NextCure Receives Fast Track Designation for SIM0505 (CDH6 ADC) in Ovarian Cancer

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- *The U.S. Food and Drug Administration (FDA) has granted Fast Track designation to SIM0505 for the treatment of women with platinum resistant ovarian cancer (PROC)*
- *Phase 1 data for SIM0505 to be presented at ASCO 2026; dose optimization in ovarian cancer expected to begin in Q2 2026*

BELTSVILLE, Md., April 07, 2026 (GLOBE NEWSWIRE) -- NextCure, Inc. (Nasdaq: NXTC), a clinical-stage biopharmaceutical company committed to discovering and developing novel, first-in-class, and best-in-class therapies to treat cancer, today announced that the U.S. Food And Drug Administration (FDA) has granted Fast Track Designation for SIM0505 for the treatment of platinum-resistant ovarian cancer. SIM0505 is an investigational antibody drug conjugate (ADC) comprised of an antibody that targets Cadherin-6 (CDH6) and a proprietary topoisomerase 1 inhibitor (TOPOi) payload.

“Securing Fast Track designation for SIM0505 validates the urgent, unmet need for new treatments for platinum resistant ovarian cancer and enables us to work more closely with FDA to accelerate development. We believe this designation will help to streamline and de-risk development through proactive and ongoing engagement with FDA,” said Michael Richman, President and CEO of NextCure. “We are committed to bringing SIM0505 to patients as quickly as possible and we plan to initiate dose optimization in ovarian cancer patients in the second quarter of 2026. In addition, we look forward to presenting Phase 1 data on the program at the upcoming 2026 American Society of Clinical Oncology conference.”

About Fast Track Designation

Fast Track Designation is an FDA process designed to facilitate the development of new therapies to treat serious conditions and fulfill an unmet medical need. Drug candidates that receive Fast Track Designation are eligible for more frequent meetings and written interactions with the FDA, rolling review and priority review.

About SIM0505

SIM0505 is a novel antibody drug conjugate (ADC) directed to cadherin-6 (CDH6 ADC), featuring a proprietary topoisomerase 1 inhibitor (TOPOi) payload. The ADC is designed for broad anti-tumor activity, fast systemic clearance and an improved potential therapeutic window. SIM0505 is being evaluated in an open-label, Phase 1 study (NCT06792552) for the potential treatment of advanced solid tumors, including ovarian cancer, with an emphasis on platinum resistant ovarian cancer. NextCure holds exclusive global rights for SIM0505, excluding China, Hong Kong, Macau, and Taiwan which are retained by Simcere Zaiming Pharmaceutical Co., Ltd.

About NextCure, Inc.

NextCure is a clinical-stage biopharmaceutical company focused on advancing innovative medicines to treat cancer patients through the use of targeted therapies including antibody-drug conjugates. We focus on advancing therapies that leverage our core strengths in understanding biological pathways and biomarkers, the interactions of cells within and beyond the tumor microenvironment, and the role each interaction plays in a biologic response.

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: market and other conditions; 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 reliance upon collaborators and international vendors for advancing clinical programs; 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.

Investor Inquiries

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

Mike Moyer
Managing Director,
LifeSci Advisors, LLC
Phone: (617) 308-4306
mmoyer@lifesciadvisors.com