

Vistagen Poised To Begin Phase 1 Trial Of A Fast-Acting Antidepressant Nasal Spray In First Quarter Of 2023

Vistagen

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In the race to create faster-acting, safer antidepressants, **Vistagen** (NASDAQ: VTGN) is starting the year strong as it gets ready to launch a Phase 1 Trial of its novel pherine nasal spray for Major Depressive Disorder (MDD). The trial, involving the Company's newly optimized formulation of PH10, is intended to confirm the favorable safety profile of PH10 established in three previous clinical studies conducted in Mexico, including a published Phase 2A study for the treatment of MDD. After receiving a "study may proceed" letter from the U.S. Food and Drug Administration (FDA) last November followed by a Fast-Track designation from the FDA in December, the late clinical-stage biopharmaceutical company is ready to start the Phase 1 trial in the first quarter of 2023.

Upcoming Phase 1 Clinical Trial Will Prepare Vistagen's Drug Candidate PH10 for Phase 2B Research

On November 30, Vistagen **announced** that it had received a "study may proceed" letter from the FDA for PH10 as a treatment for MDD. The following week, the FDA **granted** Fast-Track designation to the pherine-based nasal spray. The FDA's **fast track program**, meant to bring promising new treatments for serious conditions to patients sooner, makes Vistagen's drug eligible for more frequent meetings and communications with the FDA - which can help ensure a smoother development and review process and, potentially, an earlier drug approval date.

The FDA's decision to grant Fast-Track designation was based on Vistagen's previous preclinical and clinical research on PH10. In an earlier **Phase 2A study** of PH10, for example, the MDD treatment was found to significantly reduce depressive symptoms in participants after only one week of treatment and at the eight-week study endpoint.

The upcoming Phase 1 study will enroll 12 participants in a double-blind, placebo-controlled clinical trial with topline data expected by the end of the first quarter. The goal of the study is to confirm the favorable safety data demonstrated in earlier clinical trials and lay the groundwork for a Phase 2B study of PH10 in MDD.

On December 21, Vistagen announced its **acquisition** of Pherin Pharmaceuticals, a clinical-stage company developing a pipeline of pherine drug candidates. The acquisition will give Vistagen full

ownership of the intellectual property rights for both PH10 and its Phase 3 pherine drug candidate, PH94B, allowing the company to stop paying royalties and milestone payments for the compounds. The deal will also add three new pherine drug candidates to Vistagen's pipeline.

PH10 Is Designed To Be A Fast-Acting Antidepressant With Minimal Side Effects

In the past few years, research activity in the MDD space has picked up significantly as companies explore several new treatment options with different mechanisms of action. That's because the currently approved antidepressants aren't working for millions of people, leaving a massive unmet need that drug developers are racing to fill.

"Nearly two-thirds of diagnosed and treated depression patients do not achieve remission with first-line therapy. With 21 million adults in the U.S. suffering at least one major depressive episode in the past year, potentially millions of individuals are not getting the help they need," said Vistagen CEO Shawn Singh in a [statement](#) about the upcoming Phase 1 trial for the MDD treatment.

While some exciting progress has been made, Vistagen hopes its drug candidate, PH10, can address some of the shortcomings of the latest alternatives to hit the market. PH10 is one of two pherine nasal sprays currently in development at Vistagen. [Pherines](#) are a new class of synthetic chemosensory messenger drug candidates that may be able to provide fast-acting relief for depression and anxiety symptoms and several other unmet medical needs.

For the treatment of depression, PH10 is designed to activate chemosensory neurons in the nose that can then activate the limbic system, the areas of the brain involved in emotional response. Researchers hypothesize that it does this possibly by triggering the release of more dopamine, serotonin, and norepinephrine, three hormones that play a role in mood and happiness.

This mechanism of action sets it apart from other drugs in development for depression. **COMPASS Pathways, PLC** (NASDAQ: CMPS), for example, is working on COMP 360 – a psilocybin-based therapy for treatment-resistant depression – which has shown promise in recent clinical trials. In one Phase 2b study, a single high dose of the psilocybin compound was able to provide immediate symptom improvement with results lasting up to 12 weeks.

However, being a psychedelic, the treatment requires psychological support from a specialty-trained therapist during a psilocybin therapy session. While it may be helpful in the long run, the time-consuming process isn't as convenient as a standalone medication that could be taken daily or as needed without interrupting the rest of the day.

Meanwhile, **Relmada Therapeutics, Inc.** (NASDAQ: RLMD) is developing REL-1017, a compound that works by blocking the N-Methyl-D-aspartate (NMDA) receptor in the brain. The daily oral treatment is meant to work similarly to ketamine-derived treatments like **Johnson & Johnson's** (NYSE: JNJ) recently approved Spravato, but without the psychotropic effects.

However, the late-stage biotech announced top-line results from its Phase 3 trial of the drug candidate last October, noting that it failed to achieve its primary endpoint of significantly reducing depression symptoms compared to a placebo.

PH10, on the other hand, does not require the same systemic uptake to produce its fast-acting effects, according to Vistagen. The compound doesn't cause the same psychotropic side effects as ketamine-based treatments but has still managed to demonstrate rapid-onset and significant lasting results in the clinical studies completed so far. As trials progress, it could be worth keeping on the company as it leverages its recent wins to bring its drug to market quickly for the millions suffering from depression.

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Vistagen (Nasdaq: VTGN) is a late clinical-stage biopharmaceutical company aiming to transform the treatment landscape for individuals living with anxiety, depression and other CNS disorders. The Company is advancing therapeutics with the potential to be faster-acting, and with fewer side effects and safety concerns, than those that are currently available. Vistagen's clinical-stage candidates are targeting multiple forms of anxiety and depression. PH94B and PH10 belong to a new class of drugs known as pherines, which are investigational neuroactive steroid nasal sprays designed with a novel rapid-onset mechanism of action that activates chemosensory neurons in the nasal passages and can impact the olfactory-amygdala neural circuits without systemic uptake or direct activity on CNS neurons in the brain. Vistagen is passionate about transforming mental health care and redefining what is possible in the treatment of anxiety and depression.

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