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CStone starts phase I trial of cancer drug

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Global development of CS5001 is conducted in the form of a multi-regional clinical trial, with sites initiated in the US and Australia, and an IND application accepted by the NMPA in China

China's CStone Pharmaceuticals, a leading biopharmaceutical company focused on the research, development, and commercialization of innovative immuno-oncology therapies and precision medicines, has announced that the first patient has been enrolled in the U.S. in the Phase 1 clinical trial for CS5001. This is a remarkable milestone for CStone's Pipeline 2.0 strategy.

CS5001 is a potential global best-in-class antibody-drug conjugate (ADC), targeting receptor tyrosine kinase-like orphan receptor 1 (ROR1). As one of the three most advanced ROR1 ADCs worldwide, CS5001 has been approved for the initiation of a multi-regional clinical trial in the US and Australia. The China National Medical Products Administration (NMPA) has accepted the investigational new drug (IND) application of CS 5001. This first-in-human Phase 1 study aims to evaluate the safety, tolerability, pharmacokinetics, and preliminary anti-tumor activity of CS5001 in advanced B cell lymphomas and solid tumors.

ROR1 is an oncofetal protein with low or no expression in adult tissues but high expression in a variety of cancers including various forms of leukemia and non-Hodgkin lymphoma, breast, lung, and ovarian cancers, making it an ideal ADC target. Results from pre-clinical studies showed that CS5001 exhibited potent and selective cytotoxicity to a variety of ROR1-expressing cancer cell lines and demonstrated remarkable in vivo antitumor activity in both hematological and solid tumor xenograft models. The preclinical data were presented as a late-breaking abstract at the 33rd AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics 2021.