HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use IMAAVY safely and effectively. See full prescribing information for IMAAVY.

IMAAVY® (nipocalimab-aahu) injection, for intravenous use
Initial U.S. Approval: 2025

----------RECENT MAJOR CHANGES----------

Indications and Usage (1.2)	08/2026
Dosage and Administration (2.2, 2.3, 2.4, 2.5)	08/2026
Warnings and Precautions (5.1, 5.2, 5.3)	08/2026

----------INDICATIONS AND USAGE----------

IMAAVY is a neonatal Fc receptor blocker indicated for the treatment of:

- generalized myasthenia gravis (gMG) in adult and pediatric patients 12 years of age and older who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive. (1.1)
- warm autoimmune hemolytic anemia (wAIHA) in adult and pediatric patients 12 years of age and older currently or previously treated with corticosteroids. (1.2)

----------DOSAGE AND ADMINISTRATION----------

- See Full Prescribing Information for instructions on dosage, preparation, and administration. (2.1, 2.2, 2.3, 2.4, 2.5)
- Evaluate the need to administer age-appropriate vaccines according to immunization guidelines before initiation of IMAAVY. (2.1)
- Administer via intravenous infusion only. (2.2, 2.3)
- gMG: The recommended initial dosage is 30 mg/kg once via intravenous infusion over at least 30 minutes. Two weeks after the initial dosage, administer a maintenance dosage of 15 mg/kg via intravenous infusion over at least 15 minutes, and continue every two weeks thereafter. (2.2)
- wAIHA: The recommended initial dosage is 30 mg/kg once via intravenous infusion over at least 30 minutes. Four weeks after the initial dosage, administer a subsequent dosage of 30 mg/kg via intravenous infusion over at least 15 minutes, and continue every four weeks thereafter. (2.3)
- Must be diluted with 0.9% Sodium Chloride Injection prior to administration. (2.5)
- Administer as an intravenous infusion via a 0.2 micron in-line or add-on filter. (2.5)

----------DOSAGE FORMS AND STRENGTHS----------

- Injection: 300 mg/1.62 mL (185 mg/mL) in a single-dose vial (3)
- Injection: 1,200 mg/6.5 mL (185 mg/mL) in a single-dose vial (3)

----------CONTRAINDICATIONS----------

IMAAVY is contraindicated in patients with a history of serious hypersensitivity reaction to nipocalimab-aahu or to any of the excipients in IMAAVY. (4)

----------WARNINGS AND PRECAUTIONS----------

- Infections: Delay administration of IMAAVY to patients with an active infection. Monitor for signs and symptoms of infection in patients treated with IMAAVY. If serious infection occurs, administer appropriate treatment and consider withholding IMAAVY until the infection has resolved. (5.1)
- Hypersensitivity Reactions: Angioedema, anaphylaxis, rash, urticaria, and eczema have occurred in patients treated with IMAAVY. If a hypersensitivity reaction occurs, discontinue the infusion and institute appropriate therapy. (5.2)
- Infusion-Related Reactions: If a severe infusion-related reaction occurs, discontinue the infusion and initiate appropriate therapy; consider the risks and benefits of readministering. If a mild to moderate infusion-related reaction occurs, may rechallenge with close clinical observation, slower infusion rates, and pre-medication. (5.3)

----------ADVERSE REACTIONS----------

- The most common adverse reactions (≥10%) in patients with gMG treated with IMAAVY were respiratory tract infections, peripheral edema, and muscle spasms. (6.1)
- The most common adverse reactions (≥10%) in patients with wAIHA treated with IMAAVY were peripheral edema, diarrhea and pyrexia. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Janssen Biotech, Inc. at 1-800-526-7736 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch.*

----------DRUG INTERACTIONS----------

Closely monitor for reduced effectiveness of medications that bind to the human neonatal Fc receptor. When concomitant long-term use of such medications is essential for patient care, consider discontinuing IMAAVY and using alternative therapies. (7.1)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 08/2026

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

1.1 Generalized Myasthenia Gravis (gMG)

IMAAVY is indicated for the treatment of generalized myasthenia gravis (gMG) in adult and pediatric patients 12 years of age and older who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.

