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Kelun-Biotech receives China clearance to begin clinical development of dual-payload ADC

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The NMPA clearance allows Kelun-Biotech to evaluate SKB565, its first dual-payload antibody-drug conjugate to enter clinical development, in patients with advanced solid tumours.

Kelun-Biotech has received approval from the Center for Drug Evaluation of China's National Medical Products Administration to begin clinical development of SKB565 in advanced solid tumours.

The investigational drug application clearance makes SKB565 the company's first dual-payload antibody-drug conjugate to enter the clinical stage.

SKB565 was developed using Kelun-Biotech's proprietary OptiDC platform. The candidate is designed to deliver a toxin and an immunomodulator directly to tumour tissue, combining two payloads with complementary mechanisms of action.

While conventional antibody-drug conjugates typically use a cytotoxic payload to kill tumour cells, SKB565 is intended to combine direct tumour-cell killing with activation of an immune response within the tumour microenvironment.

Kelun-Biotech said preclinical studies demonstrated antitumour activity and a safety profile that supported the candidate's advancement into clinical development.

The programme forms part of the company's "ADC + IO" strategy, which combines antibody-drug conjugates with immuno-oncology approaches. Kelun-Biotech is evaluating several ADCs in combination with PD-1 or PD-L1 antibodies and is also developing integrated molecules that incorporate complementary functions within a single drug.

"SKB565 is one of the core representative drugs of our integrated 'ADC + IO' strategy, leveraging the synergistic mechanism of its dual payloads to enhance efficacy and overcome drug resistance," said Dr Michael Ge, Chief Executive Officer of Kelun-Biotech.

"Dual-payload ADCs are emerging as one of the key next-generation innovations in the ADC field."

Kelun-Biotech currently has more than 30 key innovative drug projects in development. Four projects covering eight indications have been approved for marketing, one project is at the new drug application stage and more than 10 are in clinical development.