

Nkarta Announces Initiation of Investigator-Sponsored Clinical Trial Evaluating NKX019 for Systemic Lupus Erythematosus

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SOUTH SAN FRANCISCO, Calif., July 24, 2024 (GLOBE NEWSWIRE) -- Nkarta, Inc. (Nasdaq: NKTX), a biopharmaceutical company developing engineered natural killer (NK) cell therapies, today announced that researchers at Columbia University Irving Medical Center (CUIMC) have initiated an investigator-sponsored trial ("IST") of NKX019, Nkarta's allogeneic, CD19-directed chimeric antigen receptor (CAR) NK-cell therapy in patients with systemic lupus erythematosus (SLE). The IST broadens the clinical evaluation of NKX019 in lupus. In June 2024, Nkarta announced the initiation of Ntrust-1, its Phase 1 clinical trial of NKX019 in patients with lupus nephritis (LN).

The single-center, single-arm, open-label Phase 1 IST is being led by Anca D. Askanase, M.D., M.P.H., Director, Lupus Center at CUIMC and the Director of Rheumatology Clinical Trials.

"People with lupus face significant challenges, including years of exposure to toxic/partially effective medications," said Dr. Askanase. "Cell therapy provides the hope of long-term, medication-free remission."

The CUIMC IST is designed to enroll up to 6 patients with SLE, regardless of renal involvement, and will evaluate safety and clinical outcomes in a potentially different population than Ntrust-1. Translational and biomarker studies, including autoantibodies, cytokine profiles and pharmacokinetics are also planned. Patients receive NKX019 on Days 0, 7 and 14 following single-agent lymphodepletion with cyclophosphamide. Patient screening is underway.

Systemic lupus erythematosus (SLE) is an autoimmune disease that causes the body's immune system to attack its own tissues. The dysregulated immune system produces antibodies that can affect various organs, including the skin, joints, kidneys, heart, and brain. Symptoms can include fatigue, joint pain, or severe life-threatening organ disease. SLE can cause lupus nephritis (LN), a severe complication that affects the kidneys.

"With its reduced-toxicity lymphodepletion regimen, enabled by cytokine engineering, we believe that NKX019 has potential to reach more patients, including those with less advanced disease," said David R. Shook, M.D., Nkarta's Chief Medical Officer and Head of R&D. "We're eager to collaborate with our academic partners at Columbia and look forward to making a difference in the lives of people living with autoimmune diseases like lupus."

About NKX019

NKX019 is an allogeneic, cryopreserved, off-the-shelf immunotherapy candidate that uses natural killer (NK) cells derived from the peripheral blood of healthy adult donors. It is engineered with a humanized CD19-directed chimeric antigen receptor (CAR) for enhanced cell targeting and a proprietary, membrane-bound form of interleukin-15 (IL-15) for greater persistence and activity without exogenous cytokine support. CD19 is a biomarker for normal B cells as well as those implicated in autoimmune disease and B cell-derived malignancies.

About Nkarta

Nkarta is a clinical-stage biotechnology company advancing the development of allogeneic, off-the-shelf, on-demand natural killer (NK) cell therapies. By combining its cell expansion and cryopreservation platform with proprietary cell engineering technologies and CRISPR-based genome engineering capabilities, Nkarta is building a pipeline of future cell therapies engineered for deep therapeutic activity and intended for broad access in the outpatient treatment setting. For more information, please visit the company's website at www.nkartatx.com.

Cautionary Note on Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Words such as "anticipates," "believes," "expects," "intends," "plans," "potential," "projects," "would" and "future" or similar expressions are intended to identify forward-looking statements. Examples of these forward-looking statements include, but are not limited to, statements concerning Nkarta's expectations (or the expectations of others) regarding any or all of the following: the therapeutic potential of cell therapies, including NKX019, for the treatment of autoimmune disease, including lupus; and the accessibility, tolerability, advantages, and safety profile of NKX019 and single-agent cyclophosphamide lymphodepletion.

Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These risks and uncertainties include, among others: Nkarta's limited operating history and historical losses; Nkarta's lack of any products approved for sale and its ability to achieve profitability; the risk that the results of preclinical studies and early-stage clinical trials may not be predictive of future results; Nkarta's ability to raise additional funding to complete the development and any commercialization of its product candidates; Nkarta's dependence on the clinical success of NKX019; that Nkarta may be delayed in initiating, enrolling or completing its clinical trials; competition from third parties that are developing products for similar uses; Nkarta's ability to obtain, maintain and protect its intellectual property; Nkarta's dependence on third parties in connection with manufacturing, clinical trials and pre-clinical studies; and the complexity of the manufacturing process for CAR NK cell therapies.

These and other risks and uncertainties are described more fully in Nkarta's filings with the Securities and Exchange Commission ("SEC"), including the "Risk Factors" section of Nkarta's Quarterly Report on Form 10-Q for the quarter ended March 31, 2024, filed with the SEC on May 9, 2024, and Nkarta's other documents subsequently filed with or furnished to the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made. Except to the extent required by law, Nkarta undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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