Preliminary Safety, PK/PD, and Clinical Activity of NKX019, an Allogeneic, CD19-Targeted, CAR NK Cell Therapy, in Idiopathic Inflammatory Myopathy: Results From an Ongoing, Phase 1/2, Open-Label, Multicenter, Dose-Escalation/Optimization, Basket Study

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Myositis: A Debilitating Disease With Substantial Unmet Need

IIM can cause muscle weakness, skin manifestations, and substantial functional impairment and disability[1,2]

IIM affects an estimated 14.0 to 21.4 per 100,000 individuals in the US[3]

~40%–65% of patients have a moderate-to-severe disability[1]

~49% of patients depend on caregivers for everyday activities[1]

Current treatments have limited moderate-to-major response rates and a high side-effect burden

- Immunosuppressants, IVIG, and glucocorticoids do not provide adequate disease control and are associated with tolerability concerns[4,5]

Systemic complications and increased risk of mortality

- ILD, malignancies, and CVD each account for **~19%** of deaths[6,*]
- Muscle, skin, lung, and joint involvement are major disease manifestations; swallowing and cardiac complications can add substantial morbidity[6]

B cells are one of the central drivers of IIM pathology[4,7-11]

- Enriched B-cell populations and the presence of myositis-associated autoantibodies support a central role for B cells[7-11]
- Due to its broad expression across B cell lineages, **CD19 is a well-validated target** to deplete relevant pathogenic B-cell populations[12,13]

*Values represent the percent mortality rates in a population of 4534 patients with IIM that experienced 510 deaths during a median follow-up period of 46 months. CVD, cardiovascular disease; IIM, idiopathic inflammatory myopathy; ILD, interstitial lung disease; IVIG, intravenous immunoglobulin.

1. Opinc AH, et al. *Rheumatol Int.* 2019; 39(7):1213-1220. 2. Feldon M, et al. *Arthritis Care Res (Hoboken)*. 3. Hossain MM, et al. *Front Med (Lausanne)*. 2022;9:842586. 4. Lundberg IE, et al. *Nat Rev Dis Primers*. 2021;7(1):87. 5. Espinosa-Ortega F, et al. *Arthritis Care Res (Hoboken)*. 2022;74(3):468-477. 6. Yu C, et al. *J Am Acad Dermatol*. 2025;93(6):1422-1431. 7. Pan Z, et al. *Inflammation*. 2025;48:118-132. 8. Preuße C, et al. *Acta Neuropathol*. 2022;144:353-372. 9. Piper CJM, et al. *Front Immunol*. 2018;9:1372. 10. McHugh NJ, et al. *Nat Rev Rheumatol*. 2018;14:290-302. 11. Ceribelli A, et al. *Front Med (Lausanne)*. 2023;10:1068402. 12. Forsthuber TG, et al. *Ther Adv Neurol Disord*. 2018;11:1756286418761697. 13. Suan D, et al. *J Immunol*. 2025;214(6):1075-1092.

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

Off-the-shelf availability
Advantage of allogeneic treatment

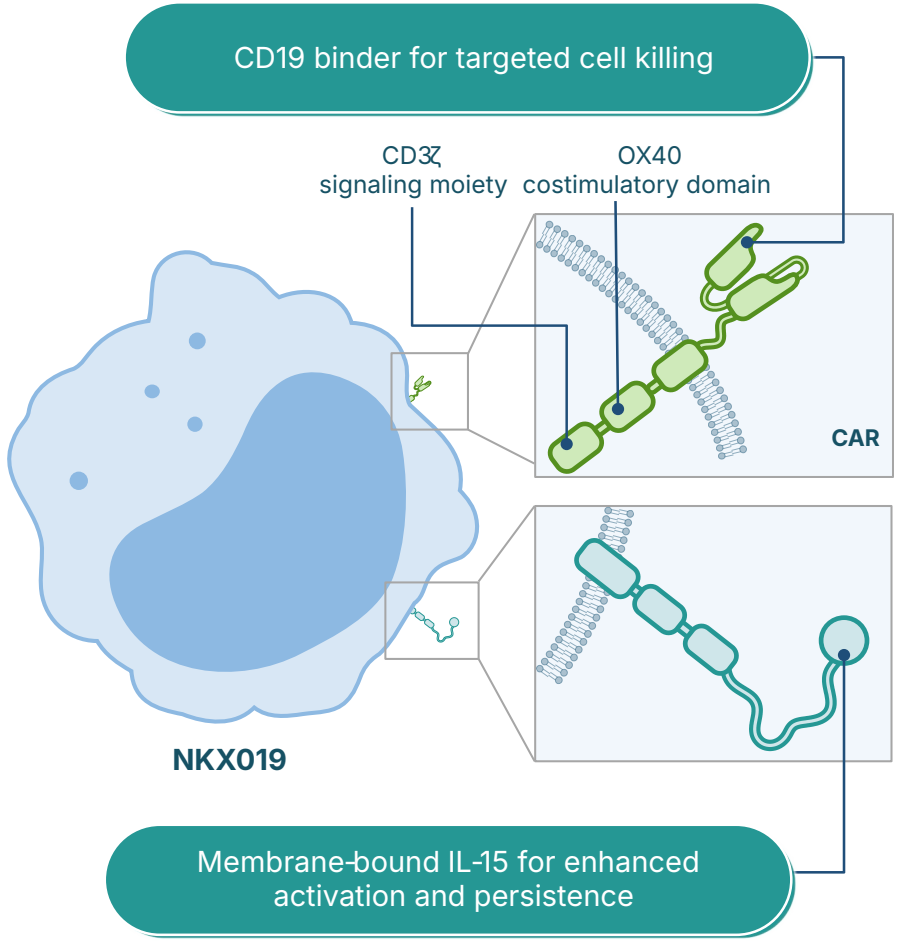
- Cryopreserved CAR NK cells available for delivery to the point of care
- Outpatient administration, with no patient leukapheresis or concern for manufacturing delays

