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ASIA EDITION

Cerecin's Tricaprilin receives ODD in the Treatment of infantile spasms

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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.