NEWS RELEASE

BioVie Announces First Patient Enrolled in BIV201 Phase 2b Clinical Trial for Ascites

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SANTA MONICA, Calif., June 24, 2021 (GLOBE NEWSWIRE) -- BioVie Inc. (NASDAQ: BIVI) ("BioVie" or "Company"), a clinical-stage company developing innovative drug therapies for the treatment of liver disease and neurological and neurodegenerative disorders and certain cancers, today announced that the first patient has been enrolled in the Company's Phase 2b trial of BIV201 (continuous infusion terlipressin) for the treatment of refractory ascites. The trial— **A Study for Evaluation of BIV201 to Reduce Ascites and Complications in Patients with Cirrhosis and Refractory Ascites** —is being conducted at nine prestigious research centers in the U.S. (NCT04112199). Two additional patients have consented to the pre-randomization observation period, and 7 more potential participants have been identified through pre-screening.

"With no approved treatments and a poor one-year survival there is a clear unmet medical need for an effective drug treatment for patients suffering from refractory ascites," said Cuong Do, chief executive officer of BioVie. "The initiation of patient enrollment is a key milestone, and we have activated most of our clinical trial sites with additional potential participants identified. Many of our sites have affiliated clinics that perform paracentesis procedures on large numbers of ascites patients on a regular basis – this is the physical withdrawal of ascites fluid with a large bore needle which is the current standard of care (SOC) since there are no FDA-approved drugs for treating this condition. We expect enrollment to accelerate in the coming weeks, and are currently on track to complete enrollment of all 30 subjects this summer, and anticipate a topline data readout in early 2022."

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. An estimated 20,000 Americans suffer from refractory ascites, which means that their ascites no longer responds to off-label diuretic therapy or they cannot tolerate these drugs. The FDA has never approved a drug for treating ascites, and once patients reach the refractory stage the estimated one-year survival rate is only approximately 50% (Bureau et al. 2017). BIV201 is a continuous infusion of terlipressin, a drug used in over 40 countries to treat related complications of liver cirrhosis

that is not available in the US or Japan.

The Phase 2b trial is evaluating the efficacy of BIV201, which has an Orphan drug designation, in addition to SOC compared to SOC alone for the treatment of refractory ascites in the home care setting. BIV201 is being 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 in two 28-day treatment cycles. 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). If the results are positive, the Company plans to conduct a pivotal Phase 3 trial commencing in 2022. BioVie previously conducted a Phase 2a trial of BIV201 in a similar patient population at a Veterans Administration hospital. The pharmacokinetics (PK) of terlipressin following continuous infusion generated in this study determined for the first time that administration of terlipressin as a low dose continuous infusion avoids high, potentially harmful, peak blood concentrations associated with intermittent IV bolus dosing. The study also found that the drug was overall well tolerated and that it was feasible to administer terlipressin by continuous infusion in an outpatient setting.

BioVie recently announced FDA guidance for the design of an additional pivotal Phase 3 study of BIV201 in the treatment of hepatorenal syndrome-acute kidney injury (HRS-AKI), which the Company plans to begin next year. BIV201 has an Orphan drug designation covering this condition which is a severe complication of ascites with a mortality rate of approximately 50% over 2-4 weeks if left untreated.

About BioVie

BioVie Inc. (NASDAQ: BIVI) is a clinical-stage company developing transformative therapies to overcome unmet medical needs in chronic debilitating conditions. 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 2 study for the treatment of refractory ascites with top-line results expected in early 2022. The Company is also planning a pivotal Phase 3 study of BIV201 in the treatment of hepatorenal syndrome-acute kidney injury (HRS-AKI) in 2022. BIV201 is administered as a patent-pending liquid formulation. The active agent is approved in about 40 countries for related complications of advanced liver cirrhosis but is not available in the US or Japan. In neuro-degenerative disease, BioVie recently acquired the assets of NeurMedix Inc., including NE3107, an ERK inhibitor that selectively reduces neuroinflammation and insulin resistance. Both are drivers of Alzheimer's and Parkinson's diseases. The FDA has authorized a pivotal Phase 3 randomized, double blind, placebo controlled, parallel group, multicenter study to evaluate NE3107 in subjects who have mild to moderate Alzheimer's disease (NCT04669028). An estimated six million Americans suffer from Alzheimer's. BioVie is planning to initiate this trial in mid-2021 and targeting primary completion in late 2022. A Phase 2 trial of NE3107 in Parkinson's Disease is planned for later this year, and related compounds have additional potential to treat certain cancers. NE3107 and related compounds are globally

patented, first-in-class molecules. For more information, visit **http://www.biovieinc.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 clinical trials and to obtain approval for our product candidates, 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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