

Cerecin received US FDA clearance to study CER-0001 under an Investigational New Drug (IND) application for Infantile Spasms

- The authorization of the IND for Infantile Spasms (IS) is the third for tricaprilin, with other INDs open in Alzheimer's disease and migraine
- A pilot study of CER-0001 in IS is ongoing in Australia and Singapore and due to complete enrollment in 1H 2023
- This IND authorization will enable the Company to conduct the next IS study globally with trial sites in the United States

Denver, Colorado and Singapore – 7 December, 2022 – Cerecin Inc., a clinical-stage biotechnology company pioneering innovative neurotherapeutics, today announced that they had received authorization from the US Food and Drug Administration for an Investigational New Drug (IND) application for CER-0001 in IS, also referred to as West Syndrome. CER-0001 is an investigational, oral drug designed to induce a state of ketosis and address the metabolic deficit in the brains of children with IS, a rare and serious form of childhood epilepsy.

The open IND gives Cerecin clearance to proceed with the next phase of the planned development for CER-0001 in IS. IS usually affects children under the age of 36 months and can lead to cognitive, neurologic and sensory problems. The disorder is commonly treated with hormonal medications (such as adrenocorticotrophic hormone and *prednisolone*) and *vigabatrin*, an anticonvulsant. Both interventions have a burden of monitoring and a significant risk of serious adverse events, hence the need for new therapies that can improve the treatment experience for patients and caregivers.

Cerecin's pilot study of CER-0001 is ongoing and will have recruited the 10th and final patient by 1H 2023. Patients enrolled in the current study are children between the ages of 3 and 36 months. The Company will plan a Phase 2 study by 2H 2023.

Dr Charles Stacey, President, and CEO at Cerecin, commented: "We are pleased to have received the authorization of the IND as it gives us the ability to progress into the next phase of research for CER-0001 in an underserved patient population. After the completion of our pilot study, we look forward to advancing CER-0001 into a Phase 2 trial in 2023."

Infantile Spasms

Infantile Spasms, also known as West Syndrome in other geographies, is a severe, ultra-rare form of epilepsy that affects infants under the age of 36 months. Incidence is estimated at approximately 2,000 new cases in the U.S. per year, which can be classified as an ultra-orphan disease. IS patients experience rapid, characteristic muscular contraction or extensions lasting one to two seconds and occurring in clusters ranging from a few spasms to more than 100 spasms per cluster. These epileptic spasms occur along with hypsarrhythmia and developmental stagnation or regression.

About Cerecin

Cerecin is a clinical-stage biotechnology company focused on developing drugs that target the metabolic bases of central nervous system diseases. Cerecin's lead compound, CER-0001, is being developed for

migraine, Alzheimer's disease and epilepsy. Cerecin's programs leverage its extensive experience in neurology and global drug development. Cerecin is supported by two multinational partners, Nestlé S.A. (NSRGY), and Wilmar International Limited (F34.SI), as well as a syndicate of leading institutional investors. By bringing together the deep expertise of its leadership team Cerecin is becoming a global leader in bioenergetics and neurometabolism.

About CER-001 (Tricaprilin)

CER-0001, also known as tricaprilin, is a specific medium chain triglyceride that Cerecin is developing for a range of neurological indications including Alzheimer's disease, migraine and infantile spasms. CER-0001 is a ketogenic compound that elevates plasma ketone levels and is thereby intended to leverage the numerous activities and benefits of ketone bodies. The safety and efficacy of CER-0001 have not been established. For further information, please contact:

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