Overall, Immune-Mediated, and Hematologic Safety Outcomes Following Fludarabine/Cyclophosphamide Lymphodepletion and NKX019, an Allogeneic CD19-Targeted CAR NK Cell Therapy, in B-Cell–Mediated Autoimmune Diseases

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Presented on November 11, 2026

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Safety Remains a Significant Concern of CAR T Cell and T Cell Engager Therapies

- **Rapid T cell activation** with or without **in vivo expansion** increases the risk of immune effector cell–associated AEs (CRS, ICANS, and immune effector cell–associated hemophagocytic lymphohistiocytosis-like syndrome) that **can increase the risk of serious AEs** or **death**[1-4]

- **Up to 80% of patients experience a CRS event** after exposure to an autologous CAR T cell therapy[5]

There is a need for novel cell therapies that deliver deep immune targeting with more predictable pharmacology, yielding an improved benefit-risk profile appropriate for patients with autoimmune diseases

AE, adverse event; CAR, chimeric antigen receptor; CRS, cytokine release syndrome; ICANS, immune effector cell–associated neurotoxicity syndrome.

1. Rocco JM and Shah NN *Blood Cancer Discov*. 2026;7(2):163-165. 2. Jørgensen LV, et al. *Exp Hematol Oncol*. 2025;14:46. 3. Ayoobkhan FS, et al. *Blood*. 2024;144(1):5163-5164. 4. Kattamuri L, et al. *Rheumatol Int*. 2025;45:18.
5. Chan SCW, et al. *Lancet Rheumatol*. 2026;8(11):e844-e852.

NKX019 Is an Investigational, Allogeneic, CD19-Targeted CAR NK Cell Therapy

Off-the-shelf availability
Advantage of allogeneic treatment

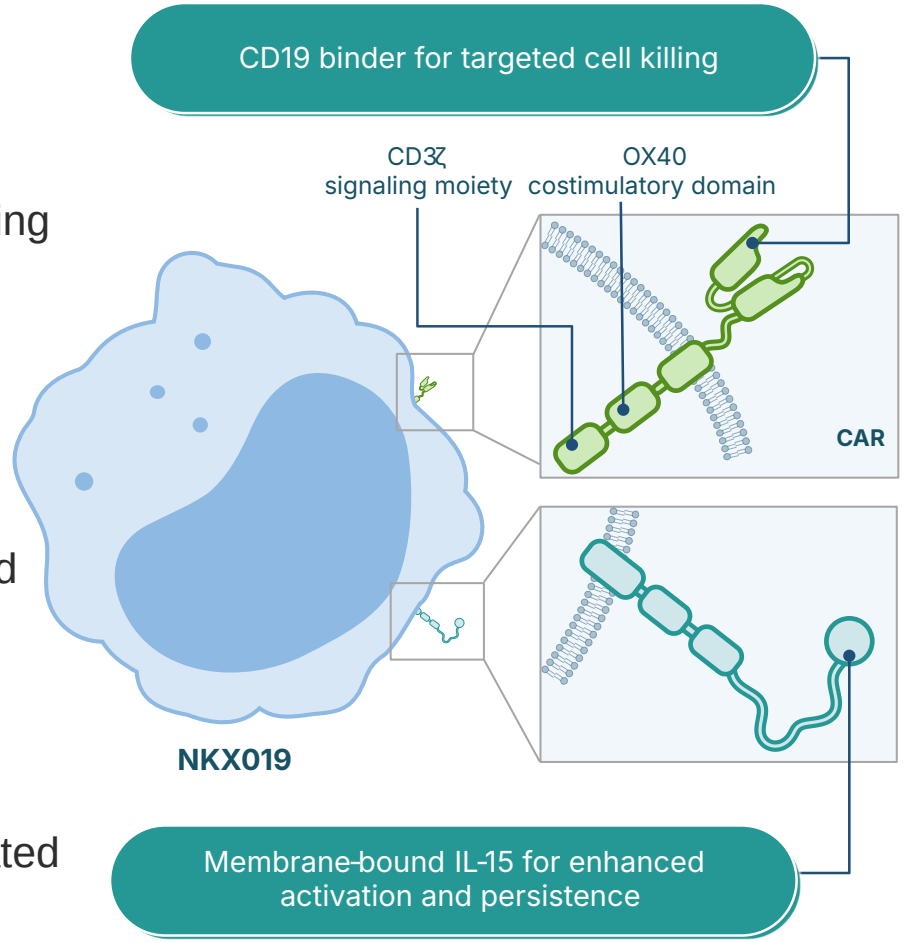
- Cryopreserved CAR NK cells available for delivery to the point of care
- Outpatient administration, with no patient leukapheresis or manufacturing delays

