Cerevel Therapeutics Announces Positive Topline Results for Tavapadon in Phase 3 Adjunctive Trial for People Living with Parkinson's Disease

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Tavapadon met the primary endpoint in the pivotal Phase 3 TEMPO-3 adjunctive trial, demonstrating a statistically significant increase in total "on" time without troublesome dyskinesia compared with placebo over 27 weeks

Results demonstrate tavapadon's potential to provide the right balance of motor control, safety and tolerability for people living with Parkinson's disease

Additional data from the trial will be presented at a future medical meeting; results from the tavapadon Phase 3 monotherapy trials (TEMPO-1 and TEMPO-2) are expected in the second half of 2024

CAMBRIDGE, Mass., April 18, 2024 (GLOBE NEWSWIRE) -- Cerevel Therapeutics (Nasdaq: CERE), a company dedicated to unraveling the mysteries of the brain to treat neuroscience diseases, today announced positive topline results from its pivotal Phase 3 TEMPO-3 trial for tavapadon, the first and only D1/D5 receptor partial agonist being studied as a once-daily treatment for Parkinson's disease. The TEMPO-3 trial evaluated the efficacy, safety and tolerability of tavapadon as an adjunctive therapy to levodopa (LD) in adults. The trial met its primary endpoint – patients treated with tavapadon adjunctive to LD experienced a clinically meaningful and statistically significant increase of 1.1 hours in total "on" time without troublesome dyskinesia compared to those treated with LD and placebo (1.7 hours vs. 0.6 hours, p <0.0001). A statistically significant reduction in "off" time, the key secondary endpoint, was also observed for the tavapadon treatment arm.

"Tavapadon's novel mechanism of action, which selectively activates the D1/D5 dopamine receptors, has demonstrated the potential to provide people living with Parkinson's disease the right balance of motor control, safety and tolerability," said Raymond Sanchez, M.D., chief medical officer, Cerevel Therapeutics. "We are highly encouraged with the results announced today, and look forward to sharing additional data later this year from the monotherapy trials, TEMPO-1 and TEMPO-2, as we seek to evaluate tavapadon's potential benefit to people living with Parkinson's disease."

Tavapadon was generally well tolerated. The safety profile observed in the TEMPO-3 trial was consistent with prior clinical trials of tavapadon. The majority of adverse events reported were mild to moderate in severity.

"Parkinson's disease is the fastest growing neurodegenerative disorder in the world, and a significant need exists for a new treatment option that provides the right balance of dopamine signaling and delivers sustained motor control without the burdensome side effects associated with current treatments," said Hubert H. Fernandez, M.D., global principal investigator and the James and Constance Brown endowed chair in movement disorders, professor of neurology and director at the Center for Neurological Restoration at Cleveland Clinic. "The results from the TEMPO-3 trial are particularly exciting as they demonstrate that tavapadon has the potential to offer an important new option for individuals living with this chronic, debilitating disease."

Full results from the TEMPO-3 study will be submitted for presentation at future medical meetings and used to support regulatory submissions of tavapadon as a treatment for Parkinson's disease. Topline results from the Phase 3 monotherapy trials for tavapadon, TEMPO-1 and TEMPO-2, are expected in the second half of 2024.

About TEMPO Clinical Development Program

The TEMPO clinical development program is evaluating the efficacy, safety and tolerability of tavapadon across a broad Parkinson's population, including two monotherapy Phase 3 trials (TEMPO-1 and TEMPO-2) and one adjunctive Phase 3 trial (TEMPO-3). Cerevel is also conducting a fourth, open-label extension (OLE) trial (TEMPO-4) to assess the long-term safety and tolerability of tavapadon.

TEMPO-3 was a Phase 3 double-blind, randomized, placebo-controlled, parallel-group, flexible-dose, 27-week trial to evaluate the efficacy, safety and tolerability of tavapadon as an adjunctive therapy to LD for advanced Parkinson's disease. Patients were provided with a home diary to assess their motor function status (Hauser diary). The primary endpoint was change from baseline in the total "on" time without troublesome dyskinesia based on the two-day average of the self-completed Hauser diary. Key secondary endpoints included change from baseline in total daily "off" time, change from baseline in total "on" and "off" time at earlier timepoints in the trial, and change from baseline in the Movement Disorder Society - Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Part I, II and III Scores.