1.2 Warm Autoimmune Hemolytic Anemia (wAIHA)

IMAAVY is indicated for the treatment of warm autoimmune hemolytic anemia (wAIHA) in adult and pediatric patients 12 years of age and older currently or previously treated with corticosteroids.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Vaccination

Evaluate the need to administer age-appropriate vaccines according to immunization guidelines before initiation of IMAAVY. Because IMAAVY causes transient reduction in IgG levels, vaccination with live vaccines is not recommended during treatment with IMAAVY *[see Warnings and Precautions (5.1)]*.

2.2 Recommended Dosage for gMG

Dilute IMAAVY prior to administration. Administer via intravenous infusion only *[see Dosage and Administration (2.5)]*.

Table 1: gMG Recommended Dose Regimen

Initial dosage	Maintenance dosage
30 mg/kg administered once via intravenous infusion over at least 30 minutes.	Two weeks after the initial dose administer a maintenance dose of 15 mg/kg via intravenous infusion over at least 15 minutes. Continue the maintenance dose every two weeks thereafter.

2.3 Recommended Dosage for wAIHA

Dilute IMAAVY prior to administration. Administer via intravenous infusion only *[see Dosage and Administration (2.5)]*.

Table 2: wAIHA Recommended Dose Regimen

Initial dosage	Subsequent dosage
30 mg/kg administered once via intravenous infusion over at least 30 minutes.	Four weeks after the initial dose administer a subsequent dose of 30 mg/kg via intravenous infusion over at least 15 minutes. Continue the subsequent dose every four weeks thereafter.

2.4 Missed Doses

If a scheduled infusion is missed, administer the dose of IMAAVY as soon as possible. Resume dosing, maintaining the treatment interval.

2.5 Preparation and Administration Instructions

Prior to administration, dilute IMAAVY single-dose vials with only 0.9% Sodium Chloride Injection using the instructions below. For patients who weigh 40 kg or more, the total volume to be administered is 250 mL; for patients who are 12 years or older and weigh less than 40 kg, the total volume to be administered is 100 mL *(see Preparation)*.

Preparation

Prepare the solution for infusion using aseptic technique as follows:

- Calculate the dosage (mg), total drug volume (mL) of IMAAVY solution required, and the number of IMAAVY vials needed, based on the patient's current weight *[see Dosage and Administration (2.2, 2.3)]*. Each single-dose vial of IMAAVY is at a concentration of 185 mg/mL.
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Check that the solution in each vial is colorless to slightly brownish, clear to slightly opalescent, and free of visible particles. Do not use if visible particles are present or if the solution is discolored (other than colorless to slightly brownish).
- Gently withdraw the calculated volume of IMAAVY from the vial(s). Discard any unused portion of the vials.
- Dilute total volume withdrawn of IMAAVY by adding to an infusion container containing 0.9% Sodium Chloride Injection to a final volume of:
    - 250 mL for patients who weigh 40 kg or more, or
    - 100 mL for patients who weigh less than 40 kg.

  Only use infusion containers made of polyolefin, polypropylene, or polyvinylchloride.
- Gently invert the infusion container at least 10 times to mix the solution. Do not shake.
- Verify that a uniform solution has been achieved by visual inspection. Do not use if particulate matter or discoloration is present.

Storage Conditions of the Diluted Solution

- Administer the diluted IMAAVY solution immediately after preparation.
- If the diluted IMAAVY solution is not used immediately:
    - Protect from light.

- Store refrigerated at 2 °C to 8 °C (36 °F to 46 °F) for no more than 24 hours.
- Do not freeze.
- After preparation or removal from the refrigerator, use or discard the IMAAVY diluted solution within 12 hours, including infusion time. During these 12 hours, store under ambient light at 15 °C to 30 °C (59 °F to 86 °F).

