U.S. FDA Grants Rare Pediatric Disease Designation to Cerecin's Investigational Drug *Tricaprilin* for the Treatment of Infantile Spasms

SINGAPORE AND DENVER, COLORADO – 08 October 2020 – Cerecin, a biopharmaceutical company focused on discovering and developing brain therapeutics, announced that the U.S. Food and Drug Administration (FDA) has granted Rare Pediatric Disease (RPD) designation 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 defines RPD as a serious or life-threatening disease, with the serious or life-threatening manifestations primarily affecting individuals from birth to eighteen, and affecting fewer than 200,000 people in the U.S. Under the FDA's RPD program, a sponsor who receives approval of a drug for a condition that has been granted RPD designation, may also qualify for a Priority Review Voucher (PRV). This voucher can be redeemed to receive a priority review of a subsequent marketing application for a different product or can be sold or transferred to another entity.

"*Tricaprilin* has the potential to treat a broad range of neurological conditions including a number of rare childhood diseases. The grant of this Rare Pediatric Disease Designation by the FDA is an important milestone for Cerecin," commented Dr Charles Stacey, President and CEO at Cerecin. "Infantile spasms is a devastating condition. The plight of these children and their families is made worse because currently available treatments are limited, and many children may not respond or be able to tolerate these drugs. For decades, the epilepsy community has used the ketogenic diet for managing this condition. We believe *tricaprilin,* a ketogenic compound, will build on this emerging science for children with this condition."

Tricaprilin, is an investigational oral drug version of a medium chain triglyceride, which has been designed to induce ketosis and thereby improve mitochondrial metabolism. Cerecin has recently conducted non-clinical studies to examine the effect of *tricaprilin* in a model of infantile spasms. The results from these non-clinical 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 PRVs

The FDA's PRVs are incentives intended to encourage the development of new treatments for rare diseases that would otherwise not attract interest from companies due to the cost of development and the small market size. Companies awarded this voucher may have any one of their drugs reviewed under the FDA's priority review system. The FDA's Priority Review program would allow the company to receive a review and decision for a new drug in a target of six months instead of the standard ten months' target.

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 medium chain triglycerides. Cerecin is led by an expert executive management team with strong global expertise in central nervous system drug development and is supported by two partners, Nestlé, the largest food and beverage 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 neurology therapeutics.

About Infantile Spasms

Infantile spasms (IS) is a distinct condition which is characterized by epileptic spasms, an abnormal brain wave pattern called hypsarrhythmia, and intellectual disability. 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. It 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.* 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.

For further information, please contact:

Thomas Harding/Khushboo Tanna/Nicole Ang

cerecin@spurwingcomms.com

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