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Nipocalimab for Warm Autoimmune Hemolytic Anemia: Results From the Phase 2/3 Randomized Double-Blind ENERGY Study

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Conflicts of Interest

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Warm Autoimmune Hemolytic Anemia is a Life-Threatening, Autoantibody-Driven Disease That May Occur in Association With Other Autoimmune Conditions

Life-threatening, relapsing-remitting, autoantibody-driven disease[1]

- IgG autoantibodies mediate premature destruction of RBCs
- Most patients have severe anemia at onset and ~half require transfusions and hospital admission[2]
- May occur as a **primary** disorder or **secondary** to an underlying condition, including autoimmune diseases such as systemic lupus erythematosus [SLE] and lymphoproliferative disorders

wAIHA results in significant patient burden[2]

- Symptoms include debilitating fatigue
- Frequently require prolonged corticosteroid use[2]
- Main complications include infections and thrombosis[3]
- 5-year mortality was ~30% in a retrospective Swedish cohort[4]

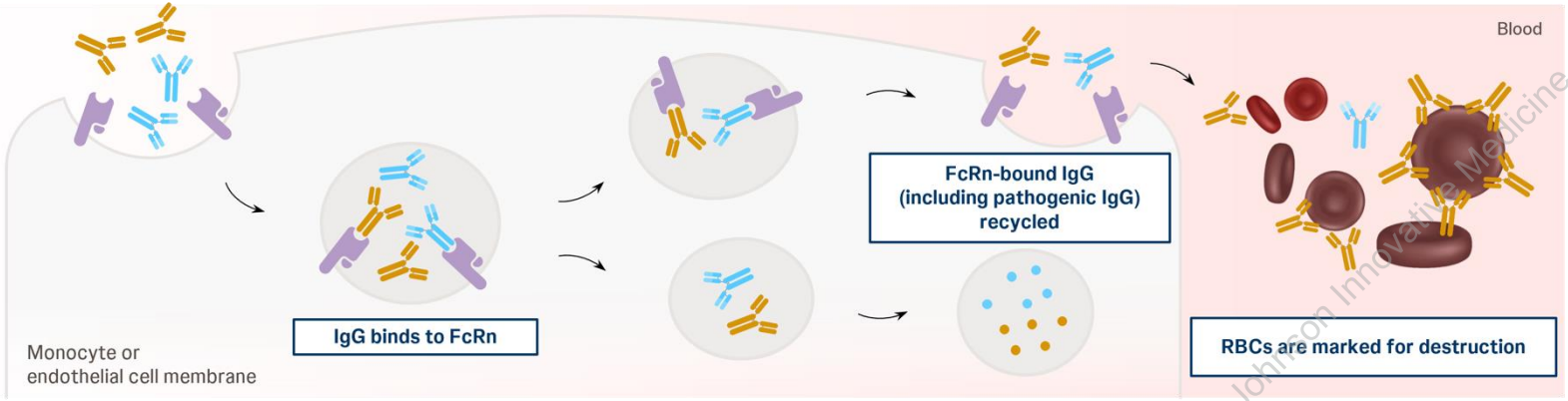
Current management involves off-label broadly immunosuppressive regimens

- Current regimens are associated with relapse and AEs
  - Corticosteroids: two-thirds of patients relapse or do not respond[3,5]
  - Rituximab: half of patients relapse; 2 to 6 months to induce a response[6,7]
- No formal treatment guidelines for the management of wAIHA (with or without other autoimmune conditions)

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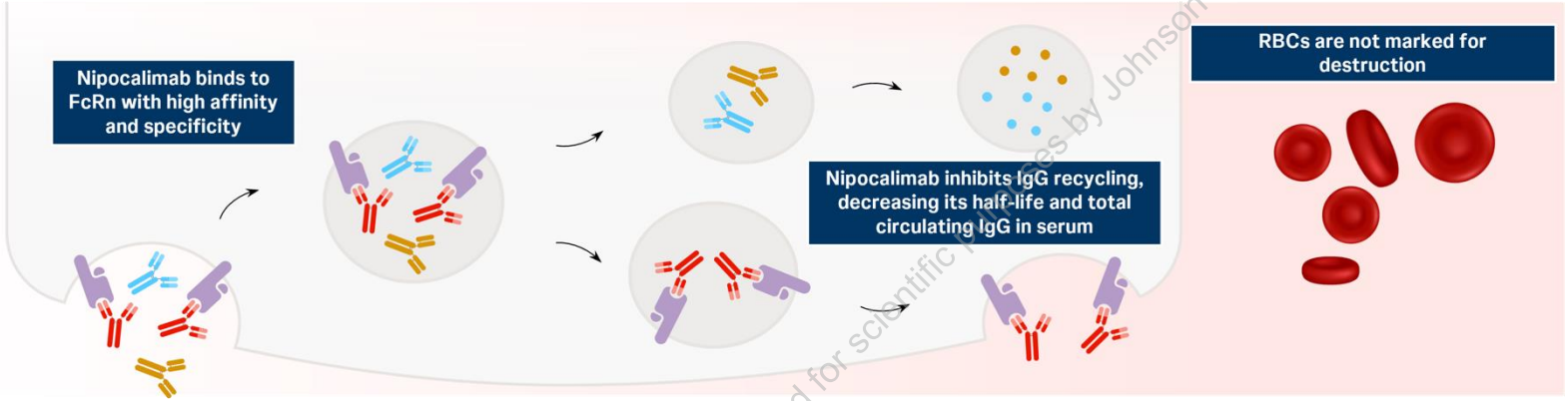
1. Barcellini W. *Transfus Med Hemother*. 2015;42(5):287-293. 2. Pons-Estel GJ, et al. Autoimmunity Rev. 2025;103858. 3. Brodsky RA. *N Engl J Med*. 2019;381(7):647-654. 4. Cherif H, et al. *Eur J Haematol*. 2025;114(1):129-138. 5. Kuter DJ *Hematology Am Soc Hematol Educ Program*. 2022;2022(1):105-113. 6. Murakhovskaya I. *Clin Med*. 2020;9(12):4034. 7. Labson D, et al. Presented at: ASH 67th Annual Meeting; December 6-9, 2025; Orlando, FL, USA.
AE=adverse event, **IgG**=immunoglobulin G, **RBC**=red blood cell, **wAIHA**=warm autoimmune hemolytic anemia.

Nipocalimab Targets FcRn to Reduce Pathogenic Autoantibodies in wAIHA



FcRn:

- A recycling or transcytosis receptor → maintains IgG levels in circulation[1-3]
- Expressed in multiple cell types, including monocytes and endothelial cells[1-3]



Nipocalimab:

- A high-affinity, fully human, IgG1 FcRn blocker → selectively blocks IgG recycling[4]
- Decreases serum IgG, including pathogenic IgG and CICs while preserving immune cell functions[4-6]
- Approved for wAIHA in the US, Brazil, and Panama[7]
- Approved for gMG in the US, Brazil, Panama, Japan, Europe, and China[7]

