

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 8-K**

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): June 1, 2026

**NextCure, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of incorporation)

**001-38905**  
(Commission File Number)

**47-5231247**  
(IRS Employer Identification No.)

**9000 Virginia Manor Road, Suite 200**  
**Beltsville, Maryland**  
(Address of principal executive offices)

**20705**  
(Zip Code)

Registrant's telephone number, including area code: **(240) 399-4900**

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value per share	NXTC	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 7.01 Regulation FD Disclosure**

On June 1, 2026, NextCure, Inc. (“Company”) issued a press release announcing the presentation of a poster containing Phase 1 dose escalation data for its investigational drug candidate SIM0505, such presentation occurring at the American Society for Clinical Oncology 2026 conference (“ASCO 2026”) in Chicago, IL, on June 1, 2026.

A copy of the Company press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K, and a copy of the ASCO 2026 poster is furnished as Exhibit 99.2 to this Current Report on Form 8-K.

On June 1, 2026, Company updated its corporate presentation to reflect pipeline updates and interim phase 1 data from its ongoing clinical trial for SIM0505. Beginning on June 1, 2026, Company will be engaging with members of the investment community, which may reference these presentation materials.

A copy of the Company presentation materials is furnished as Exhibit 99.3 to this Current Report on Form 8-K.

The information contained in this Item 7.01, including Exhibits 99.1, 99.2, and 99.3, shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any of the Company’s filings under the Exchange Act or the Securities Act, regardless of any general incorporation language in such filing.

**Item 8.01 Other Events**

On June 1, 2026, Company announced data from its Phase 1 dose escalation study (NCT06792552) evaluating SIM0505 in a multicenter, first in human global study in patients with advanced solid tumors. The reported data were from 59 cancer patients applying a data cutoff of April 07, 2026. Patients in the U.S. (n=25) and China (n=34) received SIM0505 at doses ranging from 1.6 mg/kg to 9.6 mg/kg and were enrolled without preselection for CDH6 expression.

SIM0505 efficacy data for gynecologic cancer patients (consisting of ovarian cancer patients and uterine serous carcinoma (“USC”) patients) in dose cohorts in the range of 4.8 – 8.0 mg/kg and who have had a minimum 12 weeks of follow-up as of the April 7, 2026 data cut off (n=20) are reported in the table below. All percentages reflect objective response rate (“ORR”) as determined using best response according to RECIST v1.1 criteria.

Patient Group	ORR*
All gynecologic patients (n=20)	55% (11/20)
• Ovarian cancer (n=17)	52.9% (9/17)
• USC (n=3)	66.7% (2/3)

\*Reported for patients within therapeutic SIM0505 dose cohorts of 4.8 - 8.0 mg/kg who had a minimum 12 weeks of follow-up at the April 7, 2026 data cut-off, and were determined by best response according to RECIST 1.1 criteria. Of the nine (9) ovarian patients with PR, there was one unconfirmed PR and one PR pending confirmation at next follow-up scan.

SIM0505 safety data for all patients (n=59) were as follows. No primary prophylaxis for hematological toxicities was used. The observed Grade 1 and Grade 2 treatment emergent adverse events (“TEAEs”) were predominantly hematological, nausea and vomiting. TEAEs leading to dose reduction (n=12) were predominantly hematological (4.8 – 9.6 mg/kg) and the majority occurring at 8.0 mg/kg, with nonhematological events including fatigue, dyspnoea, and nausea/vomiting (n=1 each). Observed Grade 3 and 4 TEAEs were predominantly hematological and manageable without primary prophylaxis for hematological toxicities. Treatment related adverse events (“TRAEs”) requiring dose discontinuation (n=3) were Grade 2 interstitial lung disease (“ILD”) and Grade 3 fungal pneumonia (both at 6.4 mg/kg), and Grade 4 thrombocytopenia (at 9.6 mg/kg). Adverse Events of Special Interest (“AESI”) were pneumonitis (n=1, Grade 1 at 5.6 mg/kg), and ILD (n=1, Grade 2 at 6.4 mg/kg).

Patient demographics data for all patients (n=59) were as reported in the table below:

Baseline Characteristics	All Patients (n=59)
Age, years: median (range)	58 (42-78)
Sex, %: Male/Female	3.4%/96.6%
Race, n (%)	
Asian	34 (57.6%)
Black or African American	3 (5.1%)
White	20 (33.9%)
Other	2 (3.4%)
Tumor Type, n (%)	
Ovarian	46 (78.0%)
USC/other endometrial	10 (16.9%)
Renal cell carcinoma (RCC)	3 (5.1%)
ECOG performance status, n (%)	
0	16 (27.1%)
1	43 (72.9%)
Prior systemic anti-cancer regimen: median (range)	5 (1-12)

On June 1, 2026, Company announced that it believes that its existing cash, cash equivalents and marketable securities will be sufficient to fund its planned operations into the first quarter of 2027. Company based this estimate on assumptions that may prove to be incorrect, and it could exhaust its available capital resources sooner than it currently expects.

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits

**Exhibit No. Description**

<a href="#">99.1</a>	<a href="#">Press Release issued by NextCure, Inc. dated June 1, 2026</a>
<a href="#">99.2</a>	<a href="#">ASCO 2026 Poster dated June 1, 2026</a>
<a href="#">99.3</a>	<a href="#">NextCure, Inc. Presentation dated June 1, 2026</a>
104	Cover Page Interactive Data File (formatted as inline XBRL).

**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: June 1, 2026

**NEXTCURE, INC.**

By: /s/ Steven P. Cobourn  
Name: Steven P. Cobourn  
Title: Chief Financial Officer

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**NextCure Presents Positive SIM0505 Phase 1 Dose Escalation Data in Patients with Gynecologic Cancers at ASCO 2026**

- 55% ORR in gynecologic cancers with 52.9% in ovarian and 66.7% in USC at 12 weeks by best response per RECIST 1.1 within the therapeutic dose range (4.8 – 8.0 mg/kg)
- Favorable safety and tolerability in heavily pretreated population supports ongoing Phase 1 dose-optimization with emphasis on PROC
- NextCure to host virtual Key Opinion Leader (KOL) Event June 2, 2026 at 8 AM ET

**BELTSVILLE, MD – June 1, 2026** (GLOBE NEWSWIRE) – **NextCure, Inc.** (Nasdaq: NXTC), a clinical-stage biopharmaceutical company committed to discovering and developing novel therapies to treat cancer, and **Simcere Zaiming Pharmaceutical Co., Ltd.**, (Simcere Zaiming) an oncology-focused biopharmaceutical company and a subsidiary of Simcere Pharmaceutical Group Ltd (HKEX: 2096), today announced the presentation of positive Phase 1 dose escalation data for SIM0505 at the American Society for Clinical Oncology (ASCO 2026) in Chicago, IL (poster #246). SIM0505 is an investigational antibody drug conjugate (ADC) targeting Cadherin-6 (CDH6) with a proprietary topoisomerase 1 inhibitor (TOPOi) payload. NextCure plans to host a virtual KOL Event on Tuesday, June 2, 2026 (register here) to review these data.

Platinum-resistant ovarian cancer (PROC) and uterine serous carcinoma (USC) represent two of the most challenging gynecologic malignancies. In PROC, once platinum resistance develops, response rates to available therapies drop to as low as 10–25%, with a median overall survival of approximately 11 months. USC, while accounting for only 10% of uterine cancers, is responsible for about 40% of uterine cancer deaths, with 5-year survival falling to 33% in advanced-stage disease. Taken together, these two cancers represent a persistent and significant unmet need for more effective treatment options.<sup>1-3</sup>

**The Phase 1 dose escalation study (NCT06792552)** evaluated SIM0505 in 59 heavily pre-treated cancer patients, with a data cutoff of April 07, 2026. Patients in the U.S. (n=25) and China (n=34) received SIM0505 at doses ranging from 1.6 mg/kg to 9.6 mg/kg, regardless of CDH6 expression.

**Positive efficacy data were observed**, with an objective response rate (ORR) of:

- 55% (11/20) for gynecologic cancers (ovarian cancer and USC)
- 52.9% (9/17) for ovarian cancer
- 66.7% (2/3) for USC
- Responses were observed across a range of CDH6 expression

ORRs, above, are reported for patients within therapeutic dose cohorts of 4.8 – 8.0 mg/kg who had a minimum 12 weeks of follow-up at the data cut-off, and were determined by best response according to RECIST 1.1 criteria. Of the nine (9) ovarian patients with partial response (PR), there was one unconfirmed PR and one PR pending confirmation at next follow-up scan.

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“Positive Phase 1 data presented at ASCO 2026 validate our conviction in SIM0505 as a potential best-in-class CDH6-directed therapy for gynecologic cancers. Meaningful response rates at 12 weeks, alongside a manageable safety profile, give us strong confidence in this program and reinforce our enthusiasm for the ongoing dose optimization study. We believe SIM0505 has broad potential in gynecologic cancers and beyond, and these data put us on a solid track toward pivotal studies and our goal of bringing this treatment to patients,” said **Michael Richman, President and CEO of NextCure**.