Controllable dose
Supports dose refinement

- Predictable PK enables greater control of exposure[1]
- Rigorous dose-escalation and regimen-optimization strategies informed by safety, PK/PD, and clinical response data[2]

Favorable safety profile
Robust B cell depletion without immune cascade

- Across 79 patients as of September 18, 2026, NKX019 has demonstrated favorable safety and tolerability in oncology and autoimmune disease, particularly regarding IEC-associated adverse events



CAR, chimeric antigen receptor; CD19, cluster of differentiation 19; CD3ζ, CD3 zeta chain; IEC, immune effector cell; IL, interleukin; NK, natural killer; PD, pharmacodynamics; PK, pharmacokinetics.

1. Hill B et al. Poster Presentation at the Pan Pacific Lymphoma Conference. July 2024. 2. Jørgensen LV, et al. *Exp Hematol Oncol*. 2025;14:46.

NTRUST: Phase 1/2 Studies of NKX019

NTRUST-2 (NCT06733935)

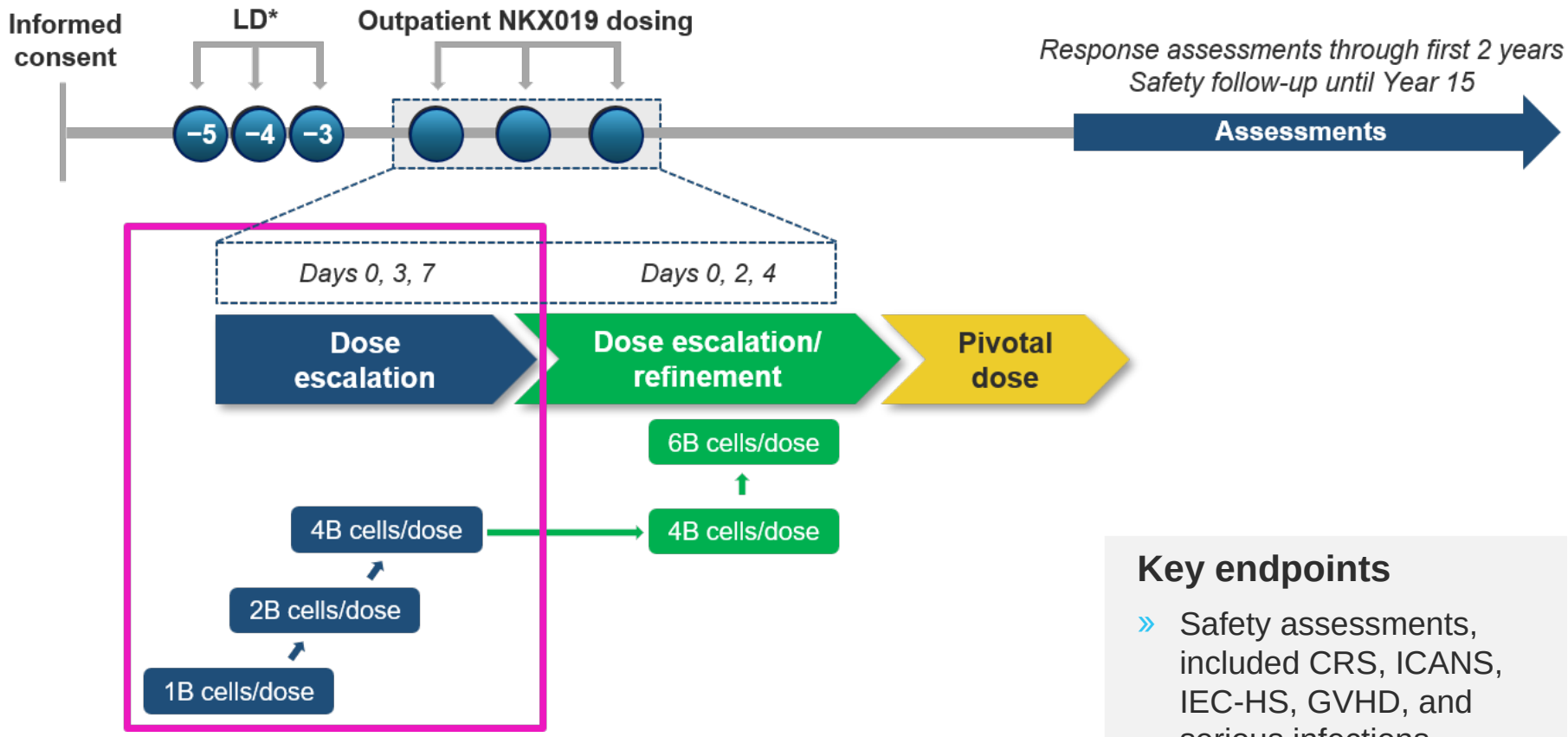
- Systemic sclerosis
- Idiopathic inflammatory myopathy
- Antineutrophil cytoplasmic antibody-associated vasculitis
- Rheumatoid arthritis