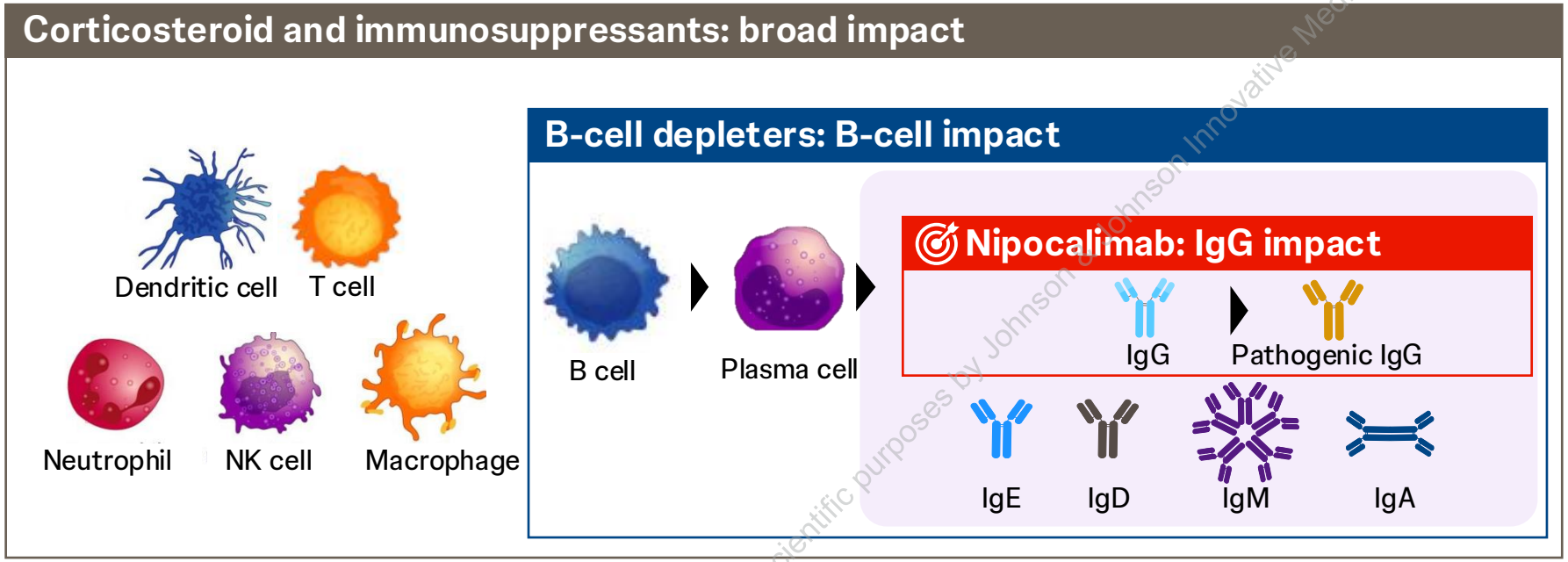
Pathogenic IgG IgG Nipocalimab FcRn

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CIC=circulating immune complex, **FcRn**=neonatal Fc receptor, **gMG**=generalized myasthenia gravis, **IgG**=immunoglobulin G, **RBC**=red blood cell, **wAIHA**=warm autoimmune hemolytic anemia.

1. Blumberg LJ, et al. *Sci Adv*. 2019;5(12):eaax9586. 2. Roopenian DC, Akilesh S. *Nat Rev Immunol*. 2007;7(9):715-725. 3. Peter HH, et al. *J Allergy Clin Immunol*. 2020;146(3):479-491.e5. 4. Seth NP, et al. *MAbs*. 2025;17(1):2461191. 5. Ling LE, et al. *Clin Pharmacol Ther*. 2019;105(4):1031-1039. 6. Noaiseh G, et al. *Lancet*. 2025;406(10518):2435-2448. 7. IMAAVY™ (nipocalimab-aahu) injection, for intravenous use [prescribing information]. Janssen Biotech, Inc.; 2025.

Nipocalimab Lowers IgG, Including Pathogenic Autoantibodies, While Preserving Immune Function[1-5]



In wAIHA, nipocalimab lowers anti-RBC pathogenic antibodies which is correlated with an increase in hemoglobin[6]

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1. Challa DK, et al. *Curr Top Microbiol Immunol.* 2014;382:249-272. 2. Ling LE, et al. *Clin Pharmacol Ther.* 2019;105(4):1031-1039. 3. Seth NP, et al. *Mabs.* 2025;17(1):2461191. 4. Yu F, et al. *Hum Vaccin Immunother.* 2026;22(1):2664331. 5. Cossu M, et al. *Hum Vaccin Immunother.* 2025;21(1):2491269. 6. Fattizzo B, et al. *HemaSphere.* 2026; 10(S1): 2055.
FcRn=neonatal Fc receptor, **IgG**=immunoglobulin G, **NK**=natural killer, **RBC**=red blood cell, **wAIHA**=warm autoimmune hemolytic anemia.

ENERGY Phase 2/3 Study Design

Objective

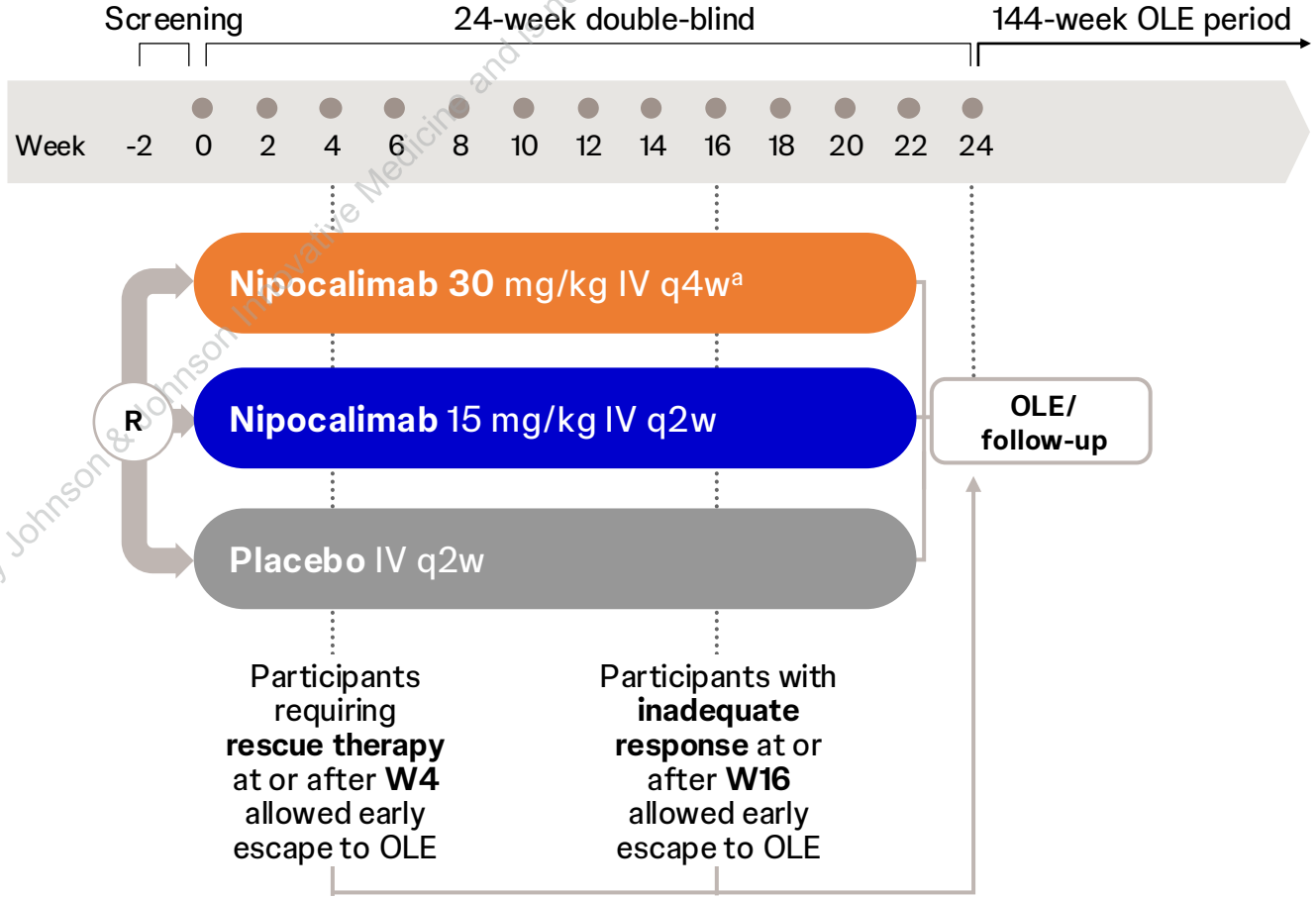
- Evaluate the safety and efficacy of nipocalimab versus placebo for the treatment of wAIHA

