NEWS RELEASE

BioVie Announces the Pausing of Patient Enrollment in Ascites Phase 2b Trial, Encouraging Efficacy Data is Announced, Initiating FDA Discussions to Conduct Pivotal Registrational Trial

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CARSON CITY, Nev., March 13, 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 patient enrollment in the Company's Phase 2b clinical trial, evaluating BIV201 for the treatment of refractory ascites, has been paused. Encouraging data from the first 15 patients in the study is announced.

Treatment with BIV201 plus standard of care (SOC) resulted in a 34% reduction in ascites fluid during the 28 days after treatment initiation compared to the 28 days prior to treatment (p=0.0046). This improvement was significantly different from those treated with SOC only who experienced a mean increase in ascites fluid of 3.1% (BIV201 vs. SOC p=0.05). Patients who completed the treatment with BIV201 experienced a 53% reduction in ascites fluid (p=0.001), which was significantly different from those treated with SOC (p=0.007). This improvement was sustained in this group during the 3 months after treatment initiation as compared to the 3-month pre-treatment period (43% reduction, p=0.06). Overall treatment appeared to be well tolerated. There were no unexpected serious adverse events and overall safety was consistent with the patient population. Detailed results will be presented at an upcoming Scientific conference.

Michael Porayko, M.D., F.A.A.S.L.D., a recently retired Professor of Medicine and Chief of Hepatology at Vanderbilt Health with over 135 publications related to Gastroenterology, Hepatology, Liver Diseases, and Liver Transplant and 38 years of experience managing patients with advanced cirrhosis and ascites commented:

"The data is very encouraging and supports that BIV201 should continue to be investigated as a potentially effective treatment for the reduction of ascites in patients with cirrhosis and refractory ascites, reducing the need for

paracentesis and potentially improving both the symptoms related to fluid buildup and quality of life."

Ascites is a common complication of advanced liver cirrhosis involving the accumulation of large volumes of fluid in the abdomen, often exceeding 5 liters, due to liver and kidney dysfunction. The FDA has never approved a drug to treat ascites, and once patients reach the refractory stage the estimated one-year survival rate is only approximately 50% [1] . BIV201 is a continuous infusion of terlipressin, a drug used in over 40 countries to treat related complications of liver cirrhosis that was recently approved in the US but not Japan. With the novel prefilled room temperature stable syringe used in this study, BIV201 could potentially provide a superior terlipressin drug delivery system throughout the world.

The current trial (NCT04112199) evaluates the efficacy of BIV201 combined with standard-of-care (SOC), compared to SOC alone, for the treatment of refractory ascites. Terlipressin was administered with a continuous low dose infusion via a portable pump in two 28-day treatment cycles. The primary endpoints are the incidence of complications of at least Grade 2 severity, and the change in cumulative ascites in the 12-week period following randomization compared to a 12-week pre-treatment period. The BIV201 trial planned to enroll 30 patients to be treated in the home care setting.

"Compelling data from the first 15 patients led us to pause enrollment," commented Cuong Do, BioVie's President and CEO. "Given the high unmet need for this condition, we believe the most prudent course is to initiate conversations with the FDA on proceeding to the pivotal Phase 3 trial so that we can bring this innovation to patients as quickly as possible."

BIV201 (continuous infusion terlipressin) has received Orphan Drug and Fast Track designations from the FDA for the treatment of ascites due to all etiologies except cancer. This would include, for instance, ascites due to advanced liver cirrhosis. First-to-market Orphan therapies typically receive seven years of market exclusivity in the US for the designated use.

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 NFB (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 topline data released in December 2022, showed 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 with respect to the clincical development of BIV201. 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.

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[1] Bureau et al. 2017