Results of Pilot Study of CER-0001 in Migraine support advancement into a pivotal global Phase 2/3 study

- *Data from the RELIEF study, a pilot study assessing the safety and efficacy of the investigational compound CER-0001 in participants with migraine, showed a positive efficacy signal*
- *The outcome supports the advancement of CER-0001 into a pivotal global Phase 2/3 dose-ranging study in 2023*
- *In June 2022, Cerecin received U.S. FDA Clearance to study CER-0001 under an Investigational New Drug (IND) application for migraine*

Singapore and Denver, CO, USA October 31, 2022, Cerecin Inc., a clinical-stage biotechnology company pioneering innovative neurotherapeutics, today announced that data from RELIEF[1], a double-blind, randomized, placebo-controlled study investigating the safety and efficacy of twice daily administration of *CER-0001* for the prevention of migraine, found an efficacy signal that warrants further development in a pivotal Phase 2/3 study.

Migraine is the most prevalent neurological disease, affecting over 1 billion people globally. Clinical, biochemical and genetic evidence indicate that migraine may result from impaired bioenergetics and abnormal brain glucose metabolism.[2] *CER-0001* is an investigational oral drug designed to induce a state of ketosis and address the metabolic deficit in the brains of people with migraine.

The RELIEF study evaluated 62 participants who experienced between 4-24 migraine headache days per month at baseline. The primary endpoint was the change from baseline in migraine headache days during the third month of treatment. At month three, the study did not meet statistical significance due to power but efficacy was seen at earlier time points. The study was highly informative and provided information for the design of the next study. In response to requests from participating investigators, a special access program for *CER-0001* was established for eligible subjects who participated in the study. The Company will present the full study data at the CNS Summit, in Florida, United States, on November 19, 2022.

Cerecin has received authorization from the U.S. Food and Drug Administration (FDA) to study *CER-0001* in migraine under an Investigational New Drug (IND) application. This will allow the Company to conduct the Phase 2/3 study globally with trial sites in the United States as well as other key geographies.

Professor Messoud Ashina, Professor of Neurology in the Faculty of Health and Medical Sciences, University of Copenhagen, Denmark said, "Migraine is a heterogeneous disease with many different factors contributing to the underlying pathology. Considerable research has pointed to the involvement of metabolic and energetic pathways. Although we have made great advances in the treatment of migraine, there is still a significant unmet clinical need. More drugs are needed, that address different mechanisms, to enable doctors to adequately manage this condition."

[1] https://clinicaltrials.gov/ct2/show/NCT04437199

[2] https://pubmed.ncbi.nlm.nih.gov/35296423/#:~:text=Increasing%20evidence%20suggests%20that%20migraine,specific%20brain%20areas%20of%20migraineurs .

Professor Mark Bloch, Associate Professor at University of New South Wales, Sydney and RELIEF study investigator commented, "The RELIEF study preliminary findings show an early efficacy signal that warrants further investigation in a larger group of migraine sufferers to explore the data."

Dr Marc Cantillon, Chief Medical Officer, Cerecin, commented: "We are pleased by the results shown in our first study of *CER-0001* in migraine and the authorization of the IND. We believe that *CER-0001* has the potential to provide patients and physicians with an effective, safe, oral treatment option. With the authorization of the IND, we are now moving to get the Phase 2/3 study underway."

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 and highly innovative programs, Cerecin is becoming a global leader in bioenergetics and neurometabolism.

Forward looking statements

This press release contains "forward-looking statements" under applicable securities laws that are based on the current expectations and beliefs of Cerecin. Such statements may be accompanied by words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "potential," "possible," "will" and other words and terms of similar meaning. All statements, except for statements of historical fact, are statements that could be deemed forward-looking statements, including but not limited to: (i) sources and availability of third party financing and investments and the projected financial performance of the Company; (ii) the expected development of the Company's business, projects, drug development programs and joint ventures; (iii) execution of the Company's vision and growth strategy, including with respect to future growth; and (iv) new developments with respect to the Company's projects that are currently underway, in development or otherwise under consideration. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early-stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. Forward-looking statements are not guaranties of future performance and undue reliance should not be placed on them. Such forward-looking statements necessarily involve known and unknown risks and uncertainties, which may cause actual performance and financial results in future periods to differ materially from projections of future performance or any result that may be expressed or implied by such forward-looking statements. 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.

For more information visit www.cerecin.com.

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