Participants

- ≥18 years of age
- Primary or secondary wAIHA (for ≥3 months)
- Current or previous treatment
- Hgb <10 g/dL
- Positive DAT (IgG or IgG+C3d)
- Evidence of hemolysis

Background treatment

- Stable doses of corticosteroids and/or immunosuppressants allowed
- Those on corticosteroids meeting the primary endpoint are required to taper corticosteroids by 10% q2w



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ClinicalTrials.gov identifier: NCT04119050.
[a]Nipocalimab 30 mg/kg IV at Week 0 and q4w through Week 20 and placebo IV at Week 2 and q4w through Week 22.
C3d=complement component 3d, **DAT**=direct antigen test, **Hgb**=hemoglobin, **IgG**=immunoglobulin G, **IV**=intravenous, **OLE**=open-label extension, **q2w**=every 2 weeks, **q4w**=every 4 weeks, **R**=randomized, **wAIHA**=warm autoimmune hemolytic anemia.

Study Endpoints

Primary Endpoint: Durable Hemoglobin Response

- Hgb ≥10 g/dL **AND**
- Hgb increase ≥2 g/dL from baseline **AND**
- For 3 consecutive visits (≥28 days) **AND**
- Starting by Week 16 **AND**
- Without rescue therapy or dose modification of ongoing stable background treatment for wAIHA, including any increase in oral corticosteroids

Key Secondary Endpoints

- Improvement in FACIT-Fatigue (Week 24)
- Corticosteroid dose reduction (Week 24; % reduction in daily corticosteroid dose[a])

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[a]Prednisone equivalent.
FACIT-Fatigue=Functional Assessment of Chronic Illness Therapy – Fatigue, **Hgb**=hemoglobin, **wAIHA**=warm autoimmune hemolytic anemia.

Baseline Characteristics Were Consistent With the wAIHA Patient Population

Baseline characteristics	Nipocalimab 30 mg/kg q4w (n=38)	Nipocalimab 15 mg/kg q2w (n=38)	Placebo (n=39)
Mean age (range), years	56.1 (24-79)	53.1 (18-80)	59.9 (24-86)
Female	55%	58%	51%
Primary wAIHA[a]	92%	87%	82%
Median (IQR) time since diagnosis, months	32 (20-60)	44 (21-81)	23 (17-71)
Mean (SD) baseline hemoglobin, g/dL	9.2 (1.4)	8.6 (1.3)	9.0 (1.4)
Mean (SD) FACIT-Fatigue score	34.5 (10.7)	35.0 (10.5)	31.1 (12.2)
Concomitant medications for wAIHA			
No concomitant treatment	11%	13%	13%
Prednisone-eq ≤20 mg/day (with or without IST)	50%	71%	62%
Prednisone-eq >20 mg/day (with or without IST)	24%	16%	15%
IST only[b]	16%	0%	10%
Mean (SD) prednisone-eq corticosteroid dose, mg/day	21.4 (17.2)	17.9 (22.7)	15.4 (17.8)
Prior treatments for wAIHA (%)			
Prior rituximab use	42%	55%	49%
Prior transfusions	58%	58%	59%
Prior splenectomy	3%	16%	10%

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[a]Stratification factors (primary or versus secondary wAIHA; screening hemoglobin ≤8.5 g/dL or versus >8.5 g/dL; no treatment or corticosteroids at dose ≤20 mg/day of prednisone or equivalent with no immunosuppressants versus immunosuppressants or corticosteroids at >20 mg/day of prednisone or equivalent or no such treatment). [b]Included azathioprine, ciclosporin, mycophenolate mofetil, cyclophosphamide, danazol. **CS**=corticosteroids, **eq**=equivalent, **FACIT-Fatigue**=Functional Assessment of Chronic Illness Therapy – Fatigue, **IQR**=interquartile range, **IST**=immunosuppressive therapy, **q2w**=every 2 weeks, **q4w**=every 4 weeks, **SD**=standard deviation, **wAIHA**=warm autoimmune hemolytic anemia.

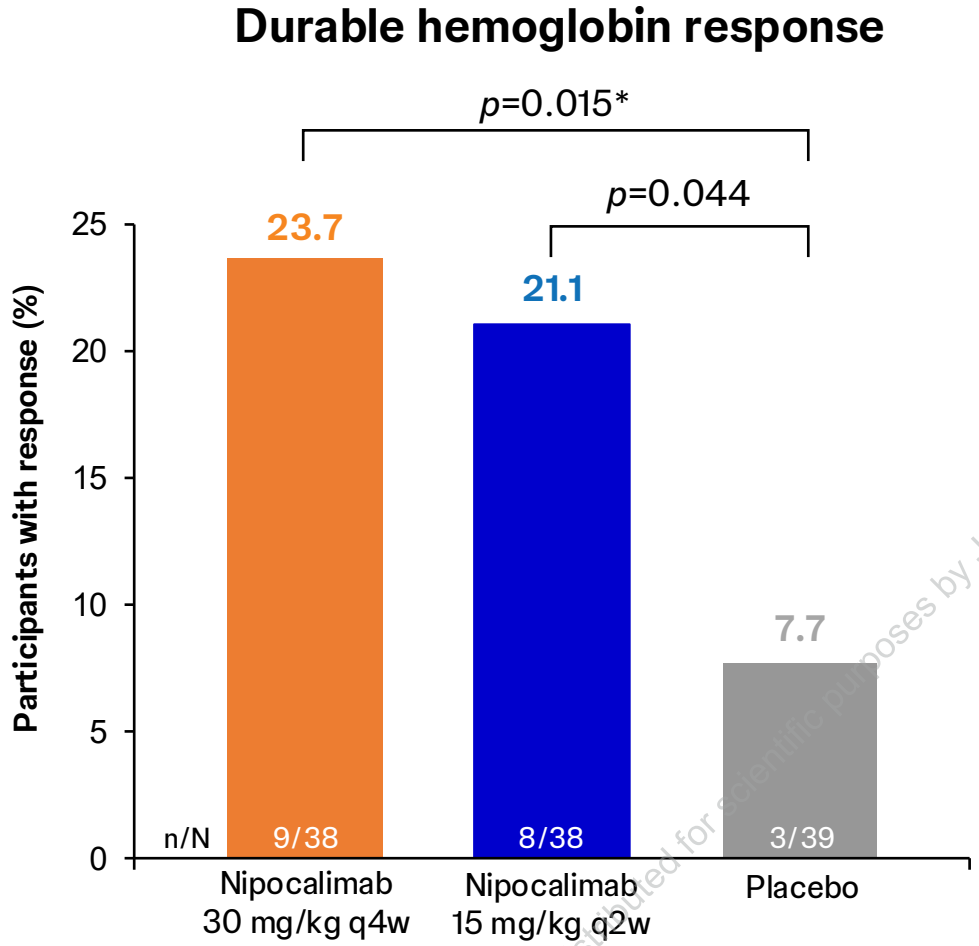
12% of Participants had Pre-Existing Conditions to wAIHA Diagnosis (Secondary wAIHA)

