NextCure Presents Initial Data from Clinical Trial of NC762 and a Trial in Progress Poster for NC410 Combo at the 2022 Society for Immunotherapy of Cancer Annual Meeting

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BELTSVILLE, Md., Nov. 07, 2022 (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 clinical trial investigator Emese Zsiros, M.D., Ph.D., Associate Professor of Oncology, Chair, Department of Gynecologic Oncology, Roswell Park Comprehensive Cancer Center, will present initial clinical data from a Phase 1 clinical trial of NC762 and Eric Christenson, M.D., Department of Medical Oncology, Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University School of Medicine, will present a Trials in Progress poster for a combo study of NC410 at the Society for Immunotherapy of Cancer (SITC) annual meeting in Boston. The initial clinical data come from a Phase 1 study evaluating NC762, a monoclonal antibody that binds specifically to B7-H4, in patients with advanced/metastatic solid tumors.

“We are pleased to share initial clinical data from our ongoing NC762 Phase 1 trial and provide additional details on our newly announced NC410 combination trial,” said Han Myint, M.D., NextCure’s chief medical officer. “We look forward to continuing NC762 in expansion cohorts where we will prospectively select B7-H4-positive tumors as assessed by a CLIA-validated assay we designed. In addition, we are excited to enroll the safety component of the NC410 combo trial and to report initial data in mid-2023.”

Details of the poster presentations are below:

A phase 1/2, open-label, dose-escalation, safety and tolerability study of NC762 in subjects with advanced or metastatic solid tumors

Initial data from the Phase 1 dose-escalation trial show that NC762 appears to be safe and well-tolerated with early signs of disease control in patients with advanced tumors. Highlights include:

- Data come from five patient cohorts (n=18), who received NC762 up to 20 mg/kg once every two weeks.
- There were no dose-limiting toxicities.
- Data show patients that stay on study for > 12 weeks have elevated number of natural killer (NK) cytotoxic cells at baseline, suggesting NC762 may modulate NK cell activity.
- Changes in NK and myeloid cell subpopulations were observed at various time points after treatment, suggesting immune activation after NC762 treatment.
- Increases in cytokines and chemokines were observed 24 hours after NC762 treatment.
- Safety expansion studies are ongoing, prospectively enrolling subjects with biopsy confirmed B7-H4 positive tumors (ovarian, endometrial, breast, and non-small cell lung) to finalize the selection of a recommended Phase 2 dose.

A Phase 1b/2, open-label, safety, tolerability and efficacy study of NC410 plus pembrolizumab for participants with immune checkpoint inhibitor (ICI) refractory or MSS/MSI-low ICI naïve advanced or metastatic solid tumors

The NC410 Phase 1b/2 combination trial is a multi-center, first-in-human, open-label, multi-arm trial to evaluate the efficacy of NC410 in combination with pembrolizumab. The company expects to enroll approximately 100 patients with immune checkpoint refractory colorectal, esophageal, endometrial and head and neck cancers or immune checkpoint naïve MSS or MSI-Low colorectal or ovarian cancers.

About NC762
NC762 is a monoclonal antibody that binds specifically to B7-H4, a protein expressed on multiple tumor types. NextCure believes NC762 acts by inhibiting tumor cell growth and killing tumor cells, including by enhancing immune response. The company has observed in preclinical studies that NC762 inhibits the growth of human melanoma tumors in mice, and believes that NC762 has the potential to treat multiple tumor types. NextCure’s research indicates that NC762 inhibits tumor cell growth independently of immune cell infiltration in the tumor microenvironment.

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.

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