NextCure Announces Initiation of Phase 1b/2 Clinical Trial to Evaluate NC410 in Combination with KEYTRUDA® (Pembrolizumab) in Patients with Immune Checkpoint Refractory or Naïve Solid Tumors

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BELTSVILLE, Md., Oct. 04, 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 the initiation of a Phase 1b/2 clinical trial to evaluate NC410 in combination with KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy, in patients with immune checkpoint refractory or immune checkpoint naïve solid tumors. In addition, NextCure announced it has entered into a supply agreement for KEYTRUDA with Merck (known as MSD outside the United States and Canada).

NC410 is a first-in-class immunomedicine designed to block immune suppression mediated by LAIR-1, an immunomodulatory receptor expressed on T cells and dendritic cells. Under the terms of the agreement, NextCure will sponsor the study and Merck will supply KEYTRUDA. The Phase 1b/2 trial will evaluate NC410 in combination with KEYTRUDA in patients with immune checkpoint refractory colorectal, esophageal, endometrial and head and neck cancers or immune checkpoint naïve patients with colorectal and ovarian cancers. The company expects to report initial Phase 1b data in mid-2023 followed by the initiation of the Phase 2 component of the study.

"We are pleased and honored that Merck is providing KEYTRUDA for this study. We have initiated a clinical trial to explore a combination with NC410 and look forward to advancing the program," said Michael Richman, NextCure's president and chief executive officer. "Elevated collagen levels in the extracellular matrix (ECM), the tissue matrix surrounding the tumor, are associated with resistance to PD-1 and PD-L1 therapies. In non-clinical colorectal models and early-stage monotherapy clinical studies, we have demonstrated that NC410 can remodel collagen in the ECM, which enhances T cell infiltration into the tumor. We believe NC410 in combination with KEYTRUDA has the potential to address the significant unmet needs of cancer patients not adequately addressed by available therapies."

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

About NC410 Phase 1b/2 Combination Trial
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 KEYTRUDA. 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 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 disease 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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