Ceruvia Lifesciences Submits FDA Investigational New Drug Application for Psilocybin Obsessive-Compulsive Disorder Program

Article

May 24, 2022 10:00 AM EDT

Based on a positive pre-IND meeting with the U.S. Food and Drug Administration (FDA), Ceruvia Lifesciences has submitted an Investigation New Drug (IND) application to begin a Phase 2 clinical trial for the treatment of obsessive-compulsive disorder with psilocybin

Preliminary results from the Ceruvia funded pilot Phase 2 study taking place at Yale School of Medicine demonstrate rapid and robust improvement in OCD symptoms with a sustained effect

GREENWICH, Conn., May 24, 2022 /PRNewswire/ -- Ceruvia Lifesciences, a leading neurotransformational medicine biopharmaceutical company today announced the submission of an IND application to begin a Phase 2, multicenter, randomized, double blind, active placebo controlled clinical trial to to determine the efficacy and safety of a single oral dose of synthetic psilocybin (SYNP-101) in treating obsessive-compulsive disorder (OCD) symptoms up to 12 weeks after dosing. The trial will be initiated in the second half of 2022, led by Principal Investigators Dr. Benjamin Kelmedi and Dr. Christopher Pittenger of Yale University School of Medicine.

According to Carey Turnbull, CEO of Ceruvia Lifesciences, "This IND application represents an important milestone in our efforts to develop neurotransformational medicines for underserved patient populations. With few effective treatment options available, we believe that psilocybin has the potential to play a critical role in improving patient quality of life for those suffering from OCD."

Almost 4 million Americans suffer from OCD, with over 79% of patients reporting severe role impairment based on the Sheehan Disability Scales. Yet, despite the significant scope of this problem, treatment options are largely limited to cognitive-behavioral therapy and anti-depressants. For many patients, these treatments, even in combination, are ineffective and the use of antidepressants results in unpleasant side-effects. The unique properties of the classic psychedelic psilocybin, may offer a significant improvement in safety and efficacy over currently available treatments for OCD.

Top News Most Read Special Reports

- Wall Street ends lower as economic data fails to ease rate hike angst
- Meta (FB) COO Sheryl Sandberg Stepping Down After 14 Years
- Salesforce (CRM) Stock Soars 8% After Earnings Beat, Analyst Says Not as Bad as Feared
- Victoria's Secret (VSCO) Stock Gains as EPS Tops Consensus, Analyst Sees 'Undervalued' Recovery Story
- S&P Global Tumbles After Suspending 2022 Guidance

sustained reductions in OCD symptoms" says Judy Ashworth, acting Chief Medical Officer, Ceruvia Lifesciences. "With this IND application we are taking an important step in advancing our drug development pipeline and clinical research program."

About Ceruvia Lifesciences

Founded in 2017, Ceruvia Lifesciences is a clinical-stage biopharmaceutical company with a mission to improve the lives of underserved patients suffering from neurological and psychiatric disorders. Founded by Carey Turnbull, Ceruvia is relentlessly focused on the development and commercialization of neurotransformational medicines to deliver meaningful relief to patients suffering from hard-to-treat headache disorders, OCD and substance abuse disorder. For too long, these communities have been poorly understood and under-served. At Ceruvia, we believe they no longer have to live this way. In partnership with leading researchers at the Yale University School of Medicine, NYU School of Medicine and the Harvard University School of Medicine Ceruvia is undertaking clinical research in order to help them return to living their lives to the fullest. For more information, please visit www.ceruvialifesciences.com

View original content to download multimedia:https://www.prnewswire.com/news-releases/ceruvia-lifesciences-submits-fda-investigational-new-drug-application-for-psilocybin-obsessive-compulsive-disorder-program-301552083.html

SOURCE Ceruvia Lifesciences

You May Also Be Interested In

- Ivy Chang is recognized by Continental Who's Who
- Steve Laserson assumes role as Vitamix CEO, becoming the first non-family member to lead the 100-year-old company
- WHITE CASTLE EXPANDS RETAIL FOOD OFFERING VIA PARTNERSHIP WITH BELLISIO FOODS; TO BRING ICONIC CHICKEN RINGS TO RETAILERS NATIONWIDE

Related Categories

Create E-mail Alert

PRNewswire, Press Releases

Related Entities

FDA