



Cerevel Therapeutics Initiates Phase 1 Clinical Trial of CVL-936, an Investigational Medicine in Development to Treat Substance Use Disorder

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BOSTON – January 30, 2020 – [Cerevel Therapeutics](http://www.cerevel.com), a company dedicated to unraveling the mysteries of the brain to treat neuroscience diseases, today announced that it has begun dosing healthy volunteers in a Phase 1 clinical trial of CVL-936, an orally-administered and potential first-in-class investigational therapy for the treatment of substance use disorder.

"An ongoing epidemic of substance use disorder is occurring in the United States, whether in the form of opioids, stimulants, alcohol, or nicotine, and the 20 million or more people who are affected are in dire need of new therapeutic options.^{1,2} For instance, despite existing treatments, approximately 90% of people living with opioid use disorder are estimated to relapse within five years, and it is estimated over half may relapse within the first six months," said John Renger, Ph.D., chief scientific officer of Cerevel Therapeutics. "Our team is developing CVL-936 as a potential first-in-class, novel mechanism treatment to restore balance in the behavioral reward system in the brain and to bring a new treatment approach to individuals who are suffering from substance use disorder, and consequently, to alleviate the suffering and stigma that they and their friends and families experience. We look forward to the results of this trial which will generate key safety, tolerability and pharmacokinetic data to inform further clinical development of CVL-936 in patients."

The randomized, double-blind, placebo-controlled Phase 1 study will evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of single ascending doses of CVL-936 in healthy volunteers ages 18 to 50. The trial will be conducted at a single center and will include up to 27 subjects across three cohorts.

About CVL-936

CVL-936 is a selective dopamine D3-preferring, D2/D3 receptor subtype antagonist in clinical development for the treatment of substance use disorder. It was designed to selectively block the binding of dopamine to D3 receptors on neurons located in the brain's reward center, while reducing, but not fully inhibiting, signaling at D2 receptors. This therapeutic approach could help re-balance the dysregulation that takes place in the reward system in the brain during substance addiction and aid in the prevention of future relapse across drugs of abuse that short-circuit this system in patients.

About Substance Use Disorder

Approximately 20.3 million people in the United States age 12 or older had a substance use disorder in 2018, according to results from the 2018 National Survey on Drug Use and Health.³ The disease affects a person's brain and behavior and leads to an inability to control the use of a legal or illegal drug or medication.³ Symptoms may vary between individuals but typically include behavioral changes, physical changes and social changes.⁴ Types of drugs associated with substance use disorder include but are not limited to heroin, oxycodone, methamphetamine, cocaine, benzodiazepines, alcohol, nicotine and ecstasy.⁵

About Cerevel Therapeutics

Cerevel Therapeutics is dedicated to unraveling the mysteries of the brain to treat neuroscience diseases. The company seeks to unlock the science surrounding new treatment opportunities through understanding the neurocircuitry of neuroscience diseases and associated symptoms. Cerevel Therapeutics has a diversified pipeline comprising five clinical-stage investigational therapies and several preclinical compounds with the potential to treat a range of neuroscience diseases, including Parkinson's disease, epilepsy, schizophrenia and substance use disorder. Headquartered in Boston, Cerevel Therapeutics is advancing its current research and development programs while exploring new modalities through internal research efforts, external collaborations or potential acquisitions. For more information, visit www.cerevel.com.

Special Note Regarding Forward-Looking Statements

This press release contains forward-looking statements that are based on management's beliefs and assumptions and on information currently available to management. In some cases, you can identify forward-looking statements by the following words: "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements involve risks, uncertainties and other factors that may cause actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this press release, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. Forward-looking statements in this press release include, but are not limited to, statements about the potential attributes and benefits of our product candidates and the format and timing of our product development activities and clinical trials. We cannot assure you that the forward-looking statements in this press release will prove to be accurate. Furthermore, if the forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. The forward-looking statements in this press release represent our views as of the date of this press release. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this press release.

Endnotes:

¹(2018). What is Addiction. Retrieved from https://www.centeronaddiction.org/addiction?gclid=EAlalQobChMI9Zfg9oSG5wIVef_jBx305QG2FAAYASAAEgJmo_D_BwE

² Thomas, S. (2020). Alcohol and Drug Abuse Statistics. Retrieved from <https://americanaddictioncenters.org/rehab-guide/addiction-statistics>

³ (2019). Key Substance Use and Mental Health Indicators in the United States. Retrieved from <https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/NSDUHNationalFindingsReport2018/NSDUHNationalFindingsReport2018.pdf>

⁴ (2019). Mental Health and Substance Use Disorders. Retrieved from <https://www.mentalhealth.gov/what-to-look-for/mental-health-substance-use-disorders>

⁵ (2017). Drug addiction (substance use disorder). Retrieved from <https://www.mayoclinic.org/diseases-conditions/drug-addiction/symptoms-causes/syc-20365112>

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