“Data presented at ASCO 2026 underscore the promise of our ADC platform and SIM0505, purpose-designed to deliver better efficacy, safety and tolerability, combining a carefully selected EC1 CDH6 epitope with our proprietary CPT116 topoisomerase payload. These results validate the science behind the SIM0505 construct and the accelerating pace of the global development program. Together with our partner, we remain deeply committed to advancing innovative medicines for patients facing hard-to-treat cancers,” said **Renhong Tang, PhD, CEO of Sincere Zaiming**.

“Treatment of gynecologic cancers has advanced meaningfully in recent years, yet the need for safer and more effective treatments remains real. CDH6 is an attractive target given its expression across ovarian, uterine, and other solid tumors. ADCs directed at this target have the potential to deliver the deeper, more durable responses these patients need. The early response rates observed for SIM0505 at ASCO 2026 are encouraging, and I believe the safety profile is manageable in routine clinical practice. I am enthusiastic about this program and its potential to advance the standard of care in gynecologic cancers,” said **Udayan Guha, MD, PhD, Chief Medical Officer of NextCure**.

**ASCO Poster Overview:** “Phase 1, multicenter, first-in-human (FIH) global study of SIM0505, an anti-CDH6 (CDH6) antibody-drug-conjugate (ADC) in patients with advanced solid tumors”

**Table 1: Study Subject Overview:**

Baseline Characteristics	All Patients (n=59)
Age, years: median (range)	58 (42-78)
Sex, %: Male/Female	3.4%/96.6%
Race, n (%)	
Asian	34 (57.6%)
Black or African American	3 (5.1%)
White	20 (33.9%)
Other	2 (3.4%)
Tumor Type, n (%)	
Ovarian	46 (78.0%)
USC/other endometrial	10 (16.9%)
Renal cell carcinoma (RCC)	3 (5.1%)
ECOG performance status, n (%)	
0	16 (27.1%)
1	43 (72.9%)
Prior systemic anti-cancer regimen: median (range)	5 (1-12)

**Table 2: Efficacy Overview:**

Patient Group	ORR*
All gynecologic patients (n=20)	55% (11/20)
• Ovarian cancer (n=17)	52.9% (9/17)
• USC (n=3)	66.7% (2/3)

\*Reported for patients within therapeutic SIM0505 dose cohorts of 4.8 - 8.0 mg/kg who had a minimum 12 weeks of follow-up at the April 7, 2026 data cut-off, and were determined by best response according to RECIST 1.1 criteria. Of the nine (9) ovarian patients with PR, there was one unconfirmed PR and one PR pending confirmation at next follow-up scan.

**Overall safety: Favorable overall data, potentially manageable in routine practice setting (n=59):**

- Grade 1 and 2 treatment emergent adverse events (TEAEs) predominantly hematological, nausea and vomiting
- Grade 3 and 4 TEAEs predominantly hematological and manageable without primary prophylaxis for hematological toxicities
- Treatment related adverse events (TRAEs) requiring dose discontinuation: n=3

A full copy of the poster will be available on the NextCure website under the Investor Relations “Events & Presentations” tab following the presentation.

**Virtual KOL Event**

NextCure will host a virtual KOL Event to discuss the ASCO 2026 data.

- Date: June 2, 2026
- Time: 8:00 AM ET
- Registration Link: [Click here](#)

A replay of the webinar will be accessible on the Events page of the NextCure website for 90 days.

**About SIM0505**

SIM0505 is a novel ADC directed to CDH6, featuring a proprietary 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 PROC. The U.S. Food and Drug Administration granted Fast Track Designation to SIM0505 for the treatment of PROC. NextCure holds exclusive global rights for SIM0505, excluding China, Hong Kong, Macau, and Taiwan which are retained by Simcere Zaiming.

**About the Phase 1 Trial of SIM0505**

SIM0505 is being evaluated in a global Phase 1 open-label, multicenter study ([NCT06792552](#)) with sites in the U.S. and China. The Phase 1 dose escalation segment has evaluated SIM0505, at dose levels from 1.6 mg/kg to 9.6 mg/kg, in heavily pre-treated cancer patients with solid tumors including gynecologic cancers and renal cell carcinoma. As of the April 7, 2026 data cutoff, 59 patients were enrolled without preselection for CDH6 expression. Follow-up is ongoing.

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In May 2026, NextCure initiated a Phase 1 dose optimization segment in gynecologic cancers, initially focusing on patients with PROC. The global study is expected to enroll up to 120 patients, with initial doses of 5.6, 6.4 and 7.2 mg/kg, at sites in the U.S., Canada, the EU and China.

#### **About Ovarian Cancer<sup>4-8</sup>**

Ovarian cancer is the fifth leading cause of cancer-related death among women. It is characterized by vague, easily overlooked symptoms like bloating, pelvic pain, and frequent urination that often go undetected until late stage. Risk factors include age, family history, BRCA1/2 mutations, and hormone therapy use. The median age at diagnosis is 63, and the overall 5-year relative survival rate is 51.6% — though early-stage diagnosis carries a 5-year survival rate of 91.7%. As of 2022, an estimated 244,000 women were living with ovarian cancer in the United States.

#### **About Uterine Serous Cancer<sup>2</sup>**

Uterine serous carcinoma is a rare but highly aggressive subtype of endometrial cancer, accounting for approximately 10% of uterine cancers and about 40% of uterine cancer deaths. It typically arises in postmenopausal women, with abnormal or postmenopausal bleeding as the most common presenting symptom. Risk factors include advancing age, a history of breast cancer, tamoxifen use, and hereditary breast-ovarian cancer syndrome. More than half of patients present with stage III or IV disease at diagnosis, contributing to its disproportionate mortality burden.

#### **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.

#### **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 is dedicated to developing groundbreaking therapies to address 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.

#### **Sources:**

1. Based on Lheureux S, Braunstein M, Oza AM. *CA Cancer J Clin.* 2019;69(4):280–304. PMID: 31099893, DOI: 10.3322/caac.21559
  2. Based on Ferriss JS, Erickson BK, Shih IM, Fader AN. *Int J Gynecol Cancer.* 2021;31(8):1165–1174. PMID: 34210768, DOI: 10.1136/ijgc-2021-002753
  3. Based on Hamilton CA, Cheung MK, Osann K, et al. *Br J Cancer.* 2006;94(5):642–646. PMID: 16495918, DOI: 10.1038/sj.bjc.6603012
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4. Based on Cabarca S, Ili C, Vanegas C, Gil L, Vertel-Morrison M, Brebi P. Drug resistance biomarkers in ovarian cancer: a bibliometric study from 2017 to 2022. *Front Oncol.* 2024 Nov 11;14:1450675. doi: 10.3389/fonc.2024.1450675. PMID: 39588300; PMCID: PMC11586235.
5. National Cancer Institute SEER Program
6. Ovarian Cancer Research Alliance (OCRA)
7. American Cancer Society
8. American Cancer Society / NCI SEER

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#### **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, our expected cash runway, 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: our expectations regarding the timing, progress and results of preclinical studies and clinical trials for SIM0505, LNCB74 and any other product candidates we develop; our estimates regarding our expenses, future revenues, capital requirements, needs for or ability to obtain additional financing and the period over which we expect our current cash, cash equivalents and marketable securities to be sufficient to fund our operations, market and other conditions; the timing or likelihood of regulatory filings for SIM0505, LNCB74 and any other product candidates we develop and our ability to obtain and maintain regulatory approvals for such product candidates for any indication; the identification, analysis and use of biomarkers and biomarker data; our drug product sourcing and manufacturing strategy, including the scalability of our methods and processes; our expectations regarding the potential benefits, activity, effectiveness and safety of SIM0505, LNCB74 and any other product candidates we develop; our intentions and ability to successfully commercialize, including through partnering, our product candidates; our expectations regarding the nature of the biological pathways we are targeting; our expectations regarding our ability to discover and advance product candidates using our technologies; the potential benefits of and our ability to maintain our relationship with LigaChem Biosciences, Inc., Simcere Zaiming Pharmaceutical Co., Ltd., and other third-party vendors and collaborators; our ability to retain key personnel; our intended reliance on and the performance of third parties, including collaborators, contract research organizations and third-party manufacturers; changes in international relations, tariffs, and other trade regulations between the U.S. and China; our ability to protect and enforce our intellectual property protection and the scope and duration of such protection; developments and

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projections relating to our competitors and our industry, including competing therapies; and the impact of current and future laws and regulations.

