



Nkarta Receives NKX019 IND Clearance from U.S. Food and Drug Administration for Treatment of Relapsed/Refractory B Cell Malignancies

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- *NKX019 to be Nkarta's second CAR NK pipeline program to enter clinical trial*

SOUTH SAN FRANCISCO, Calif., April 28, 2021 (GLOBE NEWSWIRE) -- Nkarta, Inc. (Nasdaq: NKTX), a biopharmaceutical company developing engineered natural killer (NK) cell therapies to treat cancer, today announced that the U.S. Food & Drug Administration (FDA) has cleared an Investigational New Drug (IND) application to study NKX019 in patients with relapsed or refractory B cell malignancies.

NKX019 is an off-the-shelf cancer immunotherapy candidate that uses NK cells engineered with a CD19-directed chimeric antigen receptor (CAR). The CAR is designed to target cancer cells expressing CD19, a clinically validated target, and to enhance the innate anti-tumor activity of NK cells. In addition, NKX019 is engineered with a membrane-bound form of IL-15, an important cytokine for NK cell survival, which has been shown in preclinical models to enhance NK cell proliferation, persistence and activity.

Initiation of a Phase 1 clinical trial of NKX019 in patients with relapsed/refractory B cell malignancies, including non-Hodgkin lymphoma, chronic lymphocytic leukemia and acute lymphoblastic leukemia, is planned for the second half of 2021.

"Academic studies have highlighted the ability of donor-derived NK cells, when collected from healthy donors, to effectively target and kill cancer cells without some of the safety risks commonly associated with T cell therapies," noted Kanya Rajangam, MD, PhD, Chief Medical Officer of Nkarta. "We look forward to evaluating NKX019 in our trial as a planned multi-dose, multi-cycle treatment regimen to determine its potential for enhanced anti-tumor activity with a beneficial safety profile."

"This IND clearance, our second in less than 10-months time, builds on the strong track record of the Nkarta team to deliver on challenging goals," said Paul J. Hastings, President and Chief Executive Officer of Nkarta. "Thanks to their outstanding efforts, Nkarta will soon have two differentiated co-lead programs, NKX101 and NKX019, in clinical trials as we look forward to the continued progress of our best-in-class, healthy donor-derived NK cell platform and pipeline of novel cell therapy candidates for cancer patients."

About NKX019

NKX019 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 a CD19-directed chimeric antigen receptor (CAR) and a proprietary, membrane-bound form of interleukin 15 (IL-15). CD19 is a biomarker for normal and malignant B cells, and it is a validated target for B cell cancer therapies. Via its CAR, NKX019 targets and binds to CD19 and eliminates CD19-expressing cells via a robust immune response in preclinical studies. Preclinical models also demonstrate enhanced proliferation, persistence and activity of NK cells with the membrane-bound IL-15, an important cytokine for NK cell survival. Initiation of a Phase 1 clinical trial of NKX019 in patients with relapsed/refractory B cell malignancies in multiple centers in the United States and Australia is planned for the second half of 2021.

About Nkarta's Platform and Natural Starting Materials

Nkarta's engineering platform utilizes healthy adult donors as the source for NK cells. By enlisting this natural source of NK cells, Nkarta starts with *bona fide* NK cells endowed with inherent tumor-recognizing ability and potent cytotoxic function. Healthy donor-derived NK cells are also available in abundance, providing a large quantity of cells with which to begin the efficient two-week manufacturing process. Finally, healthy donor-derived adult cells consist of a diverse repertoire of NK cells, providing Nkarta with the potential to capitalize on the inherent diversity of the innate immune system in selecting donors or NK cell populations with optimal characteristics.

About Nkarta's NK Cell Technologies

Nkarta has pioneered a novel discovery and development platform for the engineering and efficient production of allogeneic, off-the-shelf natural killer (NK) cell therapy candidates. The approach harnesses the innate ability of NK cells to identify and kill tumor cells. To enhance the inherent anti-tumor activity of NK cells, Nkarta genetically engineers the cells with a targeting receptor designed to recognize and bind to cancer cells through recognition of specific surface proteins. This receptor is fused to co-stimulatory and signaling domains, which amplify cell signaling and NK cell cytotoxicity. Upon target binding, NK cells activate and release cytotoxic granules for target cell killing as well as cytokines that enhance the cumulative immune response. All of Nkarta's current NK cell therapy candidates are also engineered with a membrane-bound IL-15, a proprietary version of an activating cytokine important for NK cell growth and enhancement of NK cell persistence.

Nkarta's manufacturing process generates an abundant supply of NK cells that, at commercial scale, is expected to be significantly lower in cost than other current cell therapies. Key to this efficiency is the rapid expansion of donor-derived NK cells using a proprietary NKSTIM cell line, leading to the production of hundreds of individual doses from a single manufacturing run. The platform also features the ability to freeze and store CAR NK cells for extended periods and is designed to enable immediate, off-the-shelf administration to patients at the point of care.

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, Nkarta is building a pipeline of cell therapy candidates generated by efficient manufacturing processes, which are engineered to enhance tumor targeting and improve persistence for sustained activity in the body. 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 statements concerning: Nkarta’s expectations regarding the future progress of its NK cell platform and pipeline; the timing of the initiation of the NKX019 clinical trial; the anti-tumor activity and safety profile of NKX019; the treatment regimen under which NKX019 will be studied; the location of the NKX019 clinical trial sites; Nkarta’s ability to capitalize on the inherent diversity of the innate immune system and select donors or NK cells with optimal characteristics; the ability of Nkarta’s technology to enhance the proliferation, persistence and anti-tumor activity of NK cells and enable off-the-shelf administration; the efficiency and cost of Nkarta’s manufacturing processes; the number of doses generated from a manufacturing run; and the proprietary nature of Nkarta’s technology. 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 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 Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 25, 2021, and our 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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