Nkarta Announces Initial Clinical Data for NKX019 in Myositis and Systemic Sclerosis at ACR Convergence

November 9, 2026

- *In myositis, 5/6 (83%) patients treated at 4 billion cells per dose with at least three months of follow-up achieved moderate or major responses, as measured by the Total Improvement Score (TIS) in the Ntrust-2 study of NKX019, an investigational, allogeneic CAR NK cell therapy.*
- *In systemic sclerosis, 6/7 (86%) patients treated at 4 billion cells per dose with at least three months of follow-up achieved a* revised Composite Response Index in Systemic Sclerosis (*rCRISS)-25 response or greater, with 5/7 (71%) patients achieving an rCRISS-50 response or greater.*
- *Rapid and deep skin responses observed in systemic sclerosis at 4 billion cells per dose, including a median 15-point reduction in modified Rodnan skin score (mRSS) at Day 90, with 5/7 (71%) patients achieving a reduction of at least 50% from baseline.*
- *No immune effector cell-associated toxicities, including cytokine release syndrome (CRS), immune effector cell-associated neurotoxicity syndrome (ICANS) and immune effector cell-associated hemophagocytic lymphohistiocytosis-like syndrome (IEC-HS), or graft-versus-host disease (GvHD), and no treatment discontinuations due to adverse events, among 40 patients treated across five indications in the Ntrust program.*
- *Webcast scheduled for today, November 9, at 8 a.m. ET*

SOUTH SAN FRANCISCO, Calif., Nov. 09, 2026 (GLOBE NEWSWIRE) -- Nkarta (Nasdaq: NKTX), a clinical-stage biotechnology company developing engineered natural killer (NK) cell therapies to treat autoimmune diseases, today announced positive initial clinical data from its Ntrust clinical trial program evaluating NKX019, its allogeneic, off-the-shelf CAR NK cell therapy candidate.

Initial clinical data from the Ntrust program are being presented this week at the American College of Rheumatology (ACR) Convergence 2026 in Orlando in two oral presentations and one poster presentation, highlighting tolerability and early efficacy in Nkarta's lead indications, myositis and systemic sclerosis. Additional translational data will be reviewed today in an investor webcast. All data are as of the September 18, 2026, ACR data cutoff.

Patients at the 4 billion-cell dose level received three doses of NKX019 on Days 0, 3 and 7 following lymphodepleting preconditioning, for a total of 12 billion cells. Efficacy was assessed using disease-specific clinical endpoints.

In myositis, the Total Improvement Score (TIS) combines muscle strength, patient and physician assessments and other disease measures. A TIS of 40 or higher represents a moderate response, reflecting broad improvement in the disease, and a TIS of 60 or higher represents a major response. In systemic sclerosis, the revised Composite Response Index in Systemic Sclerosis (rCRISS) measures skin, lung function, physical function and patient and clinician global assessments. An rCRISS-25 response represents at least 25% improvement across multiple domains of disease.

- In myositis, five of six patients (83%) treated at 4 billion cells per dose with at least three months of follow-up achieved moderate or major TIS responses.
- In systemic sclerosis, six of seven patients (86%) treated at 4 billion cells per dose with at least three months of follow-up achieved an rCRISS-25 response or greater, with five of seven patients (71%) achieving an rCRISS-50 response or greater.

NKX019 has demonstrated a favorable safety and tolerability profile among 40 patients treated across five autoimmune indications and three dose levels at the data cutoff. There were no deaths and no treatment discontinuations due to adverse events, and no increase in adverse events was observed at higher doses.

Additionally, there were no reported cases of cytokine release syndrome (CRS) of any grade, immune effector cell-associated neurotoxicity syndrome (ICANS), immune effector cell-associated hemophagocytic lymphohistiocytosis-like syndrome (IEC-HS) or graft-versus-host disease (GvHD). No cases of leukoencephalopathy, a fludarabine-associated neurotoxicity, have been reported.

Deep peripheral CD19+ B-cell depletion was observed at the 4 billion-cell dose, with median B-cell counts remaining depleted through Day 27 (n=22). In five patients with low to moderate numbers of naïve B cells at baseline, preliminary B-cell profiling showed a predominantly naïve repopulating B-cell compartment, a pattern consistent with B-cell immune reset.