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 10-Q 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**

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Median (range)	5 (1-12)
<b>Prior Therapies in Ovarian Cancer, n (%)</b>	
Prior Exposure to Bevacizumab	36 (78.3%)
Prior Exposure to PARP	30 (65.2%)
Prior Exposure to Mirvetuximab soravtansine	11 (23.9%)
<b>FIGO stage (for gynecologic cancers), n (%)</b>	
Stage II	2 (3.6%)
Stage III	12 (21.8%)
Stage IV	42 (75.0%)

- Disease (ILD) and Gr3 fungal pneumonia at 6.4mg/kg, Gr4 thrombocytopenia at 9.6mg/kg
- Adverse Events of Special Interest (AESI): Pneumonitis (n=1, Gr 1 at 5.6mg/kg), ILD (n=1, Gr 2 at 6.4mg/kg)
  - No primary prophylaxis for hematological toxicities used

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JUNE 2026



# NextCure

*Corporate Presentation*

NASDAQ: NXTC



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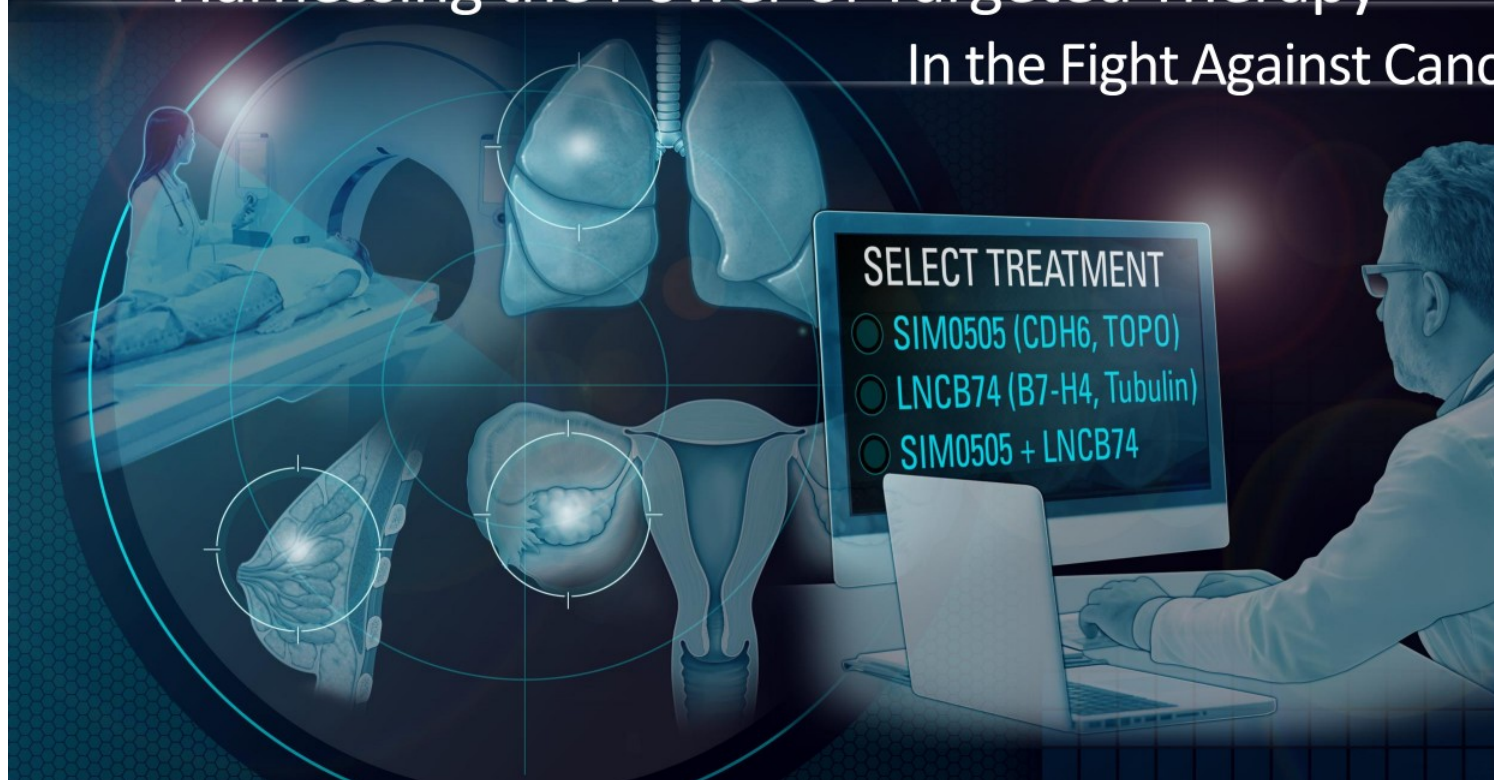
## Forward-Looking Statements

To the extent that statements contained in this presentation are not descriptions of historical facts, they may be deemed to be forward-looking statements under the Private Securities Litigation Reform Act of 1995. These statements are based on current expectations, forecasts, assumptions and other information available to NextCure as of the date hereof. Forward-looking statements include statements regarding NextCure's expectations, beliefs, intentions or strategies regarding the future and can be identified by forward-looking words such as "may," "will," "potential," "expect," "believes," "intends," "hope," "towards," "forward," "later" and similar expressions. Examples of forward-looking statements in this presentation include, among others, statements about our licensing agreement with Simcere Zaiming, statements about the development plans for our product candidates, statements about the progress and evaluation and expected timing of results of NextCure's ongoing or planned clinical trials, expectations regarding the potential benefits, activity, effectiveness and safety of our research stage, preclinical stage, and clinical stage therapeutic candidates, NextCure's financial guidance, expected upcoming milestones, and NextCure's plans, objectives and intentions with respect to the discovery and development of therapeutic products. 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 no products approved for commercial sale; NextCure's history of significant losses; NextCure's need to obtain additional financing; risks related to clinical development, marketing approval and commercialization; an unproven approach to the discovery and development of product candidates based on NextCure's discovery platform; and dependence on key personnel. More detailed information on these and additional factors that could affect NextCure's actual results are described in NextCure's filings with the Securities and Exchange Commission (the "SEC"), including in Item 1A of NextCure's most recent Form 10-K, subsequent Forms 10-Q and elsewhere in the Company's filings with the SEC. 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, except as required by law, even if expectations change.



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# Harnessing the Power of Targeted Therapy

In the Fight Against Cancer



## ADC Pipeline Progress

PROGRAMS	TARGET	PAYLOAD	PRECLINICAL	PHASE 1	PHASE 2	NEXT MILESTONE
<b>SIM0505</b> 	CDH6	TOPO	Ovarian Cancer			1Q 2027 Dose Optimization Update
			Uterine Serous Carcinoma (USC)			4Q 2026 Initiate Dose Optimization
<b>LNCB74</b> Co-development with 	B7-H4	MMAE	Breast, Ovarian, Endometrial, ACC-1			2H 2026 Trial Progress

## Accelerating Toward Pivotal Study

CDH6 ADC



**SIM0505**

- ✓ 55% ORR in gynecologic cancers
- ✓ Completed dose escalation
- ✓ Initiated dose optimization
- ✓ Fast track granted for PROC

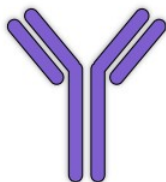
**PRODUCT  
DEVELOPMENT**

- ✓ Global exclusive license (ex China) from Simcere Zaimi
- ✓ Combine US and China data for fast & definitive POC
- ✓ US, China, Canada and Europe site expansion
- ✓ CDMO tech transfer initiated

# SIM0505 is a Differentiated CDH6 TOPOi ADC

## VALIDATED TARGET WITH PROPRIETARY TOPOi PAYLOAD

CDH6 mAb



Unique Binding Epitope  
with Increased Affinity

Linker

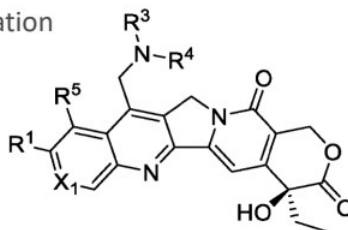
GGFG Linker

Gly-Gly-Phe-Gly Provides  
Tumor-Specific Cleavage

Cysteine conjugation

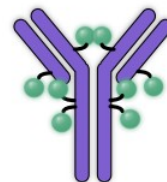


Payload CPT116 (TOPO)



High Systemic Clearance  
for Reduced Toxicity

DAR 8.0

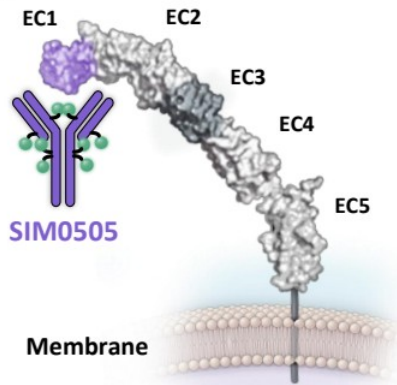


Potent Cytotoxicity with  
Anticipated Safety  
Improvement

# SIM0505 Structural and Functional Differentiation by Design

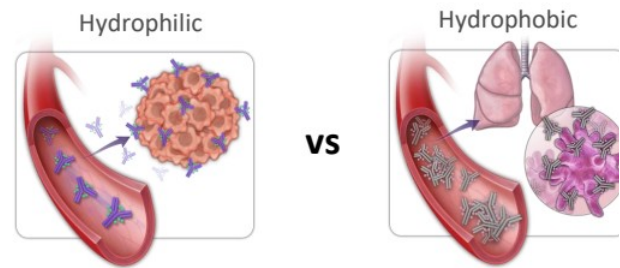
## SIM0505

- Unique distal EC1 epitope on CDH6
- Ovarian, uterine, RCC, NSCLC
- High affinity & internalization
- PK proportionality