Key eligibility: Patients aged 18 to 75 years with active or progressive disease, despite previous use of standard-of-care therapies

NTRUST-1 (NCT06557265)

- Lupus nephritis
- Primary membranous nephropathy

Key eligibility: Patients aged 18 to 75 years with active disease and proteinuria, despite previous use of standard-of-care therapies



Key endpoints

- Safety assessments, included CRS, ICANS, IEC-HS, GVHD, and serious infections

Objective: Describe the cumulative safety profile of NKX019 in 40 patients with B-cell–mediated autoimmune diseases, across all disease indications

*LD preconditioning = a total of 90 mg/m² Flu as 30 mg/m²/day on Days −5, −4, and −3 and 1 g/m² Cy as 1 g/m²/day on Day −3. Patients with cytopenia may receive Cy alone as 1 g/m² on Day –3. LD preconditioning is performed in an outpatient setting for both treatments.

B, billion; CRS, cytokine release syndrome; Cy, cyclophosphamide; Flu, fludarabine; GVHD, graft-versus-host disease; ICANS, immune effector cell–associated neurotoxicity syndrome; IEC-HS, immune effector cell–associated hemophagocytic lymphohistiocytosis-like syndrome; LD, lymphodepletion.

Baseline Demographics and Treatment History

Baseline demographics and characteristics are consistent with an active, refractory disease population

Measure	Overall N = 40	Disease Indications				
		SSc n = 15	IIM n = 13	LN n = 6	AAV n = 1	RA n = 5
Age, median (range), years	47.0 (19–66)	52.0 (30–66)	46.0 (19–63)	22.5 (21–46)	60.0	50.0 (44–61)
Female, n (%)	32 (80.0)	10 (66.7)	11 (84.6)	6 (100)	0	5 (100)
Duration of disease, median (range), years	4.7 (0.3–30.7)	4.2 (0.5–8.1)	3.5 (0.3–30.3)	SLE: 10.3 (1.0–25.0) LN: 4.9 (0.5–23.7)	4.2	24.5 (13.5–30.7)
Number of prior treatments, n (%)						
1–3	10 (25.0)	8 (53.3)	2 (15.4)	0	0	0
≥4	30 (75.0)	7 (46.7)	11 (84.6)	6 (100)	1 (100)	5 (100)
Prior treatments,* n (%)						
Systemic GCs	21 (52.5)	5 (33.3)	9 (69.2)	5 (83.3)	1 (100)	1 (20.0)
cDMARDs	37 (92.5)	13 (86.7)	12 (92.3)	6 (100)	1 (100)	5 (100)
Methotrexate	15 (37.5)	5 (33.3)	5 (38.5)	0	0	5 (100)
Mycophenolate mofetil	25 (62.5)	9 (60.0)	10 (76.9)	5 (83.3)	1 (100)	0
IVIG	8 (20.0)	1 (6.7)	7 (53.8)	0	0	0
Rituximab	9 (22.5)	2 (13.3)	5 (38.5)	0	1 (100)	1 (20.0)
Other†	28 (70.0)	9 (60.0)	8 (61.5)	6 (100)	0	5 (100)

Twenty-eight, 7, and 5 patients in this analysis as of September 18, 2026, were enrolled, received LD preconditioning, and received at least 1 dose of NKX019 at 4B, 2B, and 1B cells, respectively. *At screening prior to LD preconditioning. †Includes antimalarials, calcineurin inhibitors, Janus kinase inhibitors, and biologics.

