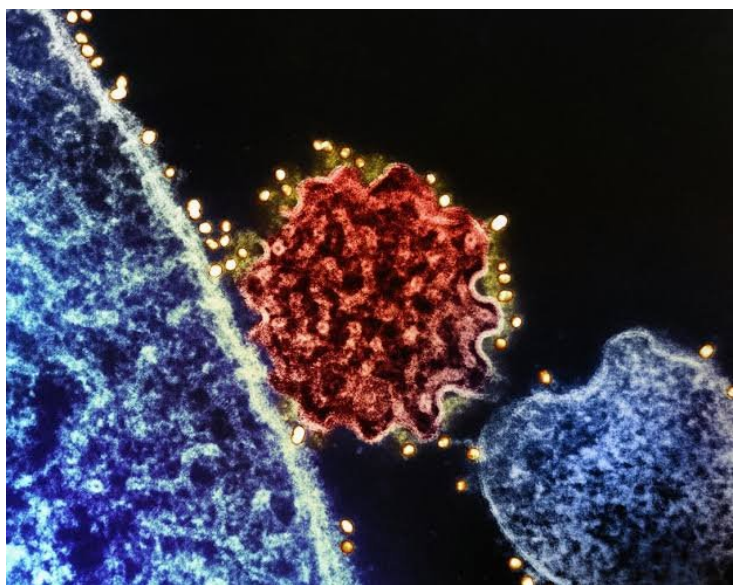


Akeso receives China Phase I clearance for EGFR/TROP2 bispecific ADC AK158D1

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The next-generation antibody-drug conjugate becomes Akeso's fourth ADC to enter clinical development and will be evaluated in patients with advanced solid tumours.



Akeso has received clearance from the Center for Drug Evaluation under China's National Medical Products Administration to initiate a Phase I clinical trial of AK158D1 in patients with advanced malignant solid tumours.

AK158D1 is a next-generation bispecific antibody-drug conjugate targeting both EGFR and TROP2.

The candidate becomes Akeso's fourth ADC to enter clinical development.

It joins a clinical-stage portfolio that includes AK146D1 targeting TROP2 and Nectin-4, AK138D1 targeting HER3 and AK157D1 targeting B7-H3.

AK158D1 is also Akeso's second bispecific ADC to enter clinical development.

The company is advancing a strategy combining next-generation immuno-oncology approaches with new ADC platforms.

EGFR and TROP2 are both highly relevant targets across multiple solid tumour types and have separately been pursued through monoclonal antibodies, small molecules and antibody-drug conjugates.

By combining both targets within one ADC, Akeso is seeking to improve tumour selectivity and expand the range of tumour cells that may be addressed by the therapy.

The Phase I study will evaluate safety, tolerability, pharmacokinetics and preliminary anti-tumour activity.

The trial will enrol patients with advanced malignant solid tumours.

The clearance further expands Akeso's clinical-stage ADC portfolio as competition increases around next-generation payloads, dual-targeting constructs and combination approaches in oncology.

Akeso is also developing a broader portfolio of immuno-oncology and targeted therapies across solid and haematological malignancies.

The Phase I programme will provide the first clinical evidence for AK158D1 and help determine appropriate dosing for further development.