Controllable dose
Supports dose refinement

- Predictable PK enables greater control of exposure[1]
- Rigorous dose-escalation and regimen-optimization strategy 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; 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-2 Study Design: A Dose-Escalation Study of NKX019

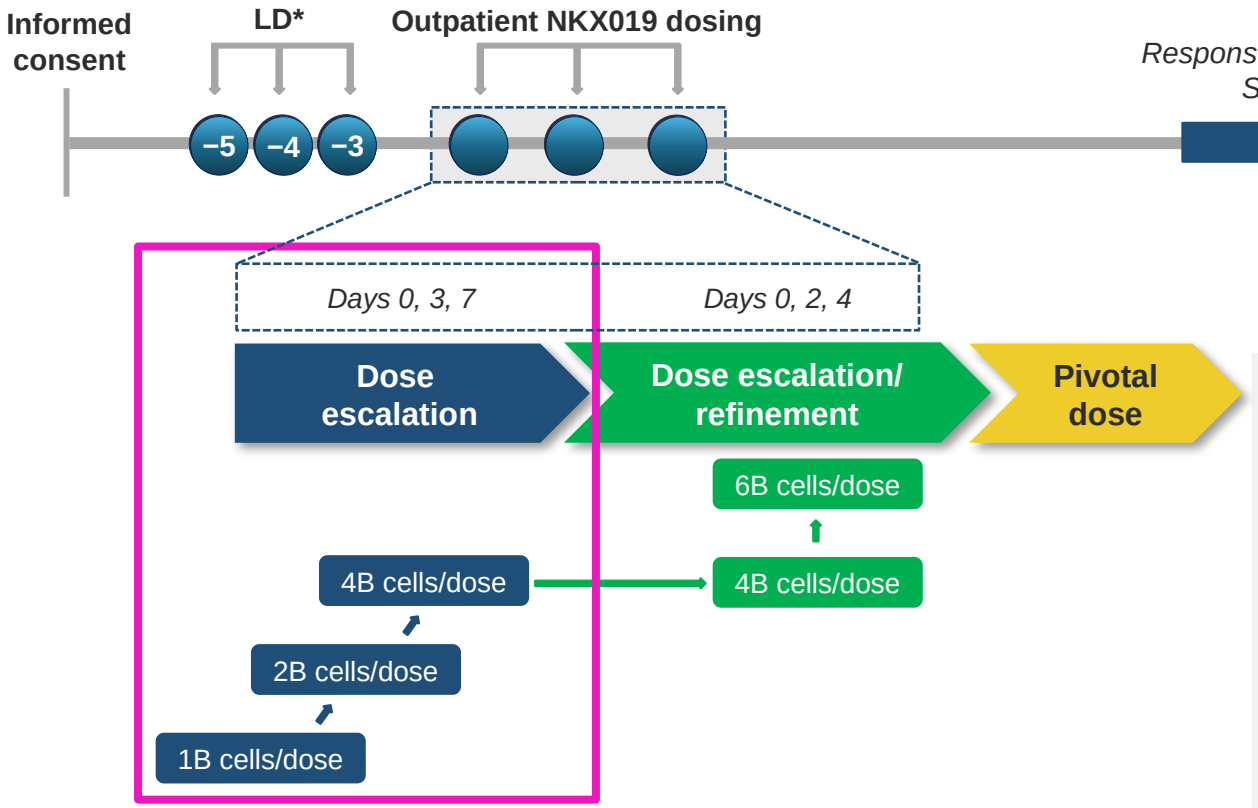
NTRUST-2 (NCT06733935)

Key IIM inclusion

- Probable or definite IIM and inadequate response to ≥2 prior immunosuppressive therapies, including glucocorticoids
- Myositis antibody positive
- Aged 18–75 years
- MMT-8 score ≥80 and <136/150

Key IIM exclusion

- Major organ dysfunction, immunodeficiencies, and previous solid organ transplant or cell therapy
- Evidence of severe chronic muscle atrophy or fibrofatty replacement



Key endpoints

- Safety assessments, including CRS, ICANS, IEC-HS, GVHD, and serious infections
- NKX019 exposure, B-cell depletion, and B-cell immune reset
- Clinical response in TIS, MMT-8, and CDASI-A

Objective: Report the safety, PK/PD, and clinical activity of NKX019 in patients with IIM during the dose-escalation phase of the NTRUST-2 study

*LD preconditioning = a total of 90 mg/m^2 Flu as 30 mg/m^2/day on Days −5, −4, and −3 and 1 g/m^2/day Cy on Day −3. Patients with cytopenia may receive Cy alone as 1 g/m^2 Cy on Day –3. LD preconditioning is performed in an outpatient setting for both treatments. B, billion; CDASI-A, Cutaneous Dermatomyositis Disease Area and Severity Index Activity Score; 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; IIM, idiopathic inflammatory myopathy; LD, lymphodepletion; MMT-8, Manual Muscle Testing 8; PD, pharmacodynamics; PK, pharmacokinetics; TIS, Total Improvement Score.