"These initial results represent an important milestone for Nkarta and provide encouraging evidence that NKX019 has the potential to deliver meaningful benefit to patients struggling with advanced forms of myositis and systemic sclerosis," said Paul J. Hastings, Chief Executive Officer of Nkarta. "Our goal has always been to combine the therapeutic potential of engineered NK cell therapy with a safety profile and ease of administration that make treatment accessible to patients and physicians beyond specialized cell therapy centers. The safety profile of NKX019 observed so far and the evidence of a dose response that we're seeing as we've escalated up to 4 billion cells per dose reinforce our conviction that CAR NK could offer a

differentiated approach for patients with autoimmune disease."

"Patients with refractory myositis and systemic sclerosis often endure years of progressive disease despite multiple lines of treatment, with few effective options remaining," said Guillermo Valenzuela, M.D., principal investigator and founding medical director of Integral Rheumatology and Immunology Specialists (IRIS). "These are diseases in which preserving muscle strength, physical function and organ health can profoundly affect both the quality of a patient's life and its duration. As a clinician who has cared for patients living with these debilitating conditions, I am encouraged by both the proportion of patients experiencing meaningful clinical improvement and the depth of responses observed. I've been participating in the Ntrust clinical trials in my community clinic, IRIS, based in Plantation, Florida, where we are treating patients with NKX019 on an outpatient basis followed by a two-hour post-infusion observation period and subsequent discharge home, similar to a biologic infusion."

Initial Clinical Results in Myositis

The Ntrust-2 basket study enrolled patients with active, treatment-refractory myositis (idiopathic inflammatory myopathy), including dermatomyositis, juvenile dermatomyositis, antisynthetase syndrome and immune-mediated necrotizing myopathy. Among 11 patients in the baseline efficacy population across all dose levels, median disease duration was 3.5 years and nine (82%) had received four or more prior therapies. Clinical activity in myositis was assessed using TIS, described above.

At the 4 billion-cell dose level:

- Five of six patients (83%) with at least three months of follow-up achieved moderate or major TIS responses spanning three disease subtypes: dermatomyositis, juvenile dermatomyositis and antisynthetase syndrome. The patient with the longest available follow-up, six months, has maintained a major response of TIS 90.
- Five of six patients (83%) with at least three months of follow-up demonstrated improvements in muscle strength, as measured by Manual Muscle Testing 8 (MMT-8). Improvements generally emerged early following treatment and were maintained through available follow-up.
- Four of eight evaluable patients (50%) achieved clinically relevant reductions in skin disease activity, as measured by the Cutaneous Dermatomyositis Disease Area and Severity Index Activity Score (CDASI-A). The remaining four patients had relatively stable scores compared with baseline.

Early evidence of a dose response was observed. NKX019 exposure increased with dose, and clinical responses at 4 billion cells per dose were more consistent than at lower dose levels, where two patients treated (one at 1 billion and one at 2 billion cells per dose) had early moderate or major responses that were not sustained.

One patient at the 4 billion-cell dose level received a low-dose steroid taper and intravenous immunoglobulin from a community rheumatologist, outside the protocol and without the investigator's knowledge. This was not due to worsening disease. The patient had already achieved a moderate response (TIS of 40 or higher) at Day 37, before additional therapy began at approximately Day 50, and went on to achieve a major response by Day 120. Both patients treated at the lower dose levels received additional immunomodulatory agents at later timepoints for increased disease activity.

These findings provide early evidence of clinical activity across multiple manifestations of myositis, including muscle weakness and inflammatory skin disease. Continued follow-up will further characterize durability of response.

Initial Clinical Results in Systemic Sclerosis

Systemic sclerosis patients enrolled in the Ntrust-2 study had active disease despite extensive prior treatment. Among 14 patients included in the baseline efficacy population across all dose levels, median disease duration was 4.6 years and nine (64%) had received at least three prior therapies. Median baseline mRSS was 26, reflecting substantial skin involvement.

Clinical activity was evaluated using the modified Rodnan skin score (mRSS), a measure of skin thickening, and rCRISS, described above, which measures improvement across skin, lung function, physical function and patient and clinician global assessments.

At the 4 billion-cell dose level, seven of nine patients had reached Day 90 as of the data cutoff. Among these patients, NKX019 demonstrated rapid and deep clinical responses through Day 90:

- Six of seven patients (86%) achieved an rCRISS-25 response or greater by Day 90, including five of seven patients (71%) who achieved an rCRISS-50 response or greater.
- Skin responses were rapid and deep, with a median improvement in mRSS of 15 points (range, 0 to 29) at Day 90. Six of seven patients (86%) had a reduction in mRSS, and five of seven patients (71%) achieved a reduction of at least 50% from baseline.

A dose response was also observed in skin. One of five patients treated at 1 billion or 2 billion cells per dose achieved an mRSS reduction of at least 50% by Day 90, compared with five of seven patients at 4 billion cells per dose.

