



NEWS RELEASE

# BioVie's Upcoming Parkinson's Disease Clinical Trial is Fully Funded

2024-11-04

CARSON CITY, Nev., Nov. 04, 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, is pleased to announce that the upcoming PD-202 A Double-Blind, Randomized, Placebo-controlled, Study of Bezisterim in Subjects with Early Parkinson's Disease is now fully funded.

Favorable capital market conditions last week enabled the company to raise over \$15 million from secondary offerings, and the proceeds allow the Company to fund fully the costs of this upcoming clinical trial. The trial is expected to start in early 2025, and topline results are expected by late 2025.

BioVie's lead asset, bezisterim (formerly NE3107), binds ERK and selectively modulates NFκB activation and TNFα production, which are believed to be responsible for significant clinical improvements in several disease indications. In clinical studies, patients treated with bezisterim experienced reduced inflammation and insulin resistance, significantly improved motor function after withholding PD medications and decreased non-motor symptoms in patients that had measurable symptoms at baseline in PD, and improved cognition and regional connectivity measured by brain imaging in AD as well as altered DNA methylation directionally consistent with decreased AD pathophysiology. The Company's strategic priorities include launching a Phase 2 trial for PD in early 2025, launching an exploratory Long Covid Phase 2 trial that has been fully funded by a grant from the U.S. Department of Defense (DOD) in early 2025 and initiating a Phase 3 trial for AD in late 2025 with a new once-daily formulation of bezisterim. The Company is also continuing partnering discussions for bezisterim's geographic rights and plans to commence an ascites Phase 3 trial for BIV201 (continuous infusion terlipressin) upon identifying a suitable partner.

BioVie will be presenting in a webinar on November 7, 2024; to register for the free webinar, please visit:

[https://redchip.zoom.us/webinar/register/WN\\_v1NL71qkR8W-fNfWM4YLCg#/registration](https://redchip.zoom.us/webinar/register/WN_v1NL71qkR8W-fNfWM4YLCg#/registration)



Questions can be pre-submitted to [BIVI@redchip.com](mailto:BIVI@redchip.com) or online during the live event.

#### 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- $\kappa$ B, and the associated neuroinflammation and insulin resistance but not ERK and NF $\kappa$ B 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](http://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.

#### Contact:

Dave Gentry, CEO  
RedChip Companies, Inc.  
1-407-644-4256

**BIVI@redchip.com**

For Investor Relations Inquiries:

Contact:

Bruce Mackle

Managing Director

LifeSci Advisors, LLC

**[bmackle@lifesciadvisors.com](mailto:bmackle@lifesciadvisors.com)**

For Media Inquiries:

Contact:

Melyssa Weible

Managing Partner

Elixir Health Public Relations

Ph: +1 201-723-5705

**[mweible@elixirhealthpr.com](mailto:mweible@elixirhealthpr.com)**