## CPT116 (PAYLOAD)

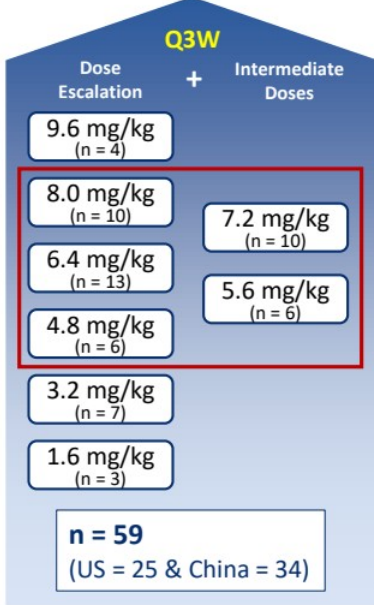
- Designed for better tolerability & safe
- Hydrophilic & high systemic clearance
- Good permeability & bystander effect
- Less aggregation than hydrophobic



# SIM0505 Development Plan

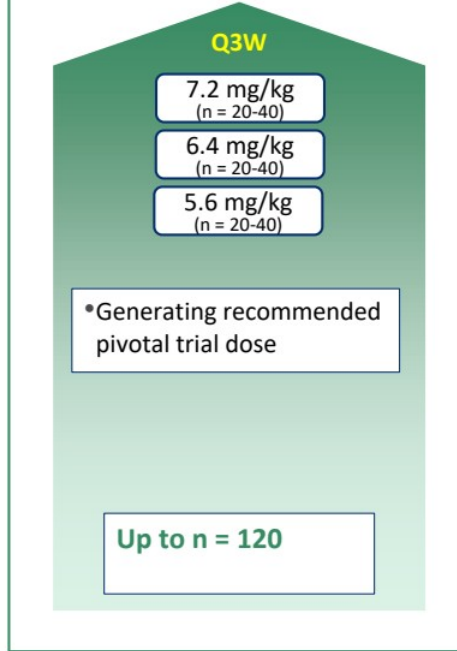
COMPLETED  
DOSE ESCALATION  
2Q 2026

## Ovarian, USC, RCC, EC



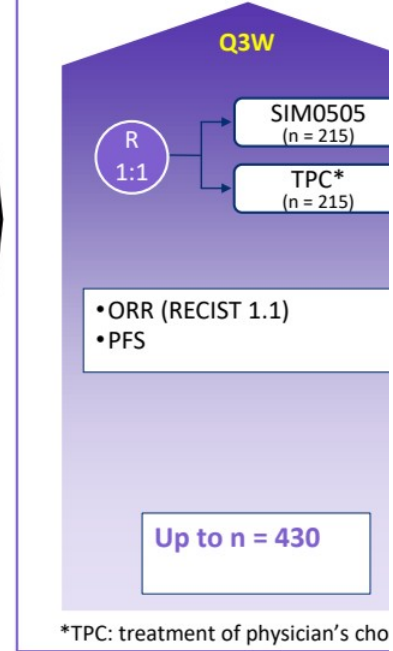
INITIATED  
DOSE OPTIMIZATION  
2Q 2026

## PROC & USC



PLANNING  
PIVOTAL TRIAL

## PROC



\*TPC: treatment of physician's cho

Baseline Characteristic	US Patients (n = 25)	China Patients (n = 34)	All Patients (n = 59)
<b>Age, years</b>			
Median (range)	63 (49-78)	56 (42-72)	58 (42-78)
<b>Sex, n (%)</b>			
Male	0 (0.0)	2 (5.9)	2 (3.4)
Female	25 (100)	32 (94.1)	57 (96.6)
<b>Tumor Type, n (%)</b>			
Ovarian	19 (76.0)	27 (79.4)	46 (78.0)
USC/other endometrial	6 (24.0)	4 (11.8)	10 (16.9)
RCC	0 (0.0)	3 (8.8)	3 (5.1)
<b>ECOG performance status, n (%)</b>			
0	8 (32.0)	8 (23.5)	16 (27.1)
1	17 (68.0)	26 (76.5)	43 (72.9)
<b>Prior systemic anti-cancer regimens</b>			
Median (range)	3 (1-9)	5 (1-12)	5 (1-12)

Data cut 07Apr26

### Patient Population

- Poor performance status
  - ~73% ECOG 1
- Heavily pretreated
- ~75% of ovarian / USC patients had FIGO Stage IV metastatic tumor burden

FIGO: International Federation of Gynecology and Obstetrics

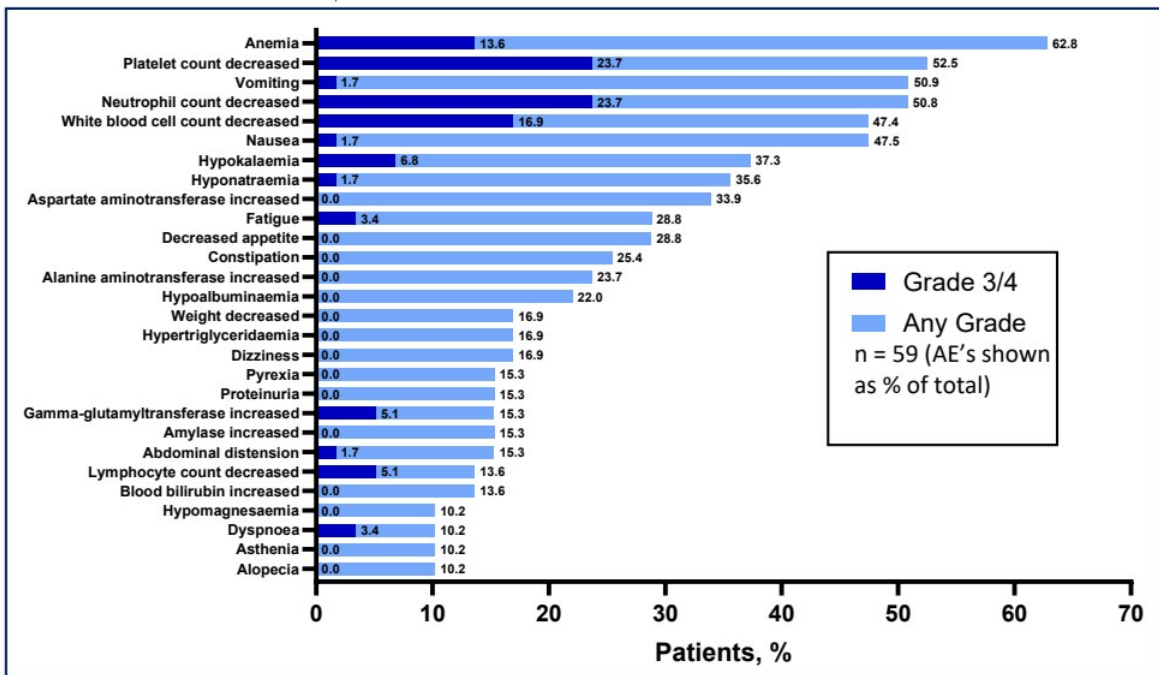
## SIM0505 Has Shown a Well Manageable Safety Profile

Overview of Adverse Events	1.6 – 9.6 mg/kg (n = 59) n (%)
Treatment-emergent adverse events (TEAEs) (%)	59 (100)
Grade $\geq 3$	32 (54.2)
Grade 5 <sup>a</sup>	2 (3.4)
TEAEs related to study drug (TRAEs) (%)	57 (96.6)
Grade $\geq 3$	28 (47.5)
Grade 5	0
Any Serious adverse events (SAEs) (%)	16 (27.1)
Treatment related SAE, n (%)	10 (16.9)
TRAE Dose modifications, n (%)	
Dose interruption	14 (23.7)
Dose reduced	11 (18.6)
Dose discontinued	3 (5.1)
Interstitial Lung Disease (ILD) / Pneumonitis <sup>b</sup>	2 (3.3)
Grade $\geq 3$	0 (0)

a. 1 Gr5 at 7.2 mg/kg related to disease progression, 1 Gr5 at 8.0 mg/kg complicated UTI (not related)  
b. 1 Gr1 ILD at 5.6mg/kg and 1 Gr2 ILD at 6.4mg/kg

