Cerevel Therapeutics Announces Fast Track Designation Granted by the U.S. FDA to CVL-871 for the Treatment of Dementia-Related Apathy

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CAMBRIDGE, Mass., June 15, 2021 (GLOBE NEWSWIRE) -- Cerevel Therapeutics (Nasdaq: CERE), a company dedicated to unraveling the mysteries of the brain to treat neuroscience diseases, announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to CVL-871, a D1/D5 partial agonist in development for the treatment of dementia-related apathy.

"Apathy is a strong predictor of dementia progression and can lead to decreased quality of life, increased morbidity and mortality, early institutionalization, and significant caregiver burden," said Raymond Sanchez, M.D., chief medical officer of Cerevel Therapeutics. "We believe that CVL-871 could be a potential treatment to address the constellation of symptoms represented by dementia-related apathy, such as social disengagement, diminished initiative and interest and loss of emotion, and we look forward to our continued collaboration with the FDA to advance the development of this important program through the Fast Track process."

Fast Track is an FDA process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The designation allows for early and more frequent communication and meetings with the FDA regarding the development of CVL-871 for the treatment of dementia-related apathy. A candidate that receives Fast Track designation is also eligible for rolling review, and potentially priority review, of the marketing application.

About Dementia-Related Apathy
Apathy has been reported as the leading neuropsychiatric symptom in patients with dementia. The social disengagement and loss of emotion in apathy can lead to impaired decision-making, lack of empathy or concern, loss of interest in personal well-being and relationships, inability to initiate and maintain normal daily activities, as well as interference with basic daily functioning.

Apathy is among the most common neuropsychiatric co-morbidities associated with dementia, placing significant burden on both caregivers and families, and correlating very highly with disease progression. An estimated 6.2 million Americans aged 65 and older are living with dementias such as Alzheimer's disease. [1] Apathy affects approximately 50 percent of people with dementia.[2]

About CVL-871
CVL-871 is a selective dopamine D1/D5 partial agonist specifically designed to achieve a modest level of partial agonism that may be useful in modulating the complex neural networks that govern apathy-related behaviors in neurodegenerative diseases. Cerevel submitted an Investigational New Drug application, or IND, to the FDA for CVL-871 in the first quarter of 2021 for the treatment of dementia-related apathy. Cerevel plans to initiate screening in a Phase 2a exploratory trial in dementia-related apathy in the next few weeks and data are anticipated in the second half of 2022.

About Cerevel Therapeutics
Cerevel Therapeutics is dedicated to unraveling the mysteries of the brain to treat neuroscience diseases. The company is tackling diseases with a targeted approach to neuroscience 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 pre-clinical compounds with the potential to treat a range of neuroscience diseases, including Parkinson's, epilepsy, schizophrenia, and substance use disorder. Headquartered in Cambridge, Mass., 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 our participation at upcoming investor conferences and the potential attributes and benefits of our product candidates. 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 such results will be predictive of future results); the impact of COVID-19 on the timing, progress and results of ongoing or planned clinical trials; other impacts of COVID-19, including operational disruptions or delays or to our ability to raise additional capital; 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; and other risks identified in our SEC filings, including those under the heading "Risk Factors" in our Quarterly Report on Form 10-Q filed with the SEC on May 17, 2021 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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[1] Alzheimer's Association. (n.d.). *Facts and Figures*. Alzheimer's Disease and Dementia. https://www.alz.org/alzheimers-dementia/facts-figures#:~:text=An%20estimated%206.2%20million%20Americans,Americans%20with%20Alzheimer's%20are%20women.

[2] World Health Organization. (n.d.). *Dementia*. World Health Organization. https://www.who.int/news-room/fact-sheets/detail/dementia#:~:text=Worldwide%2C%20around%2050%20million%20people%20have%20dementia%2C%20with%20nearly%2060,is%20between%205%2D8%25.