



Cerevel Therapeutics Initiates Phase 3 Program of Tavapadon for the Treatment of Parkinson's Disease

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Studies to Enroll Approximately 1,200 Patients to Determine Effectiveness of Tavapadon Across the Full Spectrum of Early- and Late-Stage Parkinson's

BOSTON – January 14, 2020 – [Cerevel Therapeutics](#), a company dedicated to unraveling the mysteries of the brain to treat neuroscience diseases, today announced the initiation of its registration-directed Phase 3 program evaluating tavapadon in patients with Parkinson's disease. The company plans to conduct three 27-week trials designed to evaluate the efficacy, safety and tolerability of fixed doses (TEMPO-1) and flexible doses (TEMPO-2, TEMPO-3) of tavapadon as either monotherapy in patients with early-stage Parkinson's disease or as adjunctive therapy to levodopa in patients with late-stage Parkinson's disease who are experiencing motor fluctuations. A fourth 58-week, open-label, safety extension trial will also be conducted as part of the program.

"Parkinson's disease affects approximately 10 million people worldwide, and there remains an important need for better and more effective therapies across the spectrum of this debilitating disease," said Raymond Sanchez, M.D., chief medical officer of Cerevel Therapeutics. "We believe tavapadon has the potential to improve outcomes for patients with both early-stage and late-stage Parkinson's. It is our expectation that the innovative design of each of these Phase 3 trials will allow us to demonstrate tavapadon's ability to improve patients' motor symptoms and functioning. We anticipate data from these trials to be available beginning in the second half of 2022."

The three double-blind, randomized, placebo-controlled, parallel-group Phase 3 clinical trials will enroll patients ages 40 to 80 years with either early-stage Parkinson's disease (TEMPO-1, TEMPO-2) or patients with late-stage Parkinson's disease who are experiencing motor fluctuations on levodopa treatment (TEMPO-3). Approximately 1,200 patients will be enrolled across all three trials. The primary endpoint of the TEMPO-1 and TEMPO-2 trials is the change from baseline in the Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Part II and Part III combined score. The primary endpoint of the TEMPO-3 trial is the change from baseline in total daily "on" time without troublesome dyskinesias.

In each of the three 27-week trials, participants will be randomized to tavapadon or placebo groups. In the TEMPO-1 trial, study participants will be titrated up to a fixed dose of either 5 mg once daily (QD) or 15 mg QD of tavapadon. In the TEMPO-2 and TEMPO-3 trials, participants will be titrated upward to a dose of between 5 mg and 15 mg QD in a flexible dosing paradigm.

The TEMPO-1 and TEMPO-2 trials have already initiated screening of patients, and the TEMPO-3 trial will begin screening later this year.

About Tavapadon

Tavapadon is a potent, orally-bioavailable, selective partial agonist of the dopamine D1 and D5 receptors. This investigational therapeutic is being evaluated for the once-daily symptomatic treatment of Parkinson's disease.

About Parkinson's Disease

Approximately 10 million people worldwide are living with Parkinson's disease, according to the Parkinson's Foundation. The disease is characterized by a progressive degeneration of dopaminergic neurons (the main source of dopamine) leading to a loss of critical motor and non-motor functions. Symptom severity and disease progression differ between individuals but typically include slowness of movement (bradykinesia), trembling in the extremities (tremors), stiffness (rigidity), cognitive or behavioral abnormalities, sleep disturbances and sensory dysfunction.¹ There is no laboratory or blood test for Parkinson's disease, so a diagnosis is made based on clinical observation,² which may contribute to an underestimation of the incidence of the disease.

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, 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, including trial initiation and data availability. 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 *J Neurol Neurosurg Psychiatry*. 2008;79:368-376. doi:10.1136/jnnp.2007.131045.

² *Cold Spring Harb Perspect Med*. 2012;2:a008870.

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