wAIHA disease classification[a]	Nipocalimab 30 mg/kg q4w (n=38)	Nipocalimab 15 mg/kg q2w (n=38)	Placebo (n=39)
Primary	35 (92.1)	33 (86.8)	32 (82.1)
Secondary	3 (7.9)	5 (13.2)	7 (17.9)
Chronic lymphocytic leukemia	0	1 (2.6)	3 (7.7)
SLE	0	2 (5.3)	1 (2.6)
Antiphospholipid syndrome	1 (2.6)	0	0
Autoimmune lymphoproliferative syndrome	0	0	1 (2.6)
Cutaneous T-cell lymphoma	1 (2.6)	0	0
Evans syndrome	0	1 (2.6)	0
Myelodysplastic syndrome	1 (2.6)	0	0
Rheumatoid arthritis	0	0	1 (2.6)
T-cell lymphoma	0	0	1 (2.6)
Upper respiratory tract infection	0	1 (2.6)	0

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[a]Categories based on baseline data and not the interactive response technology system.
q2w=every 2 weeks, **q4w**=every 4 weeks, **SLE**=Systemic Lupus Erythematosus , **wAIHA**=warm autoimmune hemolytic anemia.

Nipocalimab 30 mg/kg q4w Significantly Improved Durable Hemoglobin Response Versus Placebo (Primary Endpoint)



Durable hemoglobin response defined as:

- Hgb ≥10 g/dL **AND**
- Hgb increase ≥2 g/dL from baseline **AND**
- For 3 consecutive visits (≥28 days) **AND**
- Starting by Week 16 **AND**
- Without rescue therapy or dose modification of ongoing stable background treatment for wAIHA, including any increase in oral corticosteroids

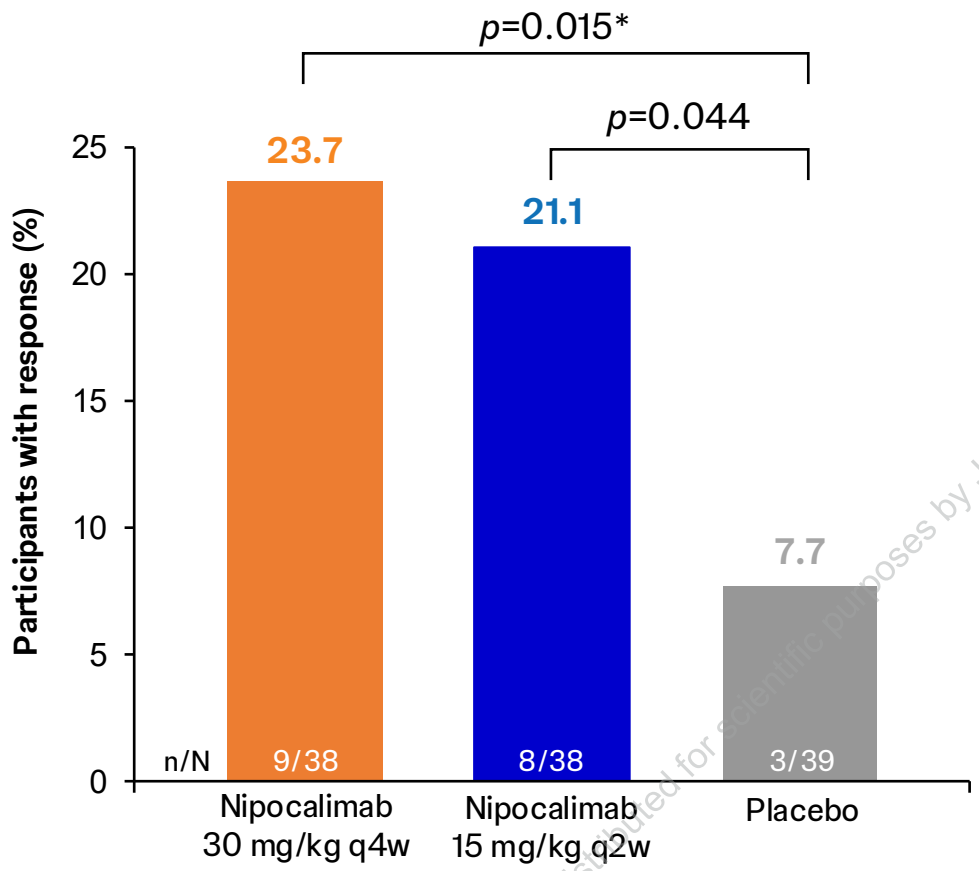
Composite analysis strategy (participants with intercurrent events [including any use of rescue therapies or initiation or dose increase of protocol-specified standard-of-care background therapy] were considered to be nonresponders). *P* values based on equal-weight approach to control the family-wise type I error rate.
*One-sided $p<0.02499$ versus placebo considered significant.

Hgb=hemoglobin, **q2w**=every 2 weeks, **q4w**=every 4 weeks, **wAIHA**=warm autoimmune hemolytic anemia.

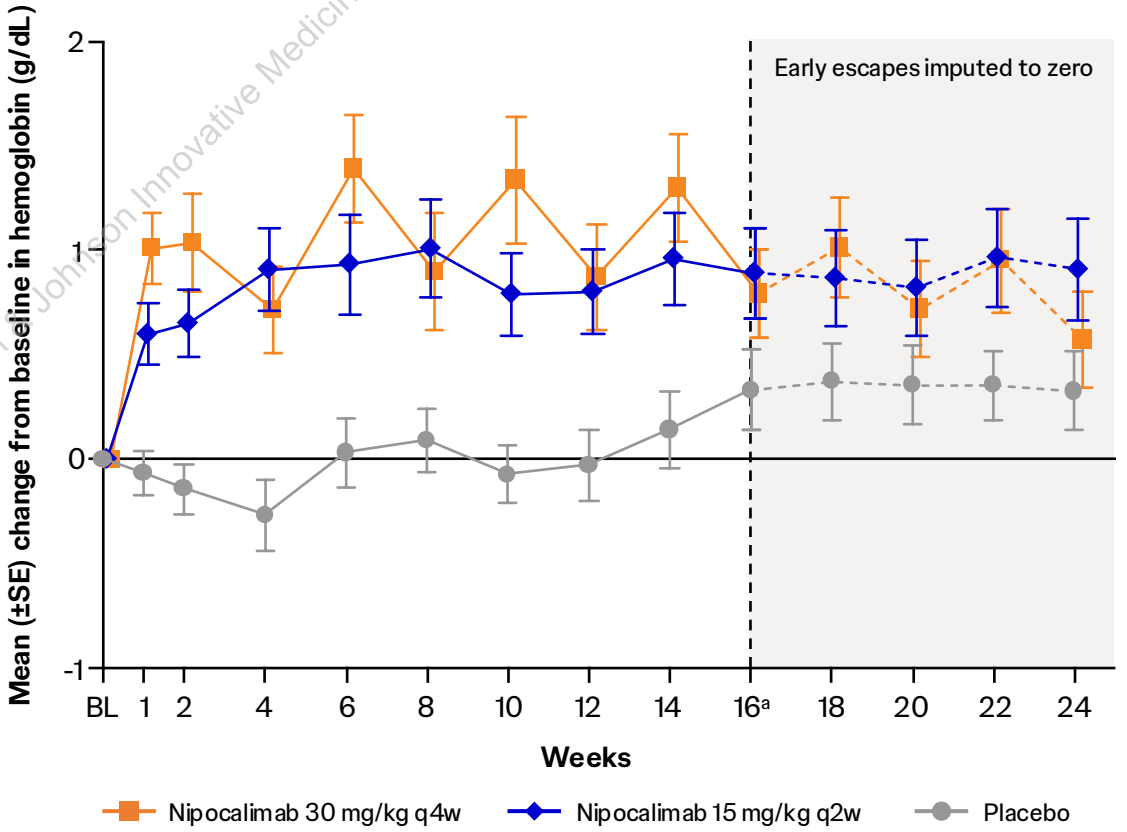
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Hemoglobin Improved by Week 1 and Was Maintained Through Week 24 in Nipocalimab Treatment Groups

