A Phase 2 Study of Anti-Siglec-15 Antibody, NC318, in Combination with Pembrolizumab (NCT04699123) Demonstrates Clinical Activity in Patients with Advanced PD-1 Axis Inhibitor Refractory NSCLC

September 12, 2023 at 8:05 AM EDT

• *Data presented at the 2023 World Conference on Lung Cancer hosted by the International Association for the Study of Lung Cancer in Singapore*

BELTSVILLE, Md., Sept. 12, 2023 (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 Phase 2 clinical data by collaborators at the Yale Cancer Center demonstrating clinical benefit in patients with advanced, PD-1 axis inhibitor refractory non-small cell lung cancer (NSCLC) treated with a combination regimen of NC318, a Siglec-15 (S15) monoclonal antibody (mAb), and pembrolizumab, an anti-PD-1 antibody.

NC318 is a humanized IgG1 mAb against S15 that blocks interactions of S15 with myeloid cells and T lymphocytes within the tumor microenvironment, relieving immune inhibitory signaling. In an earlier monotherapy study from NextCure, NC318 demonstrated single agent activity in a Phase 1/2 dose escalation trial (NCT03665285) for patients with advanced solid tumors (Tolcher et al, SITC 2019).

The ongoing NCT04699123 study is a randomized trial designed to assess the safety and efficacy of NC318 alone or in combination with pembrolizumab. The combination portion of the study is assessing efficacy in NSCLC subjects who have experienced disease progression on, or after, PD-1 axis inhibitor therapy. Key findings from the trial include:

- Efficacy data demonstrate that the combination of NC318 and pembrolizumab is active in advanced PD-1 axis inhibitor refractory NSCLC: 28% of patients (5/18) had durable clinical benefit (partial response or stable disease lasting greater than 6 months by RECIST and/or irRC) with three of these being confirmed responses.
- To date, both monotherapy and combination arms have been well tolerated, with six Grade 3 treatment-related adverse events (TRAEs) [transverse myelitis (1), infusion reactions (3), rash (1) and pneumonitis (1)] and four Grade 2 TRAEs [infusion reactions (2), pericarditis (1) and psoriasis (1)] between both arms.
    - NC318 infusion reactions were seen in seven patients (three Grade 3, four Grade 2), six receiving the combination and one NC318 alone. No additional infusion reactions occurred once NC318 infusion time was increased from 30 to 60 minutes.
    - All confirmed responses were in patients with PD-L1 negative tumors, and benefits were seen in patients with both PD-L1 positive and negative tumors.
- Additional biomarker and pharmacodynamic studies are ongoing.

“Based on these early encouraging results, Yale is continuing to enroll patients to gain further evidence of clinical activity of NC318,” said Solomon Langermann, Ph.D., NextCure’s chief scientific officer. “We look forward to continuing our collaboration with Drs. Herbst and Gettinger and the Yale Cancer Center.

“We are excited that this investigator-initiated trial, part of our NCI Lung SPORE (Specialized Program of Research Excellence), is providing new insights into the mechanisms and treatment of immune therapy resistance. We look forward to reporting more data in the future,” said Roy Herbst, M.D., Ensign Professor of Medicine (Medical Oncology) and Professor of Pharmacology; Deputy Director, Yale Cancer Center; Chief of Medical Oncology, Yale Cancer Center and Smilow Cancer Hospital; Assistant Dean for Translational Research, Yale School of Medicine; Director, Center for Thoracic Cancers, Yale Cancer Center and Smilow Cancer Hospital.

Details of the presentation are as follows:

Title: A Phase 2 study of NC318 alone or in combination with pembrolizumab in patients with advanced NSCLC
Presenter: Roy Herbst, MD
Presentation No: MA15.07
Session Title: Bringing New Discoveries into Early Phase Clinical Trials
Session Time: September 12, 2023, 10:45AM - 11:45AM SGT

NextCure has maintained a longstanding relationship with clinician scientists at Yale University stretching back to the company’s founding. NextCure’s scientific founder Dr. Lieping Chen, a leader in immunology and medical oncology, is the United Technologies Corporation Professor in Cancer Research and Professor of Immunobiology, Dermatology and Medicine (Medical Oncology) at Yale University. The immunosuppressive properties of S15 were discovered by Dr. Chen at Yale University. NextCure has exclusively licensed technologies relating to S15 from Yale University, and has since collaborated with Yale University to continue development of NC318, as well as other immuno-oncology candidates, through sponsored research and clinical trial agreements.

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 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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