AAV, antineutrophil cytoplasmic antibody-associated vasculitis; B, billion; cDMARD, conventional disease-modifying antirheumatic drug; GC, glucocorticoid; IIM, idiopathic inflammatory myopathy; IVIG, intravenous immunoglobulin; LD, lymphodepletion; LN, lupus nephritis; RA, rheumatoid arthritis; SLE, systemic lupus erythematosus; SSc, systemic sclerosis.

RESULTS

Safety Profile Across All Disease Indications

Overall, TEAEs and TRAEs were mainly hematologic and attributed to LD preconditioning

Measure, n (%)	Overall N = 40	Disease Indications				
		SSc n = 15	IIM n = 13	LN n = 6	AAV n = 1	RA n = 5
Any TEAEs*,†	34 (85.0)	13 (86.7)	10 (76.9)	6 (100)	1 (100)	4 (80.0)
Grade ≥3 events	14 (35.0)	5 (33.3)	4 (30.8)	5 (83.3)	0	0
Anemia	5 (12.5)	1 (6.7)	1 (7.7)	3 (50.0)	0	0
Neutropenia	5 (12.5)	2 (13.3)	0	3 (50.0)	0	0
Febrile neutropenia	4 (10.0)	2 (13.3)	1 (7.7)	1 (16.7)	0	0
Leukopenia	6 (15.0)	3 (20.0)	1 (7.7)	2 (33.3)	0	0
Serious TEAEs	7 (17.5)	4 (26.7)	2 (15.4)	1 (16.7)	0	0
Serious infections	2 (5.0)	1 (6.7)	1 (7.7)	0	0	0
TEAEs leading to treatment discontinuation	0	0	0	0	0	0
Deaths	0	0	0	0	0	0
Any TRAEs (related to LD or NKX019)*	30 (75.0)	11 (73.3)	9 (69.2)	6 (100)	1 (100)	3 (60.0)
Grade ≥3 events	12 (30.0)	4 (26.7)	3 (23.1)	5 (83.3)	0	0
Serious TRAEs	3 (7.5)	2 (13.3)	1 (7.7)	0	0	0
Infections (any grade)	4 (10.0)	1 (6.7)	1 (7.7)	2 (33.3)	0	0

*AEs within 30 days of last NKX019 dose. †Events were included regardless of causality (including those assessed as not related to LD preconditioning and/or NKX019). All hematologic events shown are captured using AE terms (vs laboratory values). Twenty-eight, 7, and 5 patients in this analysis as of September 18, 2026, were enrolled, received LD preconditioning, and received at least 1 dose of NKX019 at 4B, 2B, and 1B cells, respectively.
AAV, antineutrophil cytoplasmic antibody-associated vasculitis; AE, adverse event; B, billion; IIM, idiopathic inflammatory myopathy; LD, lymphodepletion; LN, lupus nephritis; RA, rheumatoid arthritis; SSc, systemic sclerosis; TEAE, treatment-emergent adverse event; TRAE, treatment-related adverse event.

Safety Profile Consistent Across Dosing Cohorts

Well tolerated across increased doses and exposure to NKX019

Measure, n (%)	Overall N = 40	Dose		
		4B n = 28	2B n = 7	1B n = 5
Any TEAEs*,†	34 (85.0)	22 (78.6)	7 (100)	5 (100)
Grade ≥3 events	14 (35.0)	7 (25.0)	4 (57.1)	3 (60.0)
Anemia	5 (12.5)	2 (7.1)	1 (14.3)	2 (40.0)
Neutropenia	5 (12.5)	1 (3.6)	3 (42.9)	1 (20.0)
Febrile neutropenia	4 (10.0)	2 (7.1)	0	2 (40.0)
Leukopenia	6 (15.0)	3 (10.7)	2 (28.6)	1 (20.0)
Serious TEAEs	7 (17.5)	5 (17.9)	0	2 (40.0)
Serious infections	2 (5.0)	2 (7.1)	0	0
TEAEs leading to treatment discontinuation	0	0	0	0
Deaths	0	0	0	0
Any TRAEs (related to LD or NKX019)*	30 (75.0)	20 (71.4)	5 (71.4)	5 (100)
Grade ≥3 events	12 (30.0)	5 (17.9)	4 (57.1)	3 (60.0)
Serious TRAEs	3 (7.5)	2 (7.1)	0	1 (20.0)
Infections (any grade)	4 (10.0)	2 (7.1)	1 (14.3)	1 (20.0)

*AEs within 30 days of last NKX019 dose. †Events were included regardless of causality (including those assessed as not related to LD preconditioning and/or NKX019). Data as of September 18, 2026. All hematologic events shown are captured using AE terms (vs laboratory values).
AE, adverse event; B, billion; LD, lymphodepletion; TEAE, treatment-emergent adverse event; TRAE, treatment-related adverse event.

