Cerevel Therapeutics Announces First Patients Dosed in all Phase 3 Trials of Tavapadon for the Treatment of Parkinson's Disease

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Company developing investigational treatment for both newly diagnosed patients and those with a more advanced form of the disease in need of adjunctive therapy

BOSTON, Oct. 30, 2020 (GLOBE NEWSWIRE) -- Cerevel Therapeutics (NASDAQ:CERE), a company dedicated to unraveling the mysteries of the brain to treat neuroscience diseases, today announced that the first participants have been dosed in all three of the clinical trials in their Phase 3 program evaluating tavapadon in patients with Parkinson's disease. The company is tackling neuroscience diseases with a differentiated approach that combines expertise in neurocircuitry with a focus on receptor selectivity. Tavapadon is an orally-bioavailable, once-daily partial agonist that selectively targets dopamine D1/D5 receptor subtypes. It has been rationally designed with the goal of balancing meaningful motor control activity while minimizing the side effects typical of drugs that non-selectively stimulate dopamine.

"We are encouraged by the benefit-risk profile of tavapadon based on the efficacy results observed in Phase 2 trials, as well as the tolerability profile we have seen in our clinical program to date," said Raymond Sanchez, M.D., chief medical officer of Cerevel Therapeutics. "We look forward to advancing the development of tavapadon and potentially bringing a differentiated, cornerstone therapy to Parkinson's patients at all stages of the disease as supported by a robust Phase 3 program."

The Phase 3 program includes three 27-week, double-blind, randomized, placebo-controlled, parallel-group trials designed to evaluate the efficacy, safety and tolerability of fixed doses (TEMPO-1) and flexible doses (TEMPO-2) of tavapadon as a monotherapy in patients with early-stage Parkinson's disease or as an adjunctive therapy to levodopa in patients with late-stage Parkinson's disease who are experiencing motor fluctuations (TEMPO-3).

Approximately 1,200 patients ages 40 to 80 years 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 dyskinesia. A fourth 58-week, open-label, safety extension trial will also be conducted as part of the program.

As the company's most advanced therapeutic program, tavapadon has been evaluated in 272 subjects in Phase 1 and Phase 2 trials, including in both early- and late-stage Parkinson's patient populations, which is required for a broad indication in Parkinson's disease. Across Phase 1b and Phase 2 trials conducted to date, tavapadon has demonstrated motor control benefit with the potential for an improved tolerability profile relative to D2/D3-preferring agonists.

Initiation of the registration-directed Phase 3 program for tavapadon began in January 2020. In response to the COVID-19 pandemic, Cerevel Therapeutics paused screening and enrollment in all trials in March 2020 and has remained vigilant about participant safety and data integrity. Now that the program is resuming, the company expects preliminary data readouts in the first half of 2023.

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 is tackling neuroscience diseases with a differentiated approach that combines expertise in neurocircuitry with a focus on receptor selectivity. 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 schizophrenia, epilepsy, Parkinson's disease 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.

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[1] *J Neurol Neurosurg Psychiatry*. 2008;79:368-376. doi:10.1136/jnnp.2007.131045.
[2] *Cold Spring Harb Perspect Med*. 2012;2:a008870.