NEWS RELEASE

BioVie Receives FDA Guidance for Phase 3 Clinical Trial of BIV201 in HRS-AKI

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SANTA MONICA, Calif., June 23, 2021 (GLOBE NEWSWIRE) -- BioVie Inc. (NASDAQ: BIVI) ("BioVie" or "Company"), a clinical-stage company developing innovative drug therapies for the treatment of liver disease and neurological and neurodegenerative disorders and certain cancers, today announced the results of a Type B meeting request submitted to the Food & Drug Administration (“FDA”) regarding its planned Phase 3 study of BIV201 (continuous infusion terlipressin) in hepatorenal syndrome–acute kidney injury (“HRS-AKI”). HRS-AKI is a life-threatening condition that may occur in patients with ascites due to advanced liver cirrhosis and has a mortality rate of approximately 50% over 2-4 weeks if left untreated. Based on communications with the FDA, the Company believes that positive results from a single pivotal Phase 3 clinical trial could potentially support the filing of a New Drug Application (NDA) and eventual approval of BIV201 for the treatment of HRS-AKI.

BioVie recently commenced a Phase 2b clinical study of BIV201 in ascites due to liver cirrhosis. Pursuing the development of BIV201 for HRS-AKI represents a strong strategic fit with the ascites program. Given the overlap of these serious complications in cirrhotic patients, our clinical team and expert medical advisors possess an in-depth understanding of HRS-AKI and the study can be conducted by the same clinical investigators at the same study centers as our ascites trial.

The Company’s Chief Scientific Officer for liver cirrhosis, Penelope Markham PhD, commented: “We greatly appreciate the FDA’s guidance for the HRS-AKI trial design. Based on their feedback, we plan to apply for a Special Protocol Assessment (SPA) to gain agreement on the key elements of the Phase 3 trial design prior to initiating the study. There are currently no FDA-approved treatments for any form of acute kidney injury and an approved treatment for the most severe form, HRS-AKI, could be transformative.”

About BioVie

BioVie Inc. (NASDAQ: BIVI) is a clinical-stage company developing transformative 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 with top-line results expected in early 2022. It 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 neuro-degenerative disease, BioVie recently acquired the assets of NeurMedix Inc., including NE3107, an ERK inhibitor that selectively reduces neuroinflammation and insulin resistance. Both are drivers of Alzheimer's and Parkinson's diseases. The FDA has authorized 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 is planning to initiate this trial in mid-2021 and targeting primary completion in late 2022. NE3107 and related compounds are globally patented first-in-class small molecules with additional potential to treat certain cancers.

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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