NEWS RELEASE

BioVie Receives Notice of Allowance for Japan Patent Application Covering Novel Liquid Formulation of Terlipressin

2024-10-15

Patents covering BioVie's terlipressin liquid formulation now secured in the United States, India, Japan and Chile, and are pending in eight additional markets

Liquid formulation has demonstrated room-temperature stability for up to 24 months, representing an important advantage for treating patients with cirrhosis and ascites in the home-care setting

CARSON, Nev., Oct. 15, 2024 (GLOBE NEWSWIRE) -- BioVie Inc. (NASDAQ: BIVI), ("BioVie" or the "Company"), a clinical-stage company developing innovative drug therapies for the treatment of neurological and neurodegenerative disorders and advanced liver disease, today announced that it has received a Notice of Allowance from the Japan Patent Office for patent application no. 2021-569344 entitled "Formulations of Terlipressin." This Notice of Allowance is expected to result in the issuance of a Japanese patent in 2 to 3 weeks once administrative processes are completed.

The allowed claims cover a novel liquid formulation of terlipressin acetate that has stability at room temperature for two years and can be packaged in a pre-filled syringe. The patent supports BioVie's liquid formulation of terlipressin for development of a more patient-centric ambulatory treatment regimen for patients with ascites and hepatic failure in the US.

Patients with cirrhosis and ascites have large volumes of fluid accumulate in the abdomen (often exceeding 5 liters) due to liver and kidney dysfunction. Patients that progress to refractory ascites face a one-year survival rate of approximately 50% [1] . To date, there is no approved medical therapy specifically for refractory ascites. Management of these patients is based upon procedures such as large-volume paracentesis and TIPS, which only provide temporary relief, lack disease-modifying effects, and lead to frequent life-threatening complications.

"Terlipressin is a drug used in over 40 countries to treat related complications of liver cirrhosis that was only recently approved in the US as a lyophilized powder for in-hospital use, which requires reconstitution with sterile sodium chloride and refrigerated storage conditions for proper administration," said Cuong Do, BioVie's President and CEO. "Our novel liquid formulation of terlipressin is stable at room temperature for up to 24 months, offering an important advantage for treating patients with cirrhosis and ascites, particularly in the home-care setting. The pre-filled syringe format can improve dosing convenience and safety. The receipt of this patent will significantly strengthen BIV201's intellectual property protection and increase the value proposition behind our BIV201 program."

In addition to the recent notice of allowance received for US and Japan, BioVie has received patent protection for its liquid formulation of terlipressin in India and Chile, and has patents pending in Australia, Canada, China, Europe, Hong Kong, South Korea, Mexico and Brazil.

About Ascites and Cirrhosis

Ascites (the excessive build-up of fluid in the abdomen) is the most common complication of advanced ("decompensated") liver cirrhosis and can be life-threatening. In advanced liver cirrhosis, the liver becomes "clogged" and blood accumulates in the region below (called the splanchnic bed). With blood pooling below the liver, the blood volume in the arteries decreases and the person with cirrhosis experiences low effective blood volume. In an effort to correct this situation, the brain sends signals via the renin-angiotensin-aldosterone system (RAAS) to the kidneys to retain extreme amounts of water and salt to attempt to reflexively increase the blood volume in the arteries. The excess liquid weeps from the lymphatic system and collects in the abdomen – which is when ascites appears.

Advanced liver cirrhosis is most-commonly caused by the progression of NASH (non-alcoholic steatohepatitis), alcoholism, and infection with Hepatitis B & C. Chronic liver disease ("CLD"), including cirrhosis, and is responsible for the death of 42,000 Americans each year. As a population, people diagnosed with both liver cirrhosis and ascites are frequently readmitted to the hospital frequently each year, incurring an estimated $5 billion in annual treatment costs. [2]

About BIV201

BIV201 (terlipressin for continuous infusion) is a prefilled syringe or vial with BioVie's patented liquid formulation of terlipressin acetate. A synthetic analogue of vasopressin, terlipressin has been studied extensively overseas and is approved in more than 40 countries for in-hospital treatment of two deadly conditions related to ascites (bleeding esophageal varices, ("BEV") and hepatorenal syndrome, ("HRS"). Terlipressin has the potential to reduce the presence of ascites in the abdomen through vasoconstricting the blood vessels where the blood is pooling, hence restoring blood flow through the kidneys and liver. This reduces portal vein pressure and increases blood volume in

the arteries. Consequently, the body may respond by shutting down the RAAS system which has been generating the ascites.

Terlipressin, a medication employed in over 40 countries to manage complications associated with liver cirrhosis, has recently gained U.S. approval as a lyophilized powder that requires reconstitution with sodium chloride and refrigerated storage up to 48 hours for proper administration. BioVie's unique liquid formulation of terlipressin has demonstrated stability, not only under refrigerated conditions, but also at room temperature for up to 24 months, which can be an important advantage for treating patients with cirrhosis and ascites, particularly in the home-care setting. The Company has received patent protection for its liquid formulation of terlipressin in India and Chile; a notice of allowance in the US and Japan; and patents are pending in Australia, Canada, China, Europe, Hong Kong, South Korea, Mexico and Brazil.

In the US, BioVie has secured Orphan Drug designation and Fast Track status covering the use of BIV201 (continuous infusion terlipressin) for the treatment of ascites due to liver cirrhosis. BIV201 also has an Orphan drug designation for treating HRS and BioVie has reached agreement with the FDA on the design, duration, dosing and endpoints of a Phase 3 trial to evaluated BIV201 for the treatment of HRS-AKI (acute kidney injury) that could potentially be sufficient to support a New Drug Application ("NDA") filing with the FDA.

About BioVie Inc.

BioVie Inc. (NASDAQ: BIVI) is a clinical-stage company developing innovative drug therapies for the treatment of neurological and neurodegenerative disorders (Long COVID, Alzheimer's disease and Parkinson's disease) and advanced liver disease. In neurodegenerative disease, the Company's drug candidate bezisterim inhibits inflammatory activation of extracellular signal-regulated kinase and the transcription factor, Nuclear factor- kB, and the associated neuroinflammation and insulin resistance but not ERK and NFkB homeostatic functions (e.g., insulin signaling and neuron growth and survival). Both neuroinflammation and insulin resistance are drivers of AD and PD. In liver disease, the Company's Orphan drug candidate BIV201 (continuous infusion terlipressin), with FDA Fast Track status, is being evaluated and discussed with guidance received from the FDA regarding the design of Phase 3 clinical testing of BIV201 for the reduction of further decompensation in participants with liver cirrhosis and ascites. The active agent is approved in the U.S. and in about 40 countries for related complications of advanced liver cirrhosis. For more information, visit 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 pre-clinical or clinical studies and to obtain approval for our product candidates, our ability 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.

References

[1] Gines P, Quintero E, Arroyo V, et al. Compensated cirrhosis: natural history and prognostic factors. Hepatology 1987; 7: 122–128.

[2] Mortimer R, Volk M., Mortimer S, et al. U.S. hospitalization burden of patients with cirrhosis and ascites receiving paracentesis. Presented as a poster presentation, Liver Meeting, Nov 2022, Washington DC

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