Durable hemoglobin response



Change from baseline in hemoglobin

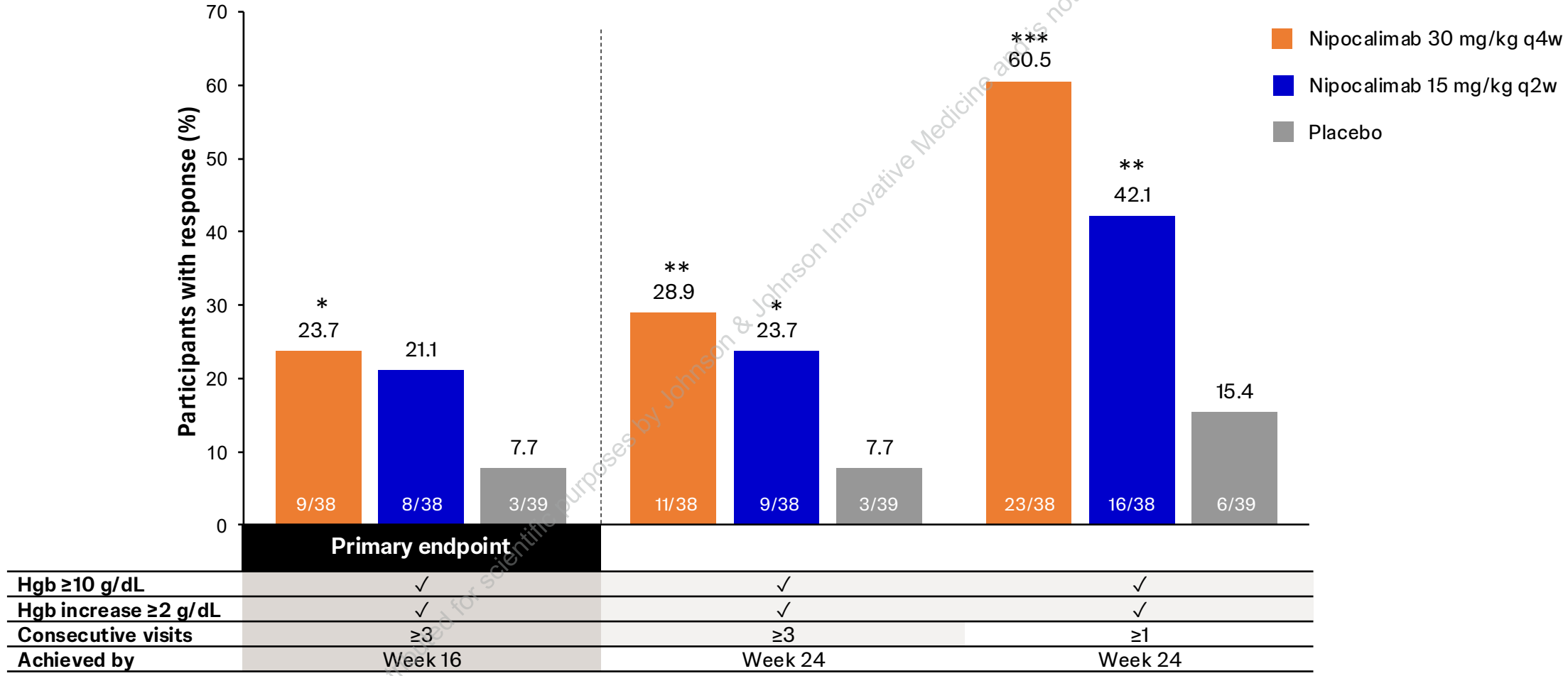


Composite analysis strategy (participants with intercurrent events [including any use of rescue therapies or initiation or dose increase of protocol-specified standard-of-care background therapy] were considered to be nonresponders). *P* values based on equal-weight approach to control the family-wise type I error rate.
*One-sided $p<0.02499$ versus placebo considered significant.

[a]Participants meeting failure criteria (ie, presence of symptoms and failure to demonstrate ≥1 g/dL hemoglobin increase) at or after Week 16 were, at the investigator's discretion, allowed discontinuation of double-blinded treatment and early escape to the OLE. **q2w**=every 2 weeks, **q4w**=every 4 weeks, **SE**=standard error.

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Prespecified Primary Endpoint Analyses Support Durable Hemoglobin Response



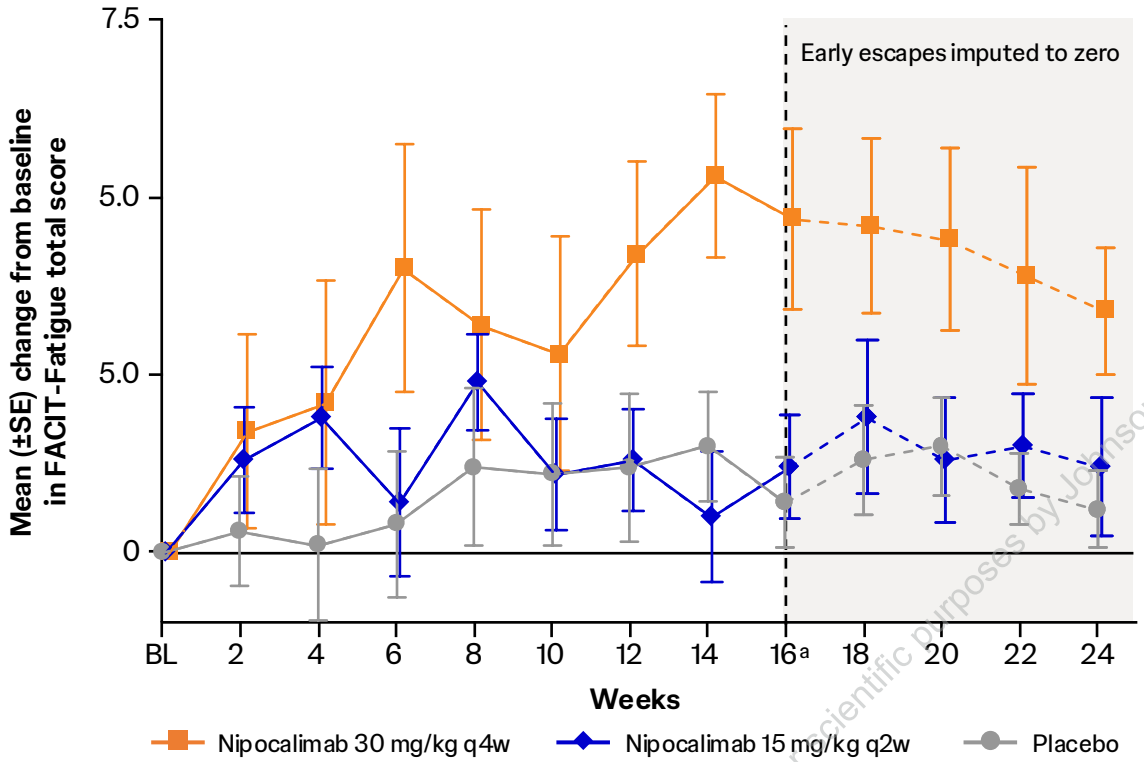
Except for the primary endpoint, all *p* values are nominal. Composite analysis strategy (participants with intercurrent events [including any use of rescue therapies or initiation or dose increase of protocol-specified standard-of-care background therapy] were considered to be nonresponders).
*$p<0.02499$, **$p<0.01$, ***$p<0.001$ versus placebo.

