NEWS RELEASE

BioVie Advances the BIV201 Clinical Program and Prefilled Syringe

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Novel BIV201 Formulation Shows Significant Improvements Over Industry Terlipressin

Prefilled Syringe May Significantly Extend Market Protection Beyond Orphan Drug Exclusivity

SANTA MONICA, Calif., June 11, 2020 (GLOBE NEWSWIRE) -- BioVie Inc. (OTCQB: BIVI) ("BioVie" or "Company"), a clinical-stage company developing innovative drug therapies for liver disease, announced today that following the company's successful Phase 2a study, it has received guidance from the US Food and Drug Administration ("FDA") regarding the next clinical trial design for BIV201 (continuous infusion terlipressin) in patients with refractory ascites due to liver cirrhosis. The Company plans to commence a randomized 24-patient Phase 2 study this year, to be followed by a larger pivotal Phase 3 clinical trial targeted to begin the first half 2021. The FDA has communicated that pending positive Phase 2 study results, a sufficiently large and well-controlled Phase 3 trial, with supportive data from the Phase 2 (statistical significance not required), could potentially yield the clinical data needed to apply for BIV201 marketing approval. The Company estimates that the pivotal Phase 3 study will involve approximately 120 ascites patients.

Terren Peizer, BioVie Chief Executive Officer, stated, "We appreciate the FDA's detailed guidance for planning the next BIV201 clinical trial in ascites patients who are seriously ill and often hospitalized with life-threatening complications of their disease. The primary goal of the upcoming Phase 2 study will be to reduce the occurrence of dangerous complications linked to refractory ascites, which is the accumulation of large volumes of fluid in the abdomen no longer responding to off-label diuretic therapy. We anticipate that the pivotal Phase 3 trial design will mirror the Phase 2 study design. Based on our US Phase 2a trial results and global studies, we believe that our Orphan Drug candidate BIV201 has the potential to greatly relieve the suffering of ascites patients and improve their health outcomes."

Importantly, BioVie may use the new patent-pending BIV201 prefilled syringe in the upcoming Phase 2 trial subject to conducting certain additional standard analytical testing that is expected to take approximately two weeks. Room

temperature stability of the prefilled syringe has been confirmed at 6 months, with the potential for 12 months or up to two years of stability (yet to be confirmed). Room temperature storage presents a key product differentiation versus terlipressin products in countries where the drug is approved. To the best of the Company's knowledge, all other terlipressin products sold globally must be stored under refrigeration and there is no prefilled syringe format of terlipressin available for treating patients in these countries. 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 setting. To solve this challenge, the Company developed a patent-pending liquid formulation for delivery via prefilled syringe. This novel drug delivery system is expected to 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. It 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 is expected to improve drug solution sterility.

"The development of a novel liquid version of terlipressin offering the potential for long-term stability at room temperature is an important breakthrough in the quest for an at-home therapy for ascites patients," commented Denise Smith, BioVie Vice President of Manufacturing and Quality Control. "In addition to simplifying product storage, it creates the opportunity for our next generation terlipressin delivery system that will be further optimized for home care."

BIV201 (continuous infusion terlipressin) has received an Orphan Drug designation from the FDA 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 begun applying for global patent protection of our proprietary liquid formulation of terlipressin. 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.

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 completed a Phase 2 clinical trial protocol 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). 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. 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 annually in medical costs in the US (HCUP Nationwide Readmissions Database 2016). Certain drugs approved for other uses may provide initial relief, but patients develop so-called refractory ascites, failing to respond to them as the ascites worsens. For refractory ascites the mean one-year survival rate is only 50% (Bureau et al. 2017). Patients with refractory ascites often progress to hepatorenal syndrome (HRS) which is the onset of kidney failure and requires emergency hospitalization. About one-half of these patients typically succumb within only 2 to 4 weeks and no drug therapies been FDA approved specifically for treating HRS.

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.

INVESTOR RELATIONS:
Dave Gentry, CEO
RedChip Companies Inc.
407-491-4498
dave@redchip.com