All Patients With IIM Had Active, Refractory Disease at Baseline Despite Treatment With GCs and Immunomodulatory Agents

Measure	Overall N = 11	Disease Subtype		
		DM / JDM* n = 6 / n = 2	ASyS n = 2	IMNM n = 1
Age, median (range), years	46.0 (19–63)	47.5 (19–63)	40.5 (22–59)	28
Female, n (%)	11 (100)	8 (100)	2 (100)	1 (100)
Disease duration, median (range), years	3.5 (0.3–30.3)	4.1 (1.3–30.3)	1.1 (0.3–1.9)	8.7
Myositis-specific autoantibody,† % positive				
Mi-2	27.3	37.5	0	0
TIF1-γ	9.1	12.5	0	0
MDA5	18.2	25.0	0	0
SRP	0	0	0	0
HMGCR	9.1	0	0	100
Jo-1	18.2	0	100	0
NXP-2	9.1	12.5	0	0

Measure	Overall N = 11	Disease Subtype		
		DM / JDM n = 6 / n = 2	ASyS n = 2	IMNM n = 1
Baseline disease activity, median (range)				
MMT-8	117.0 (85.0–135.0)	118.5 (85.0–135.0)	99.0 (86.0–112.0)	122.0
CDASI-A	17.0 (0–32.0)	19.0 (7.0–32.0)	3.5 (0–7.0)	–
HAQ-DI score	1.3 (0.8–2.8)	1.2 (0.8–2.8)	1.4 (0.9–2.0)	1.9
CGA score	6.5 (3.0–8.5)	4.6 (3.0–7.6)	7.8 (7.0–8.5)	6.8
PtGA score	7.3 (0.2–8.6)	7.2 (0.2–8.6)	7.9 (7.2–8.5)	7.6
Creatine kinase	200.0 (25.0–3240.0)	66.5 (25.0–3240.0)	334.5 (200.0–469.0)	986.0
Aldolase	5.8 (3.4–31.9)	4.5 (3.4–31.9)	9.1 (5.8–12.4)	7.6
EMA	4.1 (1.1–8.2)	4.0 (1.1–6.1)	6.3 (4.4–8.2)	4.0
Number of prior treatments, n (%)				
1–3	2 (18.2)	2 (25.0)	0	0
≥4	9 (81.8)	6 (75.0)	2 (100)	1 (100)
Prior treatments,‡ n (%)				
Systemic GCs	7 (63.6)	4 (50.0)	2 (100)	1 (100)
cDMARDs	10 (90.9)	7 (87.5)	2 (100)	1 (100)
Rituximab	4 (36.4)	3 (37.5)	0	1 (100)
IVIG	5 (45.5)	3 (37.5)	1 (50.0)	1 (100)
Other§	6 (54.5)	4 (50.0)	1 (50.0)	1 (100)