Administration

- If the diluted solution is refrigerated prior to administration, allow to warm to room temperature. Do not use external heat sources to warm IMAAVY.
- Administer the diluted solution by intravenous infusion only using an infusion set with an in-line or add-on, sterile, non-pyrogenic, low protein-binding filter made of polyethersulfone or polysulfone (pore size 0.2 micrometer or less). Administration sets must be made of either polybutadiene, polyethylene, polyurethane, polypropylene, or polyvinylchloride.
- Do not infuse IMAAVY concomitantly in the same intravenous line with other agents.
- Administer IMAAVY infusion intravenously over at least 30 minutes for the initial dose and at least 15 minutes for subsequent doses *[see Dosage and Administration (2.2, 2.3)]*.
- If an adverse reaction occurs during administration of IMAAVY, the infusion may be slowed or stopped at the discretion of the healthcare professional.
- Monitor the patient for 30 minutes after each infusion for signs or symptoms of an infusion-related or hypersensitivity reaction *[see Warnings and Precautions (5.2, 5.3)]*.

3 DOSAGE FORMS AND STRENGTHS

Injection: colorless to slightly brownish, clear to slightly opalescent solution available as:

- 300 mg/1.62 mL (185 mg/mL) in a single-dose vial
- 1,200 mg/6.5 mL (185 mg/mL) in a single-dose vial

4 CONTRAINDICATIONS

IMAAVY is contraindicated in patients with a history of serious hypersensitivity reaction to nipocalimab-aahu or any of the excipients in IMAAVY. Reactions have included anaphylaxis and angioedema *[see Warnings and Precautions (5.2)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Infections

IMAAVY may increase the risk of infection *[see Adverse Reactions (6.1)]*. In gMG Study 1 *[see Clinical Studies (14.1)]*, 42 (43%) out of 98 patients treated with IMAAVY reported 71 events of infection. Across gMG Study 1 (double-blind period) and its extension study (open label-period),

out of 186 patients treated with IMAAVY, 132 (71%) patients reported 360 events of infection and serious infections were reported in 7% of patients treated with IMAAVY. In the wAIHA Study (double-blind period), 35 (45%) out of 78 patients treated with IMAAVY reported 52 events of infection *[see Clinical Studies (14.2)]*. Across the wAIHA Study (double-blind period) and its extension study (open label-period), out of 113 patients treated with IMAAVY, 80 (71%) patients reported 184 events of infection and serious infections were reported in 12% of patients treated with IMAAVY.

Delay IMAAVY administration in patients with an active infection until the infection is resolved. During treatment with IMAAVY, monitor for clinical signs and symptoms of infection. If serious infection occurs, administer appropriate treatment and consider withholding IMAAVY until the infection has resolved.

Latent Viral Infections

Patients treated with IMAAVY may be at an increased risk of activation of latent viral infections, such as herpes zoster *[see Adverse Reactions (6.1)]*. In the extension period of gMG Study 1, there were 2 patients with serious adverse reactions related to Epstein-Barr virus (EBV) infection, and 1 of these patients had fatal complications. Patients who screened positive for hepatitis were excluded from gMG Study 1. Follow standard vaccination guidelines *[see Dosage and Administration (2.1)]*.

Immunization

The safety of immunization with live vaccines and the immune response to vaccination during treatment with IMAAVY are unknown. Because IMAAVY causes a reduction in IgG levels, vaccination with live vaccines is not recommended during treatment with IMAAVY.

Evaluate the need to administer age-appropriate vaccines according to immunization guidelines before initiation of treatment with IMAAVY.

5.2 Hypersensitivity Reactions

In clinical trials, hypersensitivity reactions, including angioedema, anaphylaxis, rash, urticaria, and eczema were observed in patients treated with IMAAVY. In gMG Study 1 and the wAIHA Study, hypersensitivity reactions were mild or moderate. In gMG Study 1, all hypersensitivity reactions occurred within one hour to 2 weeks of administration. In the wAIHA Study, 76% of hypersensitivity reactions occurred within 2 weeks of administration *[see Adverse Reactions (6.1)]*. In gMG Study 1, one patient experienced a hypersensitivity reaction (urticaria) that led to treatment discontinuation.

Management of hypersensitivity reactions depends on the type and severity of the reaction. Monitor the patient during treatment with IMAAVY and for 30 minutes after the administration is complete for clinical signs and symptoms of hypersensitivity reactions *[see Dosage and Administration (2.5)]*. If a hypersensitivity reaction occurs during administration, discontinue IMAAVY infusion and institute appropriate supportive measures if needed. IMAAVY is contraindicated in patients with a history of serious hypersensitivity to nipocalimab-aahu or any of the excipients of IMAAVY *[see Contraindications (4)]*.