A total of 507 adults between the ages of 40-80 were enrolled in the trial. All had a confirmed diagnosis of Parkinson's disease, were experiencing motor fluctuations and were on a stable dose of LD for at least 4 weeks prior to screening. Patients were randomized to receive either tavapadon adjunctive to LD, titrated to 5-15 milligrams, or placebo and LD, orally and once-daily.

More information on the trial can be found on www.clinicaltrials.gov (NCT04542499).

About Tavapadon

Tavapadon is the first and only selective D1/D5 receptor partial agonist in development for Parkinson's disease and is currently being studied as a once-daily medicine for use as both a monotherapy and as an adjunctive therapy to LD. Tavapadon is designed to selectively and optimally activate D1/D5 receptors to potentially provide the right balance of motor control, safety and tolerability for patients. By selectively activating D1/D5 dopamine receptors along the nigrostriatal pathway, tavapadon has the potential to offer the right balance of dopamine signaling to improve motor control while avoiding D2/D3 overstimulation, which is believed to underlie many of the side effects of current dopamine agonists. Additionally, as a partial agonist with a 24-hour half-life enabling once-daily dosing, tavapadon may avoid hyperactivation of the dopamine receptors, which can lead to troublesome

dyskinesias.[1,2]

About Parkinson's Disease

Parkinson's disease is a chronic neurodegenerative disorder. It primarily results in progressive and debilitating motor symptoms, including decreased bodily movement, slowness of movement, rigidity, tremors and postural instability, all of which result from the loss of dopamine-producing neurons in the brain.[3] A significant need exists for a new treatment option that has the right balance of dopamine signaling in order to provide sustained motor control without side effect tradeoffs across the disease spectrum.[4,5] As of 2022, nearly 1 million individuals in the U.S. are estimated to be affected by Parkinson's disease, which is expected to increase to over 1.6 million by 2037. [6,7]

About Cerevel Therapeutics

Headquartered in Cambridge, Mass., Cerevel Therapeutics is dedicated to unraveling the mysteries of the brain to treat neuroscience diseases. The company is tackling diseases by combining its deep expertise in neurocircuitry with a focus on targeted receptor subtype selectivity and a differentiated approach to pharmacology. Cerevel Therapeutics has a diversified pipeline comprised of five clinical-stage investigational therapies and several preclinical compounds with the potential to treat a range of neuroscience diseases, including schizophrenia, Alzheimer's disease psychosis, epilepsy, panic disorder and Parkinson's disease.

On December 6, 2023, Cerevel announced that it had entered into an agreement to be acquired by AbbVie. Cerevel continues to expect the merger to close in the middle of 2024, subject to receipt of regulatory approvals and other customary closing conditions specified in the merger agreement.

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, including tavapadon's potential to provide the right balance of motor control, safety and tolerability for people living with Parkinson's disease; the format, timing and objectives of our product development activities and clinical trials, including timing for topline results from TEMPO-1 and TEMPO-2; the ability of TEMPO-3 data to support regulatory submissions of tavapadon as a treatment for Parkinson's disease; the ability to compete with other companies currently marketing or engaged in the development of treatments for relevant indications; the size and growth potential of the markets for product candidates and ability to serve those markets; the rate and degree of market acceptance of product candidates, if approved; plans for presenting additional data from TEMPO-3 at a future medical meeting; and the anticipated closing date of the AbbVie transaction. 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. Actual performance and results may differ materially from those projected or suggested in the forward-looking statements due to various risks and uncertainties, including, among others: clinical trial results may not be favorable; uncertainties inherent in the product development process (including with respect to the timing of results and whether prior results will be predictive of future results); the impact of COVID-19 and the post-COVID landscape on the timing, progress and results of ongoing or planned clinical trials; our ability to recruit and enroll suitable patients in our clinical trials, including the effectiveness of mitigation measures; whether and when, if at all, our product candidates will receive approval from the FDA or other regulatory authorities, and for which, if any, indications; competition from other biotechnology companies; uncertainties regarding intellectual property protection; the ability of the parties to consummate the proposed merger between Cerevel and AbbVie on the timeline anticipated or at all and the possibility that various closing conditions for the merger may not be satisfied or waived, including the failure to receive any required regulatory approvals from any applicable governmental entities (or any conditions, limitations or restrictions placed on such approvals); the occurrence of any event, change or other circumstance that could give rise to the termination of the merger; and other risks identified in our SEC filings, including those under the heading "Risk Factors" in our Annual Report on Form 10-K filed with the SEC on February 27, 2024, and our subsequent SEC filings. 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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