

China NMPA Grants IND Clearance to Adcentrx Therapeutics' ADRX-0405 STEAP1 ADC for the Treatment of Late-Stage Solid Tumors, Including Prostate Cancer

- *Follows initiation of Phase 1a/1b study in the U.S.*
- *Adcentrx intends to include clinical centers in China to broaden geographic representation and accelerate patient enrollment into the Phase 1a/1b study*

SAN DIEGO, CA and SHANGHAI, China, June 8, 2026 /PR NEWSWIRE/ — [Adcentrx Therapeutics](#) (“Adcentrx”), a clinical-stage biotechnology company advancing Antibody-Drug Conjugate (ADC) therapies for cancer treatment and other life-threatening diseases, today announced that the China National Medical Products Administration (NMPA) has cleared Adcentrx’s Investigational New Drug (IND) application for ADRX-0405. The clearance enables the company to include China-based clinical centers to its ongoing Phase 1a/1b trial ([NCT06710379](#)) evaluating ADRX-0405 in patients with late-stage solid tumors, including metastatic castration resistant prostate cancer, gastric cancer, and non-small cell lung cancer.

ADRX-0405 is a potential first-in-class, next-generation ADC targeting six-transmembrane epithelial antigen of the prostate 1 (STEAP1), a cell surface protein that is overexpressed in prostate cancer and certain other cancers, with limited expression in healthy tissue.

“NMPA’s clearance of the ADRX-0405 IND is another important milestone for Adcentrx,” said Hui Li, Ph.D., Founder and Chief Executive Officer of Adcentrx. “This clearance expands our ability to enroll patients in both the U.S. and China, broadening geographic representation and allowing us to generate clinical data across more diverse patient populations. This enables ADRX-0405 to address important unmet needs across multiple tumor types.”

The first-in-human Phase 1a/b clinical trial of ADRX-0405 is an open-label, multicenter dose escalation and dose expansion study. The study is enrolling patients with select advanced solid tumors. The primary objectives of the study are to characterize the safety and tolerability and to determine the optimal dose of ADRX-0405. The company anticipates completing the Phase 1a portion of the trial by the fourth quarter of 2026.

About ADRX-0405

ADRX-0405 is a clinical-stage ADC targeting STEAP1. The ADC is composed of a humanized IgG1 antibody coupled with a novel topoisomerase inhibitor linker-payload through Adcentrx’s innovative i-Conjugation technology platform, a core element of its ADC design. The platform utilizes a cleavable linker and stable conjugation chemistry to enhance

payload delivery. This novel technology enables a highly stable ADC with a drug-antibody ratio of eight (DAR 8) to maximize payload delivery to solid tumors. ADRX-0405 preclinical studies have demonstrated its favorable pharmacokinetics, safety profile, and significant efficacy across multiple animal tumor models. ADRX-0405 is currently being evaluated in a Phase 1a/b clinical trial.

For more information about the ADRX-0405 Phase 1a/b clinical trial, please refer to the Study ID [NCT06710379](https://clinicaltrials.gov/study/NCT06710379) on ClinicalTrials.gov.

I-CONJUGATION is a trademark registered in China.

About Adcentrx Therapeutics

Adcentrx is a biotechnology company focused on accelerating breakthroughs in protein conjugate therapeutic development for cancer and other life-threatening diseases. Adcentrx has pioneered the development of an ADC technology platform addressing key components of protein conjugate design to solve challenges typically seen in ADCs. Adcentrx is developing a robust pipeline including two clinical-stage ADCs and multiple preclinical ADCs, all with first-in-class and best-in-class potential.

For more information about Adcentrx and its innovative ADC technologies, please visit <https://adcentrx.com>.

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