NextCure Presents Biomarker Data and Updated Clinical Results from Phase 1 Portion of its NC318 Clinical Trial at the 2020 Virtual American Society of Clinical Oncology Annual Meeting

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BELTSVILLE, Md., May 29, 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 announced the presentation of biomarker data and updated clinical results from the Phase 1 portion of its ongoing Phase 1/2 monotherapy trial with NC318 at the 2020 Virtual American Society of Clinical Oncology (ASCO20) Annual Meeting. NC318 is a monoclonal antibody targeting Siglec-15 (S15), a novel immunomodulatory protein that is expressed on highly immunosuppressive cells called M2 macrophages and on tumor cells.

“Because this is a trial in progress with limited samples, we cannot draw definitive conclusions, but we believe these early biomarker data provide additional evidence of NC318 activity,” said Kevin N. Heller, M.D., NextCure’s chief medical officer. “We expect to receive additional insight from the Phase 2 portion of our ongoing trial, which will include additional biomarker analyses.”

Biomarker Data and Updated Clinical Results from the Phase 1 Portion of the NC318 Clinical Trial
As of May 11, 2020, 49 patients had been dosed across seven dose cohorts between 8 mg and 1,600 mg, administered every two weeks:

- The early biomarker data suggest collectively the potential of NC318 to block S15-mediated immune suppression, as indicated by:
  - Increase of regulatory T cells in peripheral blood in the highest dose cohorts;
  - Increase of PD-1 expression on circulating CD4+ T cells while on treatment;
  - Expansion of peripheral T cell receptor clones while on treatment; and
  - Presence of proliferating CD8 T cells systemically and increase of proliferating lymphocytes within the tumor microenvironment while on treatment.
- S15 and PD-L1 expression from tumor biopsies were assessed at baseline for 15 subjects. On treatment biopsies were obtained for 9 of the 15 subjects, and relative to baseline assessments, changes in S15 or PD-L1 expression were observed while on treatment with NC318 in 7 of the 9 paired biopsies.
- As previously reported at the Society for Immunotherapy of Cancer (SITC) annual meeting in November 2019:
  - The most common tumor types enrolled included: non-small cell lung cancer (NSCLC) (13 patients), ovarian cancer (7 patients), melanoma (7 patients), breast cancer (4 patients) and colorectal cancer (3 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.
- As of May 11, 2020, two NSCLC subjects from the Phase 1 portion of the clinical trial remain on study: a complete response and a partial response for 82 and 54 weeks, respectively. In addition, 10 subjects, including 3 NSCLC, had durable stable disease for at least 24 weeks, and progressed subsequently. All responses were based on investigator tumor assessments per RECIST v1.1.
- Immune-related adverse events and treatment-related adverse events continued to be observed at a frequency consistent with what has been previously reported (e.g., treatment-related adverse events occurring in more than 5% of subjects were diarrhea, infusion reactions, fatigue, headaches, pruritis, and elevations in lipase and amylase). There were no new safety signals.

The poster presented at ASCO20 further detailing these data is available on NextCure’s website within the “Events and Presentations” section at http://ir.nextcure.com/events-and-presentations.

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 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: 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; 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 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.

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