NEWS RELEASE

BioVie Commences Patient Screening in Phase 2 Clinical Trial

2021-03-09

SANTA MONICA, Calif., March 09, 2021 (GLOBE NEWSWIRE) -- BioVie Inc. (NASDAQ: BIVI) ("BioVie" or "Company"), a clinical-stage company developing innovative drug therapies for liver disease, today announced the start of patient screening in the Company's Phase 2 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** —will be initiated at nine prestigious research centers in the U.S. One center has recently been activated and has begun screening patients. The company expects to activate additional centers over the next several weeks.

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% (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 has not been approved in the US or Japan. With a novel prefilled syringe format that is stable at room temperature, BIV201 could potentially provide a superior terlipressin drug delivery system throughout the world.

BioVie previously conducted a Phase 2a trial of continuous infusion terlipressin in this patient population at a Veterans Administration hospital. The pharmacokinetics of terlipressin following continuous infusion generated in this study determined for the first time that administration of terlipressin as a continuous infusion avoids high, potentially harmful, peak blood concentrations associated with intermittent IV bolus dosing. The study also supported that the drug was well tolerated overall and that it was feasible to administer terlipressin by continuous infusion in an outpatient setting.

The current trial will evaluate the efficacy of BIV201 in addition to standard-of-care (SOC) compared to SOC alone for the treatment of refractory ascites. Terlipressin will be administered with a continuous low dose infusion

administered 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 plans to enroll 30 patients to be treated in the home care setting.

“With no approved treatments and a poor one-year survival we believe there is a clear unmet medical need for an effective drug treatment for patients suffering from refractory ascites,” said Terren Peizer, chairman and chief executive officer of BioVie. “Interest from the research community has been strong, which we believe speaks to the need for new therapies for this Orphan drug indication. Many of our trial sites have affiliated paracentesis clinics that treat large numbers of ascites patients on a regular basis, and we expect enrollment to commence and accelerate in the coming weeks.”

About BioVie and BIV201

BioVie Inc. is developing BIV201 (continuous infusion terlipressin) an Orphan drug candidate for the treatment of ascites due to advanced liver cirrhosis. First-to-market Orphan therapies typically receive 7 years of market exclusivity in the US for the designated use. The initial disease target for BIV201 therapy is ascites, which is a serious complication of advanced liver cirrhosis, and future development opportunities include hepatorenal syndrome (HRS) and other life-threatening complications. The Company plans to commence patient enrollment in its second US Phase 2 clinical trial in early 2021, and upon completion will commence a pivotal Phase 3 trial shortly thereafter. The trial design is summarized on **www.clinicaltrials.gov** , trial identifier NCT04112199. The FDA has never approved any drug specifically for treating ascites, and the Company is not aware of any competing drugs in late-stage development for ascites. The active agent in BIV201, terlipressin, is approved for use in about 40 countries for the treatment of related complications of advanced liver cirrhosis but is not available in the US or Japan.

The Company has invented a patent-pending prefilled syringe that has been cleared by the FDA for use in our upcoming Phase 2 trial. This novel BIV201 delivery system is expected to greatly simplify at-home patient treatment and improve patient compliance by enabling easy injection of the liquid concentrate into the IV bag connected to the infusion pump. Room temperature stability has been achieved for 12 months providing an important advantage because, to the best of the Company's knowledge, all other terlipressin products sold globally must be stored under refrigeration. The novel prefilled syringe format also avoids the manual mixing of minute (2 – 4 mg) quantities of terlipressin powder in saline solution, thereby reducing the possibility of dosing errors during reconstitution and improving sterility. BioVie has begun applying for global patent protection for this novel terlipressin delivery system. The Company has also received orphan drug designation for the treatment of hepatorenal syndrome (HRS) and has FDA Fast Track status. 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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