NEWS RELEASE

# BioVie Presents Positive Clinical Safety Data from Phase 2b Trial of BIV201 in Refractory Ascites at the American Association for the Study of Liver Disease (AASLD) - The Liver Meeting® 2023

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Data Show that BIV201 in Combination with Standard of Care (SOC) is Well Tolerated with No Major Difference in Treatment-Emergent Adverse Events (TEAEs) Compared to SOC Alone

With a ~50% Mortality Rate for Refractory Patients [1] , Efficacy and Safety Findings from the Phase 2b Trial Support Acceleration of BIV201 into Confirmatory Trials

Company Reaffirms Commitment to Commencing Phase 3 Trial in Q2 2024

CARSON CITY, Nev., Nov. 13, 2023 (GLOBE NEWSWIRE) -- BioVie Inc., (NASDAQ: BIVI) (“BioVie” or the “Company”) a clinical-stage company developing innovative drug therapies for the treatment of advanced liver disease and neurological and neurodegenerative disorders, today announced positive clinical safety data from the Company’s Phase 2b open-label study evaluating the efficacy and safety of BIV201, terlipressin administered as a continuous infusion, with standard of care (SOC) in patients with refractory ascites due to cirrhosis. The data will be highlighted today in a late-breaking poster presentation titled “ Safety and Tolerability of Continuous Infusion Terlipressin (BIV201) In Patients with Decompensated Cirrhosis and Refractory Ascites: A Phase 2, Randomized, Controlled, Open-Label Study ” at **The American Association for the Study of Liver Diseases (AASLD) - The Liver** Meeting® 2023 in Boston, MA.

“Our Phase 2b results mark a significant step toward providing a treatment for cirrhosis patients with refractory ascites, of whom face a survival rate as low as 50% within a year of diagnosis. [1] Currently, the only options for these patients are transjugular intrahepatic portosystemic shunt (TIPS) surgery or liver transplantation, which are invasive and come with numerous potential life-altering complications,” said Cuong Do, BioVie’s President and Chief

Executive Officer. “These data being presented, coupled with statistically significant efficacy, allowed BioVie to halt the trial prior to completion and further strengthen our confidence in accelerating BIV201’s development into Phase 3 trials, which we expect to initiate in Q2 2024.”

Results showed that BIV201 in combination with SOC was well tolerated and had a favorable safety profile. The incidence of treatment emergent adverse events (TEAEs), including serious TEAEs, was similar in both treatment groups. Two patients who received BIV201 experienced hyponatremia that developed gradually, was asymptomatic, and was resolved upon discontinuation of the study drug. Cumulative safety data from the Phase 2a study (6 patients; 131 total days of BIV201 infusion) and Phase 2b study (10 patients; 379 total days of BIV201 infusion) further support the safety and tolerability in this population with only 1 serious adverse event related to terlipressin. Investigators concluded that the findings encourage further development and investigation of BIV201 in confirmatory trials for the treatment of diuretic-resistant ascites in patients with decompensated liver cirrhosis.

The Phase 2b trial was a dose-titration, controlled study in which adult patients with cirrhosis and refractory ascites were randomized 2:1 to receive either BIV201 in addition to SOC, or SOC alone, during the intervention period, consisting of two 28-day treatment periods separated by a wash-out interval followed by a long-term follow-up period of 180 days. Primary endpoints were safety and tolerability, and incidence of certain complications (Grade ≥2) during the 180 days following randomization.

Ascites is a common complication of advanced liver cirrhosis in which large volumes of fluid accumulate in the abdomen (often exceeding 5 liters) due to liver and kidney dysfunction. Patients that progress to refractory ascites face a one-year survival rate of approximately 50% [1] . To date, there is no approved medical therapy specifically for refractory ascites. Management of these patients is based upon procedures such as large-volume paracentesis and TIPS, which only provide temporary relief, lack disease-modifying effects, and lead to frequent life-threatening complications.

BIV201, a continuous infusion of terlipressin, received Orphan Drug Designation for treatment of ascites from the U.S. Food and Drug Administration in 2017. Terlipressin is currently used in over 40 countries to treat related complications of liver cirrhosis, though is not available in the U.S. or Japan. BioVie plans to conduct a pivotal Phase 3 trial commencing in Q2 2024. The poster will be presented today, November 13 from 1:00 PM – 2:00 PM.

In addition to the Phase 2 BIV201 data presented at The Liver Meeting® 2023, the company expects unblinded Phase 3 Alzheimer’s Disease (AD) data for its novel molecule, NE3107, in the late November/early December time frame. NE3107 selectively inhibits the inflammatory ERK signaling pathway that reduces neuroinflammation by inhibiting inflammation-driven insulin resistance and major pathological inflammatory cascades. Data pointing to the confluence of inflammation and insulin resistance in dementia is fueling an interest in developing therapies that target metabolic dysregulation in AD.

BIV201 is administered using the Company's patent-pending liquid formulation of terlipressin in a prefilled syringe format as a continuous low dose infusion with a portable pump. The primary endpoints are the incidence of serious disease-related complications and the change in cumulative ascites fluid volume in the BIV201 treated group (20 patients) versus the control group (10 patients).

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 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, 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 2 trial and details regarding the launch of its 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 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.

References:

1 Siqueria F, et al. Gastroenterol Hepatol (N Y) . 2009 Sep; 5(9): 647–656.

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