NKX019 Safety: IEC-Associated AEs or GVHD

No CRS, ICANS, IEC-HS, or GVHD events were observed with NKX019

An emerging differentiated safety profile for cell therapy

Measure, n (%)	Overall N = 40	Disease Indications				
		SSc n = 15	IIM n = 13	LN n = 6	AAV n = 1	RA n = 5
NKX019-related IRRs	5 (12.5)	1 (6.7)	1 (7.7)	2 (33.3)	0	1 (20.0)
IEC-associated AEs						
CRS	0	0	0	0	0	0
ICANS	0	0	0	0	0	0
IEC-HS	0	0	0	0	0	0
GVHD	0	0	0	0	0	0

NKX019-related IRRs occurred during or shortly after administration of NKX019 and resolved with standard care

Twenty-eight, 7, and 5 patients in this analysis as of September 18, 2026, were enrolled, received LD preconditioning, and received at least 1 dose of NKX019 at 4B, 2B, and 1B cells, respectively.
AAV, antineutrophil cytoplasmic antibody-associated vasculitis; AE, adverse event; B, billion; CRS, cytokine release syndrome; GVHD, graft-versus-host disease; ICANS, immune effector cell–associated neurotoxicity syndrome; IEC, immune effector cell; IEC-HS, IEC-associated hemophagocytic lymphohistiocytosis-like syndrome; IIM, idiopathic inflammatory myopathy; IRR, infusion-related reaction; LD, lymphodepletion; LN, lupus nephritis; RA, rheumatoid arthritis; SSc, systemic sclerosis.

Evaluation of Patients With NKX019-Related IRRs

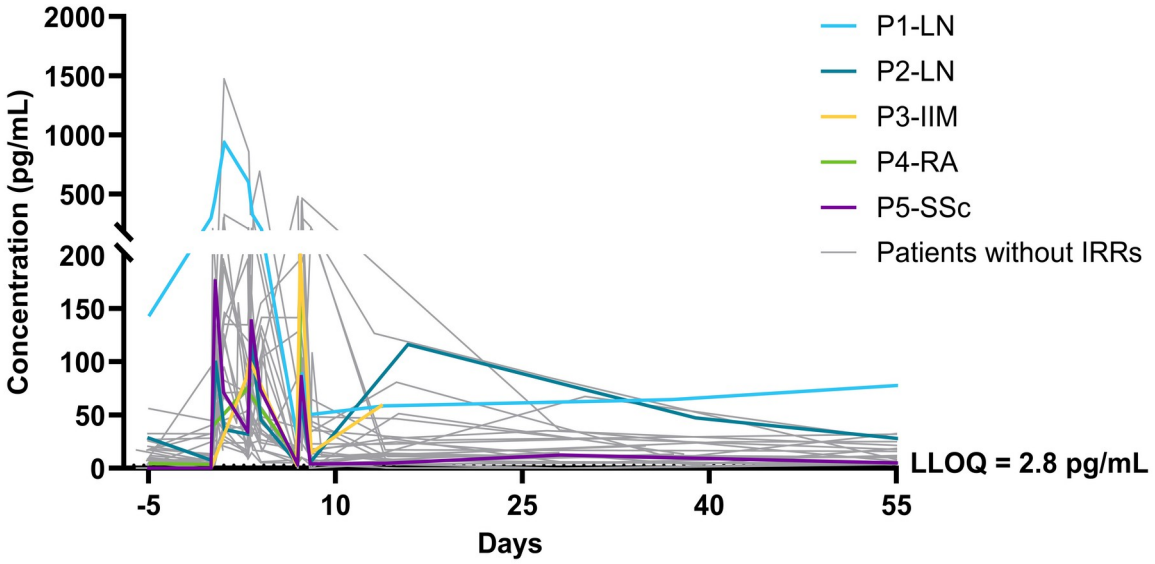
NKX019-related IRRs were infrequent and resolved with standard care

