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Taiwan's Centre for Drug Evaluation initiates new drug trial against COVID-19

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To further obtain EUA from Taiwan Food and Drug Administration

US-based Senhwa Biosciences, Inc. has announced that its novel oral drug, Silmitasertib, has been included in Taiwan's Center for Drug Evaluation: "CDE can Help: COVID-19 Regulatory Consultation Program".

Senhwa and Taiwan's CDE have entered an agreement to facilitate the development of Silmitasertib for treating COVID-19 in Taiwan.

Taiwan's CDE is an instrumental partner of the Taiwan Food and Drug Administration (TFDA), assisting in drafting regulations and guidance, while also maintaining professional connections with other regulatory agencies in major countries.

"Under the guidance of Taiwan's CDE, Senhwa plans to launch a COVID-19 clinical trial in Taiwan to further examine the safety and human efficacy of Silmitasertib in treating COVID-19. With this collaboration Senhwa's drug, Silmitasertib, will have a greater opportunity to obtain EUA from TFDA," said Tai-Sen Soong, Chief Executive Officer of Senhwa Biosciences.

Silmitasertib is already provided under compassionate use for patients with severe COVID-19 in Taiwan (treatment was initiated in June 2021). Currently two Phase 2 Investigator Initiated Trails (IIT) are enrolling moderate and severe COVID-19 patients, respectively, in the United States.