Hgb=hemoglobin.

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Improvements in Secondary Outcomes: FACIT-Fatigue and Steroid Reduction

FACIT-Fatigue total score change from baseline



Fatigue reduction from baseline to Week 24 was nominally significant for nipocalimab 30 mg/kg q4w (p=0.007) versus placebo

Reduction in average daily of corticosteroid[a,b] dose at Week 24

	Nipocalimab 30 mg/kg q4w (n=38)	Nipocalimab 15 mg/kg q2w (n=38)	Placebo (n=39)
Patients taking corticosteroids at baseline, n	26	32	28
Mean change from baseline, mg (SD)	-3.7 (8.3)	-2.5 (6.8)	-0.7 (2.7)
Mean change from baseline, % (SD)	-15.1 (28.24)	-14.0 (30.42)	-3.9 (16.33)
One-sided *p* value (based on LS means on ranks)	0.039	0.055	-

More participants experienced corticosteroid reductions at Week 24 with nipocalimab versus placebo

All p values are nominal, based on an equal-weight approach to control the family-wise type I error rate. Composite analysis strategy: participants with ICE (including any use of rescue therapies or initiation or dose increase of protocol-specified standard-of-care background therapy) are considered to have zero change from baseline if an ICE occurs before timepoint.

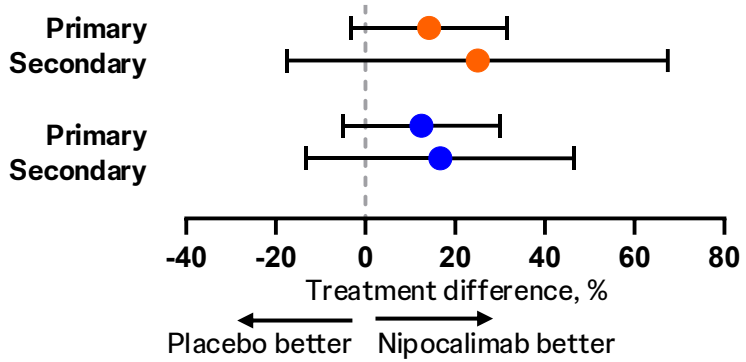
[a]Participants meeting failure criteria (ie, presence of symptoms and failure to demonstrate ≥1 g/dL hemoglobin increase) at or after Week 16 were, at the investigator's discretion, allowed discontinuation of double-blinded treatment and early escape to the OLE. [b]Among participants on corticosteroids at baseline, only those meeting the primary endpoint were allowed to taper corticosteroids.

FACIT-Fatigue=Functional Assessment of Chronic Illness Therapy – Fatigue, **ICE=**intercurrent event, **LS**=least squares, **q2w**=every 2 weeks, **q4w**=every 4 weeks, **SD**=standard deviation, **SE**=standard error.

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Improvements in Primary and Secondary wAIHA: Durable Hemoglobin Response and FACIT-Fatigue

Treatment differences in **durable hemoglobin response** by wAIHA disease classification

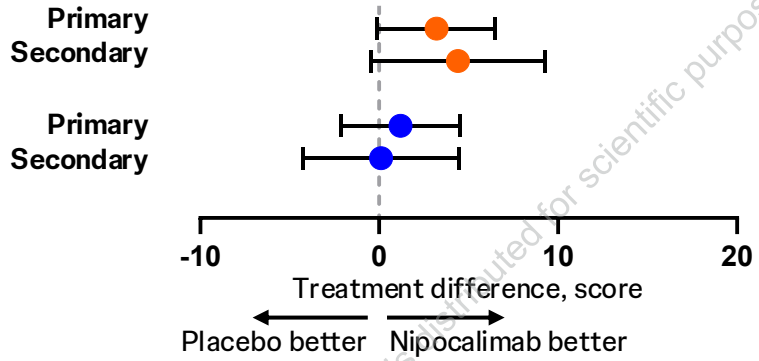


	Placebo (n)	Nipocalimab (n)	Treatment difference (95% CI)
Primary	32	34	14.2 (-3.3, 31.6)
Secondary	7	4	25.0 (-17.4, 67.4)
Primary	32	32	12.5 (-5.0, 30.0)
Secondary	7	6	16.7 (-13.2, 46.5)

Nipocalimab 30 mg/kg q4w

Nipocalimab 15 mg/kg q2w

Treatment differences in **FACIT-Fatigue total score (at Week 24)** by wAIHA disease classification



	Placebo (n)	Nipocalimab (n)	Treatment difference (95% CI)
Primary	30	33	3.2 (-0.12, 6.47)
Secondary	7	4	4.4 (-0.43, 9.27)
Primary	30	31	1.2 (-2.16, 4.53)
Secondary	7	6	0.1 (-4.28, 4.48)

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FACIT=Functional Assessment of Chronic Illness Therapy, **q2w**=every 2 weeks, **q4w**=every 4 weeks, **wAIHA**=warm autoimmune hemolytic anemia.

Improvements in Primary and Secondary wAIHA: Steroid Reduction

Reduction in average daily dose corticosteroid[a,b,c] dose at Week 24

Primary wAIHA

	Nipocalimab 30 mg/kg q4w (n=38)	Nipocalimab 15 mg/kg q2w (n=38)	Placebo (n=39)
Patients taking corticosteroids at baseline, n	23	27	25
Mean change from baseline, % (SD)	-12.7 (23.48)	-13.9 (30.50)	-4.4 (17.26)
One-sided *p* value (based on LS means on ranks)	0.053	0.100	-

Secondary wAIHA

	Nipocalimab 30 mg/kg q4w (n=38)	Nipocalimab 15 mg/kg q2w (n=38)	Placebo (n=39)
Patients taking corticosteroids at baseline, n	3	5	3
Mean change from baseline, % (SD)	-33.3 (57.74)	-15.0 (33.54)	0
One-sided *p* value (based on LS means on ranks)	0.356	0.410	-

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All *p* values are nominal. [a]Participants meeting failure criteria (ie, presence of symptoms and failure to demonstrate ≥1 g/dL hemoglobin increase) at or after Week 16 were, at the investigator's discretion, allowed discontinuation of double-blinded treatment and early escape to the OLE. [b]Composite strategy: participants are considered to have zero change from baseline if an ICE occurs before timepoint.[c]Among participants on corticosteroids at baseline, only those meeting the primary endpoint were allowed to taper corticosteroids. **ICE**=intercurrent event, **LS**=least squares, **q2w**=every 2 weeks, **q4w**=every 4 weeks, **SD**=standard deviation.

