



NextCure and Simcere Zaiming Announce Strategic Partnership for a Novel Antibody-Drug Conjugate Targeting CDH6

June 16, 2025 at 7:05 AM EDT

- NextCure gains global rights to SIM0505 excluding greater China, where Simcere Zaiming will retain rights
- Phase 1 clinical trial ongoing for SIM0505 in China; U.S. Phase 1 clinical trial is expected to begin in the third quarter of 2025
- Initial Phase 1 clinical data is expected in the first half of 2026
- NextCure also gains rights to Simcere Zaiming's proprietary linker and payload for use in an ADC directed to a NextCure novel target; Simcere Zaiming will have rights to greater China

BELTSVILLE, Md. and SHANGHAI, June 16, 2025 (GLOBE NEWSWIRE) -- [NextCure, Inc.](https://www.nextcure.com) (Nasdaq: NXTC), a clinical-stage biopharmaceutical company committed to discovering and developing novel, first-in-class and best-in-class therapies to treat cancer, and Simcere Zaiming, an oncology-focused biopharmaceutical company and a subsidiary of Simcere Pharmaceutical Group Ltd (HKEX: 2096), today announced a strategic partnership to develop SIM0505, a novel antibody-drug conjugate (ADC) targeting CDH6 (cadherin-6 or K-cadherin) for the treatment of solid tumors. SIM0505 is currently in Phase 1 clinical testing in China; NextCure expects to begin clinical testing in the U.S. in the third quarter of 2025.

SIM0505 is a novel ADC developed by Simcere Zaiming. It is directed to CDH6, a promising anti-tumor target, using a unique binding epitope with increased tumor binding compared to competing candidates. It also features Simcere Zaiming's proprietary topoisomerase 1 inhibitor (TOPOi) payload, designed for broad anti-tumor activity while offering high systemic clearance to enlarge the therapeutic window. Preclinical studies have demonstrated robust anti-tumor activity across multiple solid tumor models and a promising safety profile in toxicology models.

SIM0505 is currently in Phase 1 dose escalation studies in China. A global dose expansion study is expected following the dose escalation portion of the study to include multiple tumor types. An Investigational New Drug application has been cleared by the U.S. Food and Drug Administration.

The partnership also includes a license for NextCure to access Simcere Zaiming's proprietary linker and TOPOi payload for a preclinical-stage novel target ADC developed by NextCure. Simcere Zaiming will have Greater China rights to this additional novel target ADC.

"We believe SIM0505 has the potential to be an important new therapy for cancer patients. Partnering with Simcere Zaiming, a leader in antibody-drug conjugates, provides us with an opportunity to advance a class-leading ADC directed to CDH6. Their proprietary payload is a potent cytotoxin with a potentially improved safety and efficacy profile compared to other topoisomerase inhibitors," said Michael Richman, NextCure's president and CEO. "We look forward to initiating clinical development of SIM0505 in the United States."

"We are very pleased to collaborate with NextCure on the global development of SIM0505," said Renhong Tang, PhD, CEO of Simcere Zaiming. "SIM0505 is a significantly differentiated CDH6 targeting ADC candidate independently developed by Simcere Zaiming. Our alliance reflects NextCure's recognition of our proprietary ADC platform, and together, we aim to accelerate drug development to benefit more cancer patients worldwide."

Simcere Zaiming is eligible to receive payments throughout the potential development phases, including upfront payment, development, regulatory and sales milestones up to \$745M, as well as tiered royalties up to double digits on net sales outside of the Greater China territory.

About NextCure, Inc.

NextCure is a clinical-stage biopharmaceutical company that is focused on advancing innovative medicines that treat cancer patients that do not respond to, or have disease progression on, current therapies, through the use of differentiated mechanisms of actions including antibody-drug conjugates. We focus on advancing therapies that leverage our core strengths in understanding biological pathways and biomarkers, the interactions of cells, including in the tumor microenvironment, and the role each interaction plays in a biologic response. <http://www.nextcure.com>

About Simcere Zaiming

Simcere Zaiming is an oncology-focused biopharmaceutical company and a subsidiary of Simcere Pharmaceutical Group Limited (HKEX: 2096, "Simcere"). Founded in 2023, Simcere Zaiming dedicated to developing groundbreaking therapies to meet the unmet clinical needs of cancer patients globally. With a robust and innovative R&D pipeline featuring distinct clinical assets, Simcere Zaiming has successfully launched several innovative products in China, including COSELA[®], Enweida[®], Endostar[®], and Enlituo[®]. The company is determined to deliver potentially transformative treatment options to cancer patients worldwide through its internal R&D, manufacturing, and commercialization capabilities, complemented by strategic collaborations with leading partners.

NextCure's Cautionary Statement Regarding Forward-Looking Statements

Some of the statements contained in this press release are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including with respect to funding for our operations, objectives and expectations for our business, operations and financial performance and condition, including the progress and results of clinical trials, development plans and upcoming milestones regarding our therapies. Any statements contained herein that are not statements of historical fact may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "continue," "could," "should," "due," "estimate,"

“expect,” “intend,” “hope,” “may,” “objective,” “plan,” “predict,” “potential,” “positioned,” “seek,” “target,” “towards,” “forward,” “later,” “will,” “would” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or similar language.

Forward-looking statements involve substantial risks and uncertainties that could cause actual results to differ materially from those projected in any forward-looking statement. Such risks and uncertainties include, among others: positive results in preclinical studies may not be predictive of the results of clinical trials; NextCure’s limited operating history and not having any products approved for commercial sale; NextCure’s history of significant losses; NextCure’s need and ability to obtain additional financing on acceptable terms or at all; risks related to clinical development, marketing approval and commercialization; NextCure’s ability to maintain listing of its common stock on the Nasdaq Global Select Market; and NextCure’s dependence on key personnel. More detailed information on these and additional factors that could affect NextCure’s actual results are described under the heading “Risk Factors” in NextCure’s most recent Annual Report on Form 10-K and in NextCure’s other filings with the Securities and Exchange Commission. You should not place undue reliance on any forward-looking statements. Forward-looking statements speak only as of the date of this press release, and NextCure assumes no obligation to update any forward-looking statements, even if expectations change.

NextCure Investor Inquiries

Timothy Mayer, Ph.D.
NextCure, Inc.
Chief Operating Officer
(240) 762-6486
IR@nextcure.com

Simcere Zaiming Contacts

PR contacts: pr@zaiming.com
IR contacts: ir@zaiming.com



Source: NextCure