NEWS RELEASE

BioVie Announces Update to Parkinson's Phase 3 Development Program

2026-09-08

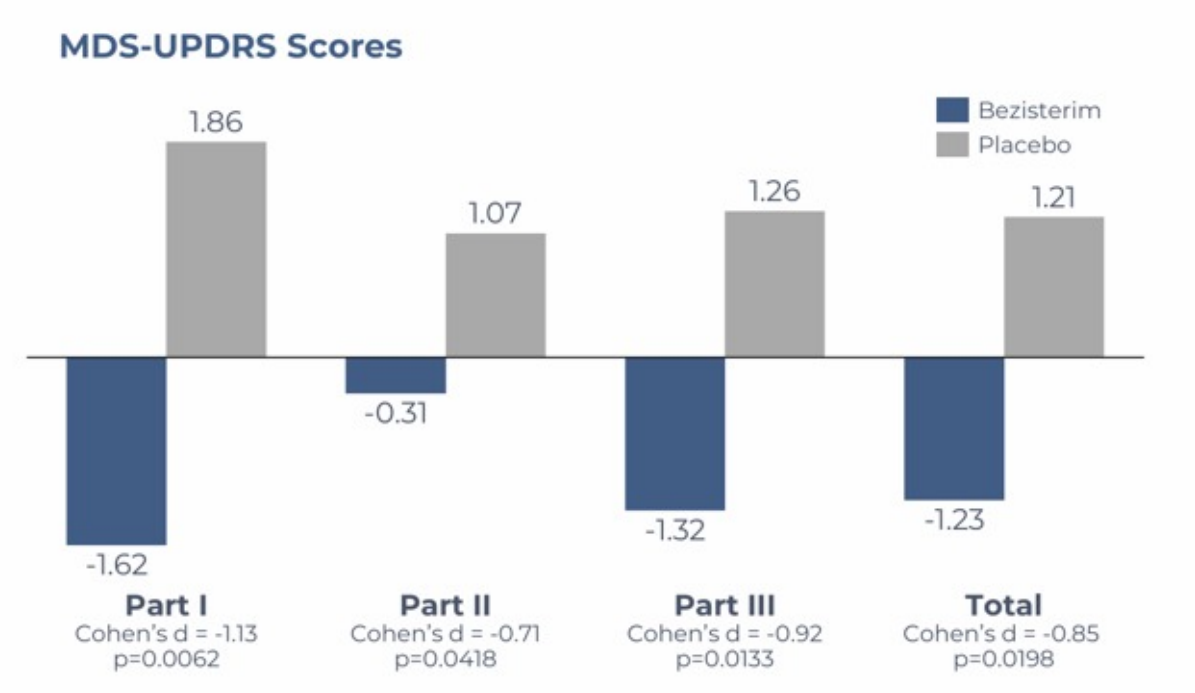
Company Corresponded with the FDA on an End of Phase 2 Meeting to Align on Phase 3 trial Design for Evaluation of Bezisterim in Early-stage Parkinson's Disease

CARSON CITY, Nev., Sept. 08, 2026 (GLOBE NEWSWIRE) -- BioVie Inc. (NASDAQ: BIVI) ("BioVie" or the "Company"), a clinical-stage company developing innovative drug therapies for neurological and neurodegenerative diseases, today announced next stage of engagement with the Food and Drug Administration (FDA) to advance the Company's Phase 3 development program evaluating bezisterim in Parkinson's disease.

"We are working closely with leading experts in Parkinson's disease clinical development to finalize a Phase 3 trial design that includes MDS-UPDRS[1] Part III as the primary endpoint, consistent with the FDA's longstanding focus on motor symptom improvement in evaluating Parkinson's therapies," said Joseph Palumbo, MD, BioVie's EVP of Research and Development and Chief Medical Officer. "At the same time, our Phase 2 data suggest that bezisterim's most meaningful clinical benefits may be in non-motor symptoms, as reflected in MDS-UPDRS Part I results, which we have selected as a co-primary or secondary endpoint. Accordingly, MDS-UPDRS Part I is expected to play an important role in the Phase 3 program, and the Company looks forward to discussing its optimal placement within the endpoint hierarchy with the FDA. Importantly, the Phase 2 findings observed patients with higher levels of inflammation derived greater benefit from treatment also provide for an enrichment strategy that we believe could support a Phase 3 trial of approximately 175 patients. By targeting both the motor and non-motor dimensions of Parkinson's disease, we believe bezisterim has the potential to become the first therapy to provide meaningful benefits across the full spectrum of Parkinson's symptoms. Based on the strength of our Phase 2 results, we believe we have a compelling foundation for a successful Phase 3 program. We have corresponded with the FDA to request an End-of-Phase 2 Meeting and look forward to discussing our proposed trial design with the FDA later this fall. We anticipate receiving formal written feedback before year-end."

