# Cerevel Therapeutics to Present at 40th Annual JP Morgan Healthcare Conference: Additional Details of Phase 2 Program for Emraclidine (CVL-231) in Schizophrenia to be Presented

January 10, 2022

*Emraclidine now the international nonproprietary name (INN) for CVL-231, an M4-selective positive allosteric modulator in development for schizophrenia*

*Company expects to initiate Phase 2 program for emraclidine in schizophrenia by the middle of 2022, with data expected in the first half of 2024*

*Phase 1 trial for darigabat in acute anxiety completed; data is expected in the next several weeks*

*Phase 2a data for CVL-871 in dementia-related apathy now expected 1H 2023; delayed from 2H 2022, due in part to ongoing COVID-19 pandemic*

CAMBRIDGE, Mass., Jan. 10, 2022 (GLOBE NEWSWIRE) -- Cerevel Therapeutics (Nasdaq: CERE), a company dedicated to unraveling the mysteries of the brain to treat neuroscience diseases, will present today at 2:15 p.m. ET at the 40th Annual JP Morgan Healthcare Conference. During the presentation, Cerevel chairperson and chief executive officer, Dr. Tony Coles, will announce the details of the upcoming Phase 2 program for emraclidine, formerly known as CVL-231, as well as review the Company's lead programs and upcoming milestones. A question-and-answer session will follow the presentation.

In June 2021, Cerevel announced positive results from its Phase 1b clinical trial of emraclidine, a novel muscarinic M4-selective positive allosteric modulator (PAM), in adult patients with schizophrenia. The results of the trial supported the advancement of emraclidine into a comprehensive Phase 2 program in schizophrenia. Cerevel also plans to explore additional related indications including dementia-related psychosis.

Today, Cerevel announces the full details of the Phase 2 program in schizophrenia:

- Two adequately-powered placebo-controlled Phase 2 trials that will enable the full exploration of the therapeutic dose range of emraclidine
- Trials will be initiated by the middle of 2022, with data for both trials expected in the first half of 2024
- Each trial will enroll 372 schizophrenia patients with acute exacerbation or relapse of psychotic symptoms and who exhibit baseline Positive and Negative Syndrome Scale (PANSS) total scores between 85 and 120
- In each trial, patients will be randomized 1:1:1 into one of two emraclidine dose arms or placebo
    - The first trial will test emraclidine 10 mg QD, emraclidine 30 mg QD, and placebo
    - The second trial will test emraclidine 15 mg QD, emraclidine 30 mg QD, and placebo
- The primary endpoint will be change in the Positive and Negative Syndrome Scale (PANSS) total score after six weeks of in-patient treatment
- In parallel, Cerevel will be prioritizing nonclinical and clinical safety pharmacology studies, including hepatic and renal insufficiency studies and an 8-week ambulatory blood pressure monitoring trial, along with other registration-enabling studies
- Cerevel also plans to initiate a 52-week open-label safety extension trial to begin development of the patient safety database that will be required for registration

"Schizophrenia is a devastating and progressive disease that affects millions of patients and their loved ones. We believe emraclidine has the potential to transform the treatment paradigm by achieving antipsychotic activity while minimizing the debilitating side effects seen with current medications," said Tony Coles, M.D., chairperson and chief executive officer of Cerevel Therapeutics. "By conducting two adequately-powered studies of emraclidine in parallel, we hope to characterize the full therapeutic dose range and assess overall efficacy and tolerability for emraclidine in patients who desperately need new alternative therapies. Excellence in trial execution has been a hallmark of Cerevel's approach to drug development, and we are eager to accelerate this program in the hopes of bringing a better-tolerated therapy for patients, caregivers and providers as rapidly as possible."

