NextCure Presents Updated Clinical Data from NC318 Phase 1/2 Clinical Trial at the 34th Annual Meeting of Society for Immunotherapy of Cancer (SITC) and Announces Initiation of Phase 2 Portion of the Trial

November 9, 2019 at 5:05 PM EST

- NC318 was well tolerated
- Single agent activity observed in multiple tumor types, including a CR and a PR in NSCLC
- Initiated Phase 2 portion of the Phase 1/2 monotherapy trial and plans for a combo trial with standard of care chemotherapies

BELTSVILLE, Md., Nov. 09, 2019 (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 announced that updated clinical results from the Phase 1 portion of its ongoing trial with NC318, a monoclonal antibody targeting Siglec-15 (S15), were presented at the SITC annual meeting. S15 is a novel immunomodulatory protein that is expressed on highly immunosuppressive cells called M2 macrophages and on tumor cells. In addition, NextCure announced the initiation of the Phase 2 portion of its ongoing Phase 1/2 clinical trial of NC318.

Updated Results from the Phase 1 Portion of the Phase 1/2 Trial
As of November 9, 2019, 49 patients had been dosed across seven dose cohorts between 8 mg and 1,600 mg, administered every two weeks:

- The most common tumor types enrolled included: non-small cell lung cancer (NSCLC) (13 patients), ovarian cancer (seven patients), melanoma (seven patients), breast cancer (four patients) and colorectal cancer (three patients).
- All of the patients enrolled were heavily pre-treated with a median of three prior therapies.
- All 13 NSCLC patients were PD-1 refractory, with a median of four prior therapies.
- Data show that NC318 was well tolerated, and the only dose-limiting toxicity was a grade 3 pneumonitis in the 1,600 mg cohort.
- Treatment-related adverse events occurring in more than 5% of subjects were diarrhea, infusion reactions, fatigue, headaches, pruritis and elevations in lipase and amylase.
- Most treatment-related adverse events were easily manageable, asymptomatic or mild or moderate, except for one grade 3 episcleritis/uveitis and two cases of grade 3 pneumonitis.
- Immune-related adverse events such as vitiligo, uveitis and pneumonitis were observed.
- Data from the trial indicate activity in multiple tumor types including durable stable disease in patients with NSCLC, endometrial cell cancer, ovarian cancer, squamous cell carcinoma, Merkel cell cancer and head and neck cancer (ongoing for 16 to 55 weeks as of November 9, 2019).
- Durable responses were observed in patients who received NC318, including one complete response (ongoing at 55 weeks), one partial response (ongoing at 28 weeks) and four stable diseases in NSCLC (ongoing for 16 to 40 weeks) and 14 stable diseases overall (ongoing for 16 to 42 weeks).
- 15 patients remain on study in the Phase 1 portion of the trial, including seven patients with NSCLC.
- All responses were based on investigator tumor assessments per RECIST v1.1.

“NC318 has been well tolerated in the Phase 1 trial, and the only dose-limiting toxicity was a grade 3 pneumonitis in the 1,600 mg cohort,” said Kevin N. Heller, M.D., NextCure’s chief medical officer. “It is encouraging to see single-agent activity among NSCLC patients refractory to PD-1 therapies, including a durable complete response and a durable partial response. Given what appears to be the non-overlapping expression of PD-L1 and S15, the results to date support the potential of NC318 to block S15-mediated immune suppression among a patient population unlikely to respond to PD-1/PD-L1-directed therapies.”

“There is a real need for new treatment options for patients who do not respond to current therapies. The tolerability and initial anti-tumor activity with NC318 reinforces our belief that NC318 has the potential to be a new therapy for patients with solid tumors and low levels of PD-L1 expression or who do not respond to current anti-PD-1/PD-L1 treatments,” said Michael Richman, NextCure’s president and chief executive officer. “In addition, the initiation of the Phase 2 portion of the trial is an important milestone for the NC318 program and reflects NextCure’s continued commitment to developing novel medicines to improve the lives of patients with cancer. We look forward to reporting initial data from the Phase 2 portion of the trial by the end of 2020. These findings also revalidate the importance of the approach of our FIND-IO™ discovery platform in identifying targets like S15 that can impact immune function.”

Slides from the SITC presentation will be posted on NextCure’s website on the “Events and Presentations” tab at http://ir.nextcure.com/events-and-presentations.

Design of NC318 Phase 1/2 Clinical Trial
The Phase 1 component of the open-label, multicenter Phase 1/2 clinical trial is designed to assess the safety and tolerability of NC318, to define the maximum tolerable dose and/or pharmacologically active dose and to assess preliminary efficacy in patients with advanced or metastatic solid tumors. NC318 is being administered on day one of each 14-day cycle in sequential dose cohorts at increasing dose levels until the maximum tolerated dose is identified.

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 approximately 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. Additional doses and dose administration schedules may be considered. The company expects to report initial data from the Phase 2 portion of the trial by the end of 2020.

Phase 2 Combination Trial
In the first half of 2020, the Company intends to initiate a Phase 2 clinical trial to evaluate NC318 in combination with standard of care chemotherapies in patients with advanced or metastatic solid tumors. This open-label trial will be designed to assess the safety and tolerability of NC318 in combination with at least two different chemotherapy regimens and to define the maximum tolerable dose of NC318 when administered with each chemotherapy. The trial will also be designed to assess preliminary efficacy of each combination in specific tumor types in a manner that can potentially support the use of such combinations in first-line therapies of advanced or metastatic solid tumors.

Event and Webcast
NextCure will host an event at the SITC conference to discuss these results in more detail with Dr. Kevin Heller today, November 9, 2019 at 6:30 pm ET. During the event, Dr. Heller will provide a review of the data presented at SITC by Dr. Anthony Tolcher and be available for a Q&A session. This event will be webcast live and archived for 90 days and may be accessed from the Investors section of the NextCure website at www.nextcure.com.

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 pace and expected timing and results of NextCure's ongoing clinical study of NC318, NextCure's expectations regarding the potential benefits, activity, effectiveness and safety of NC318, 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: 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 the unproven approach to the discovery and development of product candidates based on NextCure's FIND-IO platform. 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 Form 10-Q filed with the SEC on August 12, 2019. 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.

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