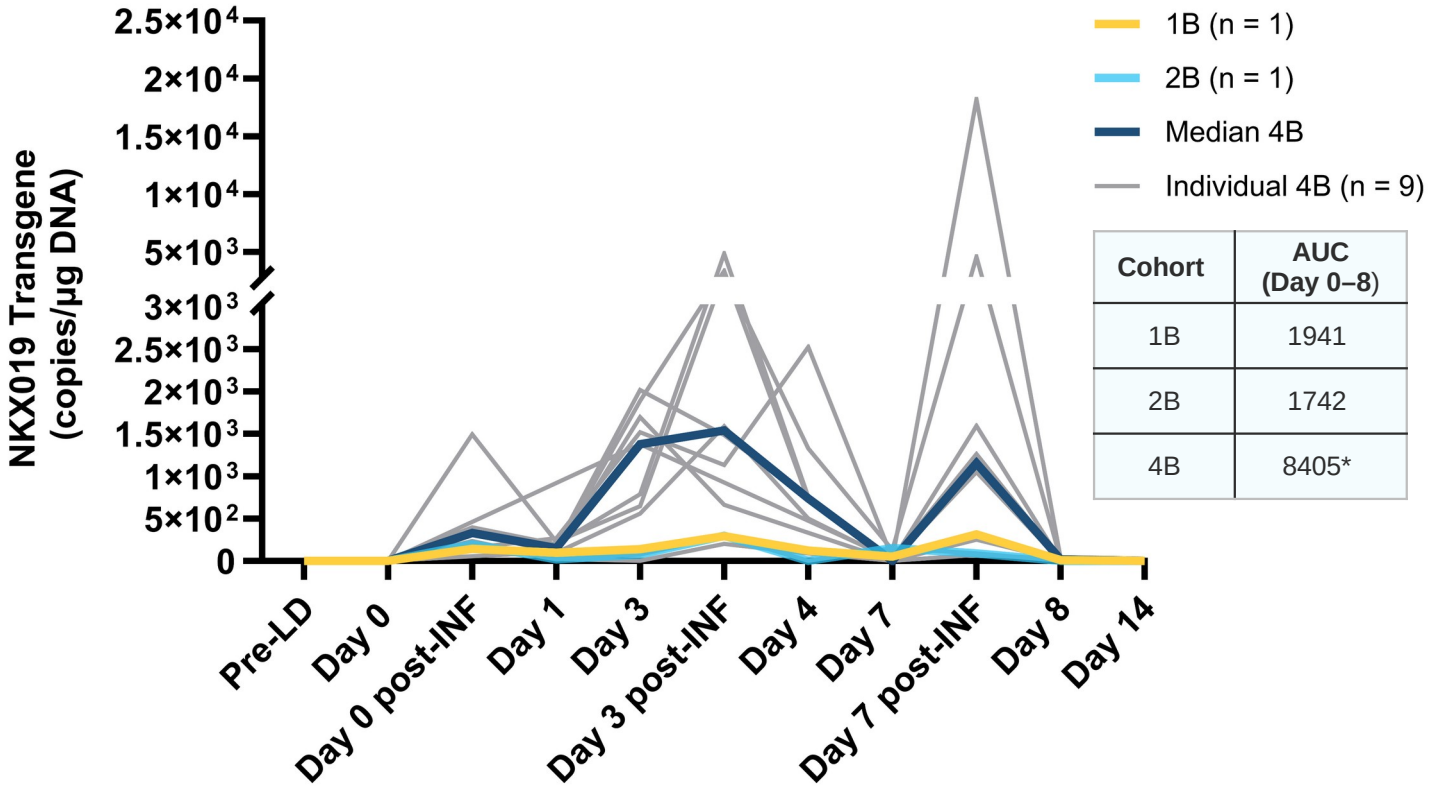
Data as of September 18, 2026. *One JDM patient was only positive for Ro 52/60 autoantibody. †Autoantibody presence is calculated in all patients. ‡At screening prior to LD preconditioning. §Other treatments included antimalarials, calcineurin inhibitors, Janus kinase inhibitors, and biologics.

ASyS, antisynthetase syndrome; CDASI-A, Cutaneous Dermatomyositis Disease Area and Severity Index Activity Score; CGA, Clinician Global Assessment; cDMARD, conventional disease-modifying antirheumatic drug; DM, dermatomyositis; EMA, extramuscular global activity; GC, glucocorticoid; HAQ-DI, Health Assessment Questionnaire Disability Index; HMGCR, 3-hydroxy-3-methylglutaryl-coenzyme A reductase; IIM, idiopathic inflammatory myopathy; IMNM, immune-mediated necrotizing myopathy; IVIG, intravenous immunoglobulin; Jo-1, histidyl-transfer RNA (tRNA) synthetase; JDM, juvenile dermatomyositis; MDA5, melanoma differentiation-associated gene 5; Mi-2, Mi-2 nuclear helicase; MMT-8, Manual Muscle Testing 8; NXP-2, nuclear matrix protein 2; PtGA, Patient Global Assessment; SRP, signal recognition particle; TIF1-γ, transcription intermediary factor 1-gamma.

RESULTS

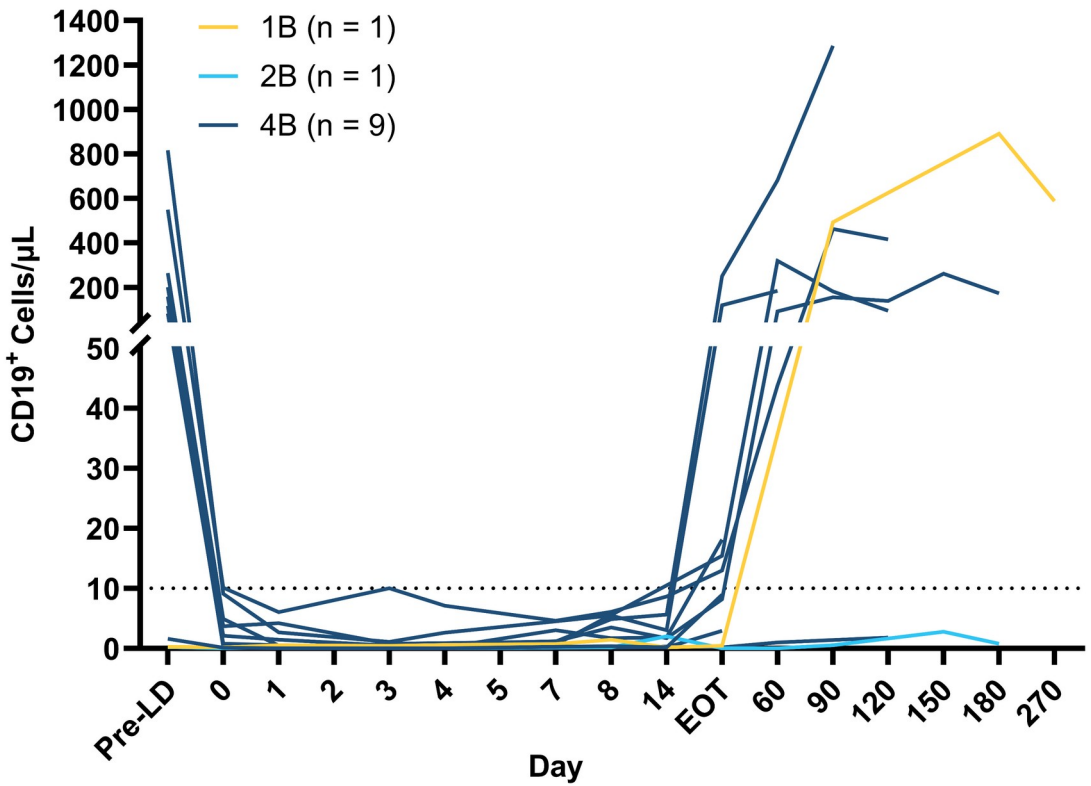
Robust CD19⁺ B Cell Depletion Was Observed

