



NEWS RELEASE

## BioVie Announces Partnership with the American Liver Foundation

2021-12-09

RENO, Nev., Dec. 09, 2021 (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 that the Company is partnering with the **American Liver Foundation** (ALF) in an educational campaign about chronic liver cirrhosis and its complications and to raise awareness among potential patients and healthcare providers about the Company's Phase 2b Study of BIV201 (continuous infusion terlipressin). The trial— **A Study for Evaluation of BIV201 to Reduce Ascites and Complications in Patients with Cirrhosis and Refractory Ascites** —is being conducted at ten prestigious research centers in the U.S. (NCT04112199).

"We are grateful to be working with the ALF on this awareness campaign," said Cuong V. Do, CEO of BioVie. "Due to the rapid increase in non-alcoholic steatohepatitis (NASH) and other ongoing causes of liver cirrhosis, the serious complication of ascites is placing a growing burden on the U.S healthcare system. Our goal for this program is to help improve the understanding among potential patients and the medical community of disease-related conditions such as ascites and hepatorenal syndrome and to evaluate more candidates for enrollment in our clinical development program."

"Our mission is to provide education, advocacy and other support services to everyone whose life is impacted by liver diseases," said Lorraine Stiehl, CEO of the American Liver Foundation. "We are grateful for the support of our industry partners and pleased to work with BioVie to enhance their efforts to make a difference in the lives of cirrhotic patients with refractory ascites."

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 the treatment of 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.

BioVie's ongoing Phase 2b clinical trial is evaluating the efficacy of BIV201, which has an Orphan drug designation, in addition to standard of care (SOC) compared to SOC alone for the treatment of refractory ascites in the home care setting. Ascites patients or their caregivers who want to learn more about this study should visit: [www.bioviepharma.com/ascites-clinical-trials-biv201/](http://www.bioviepharma.com/ascites-clinical-trials-biv201/) or the clinical trials section of the ALF website: <https://liverfoundation.org/>.

The Company's patent-pending liquid formulation of terlipressin in a prefilled syringe format (BIV201) is being used in this trial to provide 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 potentially 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.

#### About the American Liver Foundation

The American Liver Foundation (ALF) is the largest patient advocacy organization devoted to liver diseases. The ALF's mission is to promote education, advocacy, support services and research for the prevention, treatment and cure of liver disease. The American Liver Foundation receives contributions and funding from clinical trial and study sponsors. The American Liver Foundation does not evaluate or endorse any clinical trials or studies and is not affiliated with any of the sponsors.

#### About BioVie

BioVie Inc. (NASDAQ: BIVI) is a clinical-stage company developing innovative 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 due to liver cirrhosis with top-line results anticipated in mid-2022. The Company is also planning a potentially pivotal Phase 3 study of BIV201 in the treatment of hepatorenal syndrome-acute kidney injury (HRS-AKI) in 2022, subject to FDA's review and authorization. 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 neurodegenerative disease, BioVie acquired the assets of NeurMedix Inc., including NE3107 that inhibits inflammatory activation of ERK and NFB (e.g., TNF transcription) 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 subjects who have mild to moderate Alzheimer's disease (NCT04669028). An estimated six million Americans suffer from Alzheimer's. BioVie has initiated this study and is targeting primary completion in late 2022. A Phase 2 study of NE3107 in Parkinson's disease has been authorized by the FDA to start in early 2022, and related compounds have additional potential to treat certain cancers. NE3107 is patented in the United States, Australia, Canada, Europe, and South Korea. For more information, visit [www.bioviepharma.com](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. 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 studies 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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