



NextCure Provides Updates on NC318 Clinical Program

December 17, 2020

BELTSVILLE, Md., Dec. 17, 2020 (GLOBE NEWSWIRE) -- [NextCure, Inc.](#) (Nasdaq: NXTC), a clinical-stage biopharmaceutical company committed to discovering and developing novel, first-in-class immunomedicines to treat cancer and other immune-related diseases, today provided an update on the clinical trial program for NC318, its first-in-class immunomedicine against Siglec15 (S15), a novel immunomodulatory target.

"As we continue to review and analyze the available clinical and laboratory data on the NC318 program, including recently generated biomarker data, we are working to modify the clinical program to enable us to select S15-positive patients for enrollment in ongoing and future trials," said Michael Richman, NextCure's president and chief executive officer. "We remain encouraged regarding the potential of NC318 as a novel oncology treatment, given the evidence of clinical activity seen to date and recent biomarker data that continue to indicate NC318's ability to modulate immune activity. We anticipate providing additional detail in early 2021 on the next steps for the program after a new chief medical officer is on board and has had sufficient time to review the program."

Key Updates to NC318 Clinical Program

- The two objective responder patients in the Phase 1 portion of the company's ongoing Phase 1/2 clinical trial of NC318 are continuing to receive drug and remain on study at over 104 weeks and over 78 weeks.
- The company is continuing to enroll head and neck squamous cell carcinoma (HNSCC) and triple-negative breast cancer patients. As previously announced, a confirmed partial response (PR) has been observed in the HNSCC cohort, which supports advancing into the stage 2 portion of the Simon 2-stage trial. The patient remains on study at over 32 weeks.
- NC318 continues to be well-tolerated, with treatment-related adverse events (TRAEs) primarily grades 1-2. The only observed grade 3-4 TRAE was an infusion reaction in one patient.
- In the Phase 2 portion of the company's current trial, patients were selected based on tumors with a PD-L1 tumor proportion score (TPS) of less than 50%. S15 expression was analyzed retrospectively in all pretreatment biopsies successfully obtained from Phase 2 patients. Of the evaluable biopsies collected, 13% of the patients enrolled had S15-positive tumors under that criterion. Overall, the selection criterion did not result in enough S15-positive patients.
- The ongoing Phase 2 trial is being modified for S15 selection and the company expects to begin pre-selecting patients for enrollment based on S15 expression in the first quarter of 2021 in order to assess response rates in patients selected for S15 positivity.
- Biomarker analysis demonstrated an increase in peripheral immune modulation markers.
- Scientific evidence supports a combination with anti-PD-1 therapy and the company is planning to study that combination in NSCLC patients. At this time, the company no longer plans to initiate a study of NC318 in combination with chemotherapy.

About NC318

NC318 is a first-in-class immunomedicine against S15, a novel immunomodulatory target found on highly immunosuppressive cells called M2 macrophages in the tumor microenvironment and on certain tumor types. For example, tumor types expressing S15 include non-small cell lung cancer and head and neck squamous cell carcinoma, where clinical investigators have reported responses, and ovarian and triple-negative breast cancers. In preclinical research, it was observed that S15 promoted the survival and differentiation of suppressive myeloid cells and negatively regulated T cell function, allowing cancer to avoid immune destruction. In preclinical studies, NC318 blocked the negative effects of S15. NextCure believes NC318 has the potential to treat multiple cancer types.

About NextCure, Inc.

NextCure is a clinical-stage biopharmaceutical company committed to discovering and developing novel, first-in-class immunomedicines to treat cancer and other immune-related diseases. Through our proprietary FIND-IO™ platform, we study various immune cells to discover and understand targets and structural components of immune cells and their functional impact in order to develop immunomedicines. Our initial focus is to bring hope and new treatments to patients who do not respond to current cancer therapies, patients whose cancer progresses despite treatment and patients with cancer types not adequately addressed by available therapies. www.nextcure.com

Forward-Looking Statements

This press release contains forward-looking statements, including statements pursuant to the safe harbor provisions of 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," "expects," "believes," "intends," "hope," "towards," "forward," "later" and similar expressions. Examples of forward-looking statements in this press release include, among others, statements about the progress and evaluation and expected timing of results of NextCure's ongoing clinical trial of NC318, expectations regarding the potential benefits, activity, effectiveness and safety of NC318, the evaluation of biomarkers, future clinical trials of NC318, the hiring and onboarding of a new chief medical

officer and NextCure's plans, objectives and intentions with respect to the discovery and development of immunomedicines. 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: the impacts of the COVID-19 pandemic on NextCure's business, including NextCure's clinical trials, third parties on which NextCure relies and NextCure's operations; positive results in preclinical studies or early-stage clinical trials may not be predictive of the results of later 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; 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 NextCure's most recent Form 10-K and subsequent Form 10-Q. 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

Media Inquiries
Emily Wong
MacDougall
(781) 235-3060
NextCure@macbiocom.com



Source: NextCure