5.3 Infusion-Related Reactions

In clinical trials, infusion-related reactions, including headache, influenza-like illness, rash, nausea, fatigue, dizziness, chills, and erythema were observed in patients treated with IMAAVY. In gMG Study 1 and the wAIHA Study, infusion-related reactions were mild to moderate in severity. In gMG Study 1, all infusion-related reactions occurred within one hour to 2 days of administration. In the wAIHA Study, 89% of infusion-related reactions occurred within 2 days of administration *[see Adverse Reactions (6.1)]*.

Monitor patients during treatment with IMAAVY and for 30 minutes after each infusion *[see Dosage and Administration (2.5)]*. If a severe infusion-related reaction occurs, discontinue IMAAVY infusion and initiate appropriate therapy. Consider the risks and benefits of readministering IMAAVY following a severe infusion-related reaction. If a mild to moderate infusion-related reaction occurs, patients may be rechallenged with close clinical observation, slower infusion rates, and pre-medication.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling

- Infections *[see Warnings and Precautions (5.1)]*
- Hypersensitivity Reactions *[see Warnings and Precautions (5.2)]*
- Infusion-related Reactions *[see Warnings and Precautions (5.3)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Adults with gMG

In gMG Study 1 and its extension study, the safety of IMAAVY was evaluated in 186 patients with gMG who received at least one dose of IMAAVY. Of those patients, 168 patients were exposed to IMAAVY every 2 weeks for at least 6 months, and 140 patients were exposed for at least 12 months.

In gMG Study 1, 98 adult patients with gMG received IMAAVY 15 mg/kg every two weeks (after 30 mg/kg initial dose) *[see Clinical Studies (14.1)]*. Of these 98 patients, approximately 67% were female, 67% were White, 29% were Asian, and 10% were of Hispanic or Latino ethnicity. The mean age at study entry was 53 years (range 20 to 81).

Adverse reactions reported in gMG Study 1 in at least 5% of patients treated with IMAAVY and more frequently than placebo, are summarized in Table 3. The most common adverse reactions (reported in at least 10% of patients treated with IMAAVY) were respiratory tract infection, peripheral edema, and muscle spasms.

Table 3: Adverse Reactions (≥ 5%) of Patients Treated with IMAAVY and More Frequently than in Placebo in gMG Study 1

Adverse Reaction	IMAAVY N=98 %	Placebo N=98 %
Infection		
Respiratory tract infection[a]	18	13
Urinary tract infection[b]	6	3
Herpes zoster and Herpes simplex	6	2
Oral infection[c]	5	3
Peripheral edema	12	2
Muscle spasm	12	3
Hypersensitivity reaction[d]	8	7
Abdominal pain	8	3
Back pain	8	5
Pyrexia	7	1
Diarrhea	7	3
Cough	7	3
Anemia[b]	6	4
Dizziness	5	1
Nausea	5	2
Hypertension	5	2
Insomnia	5	2

Includes the following reported in patients treated with IMAAVY:

[a] COVID-19 (and other related terms), pneumonia, bronchitis, pneumonia bacteria

[b] other related terms

[c] glossitis, oral candidiasis, pericoronitis, pulpitis dental, tooth abscess, tooth infection

[d] angioedema, dermatitis atopic, eczema, gingival swelling, rash (and other related terms), urticaria

Infections

In gMG Study 1 and its extension study, infections that occurred in patients treated with IMAAVY (n=186) included upper respiratory tract infection (46%), respiratory tract infection (28%; including pneumonia, bronchitis, COVID-19), urinary tract infection (15%), herpes (8%; including herpes simplex, herpes zoster, herpes zoster oticus), influenza (8%), oral infection (8%; including candidiasis and dental infections), and skin infection (7%; including cellulitis). Two (1%) cases of infections (cellulitis and urinary tract infection) led to discontinuation of IMAAVY *[see Warnings and Precautions (5.1)]*.

