NextCure and Simcere Zaiming Announce Expansion of Ongoing Phase 1 Trial of SIM0505 (CDH6 ADC) into the United States

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- *First U.S. patient dosed at a mid-tier dose level where multiple responses have been observed*
- *Multi-regional trial to accelerate time to proof-of-concept data in 1H 2026*

BELTSVILLE, Md. and SHANGHAI, Oct. 16, 2025 (GLOBE NEWSWIRE) -- NextCure, Inc. (Nasdaq: NXTC), a clinical-stage biopharmaceutical company committed to developing novel therapies to treat cancer, and Simcere Zaiming, an oncology-focused biopharmaceutical company and a subsidiary of Simcere Pharmaceutical Group Ltd (HKEX: 2096), today announced that the first patient in the U.S. has been dosed with SIM0505 in the ongoing Phase 1 trial (NCT06792552), which is evaluating safety, tolerability, pharmacokinetics and efficacy in patients with advanced solid tumors.

SIM0505 is a novel antibody drug conjugate directed to cadherin-6 (CDH6 ADC), featuring a proprietary topoisomerase 1 inhibitor (TOPOi) payload, designed for broad anti-tumor activity, high systemic clearance and an improved potential therapeutic window. NextCure has now expanded the ongoing Phase 1 dose escalation study, which was initiated in China, by enrolling patient(s) in the U.S. into a mid-tier dose level while dose escalation is currently advancing in China. NextCure acquired an exclusive global license, excluding Greater China, for SIM0505 from Simcere Zaiming.

“We are pleased by the significant progress achieved by our partner, which has enabled us to start U.S. enrollment at doses within a therapeutic range where clinical responses have already been observed. Based on current data, SIM0505 has been well tolerated with a favorable safety profile,” said Udayan Guha, M.D., Ph.D., NextCure’s chief medical officer. “We believe that SIM0505 has the potential to become a leading ADC targeting CDH6. We look forward to accelerating the ongoing trial and presenting proof-of-concept clinical data in the first half of 2026.”

“Enrollment of the first patient in the U.S. marks a significant milestone in global clinical development of SIM0505. This achievement reflects our ongoing commitment to advancing innovative oncology treatments for patients in China and worldwide,” said Yongyu Wang, M.D., Chief Medical Officer, Simcere Zaiming.”

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.

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