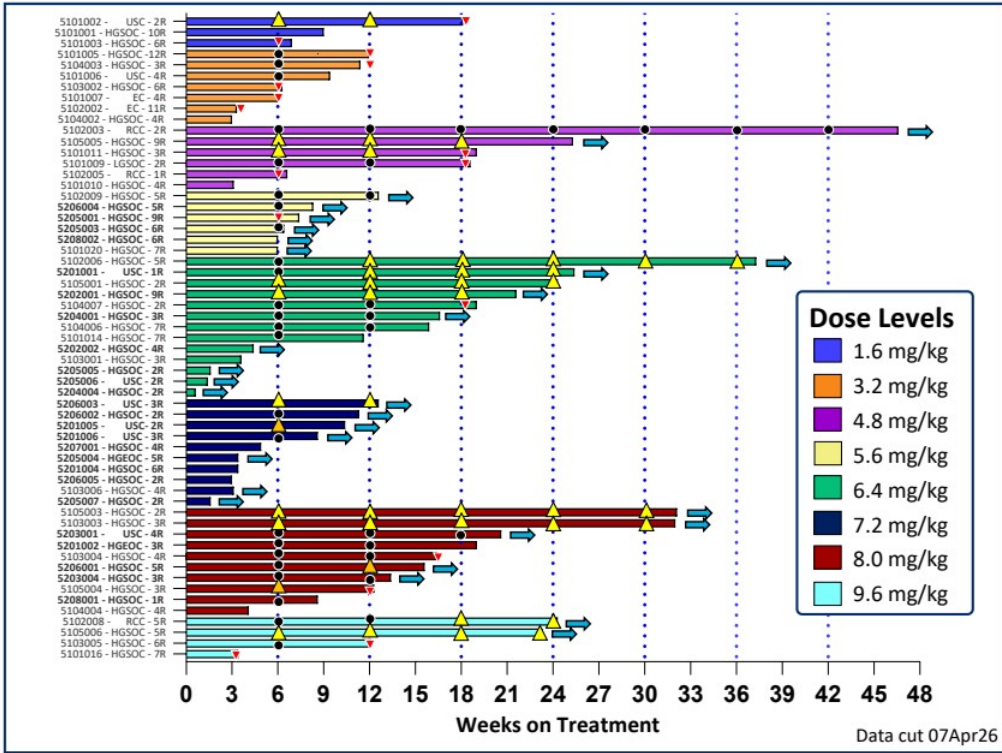
Data cut 07Apr

## Most Common TEAEs ( $\geq 10\%$ )



- MTD not reached
- No primary prophylaxis *required* for neutropenia & thrombocytopenia
- Grades 1 & 2 TEAEs v predominantly hematological, nausea vomiting
- Grades 3 & 4 TEAEs v hematological and manageable

# Swimmer Plot All Patients at All Doses



• 6 dose cohorts + 2 intermediate dose cohorts

PATIENTS ENROLLED	Total
<b>TOTAL</b>	<b>59</b>
Ovarian Cancer	46
Uterine Serous Carcinoma (USC)	8
Renal Cell Carcinoma (RCC)	3
Other Endometrial Cancer	2

• Prior systemic anti-cancer regimens: Median 5 (1-12)

**Bold** – US patients

On treatment

cPR

uPR

SD

RECIS

EC: endometrial cancer; HGSOc: high-grade serous ovarian cancer; HGEOc: high-grade endometroid cancer; LGSOc: low-grade serous ovarian cancer; RCC: renal cell carcinoma; USC: uterine serous carcinoma  
 cPR: confirmed partial response; uPR: unconfirmed partial response

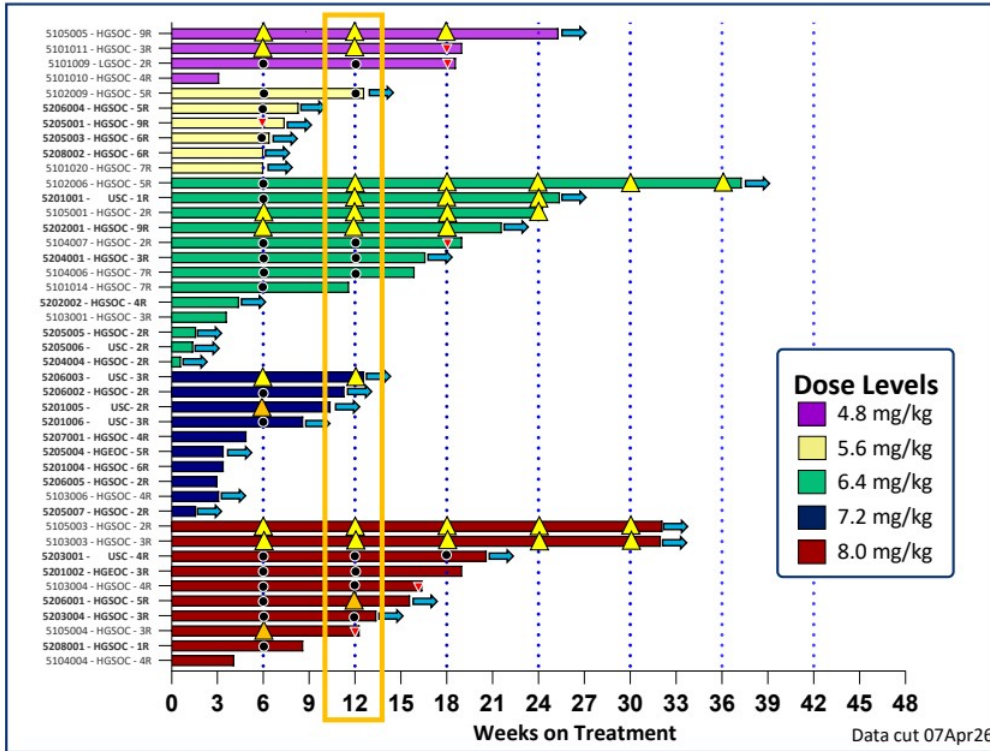
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**ORR at 4.8 – 8.0 mg/kg:  $\geq 12$  Weeks and Best Response**

Tumor type	Evaluable (n)	PRs (n)	ORR
Gynecologic Cancers (OC + USC)	20	11	55.0% (11/20)
Ovarian Cancer (OC)	17	9	52.9% (9/17)
Uterine Serous Carcinoma (USC)	3	2	66.7% (2/3)

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# Gynecologic Cancers at Therapeutic Doses (4.8 – 8.0 mg/kg)



- n = 43 enrolled
- Gynecologic cancers include ovarian and USC
- Patients with at least  $\geq 12$  week follow-up
- PRs demonstrate durability

Evaluable	PR	ORR
n = 20	11	55.0%

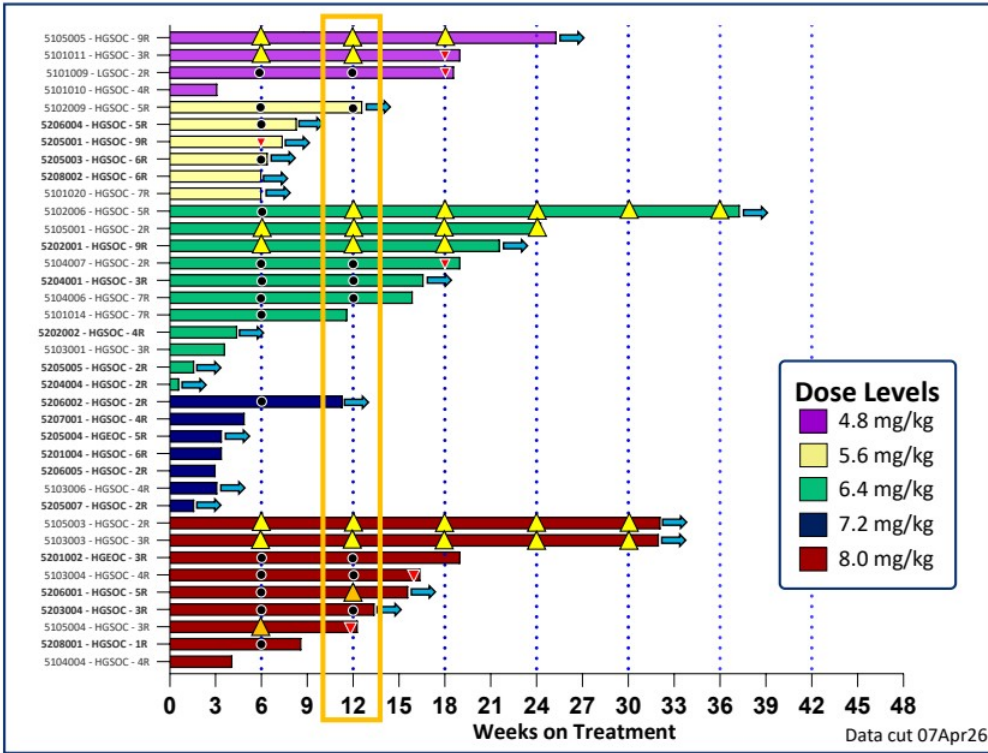
- 4 of 11 PRs from US
- Other:
  - 1 PR (USC) 1.6 mg/kg
  - 1 PR (ovarian) 9.6 mg/kg
  - 1 PR (USC) 7.2 mg/kg (has not reached 12 weeks)