Hypersensitivity Reactions

In gMG Study 1 and its extension study, out of 186 patients treated with IMAAVY, 30 (16%) patients experienced hypersensitivity reactions, which occurred within one hour to two weeks of administration. One patient experienced hypersensitivity reaction (urticaria) that required discontinuation of IMAAVY *[see Warnings and Precautions (5.2)]*.

Infusion-Related Reactions

In gMG Study 1 and its extension study, out of 186 patients treated with IMAAVY, 20 (11%) patients experienced infusion-related reactions, which occurred within one hour to 2 days of

administration. No patients experienced infusion-related reaction that required discontinuation of IMAAVY *[see Warnings and Precautions (5.3)]*.

Laboratory Findings

Lipids

In gMG Study 1 (N=98), patients treated with IMAAVY had elevations from normal to high of fasting total cholesterol (≥240 mg/dL) and LDL cholesterol (≥160 mg/dL) (24% and 11% of patients, respectively). In gMG Study 1, these changes from baseline peaked at Week 4, then decreased and plateaued by Week 24 to mean increases of 14 mg/dL and 7 mg/dL, respectively. Five percent of patients treated with IMAAVY had decreases from normal to low of fasting HDL cholesterol (<40 mg/dL).

Pediatric Patients 12 Years of Age and Older with gMG

In a 24-week, single arm study (gMG Study 2), evaluating the safety of IMAAVY in 7 pediatric patients age 12 to 16 years with gMG who were AChR positive, adverse reactions were consistent with those observed in adult patients with gMG *[see Use in Specific Populations (8.4)]*.

Adults with wAIHA

The safety of IMAAVY in patients with wAIHA was evaluated in 113 adult patients with wAIHA who received at least one dose of IMAAVY. Of these patients, 84 patients received IMAAVY for at least 6 months, and 49 patients received IMAAVY for at least 12 months. The median duration of treatment was 44 weeks.

In the double-blind phase of the wAIHA Study, 78 patients received IMAAVY across the dose regimens evaluated in the study *[see Clinical Studies (14.2)]*.

Adverse reactions that occurred in the wAIHA Study in at least 5% of patients treated with IMAAVY are summarized in Table 4. The most common adverse reactions (reported in at least 10% of patients treated with IMAAVY) were peripheral edema, diarrhea, and pyrexia.

Table 4: Adverse Reactions (≥ 5%) of Patients Treated with IMAAVY and More Frequently than in Placebo in the wAIHA Study

Adverse Reaction	**IMAAVY N=78 %**	**Placebo N=39 %**
Peripheral edema[a]	12	2.6
Diarrhea	12	8
Pyrexia	10	2.6
Dizziness	9	8
Infection Urinary tract infection[b]	9	5
Headache	6	5

[a] Includes Edema peripheral, Edema and Generalized edema.

[b] Includes Urinary tract infection, Pyelonephritis and Urinary tract infection bacterial.

Additional Clinically Relevant Adverse Reactions occurring in ≤5% of patients

- Pneumonia (5% with IMAAVY; 5% with placebo)
- Nausea (3.8% with IMAAVY; 2.6% with placebo)
- Insomnia (1.3% with IMAAVY; 0% with placebo)

Infections

In the wAIHA Study and its extension study, infections that occurred in patients treated with IMAAVY (n=113) included upper respiratory tract infection (34%), respiratory tract infection (33%), urinary tract infection (12%), gastroenteritis (5%). Three (2.7%) cases of infections (pneumonia, salmonella sepsis and spontaneous bacterial peritonitis) led to discontinuation of IMAAVY *[see Warnings and Precautions (5.1)]*.

Hypersensitivity Reactions

In the wAIHA Study and its extension study, out of 113 patients treated with IMAAVY, 9 (8%) patients experienced hypersensitivity reactions *[see Warnings and Precautions (5.2)]*.

Infusion-Related Reactions

In the wAIHA Study and its extension study, out of 113 patients treated with IMAAVY, 12 (11%) patients experienced infusion-related reactions. One patient in the wAIHA Study discontinued IMAAVY due to an infusion-related reaction (back pain) *[see Warnings and Precautions (5.3)]*.

