



NextCure Initiates Clinical Development for NC318, a Siglec-15 Targeting Antibody, for Solid Tumors

October 23, 2018 at 8:00 AM EDT

BELTSVILLE, Md. – October 23, 2018 – [NextCure, Inc.](#), a privately-held biopharmaceutical company discovering and developing next generation immunomedicines for cancer and other diseases, today announced the initiation of a Phase 1/2 clinical trial for NC318, a Siglec-15 (S15) antibody.

The Phase 1 dose-escalation portion of this open-label trial will evaluate the safety and tolerability of NC318 in patients with advanced or metastatic solid tumors and determine its pharmacologically active and/or maximum tolerated dose. After a recommended dose for the Phase 2 portion of the trial is determined, the efficacy of NC318 will be evaluated in select tumor types. The trial is being conducted at five clinical sites in the United States. Details can be found at [clinicaltrials.gov – NCT03665285](#).

"NC318 is the first antibody drug candidate developed at NextCure to enter clinical trials, marking an exciting milestone for our company," says Michael Richman, CEO of NextCure. "The trial marks a major advancement in our plan to develop our pipeline of next generation immunomedicines for cancer patients who do not respond to currently approved therapies."

S15 is a novel immunomodulatory target expressed on a restricted set of myeloid cells in the tumor microenvironment and on certain tumor types including lung, ovarian and head and neck cancers. Preclinical research shows that S15 promotes the survival and differentiation of suppressive myeloid cells and negatively regulates T cell function, allowing cancer growth. In preclinical studies, NC318 blocks the negative effects of S15. NC318 is a first-in-class immunomedicine that has the potential to treat multiple cancer types.

"Immunotherapies targeting T cell function have significantly improved patient outcomes; however, a substantial proportion of patients do not respond to currently approved PD-1 or PD-L1 antibody therapies," said Kevin N. Heller, M.D., CMO of NextCure. "Laboratory studies demonstrate that Siglec-15 modulates immune suppression in a manner independent of the PD-1/PD-L1 pathway, suggesting that NC318 may have the potential to be used in patients who do not express PD-L1. Blocking S15 with NC318 is expected to diminish immunosuppression and normalize the immune response, resulting in a clinically relevant anti-tumor immune response. A goal of our trial is to test that hypothesis."

The immune regulatory function of S15 was initially discovered in the lab of Lieping Chen, M.D., Ph.D., Founder of NextCure and United Technologies Endowed Professor of Cancer Research, Professor of Immunobiology, Dermatology, and Medicine at the Yale University School of Medicine. Dr. Chen is a renowned leader in immuno-oncology and has discovered many novel immune-related targets, including the PD-1/PD-L1 pathway. "The discoveries made by our group and others have paved the way for the first generation of immunotherapies, leading to major breakthroughs in cancer treatment. Building upon these early discoveries, and in collaboration with NextCure, we continue our research to identify new targets for modulating the immune system," stated Dr. Chen. "We expect that S15, one of the first new targets identified, will be the first in a series of next generation immunomedicines. Through a comprehensive and streamlined process, NextCure has efficiently brought NC318 to the clinic."

About NextCure, Inc.

NextCure is a biopharmaceutical company focused on discovering and developing next generation first-in-class immunomedicines for cancer and other diseases. Our novel FIND-IO™ discovery technology identifies targets based on immunomodulatory function and on which the company is building a proprietary pipeline of immunomedicines. Our initial focus is to bring hope and new treatments to patients who do not respond to current cancer therapies.

www.nextcure.com

NextCure Cautionary Statement Regarding Forward-Looking Statements

Statements made in this press release that are not historical facts are forward-looking statements. Words such as "expects," "believes," "intends," and similar expressions are intended to identify forward-looking statements. Actual results may differ materially from those projected in any forward-looking statement. Specifically, there are a number of important factors that could cause actual results to differ materially from those anticipated, such as NextCure's ability to raise additional capital, and risks related to NextCure's ability to initiate, and enroll patients in, planned clinical trials. Further, there can be no assurance of the results of any clinical trial with NC318. You should not place undue reliance on any forward-looking statements. NextCure assumes no obligation to update any forward-looking statements.

company contact

Timothy Mayer, Ph.D.
NextCure, Inc.
VP, Business Operations & Administration
(240) 762-6486
media@nextcure.com

media contact

Shai Biran, Ph.D.
MacDougall Biomedical Communications
(781) 235-3060
sbiran@macbiocom.com