▲ cPR  
▲ uPR  
● SD  
▼ RECIST

➡ On treatment

HGSOC: high-grade serous ovarian cancer; HGEOC: high-grade endometroid cancer; LGSOC: low-grade serous ovarian cancer; USC: uterine serous carcinoma  
 cPR: confirmed partial response; uPR: unconfirmed partial response

# Ovarian Cancer at Therapeutics Doses (4.8 – 8.0 mg/kg)



- n = 37 ovarian cancer patients
- Patients with at least ≥12 weeks follow-up

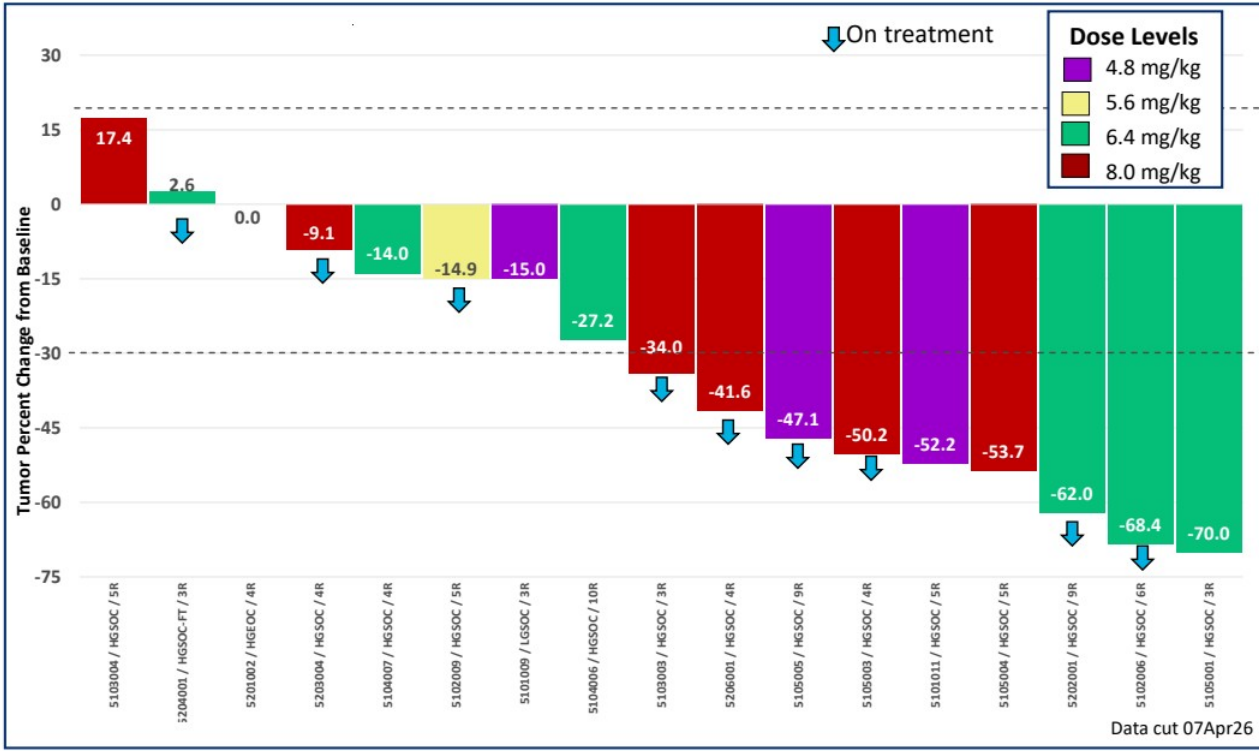
Evaluable	PR	ORR
n = 17	9	52.9%

- Other: 1 PR 9.6 mg/kg

➡ On treatment  
▲ cPR  
▲ uPR  
● SD  
▼ RECIS

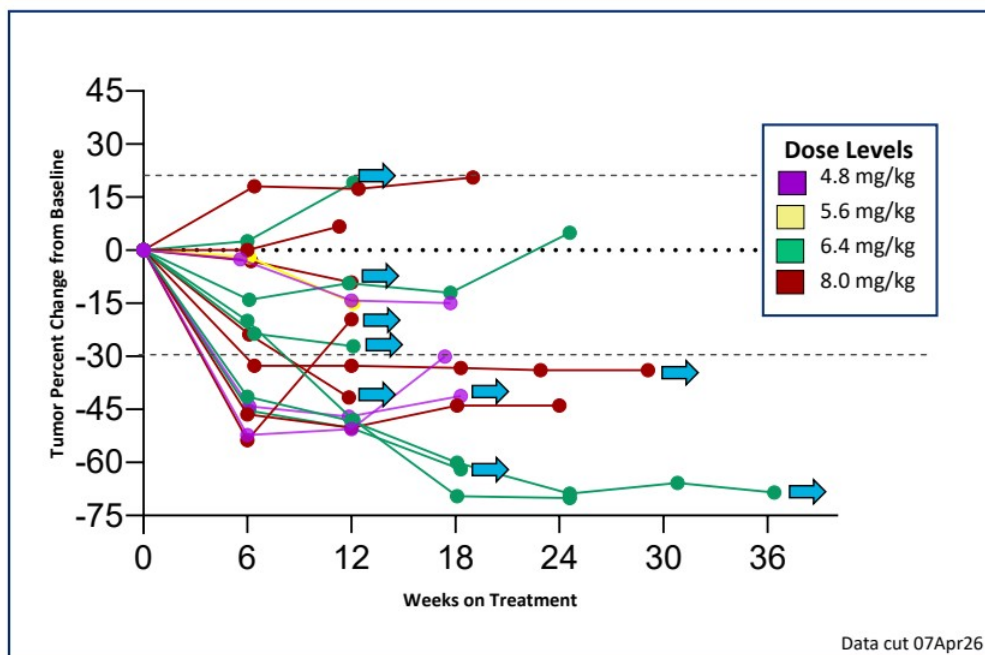
HGSOC: high-grade serous ovarian cancer; HGEOC: high-grade endometroid cancer; LGSOC: low-grade serous ovarian cancer  
 cPR: confirmed partial response; uPR: unconfirmed partial response

# Ovarian Cancer (4.8 – 8.0 mg/kg)



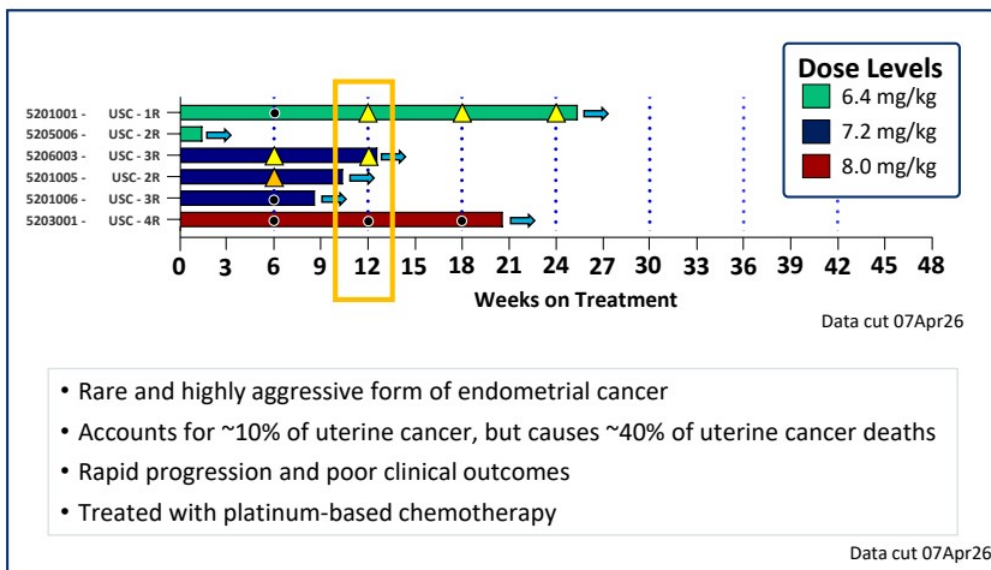
- Defined therap range
- Greatest tumor shrinkage at 6.4 mg/kg
- Up to 70% tumor shrinkage

## Ovarian Cancer (4.8 – 8.0 mg/kg)



- Most patients (15/17) had tumor shrinkage
- Increasing tumor shrinkage with continued treatment
- The greatest tumor shrinkage and durability occurred at 6.4mg/kg

