past weekend in Lisbon, Portugal, patients with moderate and severe PD treated with NE3107 appear to have experienced significant improvements in non-motor symptoms and motor control while placebo-treated patients worsened. <sup>1</sup> Furthermore, previous preclinical studies have shown NE3107 has a neuroprotective signal, whereby marmosets treated with NE3107 retained nearly twice as many dopaminergic neurons at the end of study compared to the untreated controls. <sup>2</sup>



Based on these findings, the Company is planning a Phase 2b for NE3107 as first-line monotherapy for recently diagnosed PD patients needing symptomatic therapy for the first time. The trial targets enrolling 100-150 patients in a 6-month trial with the Part 3 (motor) score on the MDS-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) as the primary endpoint. The Bayesian trial design allows an independent data monitoring board to stop the trial as soon as the treatment arm achieves the defined 4-5 points advantage compared to placebo on the UPDRS motor score. The Company anticipates initiating this trial in the late summer of 2024.

#### Alzheimer's Disease

In AD, data presented at AD/PD™ 2024 suggest that NE3107-treated patients saw an advantage compared to placebo of -0.95 (68% slowing of decline) on CDR-SB, -0.94 (26%) on ADAS-COG-12, -0.43 (139%) on ADAS-CGIC, -0.03 (27%) on ADCOMS, +1.02 (40%) on MMSE, and +3.08 (47%) on ADCS-ADL. <sup>3</sup>Significant improvements on a number of biomarkers were also observed for treated patients compared to placebo. <sup>4</sup> Due to the encouraging trending data, the Company intends to repeat the Phase 3 trial for NE3107 in patients with mild- to moderate-AD in early 2025 to take advantage of progress with a once-daily (QD) formulation of NE3107. The new QD formulation is expected to be ready in early-to-mid 2025, and the Company believes this is the more desirable presentation of the drug to help increase treatment adherence.

#### Ascites

The Company terminated its Phase 2b trial for BIV201 in refractory ascites after the study enrolled one-half of intended patients as data available showed that BIV201 reduced ascites fluid buildup by over 50% in those that completed treatment. The company has received the feedback needed from the U.S. Food and Drug Administration (FDA) to finalize the remaining preclinical requirements and design the Phase 3 protocol. Only one Phase 3 trial is potentially needed as BIV201 has already received Orphan and Fast Track designations. The trial will focus on an earlier stage of the disease progression – after cirrhotic patients with ascites have experienced an acute kidney injury (AKI) – to research whether BIV201 treatment can reduce the number of subsequent complications from cirrhosis and ascites.

The Company increased its cash balance by approximately \$18.8 million after closing on an equity financing round last week for gross proceeds of \$21 million. The funds raised allow the Company to focus on launching the PD trial this summer and completing development of the NE3107 QD formulation for the AD trial in 2025.

“Prioritizing the Parkinson's program allows us to focus limited resources on the trial that should provide topline results by mid-2025, create a significant catalyst for the Company, and potentially lead the way to the first new therapy for PD since the advent of levodopa over five decades ago,” commented Cuong Do, BioVie's President and CEO. “We have great hopes for the Alzheimer's program, but resources and the expected availability of a once-daily version of NE3107 makes delaying a year the best solution for patients and shareholders. BIV201 remains our most

de-risked program, but it unfortunately is a program that will take two years to complete. We look forward to partnering this program with a company interested in developing the first potential treatment for ascites and related complications potentially at an earlier stage of cirrhosis.”

## 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 conducted and reported efficacy data from its 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 U.S. FDA Fast Track status, is being evaluated and discussed with guidance received from the FDA regarding the design of Phase 3 clinical testing of BIV201 for the treatment of ascites due to chronic liver cirrhosis. 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. In this press release, forward-looking statements include, but are not limited to, the potential impact of NE3107 on cognition and function among study participants and topline data from the NE3107 trial and the Company's estimate of clinical trial progress for its product candidates. 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, our ability 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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- <sup>1</sup> Palumbo et al. Improvement of Non-Motor Symptoms with NE3107 Adjunctive to Carbidopa/Levodopa in Patients with Parkinson's Disease: A Phase 2A, Placebo-Controlled Study. Presented at the International Conference on Alzheimer's and Parkinson's Diseases 2024 held March 5-9, 2024 in Lisbon, Portugal.
  - <sup>2</sup> Philippens et al. Effects of NE3107 Anti-inflammatory Treatment on Motor Activity and Neurodegenerative Features of Parkinson's Disease in a Marmoset Monkey Model. Presented at the 2023 International Congress of Parkinson's Disease and Movement Disorders held August 27-31, 2023 in Copenhagen, Denmark.
  - <sup>3</sup> ADAS-Cog12 = 12-item cognitive subscale of the Alzheimer's Disease Assessment Scale (lower is improvement); ADCOMS = Alzheimer's Disease Composite Score (lower is improvement); ADCS-ADL = Alzheimer's Disease Cooperative Study-Activities of Daily Living (is higher improvement); ADCS-CGIC = Alzheimer's Disease Cooperative Study-Clinical Global Impression of Change (lower is improvement); CDR-SB = Clinical Dementia Rating, Sum of Boxes (lower is improvement), MMSE = Mini Mental State Examination (higher is improvement).
  - <sup>4</sup> Reading et al. Clinical Outcomes from a Phase 3, Randomized, Placebo-Controlled Trial of NE3107 in Subjects with Mild to Moderate Probable Alzheimer's Disease. Presented at AD/PD™ 2024.