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Senhwa Announces Multiple IND application submissions to U.S. FDA for Silmitasertib as a Potential Treatment for COVID-19

TAIPEI and SAN DIEGO, Nov. 2 , 2020 -- Senhwa Biosciences, Inc. (TPEx: 6492), a clinical-stage biopharmaceutical company focused on next-generation DNA Damage Response (DDR) therapeutics for the treatment of cancer, today announced that it has submitted an **Investigational New Drug** (IND) application with the **U.S. Food and Drug Administration** (FDA) to evaluate its investigational drug Silmitasertib for the treatment of severe Coronavirus Disease 2019 (COVID-19). Silmitasertib recently successfully rescued a patient with severe COVID-19 under Emergency IND (EIND) and the patient was discharged within five days after treatment with Silmitasertib.

"This IND submission is a key milestone in the clinical development of Silmitasertib. With the remarkable recovery demonstrated by the first patient received Silmitasertib with sever COVID-19 under EIND and with strong scientific rationale, safety data from prior clinical trials in over 200 patients, and a well-defined regulatory pathway, we believe Silmitasertib has great potential as a therapeutic for COVID-19," said Dr. John Soong, the Chief Medical Officer of Senhwa Biosciences.

"As U.S. cases spike back up and hospitals are once again overwhelmed, we hope the same result of EIND will be repeated in other patients of this phase 2 trial and Silmitasertib will save more lives in the near future," said Benny T. Hu, Chairman of Senhwa Biosciences.

This is a phase II multi-center, randomized, two- armed controlled interventional prospective study. The objective of this study is to assess the safety, clinical benefit, and anti-viral activity of Silmitasertib in up to 40 patients with severe COVID-19. The study will be led by Dr. Marilyn Glassberg Csete, Chief of Pulmonary, Critical Care, and Sleep Medicine at the University of Arizona College of Medicine/Banner – University Medical Center Phoenix.

A separate Phase II, investigator-initiated, clinical protocol will be conducted at the Center for Advanced Research and Education (CARE) in Gainesville, Georgia. The CARE trial will seek to enroll 20 patients once authorized by the U.S. FDA.

Senhwa's Silmitasertib is an oral medication, which challenges both the virus' (SARS-CoV-2) ability to replicate quickly and spread to nearby healthy cells and the body's uncontrolled inflammatory response to SARS-CoV-2 infection. Because Silmitasertib targets the host protein kinase CK2 (f.k.a. casein kinase 2) pathway, virus mutations are unlikely to affect either Silmitasertib anti-viral or anti-inflammatory efficacy.

About Silmitasertib

Silmitasertib is a first-in-class small molecule drug that targets CK2 and acts as a CK2-inhibitor. Silmitasertib is safe and well-tolerated in humans. To date, three Phase I trials of Silmitasertib in cancer patients have been completed; currently, there is one ongoing Phase I and two ongoing Phase II studies of Silmitasertib. In December 2016, Silmitasertib was granted Orphan Drug Designation by the US FDA for the treatment of Cholangiocarcinoma. In July 2020, Silmitasertib was granted Rare Pediatric Disease Designation (RPD) in Medulloblastoma by the US FDA. An eIND was granted by the US FDA on August 27, 2020, to Dr. Rayyan for use in the COVID patient treated at BUMCP.

About Senhwa Bioscience

Senhwa Biosciences, Inc. is a leading clinical-stage company focusing on developing first-in-class, next-generation DDR therapeutics for patients with unmet medical needs in oncology. Headquartered in Taiwan, with an operational base in San Diego, California, Senhwa is well-positioned to oversee the development of its compounds.

Development is currently focused on two lead products Silmitasertib (CX-4945) and Pidnarulex (CX-5461) with novel mechanisms of action and for multiple indications. Clinical trials are ongoing in Australia, Canada, United States, Korea, and Taiwan, with more currently in development.

Visit Senhwa Biosciences for more details: www.senhwabio.com