	P1-LN	P2-LN	P3-IIM	P4-RA	P5-SSc
NKX019 dose, cells	1B	2B	4B	4B	4B
Duration of fever, days	2	–	2	–	–
Peak temperature, °F	102.9	98.4	101.7	98.1	99.7
Serious AE (yes/no)	No	No	Yes	No	No
Highest grade of symptom	Grade 3	Grade 1	Grade 1	Grade 1	Grade 1
List of associated symptoms (reported term)	Neutropenic fever,* pruritus	Vomiting†	Infusion reaction (chills/rigors)‡	Pruritus*	Infusion reaction§
Received management	Yes	No	Yes	Yes	Yes
Treatments for associated symptoms**	• Acetaminophen • Piperacillin/tazobactam • Famotidine • Diphenhydramine hydrochloride	• None	• Acetaminophen	• Methylprednisolone • Diphenhydramine hydrochloride	• Acetaminophen • Meperidine

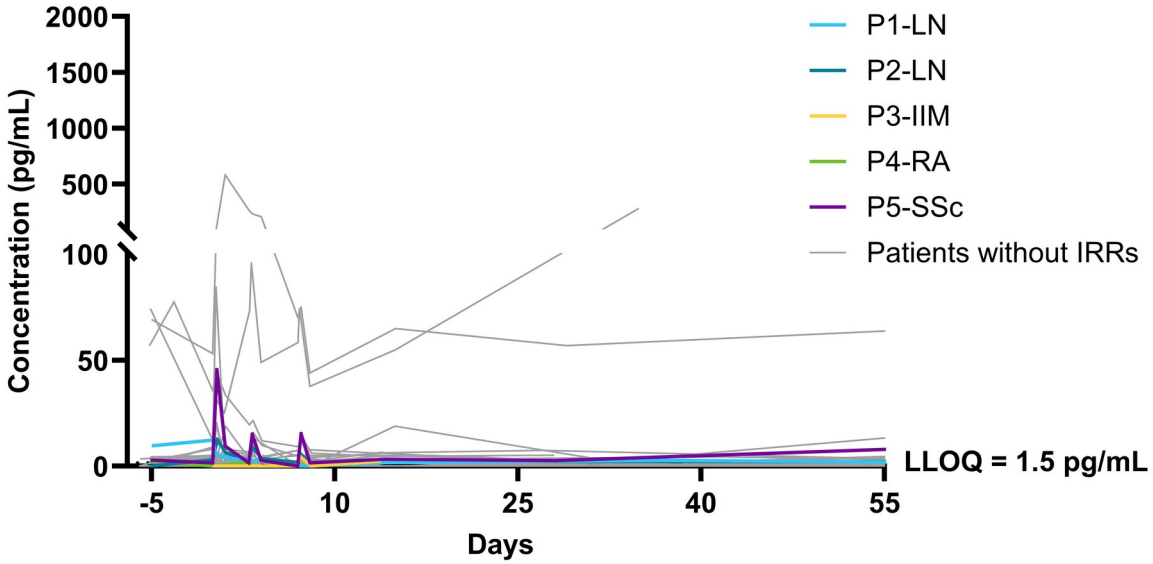
Data as of September 18, 2026. *Occurred on Day 0, the same day as the first NKX019 infusion. †Occurred on Day 1, approximately 1 day after the first NKX019 infusion. ‡Began on Day 1, approximately 1 day after the first NKX019 infusion. §Three different IRRs occurred; the first occurred on Day 0, the same day as the first NKX019 infusion; the second occurred on Day 3, the same day as the second NKX019 infusion; the third occurred on Day 7, the same day as the third NKX019 infusion. **Categorized by ATC.
AE, adverse event; ATC, anatomical therapeutic chemical; B, billion; IIM, idiopathic inflammatory myopathy; IRR, infusion-related reaction; LN, lupus nephritis; P, patient; RA, rheumatoid arthritis; SSc, systemic sclerosis.

No Difference in Cytokine Profiles in Patients With vs Without IRRs

IFN-γ levels



IL-6 levels



Data as of September 18,2026. Colored lines signify patients with IRRs. IFN-γ and IL-6 profiles are shown over the course of treatment. Additional cytokines assessed included IL-2, IL-8, IL-10, tumor necrosis factor alpha, monocyte chemoattractant protein-1, and granulocyte-macrophage colony-stimulating factor; no notable increases from baseline were observed (data not shown).
IFN-γ, interferon gamma; IL, interleukin; IMM, idiopathic inflammatory myopathy; IRR, infusion-related reaction; LLOQ, lower limit of quantitation; LN, lupus nephritis; P, patient; RA, rheumatoid arthritis; SSc, systemic sclerosis.

