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CStone secures China IND approval for EGFR/HER3 bispecific ADC CS5007

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The NMPA clearance allows CStone to expand the global Phase I programme of CS5007 into China after clinical development began in Australia in June.



CStone Pharmaceuticals has received approval from China's National Medical Products Administration to initiate clinical development of CS5007, an investigational EGFR/HER3 bispecific antibody-drug conjugate for advanced solid tumours.

The Investigational New Drug application was cleared through China's review pathway for innovative drug clinical trials in 23 working days.

The approval allows CStone to include mainland China in its ongoing global Phase I programme of CS5007.

Clinical development of the candidate began in Australia in June 2026, where the first patient was enrolled in the global multicentre Phase I study.

The programme is expected to enrol approximately 310 patients.

CS5007 is designed to simultaneously target EGFR and HER3, two receptors implicated in the growth and progression of multiple solid tumours.

By combining dual-target recognition with an antibody-drug conjugate design, CStone aims to selectively deliver a cytotoxic payload to tumour cells expressing the targets.

The programme forms part of CStone's Pipeline 2.0 portfolio, which includes antibody-drug conjugates, multispecific antibodies, immunotherapies and precision oncology candidates.

The China clearance expands the geographical scope of the Phase I programme and is intended to accelerate evaluation of the candidate across patients with advanced malignancies.

CStone is developing CS5007 as one of the key programmes within its next-generation oncology pipeline as it advances clinical development across China and international markets.