PK of NKX019



Cohort	AUC (Day 0–8)
1B	1941
2B	1742
4B	8405*

Peripheral B Cell Depletion†



At 4B cells/dose, NKX019 overall exposure translated into rapid, deep B cell depletion

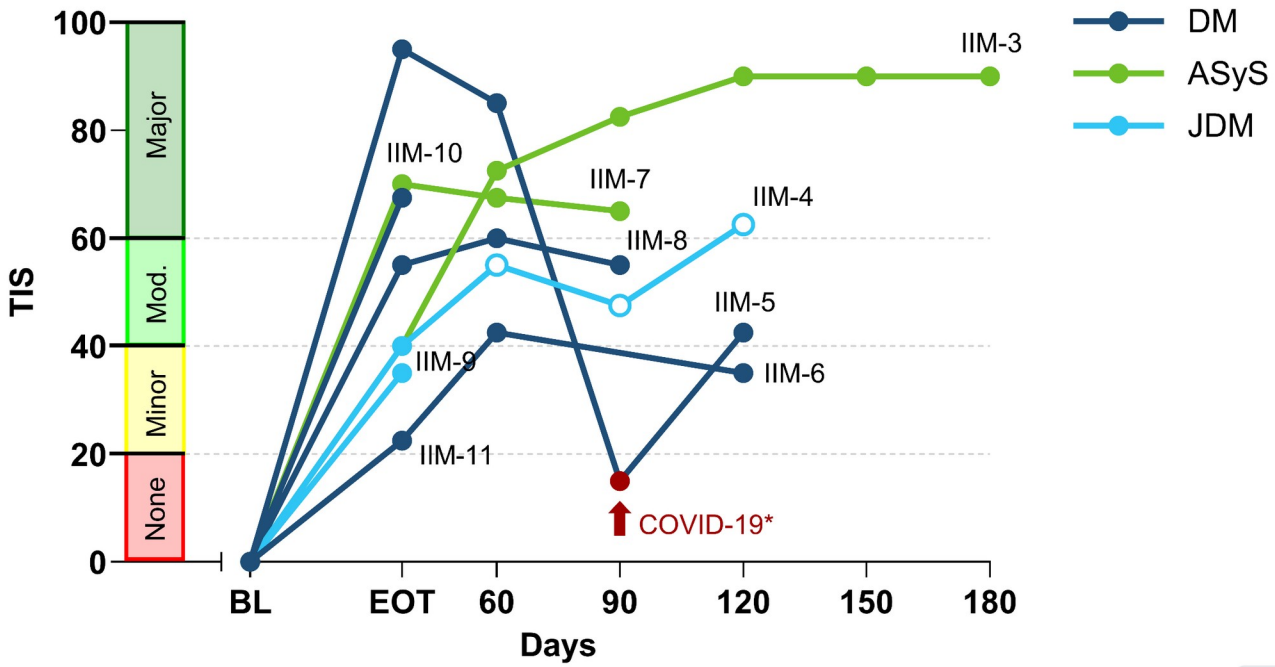
Data as of September 18, 2026. *Value represents the GM AUC. †Four patients did not have detectable B cells at baseline due to prior treatment with rituximab. Ten cells/µL is the clinically reliable threshold for peripheral B cell depletion and is represented with a dotted line.[1-2]

AUC, area under the curve; B, billion; DNA, deoxyribonucleic acid; EOT, end of treatment; GM, geometric mean; INF, infusion; LD, lymphodepletion preconditioning; PK, pharmacokinetics.

1. Revie L, et al. *Mult Scler*. 2025;31(7):813-820. 2. Rodriguez-Mogeda C, et al. *J Neuroinflammation*. 2023;20(1):215.