Safety: Hematologic Adverse Events Requiring Intervention

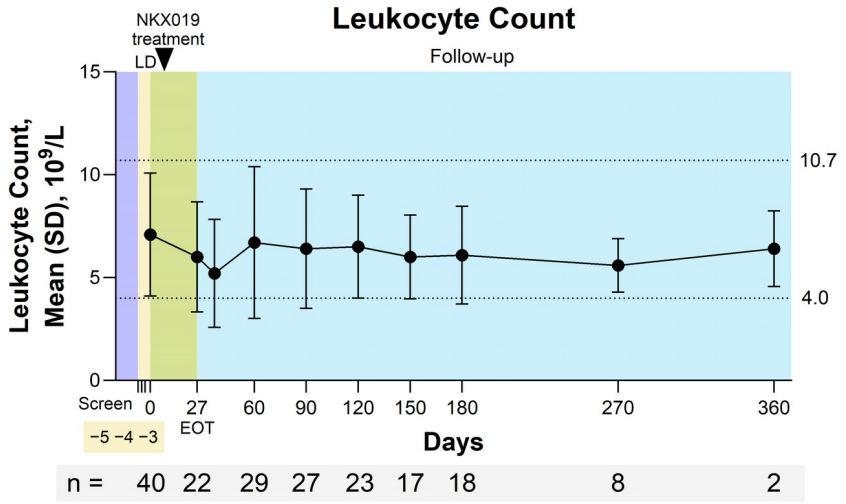
Anticipated changes in hematologic parameters were frequently attributed to LD preconditioning

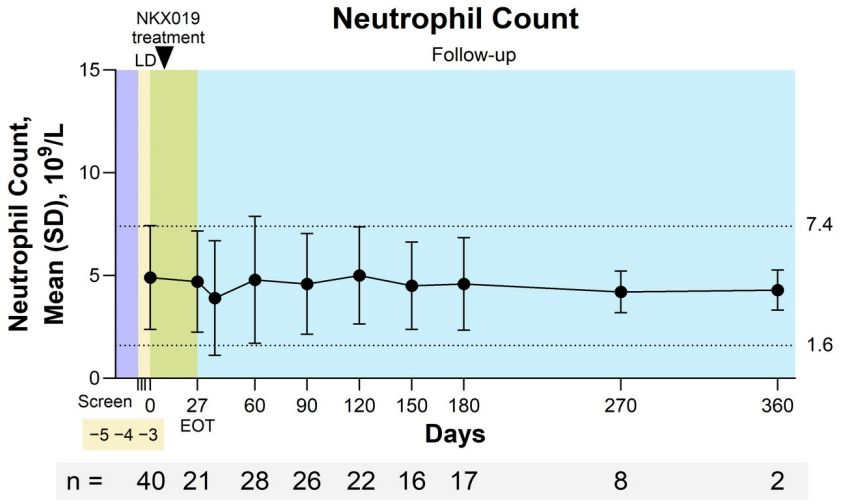
Measure, n (%)	Overall N = 40	Disease Indications				
		SSc n = 15	IIM n = 13	LN n = 6	AAV n = 1	RA n = 5
Any hematologic events requiring intervention						
Anemia requiring transfusions	6 (15.0)	3 (20.0)	0	3 (50.0)	0	0
Neutropenia requiring G-CSF	4 (10.0)	3 (20.0)*	0	1 (16.7)	0	0