Safety Was Consistent With the Known Safety Profile of Nipocalimab and the Known Clinical Risks Associated With wAIHA

AEs in the double-blind period, n (%)	**Nipocalimab 30 mg/kg q4w (n=38)**	**Nipocalimab 15 mg/kg q2w (n=37)[a]**	**Placebo (n=39)**
TEAEs	35 (92.1)	30 (81.1)	35 (89.7)
SAEs	8 (21.1)	6 (16.2)	14 (35.9)
AEs leading to discontinuation	2 (5.3)	5 (13.5)	1 (2.6)
AEs of interest			
Grade ≥3 infections	2 (5.3)	3 (8.1)	5 (12.8)
Adjudicated MACE	0	2 (5.4)	0
Adjudicated VTE (DVT and/or PE)	1 (2.6)	0	0
Hypoalbuminemia (albumin <20 g/L)	0	0	0
Death	0	2 (5.4)	0

- The majority of TEAEs were grade 2 or 3
- The most common AEs (≥10%) among all participants in the combined nipocalimab group were wAIHA (37.2%), diarrhea (11.5%), and fatigue and pyrexia (both 10.3%); the most common AEs among participants in the placebo group were wAIHA (51.3%) and COVID-19 and nasopharyngitis (both 10.3%)
- No participant experienced hypogammaglobulinemia (total IgG <1 g/L for 2 consecutive visits)
- By preferred term, no TEAE leading to discontinuation was reported in more than 1 participant
- Two cases of MACE occurred in participants with complex medical histories in the nipocalimab 15 mg/kg q2w group, later leading to death (causes of death were not related to study treatment)

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[a]One patient was randomized to nipocalimab 15 mg/kg q2w, but did not receive nipocalimab.

AE=adverse event, **DVT**=deep vein thrombosis, **IgG**=immunoglobulin G, **MACE**=major adverse cardiovascular event, **PE**=pulmonary embolism, **q2w**=every 2 weeks, **q4w**=every 4 weeks, **SAE**=serious adverse event, **TEAE**=treatment emergent adverse event, **wAIHA**=warm autoimmune hemolytic anemia, **VTE**=venous thromboembolism.

Conclusions

Nipocalimab, an FcRn blocker that can selectively lower IgG including pathogenic autoantibodies, demonstrated consistent and clinically meaningful benefits across multiple endpoints

- ✓ **Durable hemoglobin response**
  Nipocalimab 30 mg/kg q4w showed a significant durable hemoglobin response and favorable responses in prespecified supporting hemoglobin measures
- ✓ **Rapid, maintained improvement in hemoglobin**
  Hemoglobin increase was rapid, with 1 g/dL improvement observed at Week 1 and maintained over 24 weeks
- ✓ **Fatigue improvement**
  For nipocalimab 30 mg/kg q4w, improvements in fatigue were evident as early as Week 2 and maintained through Week 24
- ✓ **Consistent efficacy in secondary wAIHA**
  The primary and key secondary endpoint results were generally consistent with those in primary wAIHA and the overall study population
- ✓ **Consistent, well-tolerated safety**
  - Nipocalimab was generally well tolerated with no new safety signals identified
  - Occurrence of grade ≥3 infections were no higher than placebo, and no hypogammaglobulinemia was observed
- ✓ **FDA approved Aug 2026 for patients aged ≥ 12 years currently or previously treated with corticosteroids**

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FcRn=neonatal Fc receptor, **IgG**=immunoglobulin G, **q4w**=every 4 weeks.

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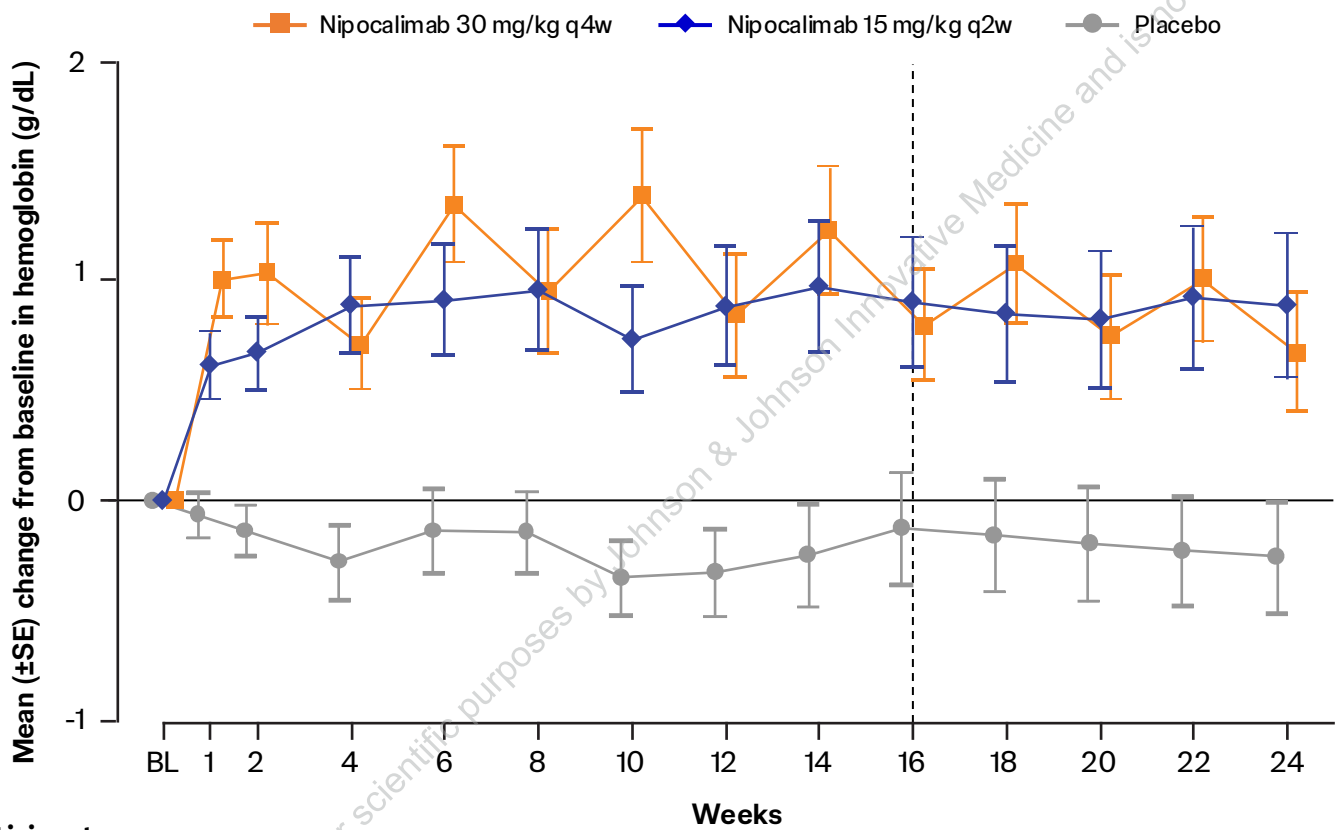
This presentation was previously presented at the European Hematology Association (EHA) Congress; June 11–14, 2026; Stockholm, Sweden.