In the SUNRISE-PD trial, a 12-week study of 57 patients, bezisterim-treated patients with elevated inflammatory

markers, as measured by platelet levels, showed statistically significant differences versus placebo across MDS-UPDRS Parts I, II, and III, as well as the total MDS-UPDRS score. These exploratory endpoints require validation in a larger, longer-duration trial.



About Bezisterim

Bezisterim (NE3107) is an investigational oral drug that crosses the blood-brain barrier and works to reduce inflammation and improve insulin sensitivity without suppressing the immune system and with a low risk of drug-drug interactions. By modulating key pathways involved in neuroinflammation (ERK, NFκB, TNFα), bezisterim may have therapeutic potential in several disease indications, including Parkinson's disease (PD), Long COVID (LC), and Alzheimer's disease (AD). The safety and efficacy of bezisterim have not been established for any indication.

In PD, BioVie completed the SUNRISE-PD trial, which enrolled 57 patients to establish proof of mechanism and proof of concept in individuals with early-stage disease who had not previously been treated with carbidopa/levodopa. Topline results showed that patients treated with bezisterim experienced changes in blood-based markers of inflammation, as well as a broad range of biomarkers associated with cellular health and neuronal integrity. These biomarker findings are exploratory and have not been validated by the FDA as surrogate endpoints for Parkinson's disease. Clinically, patients treated with bezisterim showed numerical improvements compared to placebo across multiple measures of daily functioning, motor symptoms, and non-motor symptoms.

For LC, the ADDRESS-LC trial enrolled approximately 200 patients to evaluate whether bezisterim may help reduce

brain fog, fatigue, and other lingering neurological symptoms associated with LC. The hypothesis being studied is that these symptoms may be triggered by persistent circulation of spike protein fragments that trigger inflammation via NFκB activation (which bezisterim has been shown to modulate). Topline data is expected late summer 2026.

In AD, BioVie has conducted Phase 2 and Phase 3 trials. Preliminary data from these trials suggest improvements in cognition and biomarkers, supporting further trials to evaluate its potential as a therapy for the six million Americans living with AD.

About BioVie Inc.

BioVie Inc. (NASDAQ: BIVI) is a clinical-stage biopharmaceutical company focused on developing therapies for neurological disorders and advanced liver disease. Its lead investigational drug candidate, bezisterim (NE3107), targets neuroinflammation and insulin resistance, which are believed to be key drivers of Alzheimer's and Parkinson's disease. Bezisterim is also being studied for Long COVID, where persistent inflammation is thought to underlie symptoms such as brain fog and fatigue.

In liver disease, BioVie is advancing BIV201, a continuous infusion of terlipressin treatment that has received FDA Orphan and Fast Track designations. The active agent is approved in the U.S. and in about 40 countries for related complications of advanced liver cirrhosis, and the Company plans to study BIV201 in a Phase 3 trial for the reduction of further decompensation in patients with cirrhosis and ascites. 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," "potential," "may," or words of similar meaning. Forward-looking statements in this release include, but are not limited to, statements regarding: the potential for bezisterim to address unmet clinical needs in Parkinson's disease; the design and conduct of future clinical trials, including a potentially pivotal Phase 3 trial; the potential clinical significance of biomarker and proteomic observations; and the Company's ability to advance bezisterim through clinical development. The biomarker and proteomic endpoints reported in this release are exploratory in nature. Changes in such biomarkers may not correlate with clinical benefit or support regulatory approval. The FDA has not validated these biomarkers as surrogate endpoints for Parkinson's disease. 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 risks related to the early stage of development of bezisterim and other product candidates, the possibility that results observed in this Phase 2 study

of 57 patients over 12 weeks may not be replicated in larger or longer-duration trials, 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, the possibility that clinical trial results may not be indicative of results in subsequent or larger trials, 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.

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[1] The Movement Disorders Society's Unified Parkinson's Disease Rating Scale. Part I (Non-motor), Part II (Activities of Daily Living); and Part III (Motor)

A photo accompanying this announcement is available at
https://www.globenewswire.com/NewsRoom/AttachmentNg/750e75d4-7a2e-40ca-96fa-dc29b9964fde

Source: BioVie, Inc.

Figure 1

MDS-UPDRS Scores