NEWS RELEASE

BioVie to Present Design of Planned Phase 2 Study of Bezisterim for the Treatment of Long COVID at the Demystifying Long COVID International Conference

2024-11-20

CARSON CITY, Nev., Nov. 20, 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 an abstract on the design of its planned Phase 2 trial evaluating bezisterim in Long COVID has been accepted as a poster presentation at the Demystifying Long COVID International Conference, November 21 st & 22 nd 2024, in Barcelona Spain.

The planned Phase 2 study, which is fully funded by a grant from the U.S. Department of Defense (DOD), is a double-blind, randomized (1:1), placebo-controlled, multicenter trial in approximately 200 patients to evaluate the safety, tolerability and potential efficacy of 3 months of treatment with bezisterim to reduce the neurocognitive symptoms associated with Long COVID.

Details for the presentation are as follows:

Title : A Double-Blind, Randomized Study to Evaluate the Efficacy and Safety of Bezisterim (NE3107) in Adults with Long COVID
Poster number : 28
Presentation date : November 21, 2024
Presenter : Penelope Markham, Ph.D, Senior Vice President and Program Lead, Long COVID, BioVie Inc.

About Long COVID
Long COVID is a condition in which symptoms of COVID-19, the acute respiratory disease caused by the SARS-CoV-2 virus, persist for an extended period of time, generally three months or more. Common symptoms include lingering loss of smell and taste, extreme fatigue, and "brain fog," though persistent cardiovascular and respiratory

problems, muscle weakness, and neurologic issues have also been documented. The Centers for Disease Control recently reported that 6.8% of adults in the United States (more than 17 million individuals) currently or previously have long COVID [1] though a recent analysis using real world data estimates the prevalence could be as high as 22% [2] . The loss in quality of life and earnings and increased medical costs has an enormous economic impact estimated to be $3.7 trillion [3] . To date there are no non-pharmacological or pharmacological therapies proven effective for treatment of long COVID.

Terms of the Department of Defense Award
The work is supported by the Assistant Secretary of Defense for Health Affairs endorsed by the Department of Defense, by a fully funded award in the amount of $13,137,150 through the Peer Reviewed Medical Research Program (PRMRP) under Award No. HT9425-24-1-0113. Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the Assistant Secretary of Defense for Health Affairs or the Department of Defense.

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. Persistent systematic inflammation and neuroinflammation are key features in patients with neurological symptoms of Long COVID. 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** .

References

[1] Ford ND, Agedew A, Dalton AF, Singleton J, Perrine CG, Saydah S. Notes from the Field: Long COVID Prevalence Among Adults — United States, 2022. MMWR Morb Mortal Wkly Rep 2024;73:135–136. DOI: **http://dx.doi.org/10.15585/mmwr.mm7306a4** .

[2] Azhir A et al. "Precision Phenotyping for Curating Research Cohorts of Patients with Unexplained Post-Acute Sequelae of COVID-19" Med DOI: 10.1016/j.medj.2024.10.009, in press

[3] Cutler, David M. 2022 The economic costs of Long COVID: An update. **long_covid_update_7-22.pdf (harvard.edu)**

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.

For Investor Relations Inquiries:
Bruce Mackle
Managing Director, LifeSci Advisors, LLC
bmackle@lifesciadvisors.com

For Media Relations Inquiries:
Melyssa Weible
Managing Partner, Elixir Health Public Relations
mweible@elixirhealthpr.com