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Backups

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Mean Hemoglobin Change From Baseline (Last Observation Carried Forward)

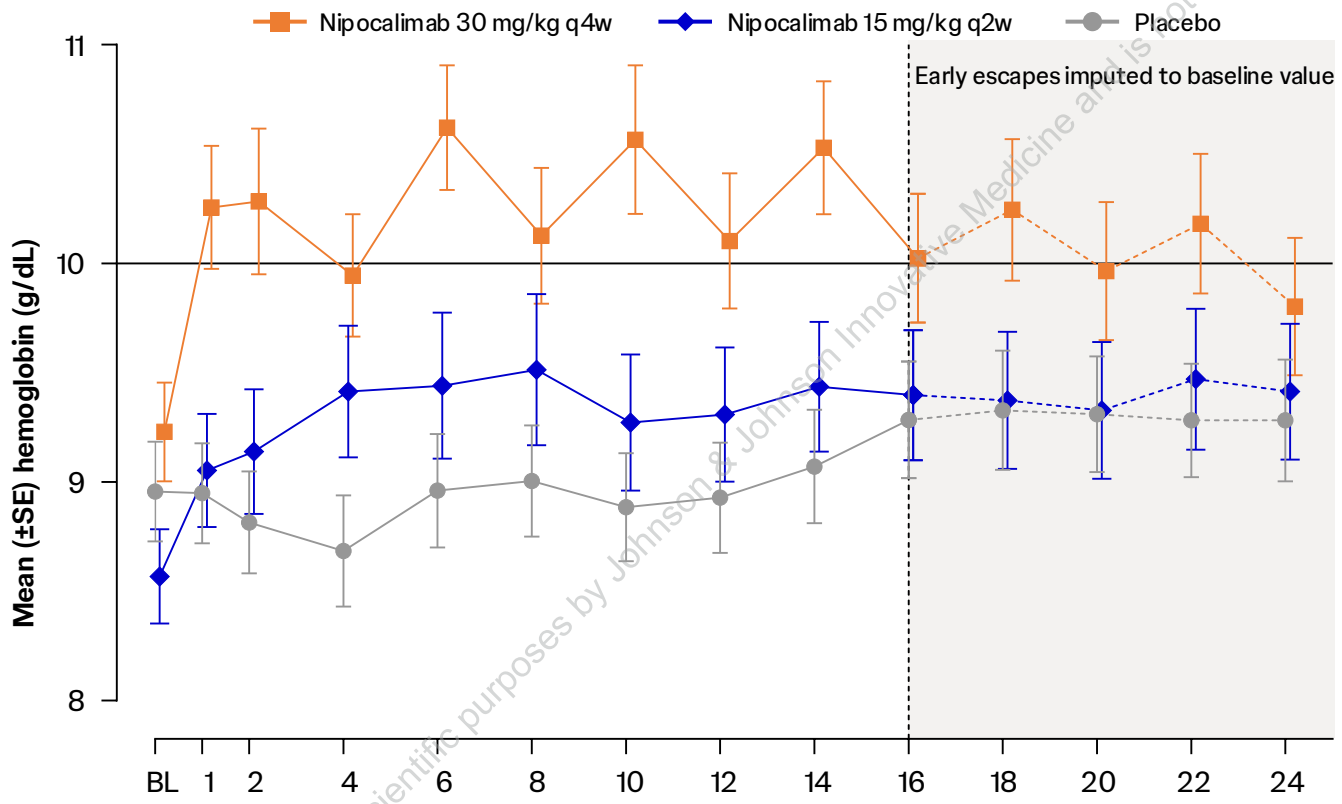


Participants														
Nipocalimab 30 mg/kg IV q4w	38	37	37	38	38	38	38	38	38	38	38	37	38	38
Nipocalimab 15 mg/kg IV q2w	38	33	35	36	36	36	35	36	35	36	36	36	36	36
Placebo	39	35	39	38	38	38	39	39	38	38	39	39	38	39

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BL=baseline, **IV**=intravenous, **q2w**=every 2 weeks, **q4w**=every 4 weeks, **SE**=standard error, **wAIHA**=warm autoimmune hemolytic anemia.

Absolute Hemoglobin Levels Over Time

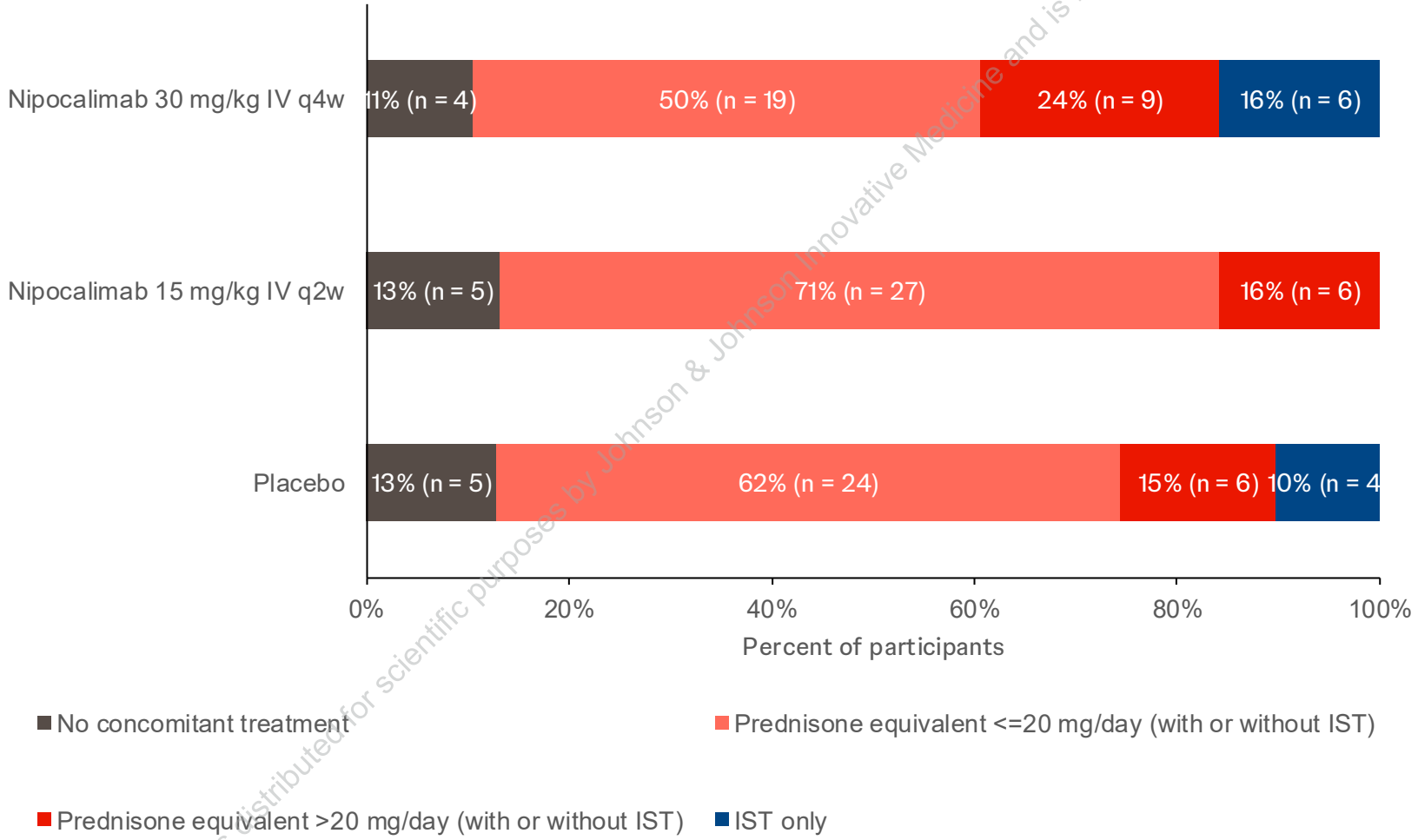


Participants														
Nipocalimab 30 mg/kg IV q4w	38	37	37	38	38	38	38	38	38	38	38	37	38	38
Nipocalimab 15 mg/kg IV q2w	38	34	36	37	37	37	36	37	36	37	37	37	37	37
Placebo	39	35	39	38	38	38	39	39	38	38	39	39	38	39

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Baseline Concomitant Therapies



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