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Akeso receives China clinical trial clearance for B7-H3 ADC AK157D1

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The Phase I programme will evaluate the next-generation antibody-drug conjugate in advanced solid tumours, with combination studies involving ivonescimab and cadonilimab also planned.

Akeso has received clinical trial clearance from China's Center for Drug Evaluation for AK157D1, a next-generation antibody-drug conjugate targeting B7-H3.

The clearance allows the company to initiate a Phase I clinical trial in patients with advanced malignant solid tumours.

Akeso also plans to evaluate AK157D1 in combination with its bispecific antibodies ivonescimab and cadonilimab.

B7-H3 is expressed across a broad range of solid tumours while showing comparatively limited expression in normal tissues, making it an emerging target for antibody-drug conjugate development.

Tumour types associated with B7-H3 expression include non-small cell and small cell lung cancers, prostate cancer, oesophageal cancer, nasopharyngeal carcinoma, colorectal cancer, breast cancer and glioblastoma.

Akeso said AK157D1 demonstrated anti-tumour activity and an encouraging safety profile in preclinical studies.

The company is developing the candidate as part of its strategy combining next-generation immuno-oncology therapies with antibody-drug conjugates.

AK157D1 is Akeso's third next-generation ADC to enter clinical development.

The company's other clinical-stage ADC programmes include AK146D1, targeting TROP2 and Nectin-4, and the HER3-targeting AK138D1.

Akeso is also exploring combinations between its ADC pipeline and bispecific immunotherapies as it seeks to develop new treatment strategies for solid tumours.

The Phase I study will provide initial clinical information on AK157D1's safety, tolerability and activity across advanced malignancies.

The regulatory clearance further expands Akeso's oncology development portfolio as the company advances multiple ADC and bispecific antibody programmes in parallel.