# Uterine Serous Carcinoma (4.8 – 8.0 mg/kg)



- n = 6 USC patients enrolled
- Patients with at least ≥12 weeks follow-up

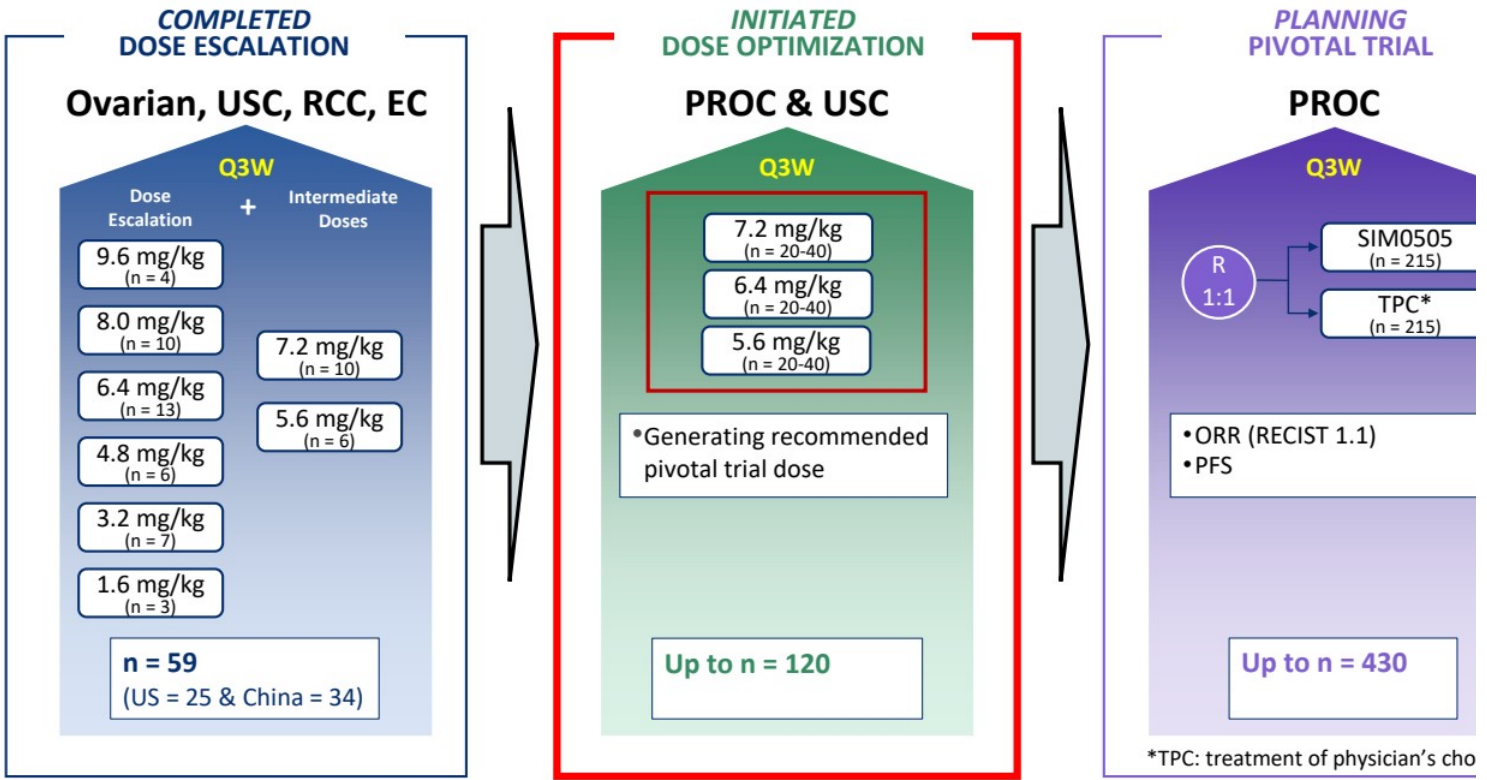
Evaluable	PR	ORR
n = 3	2	66.7%

- Other:
  - 1 PR 1.6 mg/kg
  - 1 PR 7.2 mg/kg (has not reached 12 weeks)

➡ On treatment  
▲ cPR  
▲ uPR  
● SD  
▼ RECIS

cPR: confirmed partial response; uPR: unconfirmed partial response

# SIM0505 Development Plan: Dose Optimization



## SIM0505 Roadmap to Potential Best-in-Class CDH6 ADC



### SIM0505

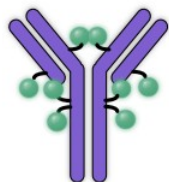
- ✓ 55% ORR in gynecologic cancers
- ✓ Therapeutic window defined
- ✓ Observed to be well-tolerated
- ✓ Fast track granted for PROC

### PRODUCT DEVELOPMENT

- ✓ Initiated dose optimization (5.6, 6.4 & 7.2 mg/kg)
- ✓ Additional sites in US, China, Canada & 4 European countries
- ✓ Securing supply chain & preparing for pivotal study
- ✓ RCC and NSCLC potential near-term development expansion

# Opportunity to Develop Differentiated CDH6 ADC Therapeutic

SIM0505



CDH6 ADC



POTENTIAL FOR IMPROVED SAFETY & EFFICACY

ONGOING DOSE OPTIMIZATION TRIAL IN US & CHINA

UPDATE DOSE OPTIMIZATION 1Q 20

# LNCB74 – B7-H4 ADC for Ovarian Cancer

## *ONGOING*

### DOSE ESCALATION

- Differentiated ADC with unique linker
  - Trial ongoing in US
  - CLIA validated IHC assay for patient selection
- 



## *PLANNING*

### DOSE OPTIMIZATION

- 2 doses
  - 80 patients
  - Defining recommended Ph2 dose
-

## LNCB74 is a Differentiated Anti-B7-H4 MMAE ADC

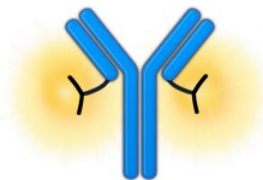
### STRUCTURAL DIFFERENTIATION

Antibody



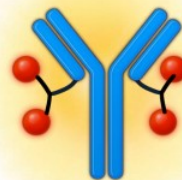
**Fc Modification**  
Protects immune cells

Linker



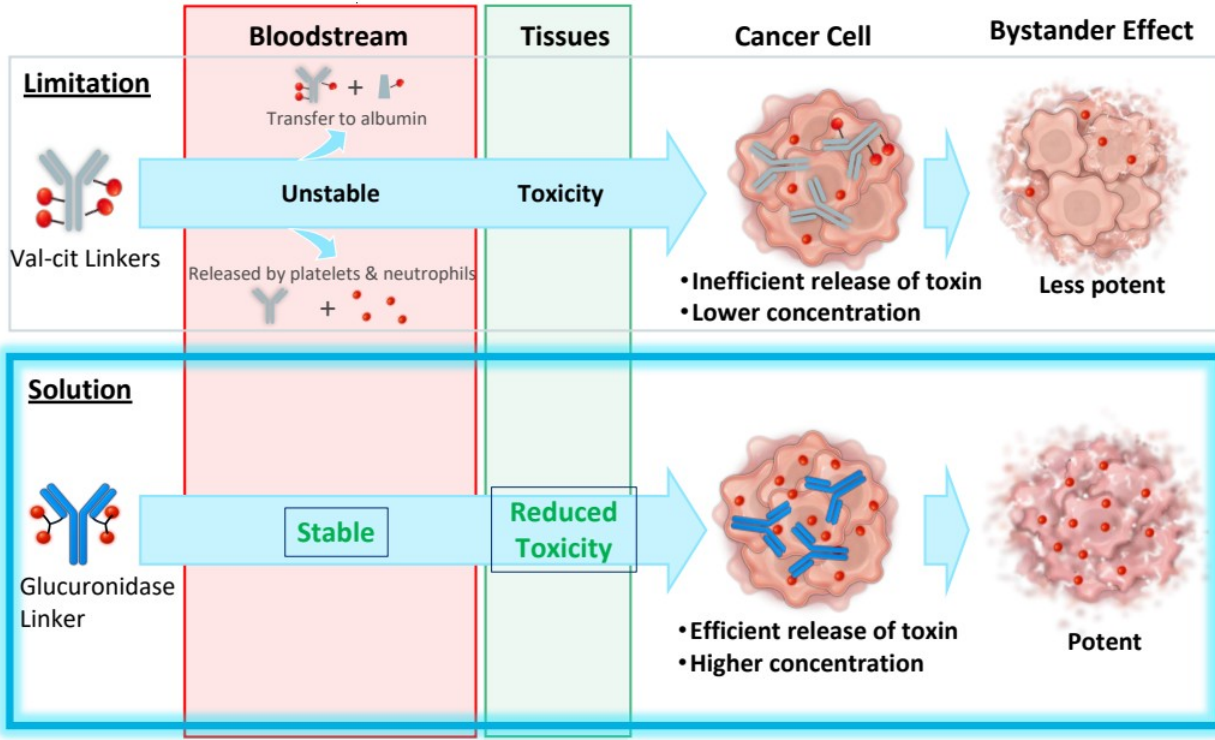
**Tumor Selectivity**  
Glucuronidase cleavable linker  
provides improved safety &  
increased efficacy