Among patients treated at lower dose levels, one patient in the 2 billion-cell dose cohort, with nine months of follow-up, has maintained an rCRISS-70 response through Day 270.

Safety

Adverse events were mainly hematologic and attributed to lymphodepleting preconditioning, and were generally transient, typically recovering within one to two months. Across all indications and dose levels, no cases of CRS of any grade, ICANS, IEC-HS or GvHD were observed. Infusion-related reactions, the main events associated with NKX019 administration, occurred in five patients (12.5%), most of them grade 1. All resolved within 24 to

48 hours with standard supportive care, without the use of tocilizumab.

The Ntrust protocols have included a safety standard for patients with compromised kidney function since fludarabine was added to the lymphodepletion regimen, requiring either a reduced dose of fludarabine or exclusion from the trial. No cases of leukoencephalopathy, a fludarabine-associated neurotoxicity, have been reported to date.

Additional integrated safety data from the Ntrust program will be presented by Dr. Valenzuela in an oral presentation at ACR Convergence 2026 on Wednesday, November 11.

Registrational Preparations Underway

Based on pharmacokinetic and T-cell recovery data showing that host T cells begin to recover before the Day 7 dose, Nkarta recently amended the Ntrust protocols to compress dosing to Days 0, 2 and 4, and plans to evaluate 6 billion cells per dose.

Nkarta anticipates upcoming interactions with the U.S. Food and Drug Administration to discuss potential registrational pathways in both indications. The company also expects to report additional clinical follow-up in myositis and systemic sclerosis, as well as retreated patients, together with a plan for registrational dose selection, in the first half of 2027.

About the Ntrust℠ Clinical Trials in Autoimmune Disease
Ntrust-1 (NCT06557265) and Ntrust-2 (NCT06733935) are multi-center, open-label, dose-escalation clinical trials in patients with autoimmune disease receiving lymphodepletion followed by CD19-targeted CAR NK cell therapy. Both trials assess the safety of NKX019 in people living with autoimmune diseases as well as its potential to achieve durable remission via a “reset” of the immune system through the elimination of pathogenic B cells.

The Ntrust trials are enrolling up to 12 patients per dose level per disease indication. Additional patients may be enrolled if needed to refine patient populations for further study.

In both studies, patients receive a three-dose cycle of NKX019 following lymphodepleting preconditioning with fludarabine and cyclophosphamide or cyclophosphamide alone, if they have significant cytopenia at baseline. This approach is designed to evaluate the single-agent activity of NKX019 and facilitate a more rapid path to regulatory approval. Patients in both trials may also 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 people living with autoimmune diseases. By harnessing the power of the innate immune system to eliminate pathogenic B cells driving the autoimmune response, Nkarta is advancing novel cell therapies engineered for deep therapeutic impact. The on-demand availability and outpatient dosing of our CAR NK cells enable a broad population of patients with different autoimmune conditions to conveniently access NK cell therapy in community health settings. 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 potential of NKX019 (including the future availability and disclosure of clinical data and other updates from Nkarta’s clinical trials, planned changes to dosing schedules and dose levels, the potential effects of such changes, the potential durability of clinical responses, the safety and efficacy of retreatment, anticipated interactions with the U.S. Food and Drug Administration, potential registrational pathways and the timing of registrational dose selection); and the therapeutic potential, accessibility and tolerability of NKX019 for the treatment of autoimmune diseases, including as a result of advancing Nkarta’s dose escalation and expansion of outpatient dosing in community-based settings.

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; the risk that initial, interim or preliminary data from Nkarta’s clinical trials, including the data presented at ACR Convergence 2026, reflect a limited number of patients with limited follow-up, may change as more patient data become available and 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, including in its lead indications of myositis and systemic sclerosis; risks associated with outpatient administration of NKX019 at community-based sites; the risk that the U.S. Food and Drug Administration may not agree with Nkarta’s proposed registrational pathways or dose selection; the risk that changes to dosing schedules or dose levels may not achieve the anticipated results or may result in additional safety or tolerability concerns; 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 preclinical studies; and the complexity of the manufacturing process for CAR NK cell therapies.

The data described in this press release are preliminary, are from a small number of patients with limited follow-up and may change as additional data become available. No head-to-head studies have been conducted comparing NKX019 with other therapies, and caution should be exercised in drawing conclusions from comparisons of data across separate trials, which may differ in design, patient populations and other factors.

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 September 30, 2026, filed with the SEC on November 5, 2026, 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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