NextCure Presents Phase 1b Data on NC410 and Pembrolizumab Combination at ASCO 2024

May 30, 2024 at 4:05 PM EDT

- *Of the evaluable ICI-naïve MSS/MSI-L CRC patients without liver metastasis, there were 2 confirmed ongoing PRs and a disease control rate of 51%*
- *Of the 7 evaluable ovarian cancer patients, there were 3 PRs and a disease control rate of 43%*
- *Data to be presented June 1, 2024, 9:00 am-12:00 pm CT*

BELTSVILLE, Md., May 30, 2024 (GLOBE NEWSWIRE) -- NextCure, Inc. (Nasdaq: NXTC), a clinical-stage biopharmaceutical company committed to discovering and developing novel, first-in-class and best-in-class therapies to treat cancer, today announced that clinical data from the Phase 1b portion of a Phase 1b/2 study evaluating NC410, a LAIR-2 fusion protein, in combination with pembrolizumab will be presented at the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago. The trial evaluated the combination in immune checkpoint inhibitor (ICI) naïve and refractory microsatellite stable (MSS)/microsatellite instability-low (MSI-L) colorectal cancer (CRC) and ovarian cancer and demonstrated clinical activity in these hard-to-treat cancers. The data will be presented in a poster session by clinical trial investigator Eric S. Christenson, M.D., Assistant Professor of Oncology at Johns Hopkins Sidney Kimmel Comprehensive Cancer Center.

The poster presentation highlights the safety and tolerability of doses between 30-200 mg of NC410 in combination with 400 mg of pembrolizumab. The combination resulted in partial responses (PR) and stable disease in both CRC and ovarian cancer. Most adverse events were limited to Grades 1 and 2.

“While MSS/MSI-L CRC and ovarian cancer are difficult to treat and recalcitrant to immunotherapy, the combination of NC410 and pembrolizumab demonstrated clinical activity against both tumor types. MSS/MSI-L CRC study subjects who achieved clinical benefit of partial responses or stable disease by the first scan at 9 weeks maintained continued disease control with a median duration of 5.5 months, which is clinically meaningful for this patient population,” said Michael Richman NextCure’s President and chief executive officer. “In addition, biomarker data support the proposed mechanism of action of NC410 in remodeling the ECM, enhancing infiltration and activation of immune cells in the TME. While the focus of the current presentation is on the targeted CRC patient population, we look forward to reporting the results from the ongoing ovarian cancer cohort expansion later this year.”

Key findings:

- Of the 37 evaluable ICI-naïve MSS/MSI-L CRC patients without liver metastasis treated with 100 mg of NC410, there were 2 confirmed ongoing PRs (12.5 months and 7.4 months) and 17 with stable disease. For this cohort, the median duration of disease control was 5.5 months, the disease control rate (DCR) was 51.3% [CI: 34.4, 68.1] and the overall response rate (ORR) was 5.4% [CI: 0.7, 18.2].
- Of the 7 evaluable ovarian cancer patients in the 100 mg and 200 mg cohorts, there were 3 PRs {1 continued for 7.9 months (200 mg), 1 for 4.1 months (100 mg), and 1 ongoing at 5.1 months (100 mg)}. For this cohort, the DCR was 43% and ORR was 43%.
- Diarrhea and fatigue were the most commonly reported adverse events (AEs). Amongst the 81 patients treated at all dose levels of NC410 in the Phase 1b portion of the trial, 39.5% had Grade ≥3 Treatment Emergent (TEAE) and 4.9% had Grade ≥3 Treatment-Related (TRAE); 1 participant discontinued study due to Grade 3 myocarditis.

Details of the presentation are as follows:

Title: A Phase 1b study of NC410 in combination with pembrolizumab in immune checkpoint inhibitor (ICI) naïve, and refractory microsatellite stable (MSS)/microsatellite instability-low (MSI-L) colorectal cancer (CRC) and ovarian cancer
Date and Time: June 1, 2024, 9:00 am-12:00 pm CT
Session: Poster Session: Developmental Therapeutics—Immunotherapy
Abstract Number: 2538

About NextCure, Inc.

NextCure is a clinical-stage biopharmaceutical company that is focused on advancing innovative medicines that treat cancer patients that do not respond to, or have disease progression on, current therapies, through the use of differentiated mechanisms of actions including antibody-drug conjugates, antibodies and proteins. We focus on advancing therapies that leverage our core strengths in understanding biological pathways and biomarkers, the interactions of cells, including in the tumor microenvironment, and the role each interaction plays in a biologic response.
www.nextcure.com

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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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