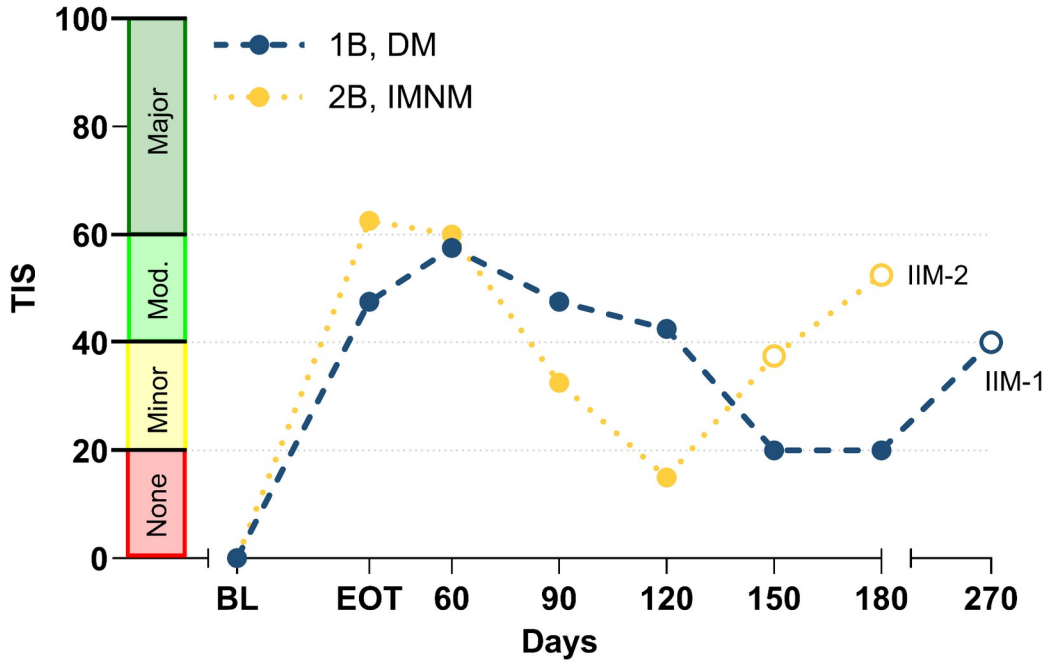
Moderate-to-Major TIS Responses Were Achieved at 4B Cells/Dose

NKX019 4B Cells/Dose



4B cells/dose, n =	9	9	6	5	4	1	1

NKX019 1B and 2B Cells/Dose



1B cells/dose, n =	1	1	1	1	1	1	1	1
2B cells/dose, n =	1	1	1	1	1	1	1	0

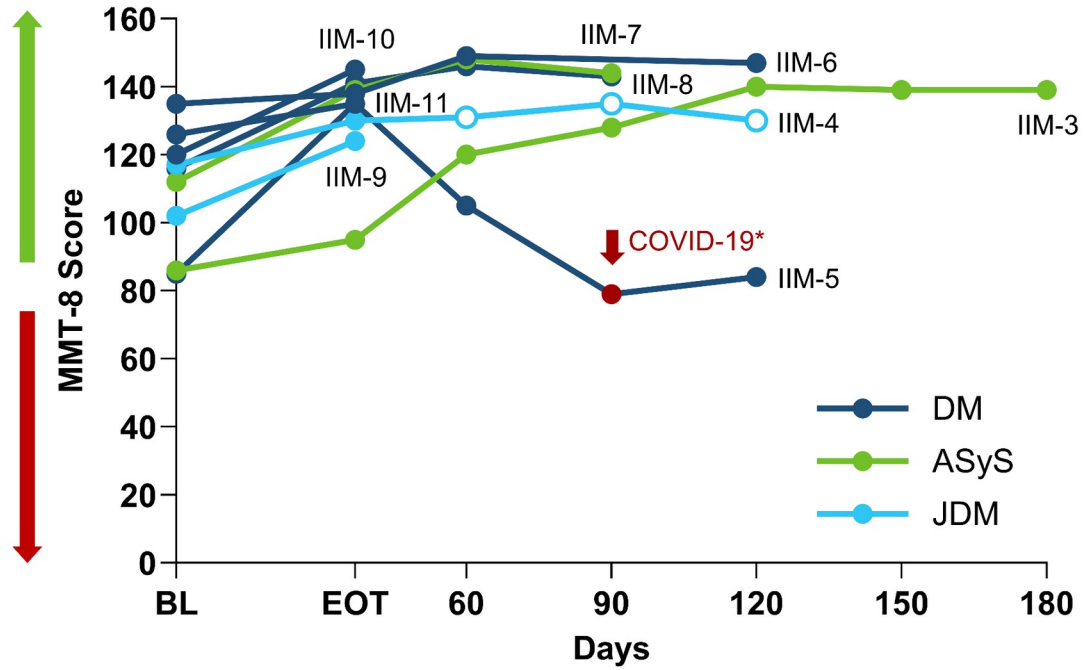
Five of 6 (83.3%) patients receiving 4B cells/dose with ≥3 months follow-up achieved a moderate-to-major TIS response

Data as of September 18, 2026. TIS was evaluated in patients who received LD preconditioning and 3 doses of NKX019 and had at least 1 post-baseline efficacy-evaluable assessment. Open circles indicate visits where administration of additional immunomodulatory agents (cDMARDs, IVIG, and/or rituximab) may have contributed to clinical efficacy. *IIM-5 diagnosed with COVID-19 infection, followed by a DM flare.

