NEWS RELEASE

BioVie Manufactures Novel Terlipressin Prefilled Syringe

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SANTA MONICA, Calif., Dec. 09, 2019 (GLOBE NEWSWIRE) -- BioVie Inc. (OTCQB: BIVID) (“BioVie” or “Company”), a clinical-stage company developing innovative drug therapies for liver disease, announced today that its first batch of BIV201 prefilled syringes containing a patent-pending formulation of terlipressin liquid concentrate has been manufactured and released following quality control testing. BIV201 (continuous infusion terlipressin) has not yet been approved for human use. The Company is planning to submit an amendment to its CMC package to the FDA for review and will test the new prefilled syringe in an upcoming US Phase 2b/3 clinical trial if cleared to proceed.

“Our new prefilled terlipressin syringe represents a potential breakthrough in dosing convenience and safety. Over time it should enable us to build the market for outpatient terlipressin therapy around the world,” commented Terren Peizer, BioVie Chief Executive Officer. “BioVie recently submitted a detailed protocol to the FDA to evaluate BIV201 in a large-scale US Phase 2b/3 clinical trial in refractory ascites patients. We are excited about testing this new simplified method for delivering BIV201 therapy in the home care setting.”

BIV201 (continuous infusion terlipressin) has an Orphan drug designation for the treatment of ascites. First-to-market Orphan therapies typically receive 7 years of market exclusivity in the United States for the designated use(s). In addition, the Company has a pending patent application covering the proprietary liquid formulation of terlipressin to be used in its planned Phase 2b/3 trial, subject to FDA clearance. This could eventually provide up to 20 years of patent coverage in each country for which the Company seeks patent protection, including the US, according to the patent laws of that country.

Terlipressin, which is not available in the US or Japan, is often sold as a lyophilized powder for reconstitution in hospital pharmacies in Europe and Asia. The traditional powder format is satisfactory for hospital use but creates a logistical challenge when administering terlipressin via ambulatory infusion pump in patients located outside the hospital. BioVie experienced this drug-delivery challenge when supplying BIV201 to the refractory ascites patients who participated in our recently completed US Phase 2a clinical trial. To solve it, the Company developed a novel

liquid formulation for delivery via prefilled syringe. This is expected to greatly improve convenience by enabling easy injection of the liquid concentrate into the IV bag connected to the infusion pump for at-home terlipressin administration. It will avoid 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 is expected to improve drug solution sterility.

BioVie's new patent-pending formulation of terlipressin has demonstrated the potential for room-temperature storage. If extended room-temperature product stability can be shown, this feature could provide another key product advantage. To the best of the Company's knowledge, all other terlipressin products sold globally must be stored under refrigeration and there are no prefilled syringe formats available for treating patients.

About BIV201

BIV201 (continuous infusion terlipressin) is being investigated as a potential new therapy for patients suffering from ascites, and future development opportunities include hepatorenal syndrome (HRS) and other life-threatening complications of advanced liver cirrhosis. The initial disease target for BIV201 therapy is ascites, which is a serious complication of advanced liver cirrhosis. The Company has submitted a Phase 2b/3 clinical trial protocol to the FDA that 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. BIV201 has received Orphan Drug designations for the treatment of ascites and for HRS and has FDA Fast Track status. For more information about BioVie, please visit our website: **www.biovieinc.com** .

About Liver Cirrhosis, Ascites, and Hepatorenal Syndrome

Chronic liver cirrhosis and its complications are the eighth leading cause of death in the US (Runyon 2013). Patients with cirrhosis and ascites account for an estimated 116,000 US hospital discharges annually with frequent early readmissions. Those requiring paracentesis (physical removal of ascites fluid with a large-bore needle) experience an average hospital stay lasting 8 days and generate approximately $5 billion in medical costs (HCUP Nationwide Readmissions Database 2016). Cirrhosis results primarily from hepatitis, alcoholism, and nonalcoholic steatohepatitis (NASH) linked to fatty liver disease and obesity. Ascites is the most common serious complication of advanced liver cirrhosis. Certain drugs approved for other uses may provide initial relief, but patients often fail to respond to them as the ascites worsens. At this stage, known as refractory ascites, patients often progress to hepatorenal syndrome (HRS) which is the onset of kidney failure and requires emergency hospitalization. Refractory ascites survival is reported to be only approximately 50% at six months (Moreau 2004) and 33% at one year (Planas 2006). Nor have any drug therapies been approved specifically for treating HRS, and about one-half of these patients typically succumb within only 2 – 4 weeks.

Forward-Looking Statements

This press release contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 that involve risks, uncertainties and assumptions that could cause BioVie's actual results and experience to differ materially from anticipated results and expectations expressed in these forward-looking statements. BioVie has in some cases identified forward-looking statements by using words such as "anticipates," "believes," "hopes," "estimates," "looks," "expects," "plans," "intends," "goal," "potential," "may," "suggest," and similar expressions. Among other factors that could cause actual results to differ materially from those expressed in forward-looking statements are BioVie's need for, and the availability of, substantial capital in the future to fund its operations and research and development; and the risks that BioVie's compounds may experience delays or difficulties in commencing or successfully completing pre-clinical testing or clinical studies, or may not be granted regulatory approval to be sold and marketed in the United States or elsewhere. BioVie cannot guarantee the effectiveness of its Orphan Drug designations or any patents that BioVie may be issued. A more complete description of these risk factors is included in BioVie's filings with the Securities and Exchange Commission. In addition to the risks described above and in BioVie's filings with the SEC, other unknown or unpredictable factors also could affect BioVie's results. No forward-looking statements can be guaranteed and actual results may differ materially from such statements. Given these uncertainties, you should not place undue reliance on any forward-looking statements. BioVie undertakes no obligation to release publicly the results of any revisions to any such forward-looking statements that may be made to reflect events or circumstances after the date of this press release or to reflect the occurrence of unanticipated events, except as required by applicable law or regulation.

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