

# Phase I Clinical Trials

December 2025

# Nextcure

A Phase I First-in-human, Open-label, Multicenter Study to Investigate the Safety, Tolerability, Pharmacokinetics and Preliminary Antitumor Activity of SIM0505 in Adult Participants with Advanced Solid Tumors

SIM0505 is an ADC targeting CDH6, an adhesion protein involved in tumor growth and metastasis.

We are looking for patients with **high-grade serous ovarian cancer, high-grade endometrioid ovarian cancer, fallopian tube cancer and primary peritoneal cancer, uterine serous carcinoma, clear cell RCC, papillary RCC and adenocarcinoma of NSCLC without actionable mutation of epidermal growth factor receptor (EGFR)**. No testing of CDH6 expression is required. For participants with NSCLC, presence of CDH6 expression through immunohistochemical examination of tumor tissue by central laboratory is required.



An Open-Label, Single-Arm, Multi-Center Phase I Clinical Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of ALK201 in Subjects with Advanced Solid Tumors

ALK201 is a novel ADC against FGFR2b.

We are looking for patients with **FGFR2b + esophageal squamous cell cancer, gastric/GE junction adenocarcinoma, squamous NSCLC, breast cancer, H/N squamous carcinoma, biliary tract cancer, endometrial/ovarian/cervical cancers and urothelial carcinoma who fail SOC.**

# Olema

A Phase 1 First in Human, Open-Label, Multicenter Study of OP-3136 in Adult Participants with Advanced or Metastatic Solid Tumors

The trial is testing a novel KAT6 inhibitor that suppresses ER pathways and other growth related genes in cancer through epigenetic regulation. KAT6 acetylates chromatin enabling DNA unwinding. KAT6 inhibitor functions by inhibiting DNA unwinding and gene transcriptions such as MYC. It is an oral drug. We are looking for patients with **ER+ mBC, advanced NSCLC and hormone refractor prostate cancers who fail SOC**, without the need to express any biomarkers (this is a phase Ia or dose escalation trial).

# Scorpion

First-in-Human Study of STX-478, a Mutant-Selective PI3K $\alpha$  Inhibitor as Monotherapy and in Combination With Other Antineoplastic Agents in Participants With Advanced Solid Tumors

STX-478 is a second generation, mutant-selective, PI3K $\alpha$  small molecule inhibitor. It is highly selective for the prevalent H1047X (eg, H1047L and H1047R), M1043I, and G1049R kinase-domain mutations that comprise over 40% of all PI3K $\alpha$  mutations in breast cancers. In preclinical studies, STX-478 also demonstrated efficacy against E542K and E545K helical-domain mutant tumors at dose levels that did not cause metabolic dysfunction. STX-478 may offer an improved profile with a wider therapeutic window and more breast, endometrial, and other cancers in which PI3K $\alpha$  is frequently mutated

We are looking for **ER+ MBC that fails first line hormonal therapy and carries PI3K mutation.**