NextCure and Collaborators Provide Clinical and Research Updates on NC318 and NC410 Candidates at Society for Immunotherapy of Cancer Annual Meeting

November 13, 2021 at 2:00 PM EST

BELTSVILLE, Md., Nov. 13, 2021 (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 new data from two clinical studies and one research study presented at the Society for Immunotherapy of Cancer (SITC) annual meeting in Washington, D.C., and on a virtual platform. The data come from clinical studies evaluating NC318, a Siglec-15 (S15) antibody, and NC410, a fusion protein of LAIR-2, in patients with advanced/metastatic solid tumors, as well as from a research study evaluating NC410's impact on T cell activation and myeloid cell polarization conducted in collaboration with the National Cancer Institute at the National Institutes of Health.

"We are pleased to share promising data from our NC318 and NC410 programs at this year's SITC annual meeting," said Han Myint, MD, NextCure's chief medical officer. "Results from our ongoing Phase 1 and Phase 2 trials suggest that NC318 may have a clinical benefit in patients. Retrospective analysis of patient biopsies from the Phase 1 and Phase 2 trials showed better outcomes in S15+ patients compared to S15- patients receiving NC318. Selecting for patients with S15+ expression coupled with a higher and more frequent dosing regimen that increases overall drug exposure is anticipated to impact clinical outcomes. Additionally, data from our NC410 program show that NC410 is safe and well-tolerated in patients and demonstrates early indications of immune modulation. We look forward to continuing the advancement of both programs to improve the treatment landscape for cancer patients."

Details of the oral and poster presentations are below:

Clinical benefit through S15 targeting with NC318 antibody in subjects with S15 positive advanced solid tumors

Combined Phase 1 and Phase 2 data from the NC318 study show early evidence of possible clinical benefit in patients with lung cancer, squamous cell carcinoma of the head and neck and breast cancer and other advanced/metastatic solid tumors with dosing once every two weeks during dose escalation and with the 400mg dose selected for the Phase 2 studies. Highlights include:

- Data are derived from patient cohorts in both Phase 1 (n=49) and Phase 2 (n=47) of these studies.
- One NSCLC CR and one NSCLC PR patient from the Phase 1 study remain on therapy for 2.8 and 2.2 years, respectively.
- NC318 appears to show evidence of disease control with better outcomes in S15+ patients compared to S15- patients.
- The disease control rate across all tumors in both studies was 37% with a median progression-free survival (PFS) of 5.0 months.
- Patients in the lung cohort from both studies showed 45% disease control rate with a median PFS of 5.2 months.
- Data indicate that soluble S15 (sS15) level may serve as a biomarker for patient selection.
- Pharmacokinetic and pharmacodynamic modeling predict that a dose of 800 mg once a week results in nearly 10 times greater drug exposure which may impact drug activity and clinical outcomes.

NC410, a fusion protein of LAIR-2 (Leukocyte Associated Immunoglobulin-like Receptor) fused to human IgG1 Fc domain appears safe and well-tolerated with evidence of immune modulation in subjects with advanced solid tumors

Interim data presented from the Phase 1 dose-escalation study show that NC410 appears to be safe and well-tolerated in patients with advanced tumors and show evidence of immune modulation. Highlights include:

- The data come from the first five patient cohorts (n=19), who received doses of NC410 up to 60 mg once every two weeks.
- There were no dose-limiting toxicities.
- Data show a transient reduction in peripheral C1q, suggesting target binding of NC410.
- LAIR-2 levels in peripheral blood increase in a dose-dependent fashion and may suggest mechanistic evidence of immune normalization.
- Early evidence of extracellular matrix (ECM) remodeling and immune activation was shown by an increase in serum C4G, a Granzyme B-mediated collagen fragment, and a reduction in serum Pro-C3 and Pro-C6 fragments.
- Time-dependent increase in CD4+ and CD8+ T cells without an increase in LAIR-1 expression provides further early evidence of immune activation.
- Safety, tolerability, efficacy, and biomarker analyses are ongoing in higher dose cohort patients.

Blockade of the inhibitory collagen receptor LAIR-1, PD-L1, and TGF-β promotes anti-tumor activity through T cell activation and myeloid cell polarization

Non-clinical data from a research study conducted in collaboration with the National Cancer Institute at the National Institutes of Health show NC410's impact on T cell activation, myeloid cell polarization and anti-tumor activity. Highlights include:

- NC410 and bintrafusp alpha, a TGF-beta trap molecule, synergize for effective tumor control in a mouse model of colon cancer.
- Tumor control is mediated by an increase in activated CD8+ T cells and a reduction in M2 tumor-associated macrophages in tumor infiltrates.
- Collagen remodeling is demonstrated in tumors treated with NC410.

About NC318
NC318 is a first-in-class immunomedicine against Siglec-15 (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 NC410
NC410 is a first-in-class immunomedicine designed to block immune suppression mediated by LAIR-1, an immunomodulatory receptor expressed on T cells and myeloid cells, including dendritic cells, a type of antigen presenting cell. In preclinical research, it has been shown that LAIR-1 inhibits T cell function and myeloid activity. In preclinical studies, NC410 blocks the negative effects of LAIR-1 and promotes T cell function and myeloid cell activity. NextCure believes NC410 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. http://www.nextcure.com

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," "hope," "forward" and similar expressions are intended to identify forward-looking statements. Examples of forward-looking statements in this press release include, among others, statements about NextCure's plans, objectives, and intentions with respect to the discovery of immunomedicine targets and 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: our limited operating history and no products approved for commercial sale; our history of significant losses; our need to obtain additional financing; risks related to clinical development, including that early clinical data may not be confirmed by later clinical results; risks that pre-clinical research may not be confirmed in clinical trials; risks related to marketing approval and commercialization; and the unproven approach to the discovery and development of product candidates based on our 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. 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

Source: NextCure