ASyS, antisynthetase syndrome; B, billion; BL, baseline; cDMARD, conventional disease-modifying antirheumatic drug; DM, dermatomyositis; EOT, end of treatment; IIM, idiopathic inflammatory myopathy; IMNM, immune-mediated necrotizing myopathy; IVIG, intravenous immunoglobulin; JDM, juvenile dermatomyositis; LD, lymphodepletion; mod, moderate; TIS, Total Improvement Score.

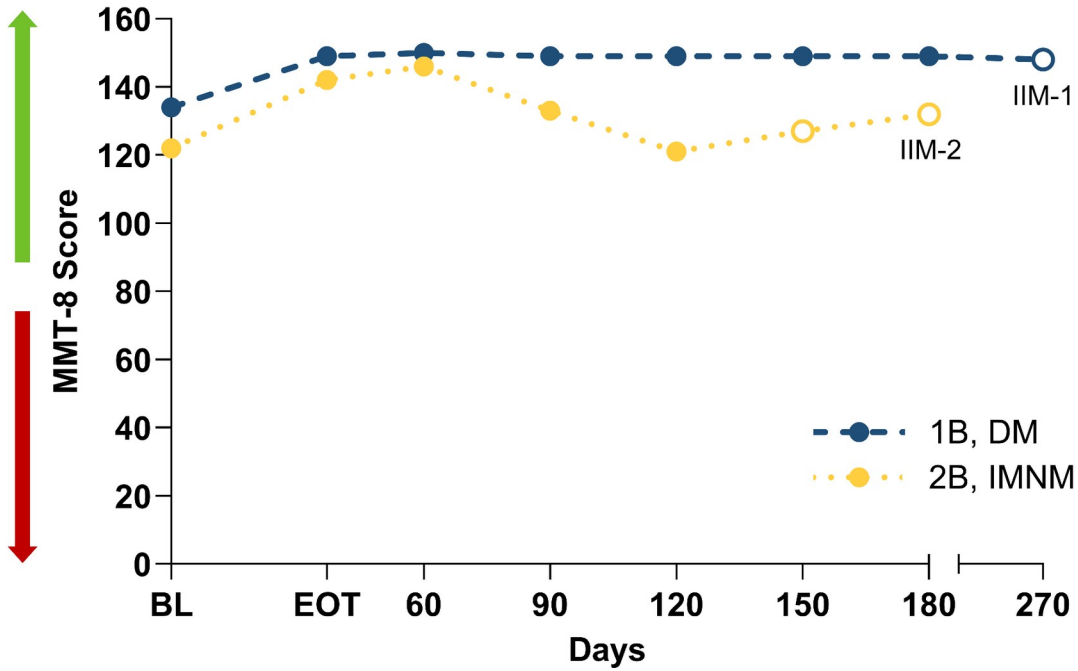
Treatment With NKX019 Led to Improvements in MMT-8 Score

NKX019 4B Cells/Dose



4B cells/dose, n =	9	9	6	5	4	1	1

NKX019 1B and 2B Cells/Dose



1B cells/dose, n =	1	1	1	1	1	1	1	1
2B cells/dose, n =	1	1	1	1	1	1	1	0

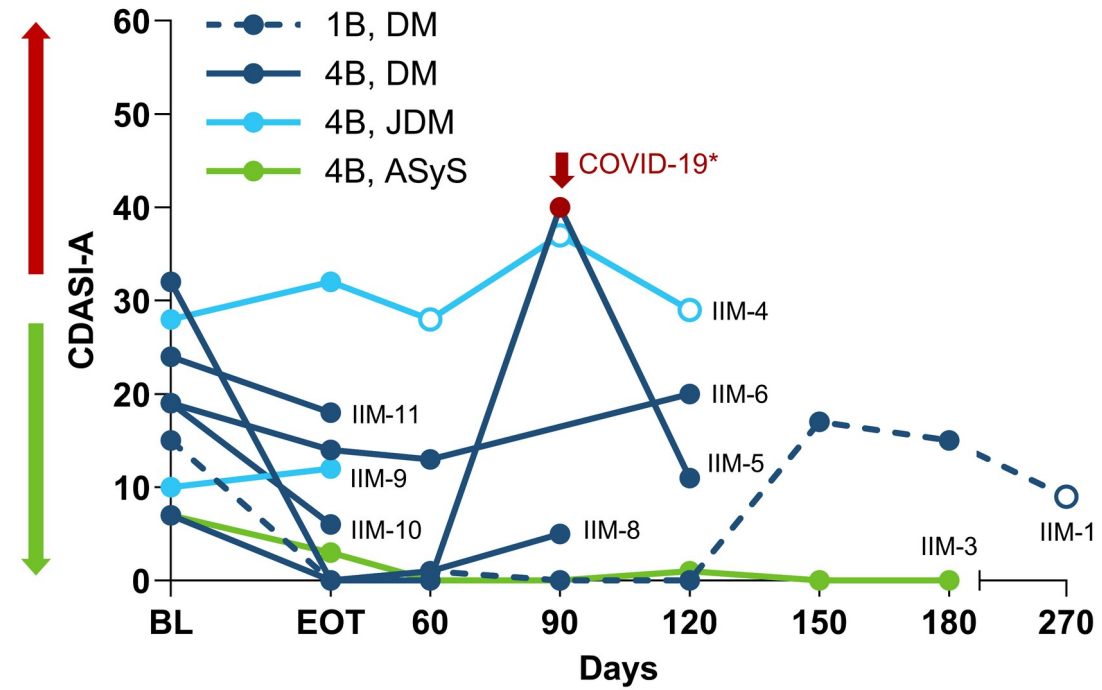
Five of 6 (83.3%) patients receiving 4B cells/dose with ≥3 months follow-up achieved increases in their MMT-8 score

