



Nkarta Announces Updates to NKX019 and NKX101 Clinical Development Programs

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- *First patients dosed in Phase 1 clinical trial evaluating NKX019 in CD19+ advanced B cell malignancies*
- *Initial data from the NKX019 clinical trial expected in 2022*
- *Initial data from Phase 1 clinical trial evaluating NKX101 in AML and MDS expected in 1H 2022*

SOUTH SAN FRANCISCO, Calif., Oct. 07, 2021 (GLOBE NEWSWIRE) -- Nkarta, Inc. (Nasdaq: NKTX), a biopharmaceutical company developing engineered natural killer (NK) cell therapies to treat cancer, today announced NKX019 and NKX101 clinical development program updates.

Patients have been dosed in the international Phase 1 clinical trial of NKX019 in advanced B-cell malignancies. NKX019 is an NK cell immunotherapy that is engineered to eradicate tumors expressing CD19, a validated B-cell cancer target.

"We are excited to explore the potential of NKX019, our second clinical-stage, engineered chimeric antigen receptor (CAR) NK cell therapy candidate, to become a leading treatment of B-cell malignancies for eventual use in a broadly accessible outpatient setting," said Paul J. Hastings, President and Chief Executive Officer of Nkarta. "NKX019 builds upon the potent innate anti-tumor biology and promising safety profile of natural killer cells. This trial moves us one step closer to bringing game-changing, off-the-shelf cell therapies to cancer patients. We anticipate reporting initial data from the NKX019 study in 2022."

Nkarta is producing the clinical supply of NKX019 at its in-house cGMP clinical manufacturing facility in South San Francisco, California.

Nkarta is also updating guidance on when it expects to announce initial data from the first-in-human Phase 1 clinical trial of NKX101, an engineered CAR NK cell therapy candidate targeting the NKG2D ligand, in patients with relapsed or refractory acute myeloid leukemia (AML) or higher-risk myelodysplastic syndromes (MDS) to the first half of 2022.

Multiple factors have affected the cadence of the NKX101 Phase 1 study, including the use of haplomatched donor derived cells in the original study design, requirement for a staggered enrollment of patients that was longer than originally expected, and COVID-19 related disruptions. As previously announced, the clinical trial protocol was later amended in consultation with the U.S. Food and Drug Administration to be able to dose patients with either off-the-shelf or haplomatched cells, shorten the stagger between certain patients, and introduce a second parallel dosing regimen. The new timing is intended to allow Nkarta to report a robust data set from the study, which is currently enrolling patients at several locations in the United States.

About the NKX019-101 Clinical Trial

The NKX019-101 clinical trial is a Phase 1, multi-center, open-label, dose-finding and dose-expansion study to evaluate the safety and anti-tumor activity of NKX019 as a multi-dose, multi-cycle monotherapy. Patients with CAR T naïve relapsed/refractory non-Hodgkin lymphoma (NHL), chronic lymphocytic leukemia (CLL) or B-cell acute lymphoblastic leukemia (B-ALL) will be enrolled in the dose-finding portion of the study. Following the selection of a recommended Phase 2 dose, patients with r/r B-ALL, CLL, or other subtypes of NHL, including patients who did not achieve a durable response after treatment with a CD19 CAR T cell therapy, will be enrolled in the dose-expansion portion of the trial. To learn more about the clinical trial of NKX019 in advanced B cell malignancies, please visit [ClinicalTrials.gov](https://clinicaltrials.gov).

About NKX019

NKX019 is an investigational, allogeneic, off-the-shelf cancer immunotherapy that uses natural killer (NK) cells derived from the peripheral blood of healthy adult donors. It is engineered with a humanized CD19-directed CAR for enhanced tumor 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 and malignant B cells, and it is a validated target for B cell cancer therapies.