Payload



**MMAE DAR 4**  
Improves targeted release and  
safety

# LNCB74 Uses Differentiating Glucuronidase Linker Designed for Improved Safety & Increased Efficacy NextGen



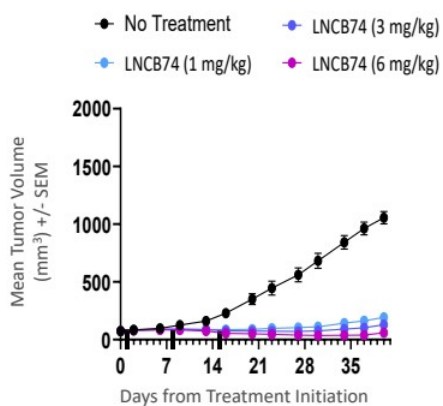
Linker	Protease o esterase cl
Payload	Tubulin or inhibitors
Conjugation	Site Specif specific cy:
DAR	~4, 6, 8

Linker	Glucuronid cleavable
Payload	Tubulin in
Conjugation	Site Specif
DAR	4

# LNCB74 Showed Potent Anti-Tumor Activity in CDX and PDX Models

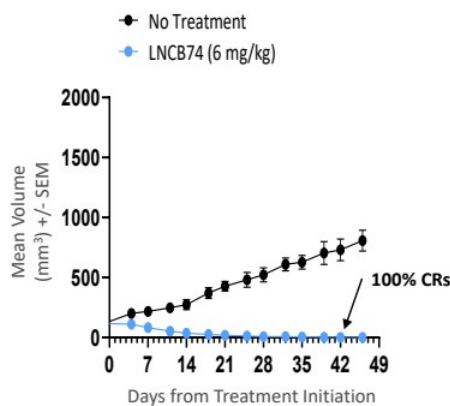
## CDX

### BREAST (ZR-75-1)



Q7D x 3  
8 mice / group

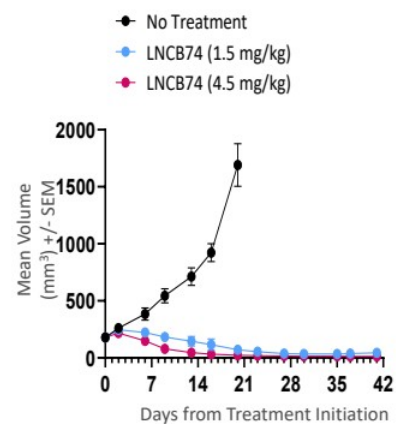
### OVARIAN (OVCAR-3-B7-H4-OE)



Single dose  
5 mice / group

## PDX

### TNBC (CTG-0012)



1.5 mg/kg: Q7D x 3  
4.5 mg/kg: single dose  
8 mice / group

## ONGOING DOSE ESCALATION

Breast, Ovarian, Endometrial, ACC-1

Q3W

Cohort 6

Cohort 5

Cohort 4

Cohort 3

Cohort 2

Cohort 1

TOTAL n = 54



## PLANNING DOSE OPTIMIZATION

2 Tumor Types

Dose Level X

Dose Level Y

- Recommended pivotal trial dose

TOTAL n = 80

ACC-1: Adenoid Cystic Carcinoma type 1



Ph1 Dose Escalation Study Initiated January 2025



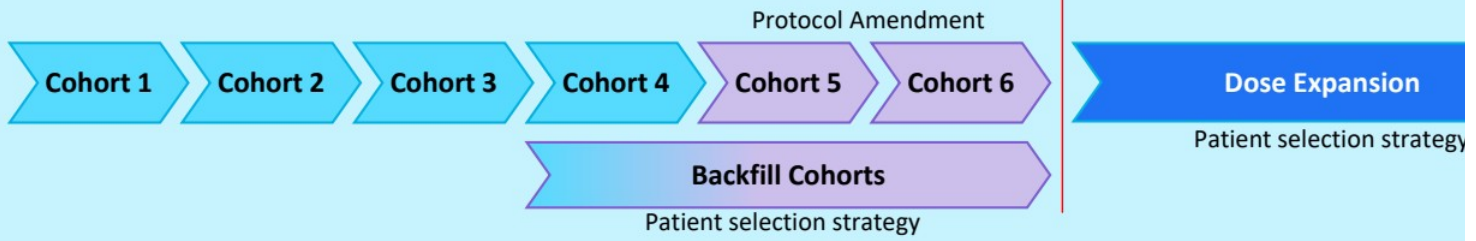
## Dose Escalation

- 6 dose cohorts
- Regimen Q3W
- n = 54 subjects

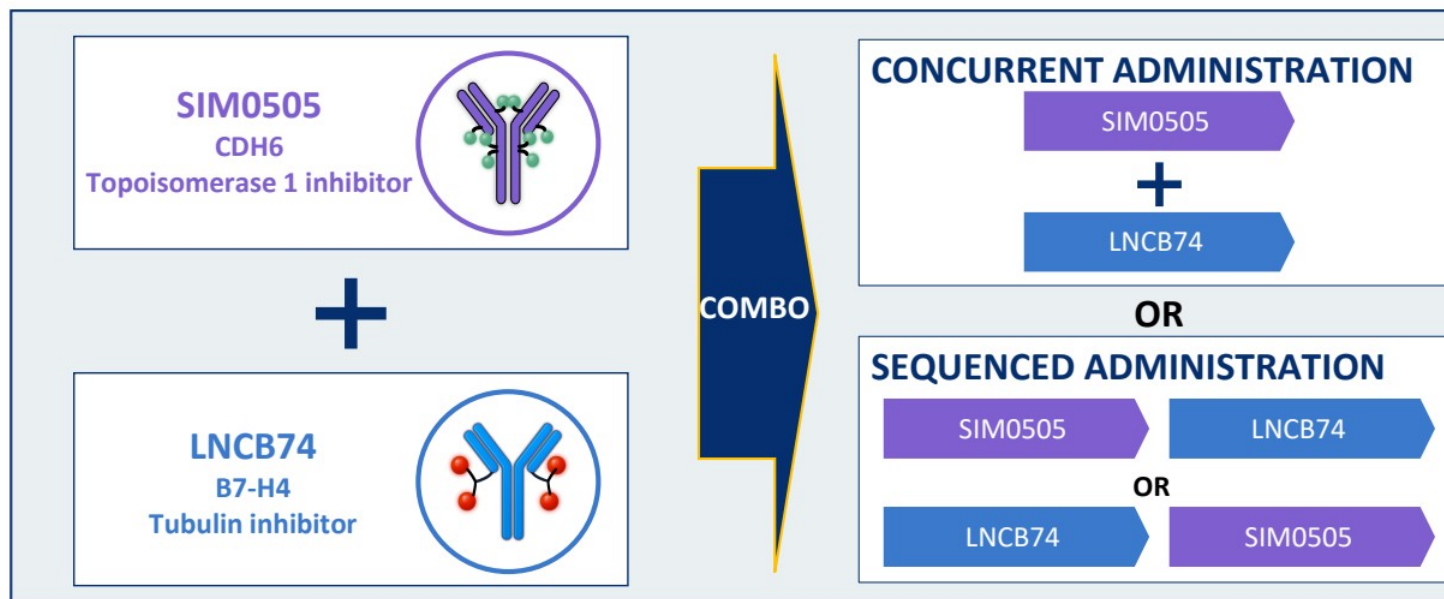
**Readout:** Scans every 6 weeks  
**Endpoint:** Safety & ORR

## Dose Expansion

- 2 dose cohorts
- 2 tumor types
- n = 80 subjects
- Pre & on treatment bi



## Product Life Cycle Management: Options to Address Resistance



# Opportunity to Develop Differentiated B7-H4 ADC Therapeutic



**B7-H4 ADC**



**DESIGNED TO IMPROVE  
SAFETY & INCREASE  
EFFICACY**

**UNMET NEED IN BREAST &  
GYNECOLOGICAL CANCERS**

**PATIENT SELECTION  
STRATEGY**



## Programs Available for Partnering

PROGRAMS	TARGET	CELLS	DISCOVERY	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3
NC410 Combo	LAIR-2	Extracellular Matrix	Ovarian				
			Colorectal (CRC)				
NC525	LAIR-1	Leukemia	Acute Myeloid Leukemia				
NC605	S15	Osteoclasts	Osteogenesis Imperfecta				
NC181	APOE4	Microglia & Neurons	Alzheimer's Disease				

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## Expected Milestones & Deliverables

### PHASE 1 CLINICAL ASSETS

- SIM0505 and B7-H4 ADCs
  - Differentiated ADCs
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### 2026 UPDATES

- SIM0505 (CDH6) update dose optimization in PROC 1Q 2027 and initiate dos optimization in USC 4Q 2026
  - LNCB74 (B7-H4) trial progress update in 2H 2026 (Breast, Ovarian, Endometr and ACC-1)
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### RUNWAY

- \$29.7M as of March 31, 2026
  - Into 1Q 2027
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