

NextCure Provides an Interim Update of the Phase 2 Portion of the NC318 Monotherapy Phase 1/2 Trial and Announces Departure of Chief Medical Officer

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BELTSVILLE, Md., July 13, 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 interim update for the Phase 2 portion of its NC318 monotherapy phase 1/2 trial.

Based on the current enrollment criteria and clinical response data, at this time the company does not plan to advance the non-small cell lung cancer (NSCLC) and ovarian cancer cohorts into the stage 2 portion of the Simon 2-stage trial. The analysis of biomarker data for these cohorts has been delayed and is not yet complete. The company will evaluate whether to pursue additional monotherapy studies in NSCLC and ovarian cancer after a review of that information. The company continues to enroll in head and neck squamous cell carcinoma (HNSCC) and triple-negative breast cancer cohorts. One confirmed partial response has been observed in HNSCC and this indication has been advanced to the stage 2 portion of the Simon 2-stage trial. The company is continuing to assess Siglec-15 (S15) biomarker data as a basis for patient selection.

"While the monotherapy data in the NSCLC and ovarian cancer cohorts are disappointing, we continue to evaluate patient selection criteria for our ongoing NC318 clinical trials," said Michael Richman, NextCure's president and chief executive officer. "We expect to provide an NC318 clinical data update and additional biomarker data in the fourth quarter of 2020."

NextCure also announced that Kevin N. Heller, M.D., the company's chief medical officer, has resigned, effective August 4, 2020 to pursue a new opportunity. Dr. Heller will serve as a consultant to the company. The company has initiated a search for a new chief medical officer.

"We thank Kevin for all of his work on behalf of the company and look forward to his continued support as a clinical consultant," said Mr. Richman.

About the Phase 2 Portion of the NC318 Phase 1/2 Clinical Trial

The Phase 2 component of the Phase 1/2 clinical trial is designed as a single-arm trial to evaluate the efficacy of NC318 at a 400 mg dose administered every two weeks. NextCure expects to enroll up to 100 patients with NSCLC, ovarian cancer, head and neck cancer and triple-negative breast cancer. The primary endpoints are safety and tolerability, and secondary endpoints include response rate, progression-free survival, duration of response and overall survival.

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 including lung, ovarian and head and neck 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 planned combination trial of NC318, expectations regarding the potential benefits, activity, effectiveness and safety of NC318, the departure of Dr. Heller including his service as a consultant and the search for 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 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; the unproven approach to the discovery and development of product candidates based on NextCure's FIND-IO 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 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 Shai Biran, Ph.D. MacDougall (781) 235-3060 NextCure@macbiocom.com



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