Data as of September 18, 2026. MMT-8 was evaluated in patients who received LD preconditioning and 3 doses of NKX019 and had at least 1 post-baseline efficacy-evaluable assessment. Open circles indicate visits where administration of additional immunomodulatory agents (cDMARDs, IVIG, and/or rituximab) may have contributed to clinical efficacy. *IIM-5 diagnosed with COVID-19 infection, followed by a DM flare.

ASyS, antisynthetase syndrome; B, billion; BL, baseline; cDMARD, conventional disease-modifying antirheumatic drug; DM, dermatomyositis; EOT, end of treatment; IIM, idiopathic inflammatory myopathy; IMNM, immune-mediated necrotizing myopathy; IVIG, intravenous immunoglobulin; JDM, juvenile dermatomyositis; LD, lymphodepletion; MMT-8, Manual Muscle Testing-8.

Treatment With NKX019 Led to Reductions in CDASI-A

NKX019 1B and 4B Cells/Dose



1B cells/dose, n =	1	1	1	1	1	1	1	1
4B cells/dose, n =	8	8	5	4	4	1	1	0

Four of 8 (50.0%) patients receiving 4B cells/dose achieved clinically relevant reductions in CDASI-A, with 4 patients remaining relatively stable compared to baseline

Data as of September 18, 2026. CDASI-A was evaluated in patients who received LD preconditioning and 3 doses of NKX019 and had at least 1 post-baseline efficacy-evaluable assessment. Open circles indicate visits where administration of additional immunomodulatory agents (cDMARDs, IVIG, and/or rituximab) may have contributed to clinical efficacy. *IIM-5 diagnosed with COVID-19 infection, followed by a DM flare.
ASyS, antisynthetase syndrome; B, billion; BL, baseline; CDASI-A, Cutaneous Dermatomyositis Disease Area and Severity Index Activity Score; cDMARD, conventional disease-modifying antirheumatic drug; DM, dermatomyositis; EOT, end of treatment; IIM, idiopathic inflammatory myopathy; IVIG, intravenous immunoglobulin; JDM, juvenile dermatomyositis; LD, lymphodepletion.

NKX019 Treatment Resulted in No Events of CRS, ICANS, IEC-HS, GVHD, or Deaths

Measure, n (%)	Overall N = 11	Disease subtype		
		DM / JDM n = 6 / n = 2	ASyS n = 2	IMNM n = 1
Any NKX019-related AEs	4 (36.4)	4 (50.0)	0	0
Grade ≥3 events	1 (9.1)	1 (12.5)	0	0
Serious NKX019-related AEs	1 (9.1)*	1 (12.5)*	0	0
Serious infections	0	0	0	0
IRRs	1 (9.1)*	1 (12.5)*	0	0
NKX019-related Grade ≥3 hematologic disorders				
Neutropenia	1 (9.1)	1 (12.5)	0	0
Febrile neutropenia	0	0	0	0
Prolonged cytopenias (>28 days)	0	0	0	0
IEC-associated AEs	0	0	0	0
CRS	0	0	0	0
ICANS	0	0	0	0
IEC-HS	0	0	0	0
GVHD	0	0	0	0
Death	0	0	0	0

Data as of September 18, 2026. *Represents the same event

AE, adverse event; ASyS, antisynthetase syndrome; CRS, cytokine release syndrome; DM, dermatomyositis; GVHD, graft-versus-host disease; ICANS, immune effector cell–associated neurotoxicity syndrome; IEC-HS, immune effector cell–associated hemophagocytic lymphohistiocytosis-like syndrome; IMNM, immune-mediated necrotizing myopathy; IRR, infusion-related reaction; JDM, juvenile dermatomyositis.

Key Takeaways

- Five of 6 (83.3%) patients receiving 4B cells/dose with ≥3 months of follow-up achieved a moderate-to-major TIS response
- Robust peripheral B cell depletion was observed following NKX019 infusion
- NKX019 was well tolerated overall and within each IIM subtype
- No CRS, ICANS, IEC-HS, GVHD, or deaths were reported
  - No serious NKX019-related hematologic events were reported

Preliminary NKX019 data in IIM demonstrated a **well-tolerated safety profile** and encouraging clinical activity in the 4B cells/dose cohort; further investigation is warranted

Data as of September 18, 2026.
B, billion; 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; IIM, idiopathic inflammatory myopathy; TIS, Total Improvement Score.

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