Cerecin Announces Orphan Drug Designation from U.S. FDA for *Tricaprilin* in the Treatment of Infantile Spasms

SINGAPORE AND DENVER, COLORADO – 29 October 2020 – Cerecin, a biopharmaceutical company focused on discovering and developing brain therapeutics, announced today that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) to *tricaprilin,* an investigational drug under development for the treatment of infantile spasms (also known as West's syndrome), a rare form of childhood epilepsy.

The FDA grants orphan drug status to products intended for underserved patient populations, or patients suffering from rare diseases and conditions that affect fewer than 200,000 people in the US. ODD provides drug developers up to seven years of market exclusivity, called Orphan Drug Exclusivity (ODE), upon FDA approval of the drug for the designated condition. Companies may also receive waivers or reductions on FDA User Fees and tax credits for qualified clinical trial costs.

Earlier in October, Cerecin also received Rare Pediatric Disease Designation (RPD) for *tricaprilin* in the treatment of infantile spasms.

"This is another important landmark for Cerecin and the infantile spasm community. Receiving Orphan Drug status shortly after the Rare Pediatric Disease Designation highlights the therapeutic potential of tricaprilin to address an unmet need for children with this devastating condition" commented Dr Charles Stacey, President and CEO at Cerecin.
Tricaprilin is an investigational, oral drug version of a medium-chain triglyceride, designed to induce ketosis and improve mitochondrial metabolism. Cerecin has recently conducted non-clinical studies to examine the effect of *tricaprilin* in an animal model of infantile spasms. The results from these studies were positive and demonstrated that *tricaprilin* elevated ketones above control levels and reduced spasm counts.

Cerecin plans to meet with the FDA prior to submitting an Investigational New Drug application to advance *tricaprilin* into clinical studies for infantile spasms in 2021.

About Orphan Drug Designations (ODDs)

Under the Orphan Drug Act, drug companies can apply to FDA for an ODD. If a product is approved by FDA under a New Drug Application (NDA), ODD status grants the company exclusive marketing rights and prevents FDA from approving any other application for the same drug for the same orphan disease for 7 years. ODD also provides drug companies certain development rights and other benefits to help recover the costs of research and drug development. The FDA also provides protocol assistance, discount on registration fees and tax credits for qualified clinical testing costs.

About Cerecin

Cerecin is a biopharmaceutical company focused on the discovery and development of drugs to treat diseases of the brain. Cerecin's development program leverages its extensive experience in lipid science to explore the potential therapeutic benefits of ketogenic compounds. Cerecin is led by an expert executive management team with strong global expertise in central nervous system drug development and is supported by two corporate partners, Nestlé, the largest food and wellness company in the world, and Wilmar, one of the world's leading manufacturers and traders of fatty acids and lipids. Bringing together the deep industry expertise of its leadership team, and a highly differentiated drug development program, Cerecin is becoming a global leader in neurotherapeutics.

About tricaprilin (CER-0001)

Tricaprilin, also known as CER-0001, is a specific medium chain triglyceride that Cerecin is developing for a range of neurological indications including Alzheimer's disease, migraine and infantile spasms. Tricaprilin is a ketogenic compound that elevates plasma ketone levels and is thereby intended to leverage the numerous activities and benefits of ketone bodies.

About Infantile Spasms

Infantile spasms (IS) is a distinct condition which is characterized by epileptic spasms, an abnormal brain wave pattern called hypsarrhythmia, and developmental delay. It is a unique and rare disorder with an incidence rate up to 6.7 per 10,000 live births, globally. The onset of seizures, in the form of epileptic spasms, usually occurs within the first year of life, with a peak age of three to five months. 90% of children affected by IS present at less than 1 year of age with a peak incidence of 3 to 7 months. Infantile spasms is commonly treated with hormonal treatments (such as ACTH, prednisone, prednisolone) and vigabatrin, an anticonvulsant. Both of these interventions have a burden of monitoring and a significant risk of serious adverse events. Ketogenic diets have also been used for decades in this condition. A recent systematic review and meta-analysis from *Lyons et al*. (Epilepsia. 2020;61:1261–1281) on the use of ketogenic diets in infants with epilepsy found that approximately 60% of infants achieved ≥50% seizure reduction, with 33% becoming seizure-free. These human data from ketogenic diets support the investigation of *tricaprilin* for infantile spasms.

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Although forward-looking statements contained in this press release are based upon what management of Cerecin believes are reasonable assumptions, there can be no assurance or guarantee that forward-looking statements will prove to be accurate, as actual results and future events could differ materially from those anticipated in such statements. Cerecin undertakes no obligation to update forward-looking statements if circumstances or management's estimates or opinions should change except as required by applicable securities laws. The reader is cautioned not to place undue reliance on forward-looking statements.