About NKX101

NKX101 is an investigational, off-the-shelf cancer immunotherapy that uses natural killer (NK) cells derived from the peripheral blood of healthy donors and engineered with membrane-bound IL-15 and a chimeric antigen receptor (CAR) targeting NKG2D ligands on tumor cells. NKG2D, a key activating receptor found on naturally occurring NK cells, induces a cell-killing immune response through the detection of stress ligands that are widely expressed on cancer cells. By engineering NKX101 with the proprietary NKG2D-based CAR, the ability of NK cells to recognize and kill tumor cells in pre-clinical models is increased significantly compared to non-engineered NK cells. The addition of membrane-bound IL15, a proprietary version of a cytokine for activating NK cell growth, has been shown in pre-clinical models to enhance the proliferation, persistence and sustained activity of NK cells. To learn more about the NKX101 clinical trial in adults with AML or MDS, please visit [ClinicalTrials.gov](https://clinicaltrials.gov).

About B-Cell Cancers

B-cell lineage cancers are a worldwide healthcare burden. Over 500,000 new cases of non-Hodgkin lymphoma (NHL) and 50,000 new cases of acute lymphoblastic leukemia (ALL) are diagnosed world-wide each year (seer.cancer.gov, Smith 2015, Solomon 2017). Despite progress in treatment, many patients diagnosed with this heterogeneous group of cancers still succumb to their diseases. Autologous chimeric antigen receptor (CAR) T cells specific for CD19 have altered the treatment landscape for some patients with relapsed or refractory B-cell malignancies, though significant toxicities associated with T-cell expansion and the necessity for bespoke manufacturing have limited their use.

About AML and MDS

Acute Myeloid Leukemia (AML) is a rapidly progressing blood cancer caused by abnormalities of myeloid cells, a cell type in the bone marrow that would normally develop into different types of blood cells. AML usually worsens rapidly and can lead to death if not treated. Over 120,000 new cases of

AML are diagnosed world-wide each year.* Despite recent advancements, an unmet need for novel treatment options remains high. After treatment with approved therapies for AML, many patients either do not achieve complete response (CR) or relapse after CR. There is no approved therapy and limited treatment options for patients with relapsed or refractory (r/r) AML. CR rates of 12% to 18% with repeated cycles of chemotherapy are reported in this patient population.**

Myelodysplastic Syndromes (MDS) are a group of bone marrow disorders in which the blood-forming cells in the bone marrow do not produce enough healthy blood cells. Some patients with MDS have too many young, immature blood-making cells in the bone marrow. The median overall survival rate of higher risk MDS patients is 0.8 to 3.0 years. There is currently no curative treatment for patients who relapse after front-line therapy or do not respond to front-line therapy. MDS can progress to AML in about one-third of patients.

*Ming Yi et al, J Hematol Oncol. 2020; 13: 72.

**Roboz et al, JCO 2014; 32: 18. Faderl et al, JCO 2012; 30: 20. Ravandi et al, Lancet 2015; 16: 9.

About Nkarta

Nkarta is a clinical-stage biotechnology company advancing the development of allogeneic, off-the-shelf natural killer (NK) cell therapies for cancer patients. 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 anti-tumor 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 regarding any or all of the following: the safety, anti-tumor activity, success, and accessibility of Nkarta's NK cell therapy candidates, including NKX019 for the treatment of B-cell malignancies; the timing of the initial NKX019 and NKX101 clinical trial data, and the nature of those data; Nkarta's ability to build and advance a pipeline of cell therapies; and Nkarta's ability to produce clinical supply of NKX019. 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; Nkarta's ability to raise additional funding to complete the development and any commercialization of its product candidates; Nkarta's dependence on the success of its co-lead product candidates, NKX101 and NKX019; that Nkarta may be delayed in initiating, enrolling or completing any 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; the complexity of the manufacturing process for CAR NK cell therapies; and risks relating to the impact on our business of the COVID-19 pandemic or similar public health crises.

These and other risks 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 June 30, 2021, filed with the SEC on August 12, 2021, 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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