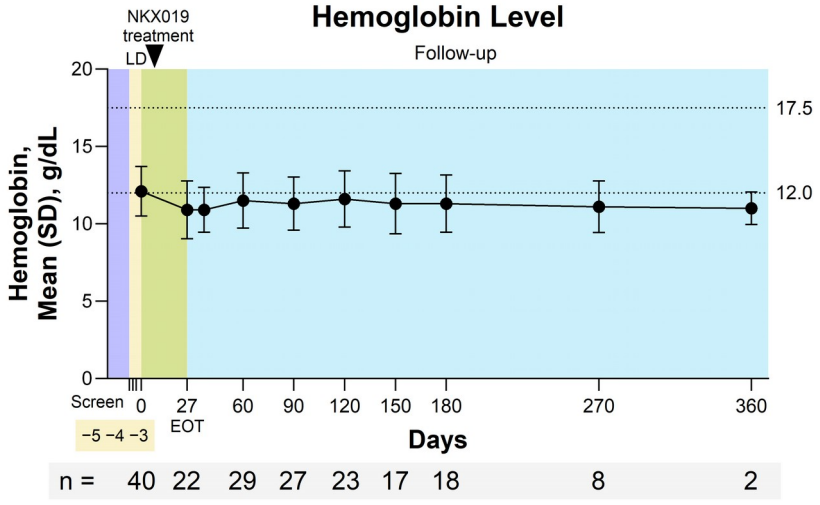
*Only 1 patient (SSc) had a hematologic event requiring intervention that was considered related to NKX019

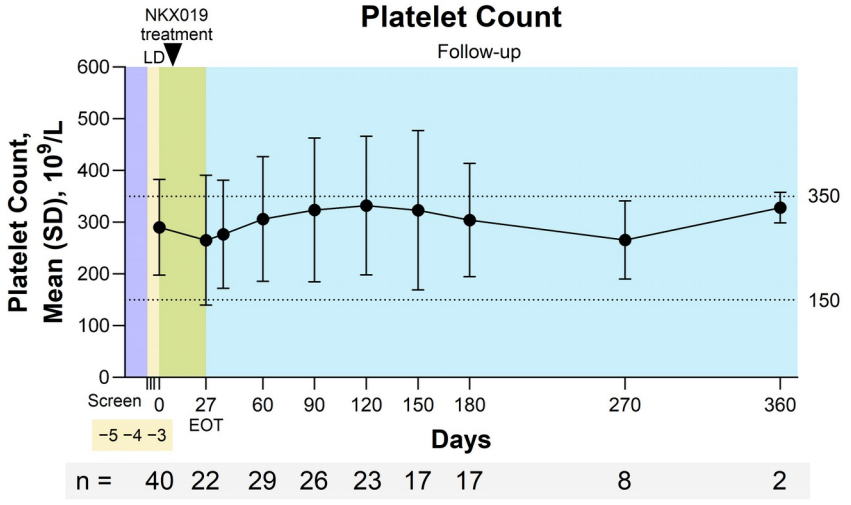
All hematologic events shown are captured using adverse event terms (vs laboratory values). Twenty-eight, 7, and 5 patients in this analysis as of September 18, 2026, were enrolled, received LD preconditioning, and received at least 1 dose of NKX019 at 4B, 2B, and 1B cells, respectively.
AAV, antineutrophil cytoplasmic antibody-associated vasculitis; B, billion; G-CSF, granulocyte colony-stimulating factor; IIM, idiopathic inflammatory myopathy; LD, lymphodepletion; LN, lupus nephritis; RA, rheumatoid arthritis; SSc, systemic sclerosis.

Shifts in hematologic parameters generally recovered to baseline levels within 1 to 2 months









Data as of September 18,2026. Only patients who received Flu and Cy LD preconditioning and at least 1 dose of NKX019 were included in this analysis. Flu: 90 mg/m^2 total (30 mg/m^2/day on Days −5, −4, and −3); Cy: 1 g/m^2 total (1 g/m^2 on Day −3).
Dashed lines represent the central laboratory conventional references for upper and lower limits of normal. The hemoglobin upper limit of normal represents the male population's upper limit of normal.
Cy, cyclophosphamide; EOT, end of treatment; Flu, fludarabine; LD, lymphodepletion; SD, standard deviation.

Key Takeaways

- NKX019 was generally well tolerated, with no cases of CRS, ICANS, IEC-HS, GVHD, related serious infections, or deaths
- The most common adverse events were hematologic, typically attributed to lymphodepletion preconditioning, and were generally transient
- IRRs occurred in 12.5% of patients and were managed with standard care
- No dose-related adverse events were observed

Preliminary data to date suggests NKX019 offers improved tolerability compared with CAR T cell therapy across several autoimmune diseases

CRS, cytokine release syndrome; GVHD, graft-versus-host disease; ICANS, immune effector cell–associated neurotoxicity syndrome; IEC-HS, immune effector cell–associated hemophagocytic lymphohistiocytosis-like syndrome; IRR, infusion-related reaction.

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