Laboratory Findings

Lipids

In the double-blind phase of the wAIHA Study (N=78), 2.3% of patients treated with IMAAVY had elevations from normal to high of fasting total cholesterol (≥240 mg/dL) and LDL cholesterol remained <160 mg/dL for all patients at Week 24. These changes from baseline peaked between Week 4 and Week 12, then decreased and plateaued by Week 24 to mean increases in fasting total cholesterol of 6 mg/dL and fasting LDL of 4.2 mg/dL. Of the patients treated with IMAAVY, 12% had fasting HDL cholesterol of <40 mg/dL.

7 DRUG INTERACTIONS

7.1 Effect of IMAAVY on Other Drugs

Concomitant use of IMAAVY with medications that bind to the human neonatal Fc receptor (FcRn) (e.g., immunoglobulin products, monoclonal antibodies, or antibody derivates containing the human Fc domain of the IgG subclass) may lower systemic exposures and reduce effectiveness of such medications. Closely monitor for reduced effectiveness of medications that bind to the human neonatal Fc receptor. When concomitant long-term use of such medications is essential for patient care, consider discontinuing IMAAVY, and using alternative therapies *[see Clinical Pharmacology (12.3)]*.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are limited data on the use of IMAAVY in pregnant women to inform a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes.

There was no evidence of direct adverse effects on fetal development following administration of nipocalimab-aahu to pregnant monkeys; however, adverse effects on the placenta were associated with fetal loss at both doses tested *(see Data)*.

The background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background rate of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

There is a pregnancy safety study for IMAAVY. If IMAAVY is administered during pregnancy, or if a patient becomes pregnant while receiving IMAAVY, healthcare providers should report IMAAVY exposure by contacting Janssen at 1-800-526-7736 or www.IMAAVY.com

Clinical Considerations

Fetal/Neonatal Adverse Reactions

Monoclonal antibodies are increasingly transported across the placenta as pregnancy progresses, with the largest amount transferred during the third trimester. Because IMAAVY reduces maternal serum IgG concentration and impedes placental IgG transfer to the fetus, passive immunity in the infant may be reduced for 6 months or more; therefore:

- Monitor for the development of serious infection.
- Effectiveness of vaccines may be reduced.
- Consider the risks and benefits prior to administering live vaccines to infants exposed to IMAAVY *in utero*.

Data

Animal Data

Intravenous administration of nipocalimab-aahu (0, 100, or 300 mg/kg) to pregnant monkeys weekly from the end of organogenesis (gestation day 45) through parturition resulted in placental ischemia, associated with fetal loss and decreased levels of immunoglobulin (IgG) in the offspring at both doses tested. IgG levels in offspring returned to normal levels and no adverse effects on immune function were evident by 6 months after birth. Mean systemic exposures achieved at the doses tested were 5- and 24-times the population PK model simulated mean steady state exposure at the recommended human maintenance dose for gMG (15 mg/kg) and 5.5- and 28-times the

population PK model simulated mean steady state exposure at the recommended human maintenance dose for wAIHA (30 mg/kg) on an AUC basis.

8.2 Lactation

Risk Summary

Nipocalimab-aahu is excreted in human colostrum and breastmilk based on limited data from an investigational study of 13 pregnant women administered nipocalimab-aahu during pregnancy where colostrum and breastmilk was assessed in the first 8 days after birth. There are insufficient data on the effect of IMAAVY in the breastfed infant. There are no data on the effect of nipocalimab-aahu on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for IMAAVY, and any potential adverse effects on the breastfed infant from IMAAVY, or from the underlying maternal condition.

8.4 Pediatric Use

gMG

The safety and effectiveness of IMAAVY for the treatment of gMG have been established in pediatric patients 12 years of age and older. Use of IMAAVY in pediatric patients for this indication is supported by evidence from an adequate and well-controlled trial in adults with additional pharmacokinetic and safety data in pediatric patients who are 12 years of age and older *[see Adverse Reactions (6.1), Clinical Pharmacology (12.3), and Clinical Studies (14.1)]*.

