Nkarta Announces FDA Agreement on Outpatient Dosing of NKX019 in Autoimmune Disease, Expanding Access to Community Rheumatology Centers

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- *Expanded treatment in community settings will reduce patient burden*
- *Option to redose patients granted in both Ntrust-1 and Ntrust-2 studies*
- *Rheumatoid arthritis cohort to be added to Ntrust-2*
- *Dosing continues at 4 billion cell dose level (12 billion cells in 3-dose cycle) with initial data expected to be presented at a medical meeting this year*

SOUTH SAN FRANCISCO, Calif., April 15, 2026 (GLOBE NEWSWIRE) -- Nkarta, Inc. (Nasdaq: NKTX), a clinical-stage biotechnology company developing engineered natural killer (NK) cell therapies to treat autoimmune diseases, today announced that it has reached agreement with the U.S. Food and Drug Administration (FDA) on key changes to the ongoing Ntrust-1 and Ntrust-2 clinical trials. The protocol amendments are designed to alleviate the need for overnight stays and reduce the overall burden on patients, enabling outpatient administration of NKX019 – an investigational CAR-NK cell therapy – by community research centers and community rheumatologists.

“We are pleased to reach agreement with the FDA on several protocol enhancements that will meaningfully improve the patient and trial site experience while supporting continued advancement of our NKX019 clinical program,” said Paul J. Hastings, Chief Executive Officer of Nkarta. “Reaching agreement with the FDA on outpatient dosing – reducing the need for patient monitoring from 24 hours to 2 hours – will reduce patient burden and expand access. It will also allow us to partner with community rheumatology centers, better positioning us to execute efficiently across our clinical program while expanding access to next-generation innovation to people from all walks of life, putting patients first.”

“Our agreement with the FDA expands who we can treat – and how – in clinical trials. When the amended protocol completes IRB review and is finalized, we can begin enrolling patients with rheumatoid arthritis in Ntrust-2. We’re also gaining the flexibility to re-dose participants in both studies, if needed, as an option to help optimize treatment responses in individual patients.”

NKX019 Clinical Program Progress and Upcoming Milestones
Following submission of the final amendments to FDA and IRB approvals:

- Outpatient administration will be enabled for both Ntrust-1 and Ntrust-2.
- Option to re-dose will be allowed, if needed, in Ntrust-1 and Ntrust-2.
- Rheumatoid arthritis cohort will be added as an indication in Ntrust-2, expanding the study scope to address an additional autoimmune disease with significant unmet need.
- No geographic monitoring requirements remain, further reducing patient burden.

About the Ntrust℠ Clinical Trials in Autoimmune Disease
Ntrust-1 (NCT06557265) and Ntrust-2 (NCT06733935) are multi-center, open label, dose escalation clinical trials that build on academic studies of durable, drug-free remissions in patients with autoimmune disease after CD19-targeted cell therapy. Both trials will assess the safety of NKX019 in people living with autoimmune diseases as well as its ability to enable durable remissions via a “reset” of the immune system through the elimination of pathogenic B cells.

The Ntrust trials are enrolling people living with lupus nephritis, primary membranous nephropathy, systemic sclerosis, idiopathic inflammatory myopathy, and ANCA-associated vasculitis, with rheumatoid arthritis expected to be added following final submission of the protocol amendment.

In both studies, patients receive a three-dose cycle of NKX019 on Days 0, 3, and 7 following lymphodepletion with fludarabine and cyclophosphamide or cyclophosphamide alone, if they have significant cytopenia at baseline. Leveraging the engineering of NKX019, no patients in either trial will receive supplemental cytokines or antibody-based therapeutics. This approach is designed to evaluate the single-agent activity of NKX019 and facilitate a more rapid path to regulatory approval. Patients in Ntrust-1 and Ntrust-2 may receive additional cycles, if needed, to restore response or enable a deeper response.

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. Nkarta is evaluating NKX019 in multiple autoimmune conditions.

About Nkarta
Nkarta is a clinical-stage biotechnology company advancing the development of allogeneic, off-the-shelf natural killer (NK) cell therapies for autoimmune diseases. By combining its cell expansion and cryopreservation platform with proprietary cell engineering technologies, 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 regarding any or all of the following: Nkarta's position, plans, strategies, and timelines for the continued and future clinical development and commercial potential of NKX019 (including planned protocol amendments to its Ntrust-1 and Ntrust-2 clinical trials, the implementation of outpatient administration, redosing, additional indications including rheumatoid arthritis, and relaxed geographic monitoring requirements, the future availability and disclosure of clinical data and other updates from Nkarta's clinical trials, and the regulatory pathway for NKX019, including FDA agreement on the path forward for protocol amendments); the therapeutic potential, accessibility, tolerability, advantages, and safety profile of NK cell therapies, including NKX019 for the treatment of autoimmune diseases, such as lupus, primary membranous nephropathy, systemic sclerosis, myositis, vasculitis, and rheumatoid arthritis; and Nkarta's expected cash runway.

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 patients in 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; the complexity of the manufacturing process for CAR NK cell therapies; and the success of Nkarta's recent (and any future) cost containment measures.

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