

FDA Authorizes New Drug Application For Trial to Evaluate Treatment for Long COVID

Bezisterim, an anti-inflammatory insulin sensitizer, will be authorized to proceed to a phase 2 clinical trial.

BioVie Inc announced today that the FDA has authorized their Investigational New Drug application to evaluate bezisterim (NE3107) for the treatment of patients with neurological symptoms associated with long COVID, according to a news release from the company.¹

The planned phase 2 trial will randomize approximately 200 patients to evaluate the tolerability and safety of 3 months of bezisterim treatment, in addition to the potential to reduce neurocognitive symptoms associated with long COVID.¹



Long COVID can be burdensome for a long period of time, especially with no approved treatments.

“A growing body of evidence points to inflammation as a key driver of long COVID, and we believe that bezisterim has shown promise in addressing these underlying mechanisms,” Cuong Do, president and CEO of BioVie, said in the news release. “This is a significant milestone that brings us closer to exploring how bezisterim could help patients with this debilitating condition.”¹

Other treatment options for long COVID have been studied in recent years. Metformin, a drug typically used to treat diabetes, was [found to](#) reduce the likelihood of developing long COVID by 40% compared with placebo in a cohort of patients in the COVID-OUT trial. Furthermore, hyperbaric oxygen therapy was [shown to](#) repair brain tissue damaged by COVID-19, leading to potentially sustained improvements in long COVID.^{2,3}

In patients with long COVID, the expression of proteins associated with inflammation, such as CD48 and TNF, and immune regulation, such as IL1RN and CD22, have been elevated compared to fully recovered individuals. Particularly in people with “brain fog,” persistent localized blood-brain-barrier (BBB) dysfunction and sustained systemic inflammation are key physiological aspects.¹

Bezisterim is an orally bioavailable insulin sensitizer that is also anti-inflammatory and has a low risk of drug-to-drug interactions, according to BioVie. The drug has been shown to ease inflammation by modulating the activation of NFκB. Viral spike proteins that persistently circulate during long COVID are believed to be the culprit of TLR-4 driven activation of NFκB and the following expression of inflammatory cytokines.¹

Long COVID is a condition in which the symptoms of COVID-19 persist, generally for 3 months or more. Symptoms that began with an initial COVID-19 diagnosis – loss of taste and smell, fatigue and “brain fog,” – sustain themselves weeks afterwards.¹

The CDC has reported that 5.5% adults in the US currently have the condition, with 18.3% having experienced it at some point since the pandemic began. Furthermore, 3.6 million people have reported significantly changing their daily activities and a reduction in quality of life due to long COVID, with no pharmacological or non-pharmacological therapies approved.^{1,4}

In addition to being investigated for long COVID, bezisterim is being examined as a potential treatment for Alzheimer disease (AD) and Parkinson disease. A phase 2 trial showed that patients with AD treated with the drug experienced improved biomarker levels and cognition, showing the potential for its anti-inflammatory properties to stretch across multiple disease states.¹

“Drugs modulating inflammation, and that work to regulate the BBB integrity, could represent potential therapeutic mechanisms for treating neurological symptoms of long COVID,” the news release reads.¹

Key Takeaways

1. The FDA has approved the investigational new drug application for bezisterim to treat long COVID.
2. Bezisterim will be evaluated in a phase 2 trial among 200 patients for about 3 months of treatment.
3. No approved treatments for long COVID exist, indicating the need for effective and safe treatment options.

REFERENCES

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