Safety and effectiveness of IMAAVY for the treatment of gMG in pediatric patients below the age of 12 years have not been established.

wAIHA

The safety and effectiveness of IMAAVY for the treatment of wAIHA have been established in pediatric patients 12 years of age and older currently or previously treated with corticosteroids. Use of IMAAVY in pediatric patients for the treatment of wAIHA is supported by evidence from an adequate and well-controlled trial in adults with additional pharmacokinetic data in pediatric patients who are 12 years of age and older *[see Adverse Reactions (6.1), Clinical Pharmacology (12.3), and Clinical Studies (14.2)]*.

Safety and effectiveness of IMAAVY for the treatment of wAIHA in pediatric patients below the age of 12 years have not been established.

8.5 Geriatric Use

There were 86 patients 65 years of age and older in the clinical studies for gMG (n=37) and wAIHA (n=49) *[see Clinical Studies (14)]*. Of the total number of IMAAVY-treated patients in gMG, 12 were 65 to 74 years of age and 6 were 75 to 84 years of age. Of the total number of IMAAVY-treated patients in wAIHA, 19 were 65 to 74 years of age and 12 were 75 to 84 years of age.

Clinical studies of IMAAVY did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger adult patients.

11 DESCRIPTION

Nipocalimab-aahu, a neonatal Fc receptor blocker, is a recombinant human immunoglobulin G1 lambda (IgG1λ) monoclonal antibody, expressed in a genetically engineered Chinese hamster ovary cell line. Nipocalimab-aahu has an aglycosylated Fc region, therefore it lacks effector functions. Nipocalimab-aahu has an approximate molecular weight of 142 kilodaltons (kDa).

IMAAVY® (nipocalimab-aahu) injection is a sterile, preservative-free, colorless to slightly brownish, clear to slightly opalescent solution, supplied in a single-dose vial for intravenous infusion after dilution.

Each single-dose vial contains either 300 mg/1.62 mL or 1,200 mg/6.5 mL of nipocalimab-aahu at a concentration of 185 mg/mL. In addition, each mL of solution contains arginine hydrochloride (25.35 mg), histidine (0.77 mg), L-histidine monohydrochloride monohydrate (1.07 mg), methionine (1.0 mg), polysorbate 80 (0.60 mg), sucrose (64.3 mg), and water for injection, USP, at a pH of 6.0.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Nipocalimab-aahu is a human IgG1 monoclonal antibody that binds to neonatal Fc receptor (FcRn), resulting in the reduction of circulating IgG levels.

12.2 Pharmacodynamics

gMG

In gMG Study 1 *[see Clinical Studies (14.1)],* the pharmacological effect of nipocalimab-aahu was assessed by measuring the decrease in serum IgG levels and anti-AChR and anti-MuSK autoantibody levels. In patients positive for AChR and MuSK autoantibodies who were treated with IMAAVY, there was a reduction in AChR and MuSK autoantibodies relative to baseline. Decreases in total IgG levels followed a similar pattern. A similar reduction in AChR autoantibodies was observed in adolescent patients with gMG compared to adults.

wAIHA

In the wAIHA Study *[see Clinical Studies (14.2)]*, the pharmacological effect of nipocalimab-aahu was assessed by measuring the decrease in serum IgG levels and pathogenic anti-RBC IgG autoantibody levels. In patients treated with IMAAVY, there was a reduction in total IgG and anti-RBC IgG autoantibody relative to baseline.

12.3 Pharmacokinetics

Nipocalimab-aahu exhibits nonlinear pharmacokinetics. Following a single intravenous infusion of IMAAVY at doses ranging from 0.3 to 60 mg/kg (4 times the recommended maintenance dosage for gMG) in healthy participants, C_{max} of nipocalimab-aahu increased in a dose-proportional manner while AUC increased in a greater than dose-proportional manner.

Distribution

Mean volume of distribution of nipocalimab-aahu is 2.67 L.

Metabolism

Nipocalimab-aahu is expected to be degraded by proteolytic enzymes into small peptides and amino acids.

Elimination

Nipocalimab-aahu exhibits concentration-dependent pharmacokinetics. After a single intravenous administration of 15 mg/kg nipocalimab-aahu, the mean clearance is 0.0627 L/h and half-life is 29.3 hours.