At the presentation, Dr. Coles will also review two other lead programs, darigabat and tavapadon. The Phase 1 acute anxiety trial of darigabat has been completed and data is expected in the next several weeks. Darigabat is also being studied in an ongoing Phase 2 trial in focal epilepsy, with data expected in the second half of 2022. Tavapadon is currently being studied in Phase 3 for early- and late-stage Parkinson's disease. The key expected upcoming milestones for the Company are listed below in chronological order:

- Q1 2022: Phase 1 acute anxiety data for darigabat
- 2H 2022: Phase 2 proof-of-concept data for darigabat in focal epilepsy
- 1H 2023: Phase 2a exploratory data for CVL-871 in dementia-related apathy (delayed from 2H 2022, in part, due to the ongoing COVID-19 pandemic)
- 1H 2023: Phase 3 TEMPO-3 data of tavapadon in late-stage Parkinson's
- 2H 2023: Phase 3 TEMPO-1 and TEMPO-2 data of tavapadon in early-stage Parkinson's
- 1H 2024: Phase 2 data for both trials of emraclidine in schizophrenia

Cerevel expects that its current cash balance will continue to fund operations into 2024.

**Webcast Information**

The live webcast and accompanying slides can be accessed on the investor relations section of the Cerevel Therapeutics website here. A replay will be available in the same section of the company's website.

**About Emraclidine (CVL-231)**

Emraclidine is a positive allosteric modulator designed to selectively target the M4 muscarinic receptor. M4 muscarinic receptors have been shown to influence the activation levels of acetylcholine, and subsequently, dopamine receptors, key neurotransmitter pathways in the brain that are known to be dysregulated in patients with schizophrenia. Topline results from a Phase 1b trial of emraclidine in schizophrenia found both doses of the therapy demonstrated a clinically meaningful and statistically significant improvement in the Positive and Negative Syndrome Scale (PANSS) total score at six weeks and were overall well-tolerated compared with placebo. Cerevel plans to advance emraclidine to a comprehensive Phase 2 development program in schizophrenia and to evaluate the potential for this mechanism in other populations, including dementia-related psychosis.

**About Schizophrenia**

Schizophrenia is a serious, complex and debilitating mental health disorder characterized by a constellation of symptoms, including delusions, hallucinations, disorganized speech or behavior, slowed speech and blunted affect. Schizophrenia is also often associated with significant cognitive impairment, which further limits a patient's ability to be gainfully employed and maintain relationships. Diagnosis of schizophrenia is usually made in young adulthood and the disease follows a chronic and indolent course characterized by periods of remission and relapse. Only 20% of patients report favorable treatment outcomes and medication adherence is poor, with a compliance rate of about 60% and a discontinuation rate of 74% within 18 months.[1,2] Patients who discontinue their medication suffer from high relapse rates of 77% at one year and 90% at two years.[3] People with schizophrenia have a 10 to 25-year reduction in life expectancy compared to the general population.[4] An estimated 20 million people worldwide suffer from schizophrenia.[5]

**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 six 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 the potential attributes and benefits of our product candidates, the format and timing of our product development activities and clinical trials, including the timing, details and objectives of the emraclidine Phase 2 program and related nonclinical and clinical safety pharmacology studies, evaluation of this mechanism in other populations, including dementia-related psychosis, the timing of the darigabat Phase 1 anxiety data, the timing of other key upcoming milestones and other statements regarding the design of clinical trials and preclinical studies and the timing of initiation, completion and data readouts for clinical trials, the timing and outcome of IND submissions and other regulatory interactions and the sufficiency of our financial resources and our cash runway. 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 November 10, 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.

**Media Contact:**
Anna Robinson
Cerevel Therapeutics
anna.robinson@cerevel.com

**Investor Contact:**
Matthew Calistri

Cerevel Therapeutics
matthew.calistri@cerevel.com

[1] Patel, K. (2014). Schizophrenia: Overview and Treatment Options. *Pharmacy and Therapeutics*. Published. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4159061/

[2] Higashi, K. (2013). Medication adherence in schizophrenia: factors influencing adherence and consequences of nonadherence, a systematic literature review. *Psychopharmacology*. Published. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3805432/

[3] Zipursky, R. (2013). Risk of symptom recurrence with medication discontinuation in first-episode psychosis: a systematic review. *Pub Med*. Published. https://pubmed.ncbi.nlm.nih.gov/23972821/

[4] World Health Organization. (n.d.). *Information sheet*. https://www.who.int/mental_health/management/info_sheet.pdf

[5] Global, regional, and national incidence, prevalence, and years lived with disability for 354 diseases and injuries for 195 countries and territories, 1990–2017: a systematic analysis for the Global Burden of Disease Study 2017. (2018). *The Lancet*. Published. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)32279-7/fulltext