Specific Populations

Age, Sex, and Race

The pharmacokinetics of nipocalimab-aahu were not affected by age, sex, or race based on a population pharmacokinetics analysis.

Pediatric Patients

gMG

Following the recommended intravenous doses of IMAAVY in pediatric patients 12 to 16 years of age with gMG (N=7), the observed steady-state serum nipocalimab-aahu concentrations were within the range of those observed for adult patients with gMG *[see Use in Specific Populations (8.4)]*.

wAIHA

Steady-state serum concentrations are predicted to be similar between adults and pediatric patients 12 to <18 years of age with wAIHA *[see Use in Specific Populations (8.4)]*.

Patients with Renal Impairment

No dedicated pharmacokinetic study has been conducted in patients with renal impairment. Renal impairment is not expected to affect the pharmacokinetics of nipocalimab-aahu. Based on a population pharmacokinetic analysis, which included participants with mild to severe renal impairment (estimated glomerular filtration rate [eGFR] 22-204 mL/min/1.73 m^2), renal function had no clinically significant effect on nipocalimab-aahu clearance. No dose adjustment is required in patients with renal impairment.

Patients with Hepatic Impairment

No dedicated pharmacokinetic study has been performed in patients with hepatic impairment. Nipocalimab-aahu is not metabolized by cytochrome P450 enzymes, and hepatic impairment is not expected to affect the pharmacokinetics of nipocalimab-aahu. Based on a population pharmacokinetic analysis, which included participants with mild to moderate hepatic impairment,

there was no clinically significant effect on nipocalimab-aahu clearance. No dose adjustment is required in patients with hepatic impairment.

Drug Interactions with Other Drugs or Biological Products

IgG-Based Monoclonal Antibodies

Nipocalimab-aahu decreases concentrations of compounds that bind to the human FcRn, including IgG based monoclonal antibodies.

Cytochrome P450 Enzymes

Nipocalimab-aahu is not metabolized by cytochrome P450 enzymes; therefore, interactions with concomitant medications that are substrates, inducers, or inhibitors of cytochrome P450 enzymes are unlikely.

12.6 Immunogenicity

The observed incidence of anti-drug antibodies is highly dependent on the sensitivity and specificity of the assay. Differences in assay methods preclude meaningful comparisons of the incidence of anti-drug antibodies in the studies described below with the incidence of anti-drug antibodies in other studies, including those of nipocalimab-aahu or of other nipocalimab products.

gMG

In gMG clinical trials, antibodies to nipocalimab-aahu were detected in 49/102 (48%) adult and pediatric patients 12 years of age and older during 24-week treatment period.

Out of the 49 patients who were positive for antibodies to nipocalimab-aahu, 19 (38.8%) patients had neutralizing antibodies to nipocalimab-aahu. There was no identified clinically relevant effect of antibodies, including neutralizing antibodies, to nipocalimab-aahu on the pharmacokinetics, pharmacodynamics, safety, or effectiveness of IMAAVY.

wAIHA

In wAIHA clinical trials, antibodies to nipocalimab-aahu were detected in 43% (31/72) adults during the 24-week treatment period.

Out of the 31 patients who were positive for antibodies to nipocalimab-aahu, 17 (55%) patients had neutralizing antibodies to nipocalimab-aahu. There was no identified clinically relevant effect of antibodies, including neutralizing antibodies, to nipocalimab-aahu on the pharmacokinetics, pharmacodynamics, safety, or effectiveness of IMAAVY.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Studies to assess the carcinogenic potential of nipocalimab-aahu have not been conducted.

Mutagenesis

Studies to assess the genotoxic potential of nipocalimab-aahu have not been conducted. As an antibody, nipocalimab-aahu is not expected to interact directly with DNA.

Impairment of Fertility

Once or twice weekly intravenous administration of nipocalimab-aahu (0, 20, 50, 100, or 300 mg/kg) to male and female monkeys for 26 weeks resulted in no adverse effects on reproductive organs upon histopathological examination. Mean systemic exposures achieved at the highest dose tested are 42-times or 49-times the population PK model simulated mean steady state exposures at the recommended human maintenance dose for gMG (15 mg/kg) or wAIHA (30 mg/kg), respectively, on an AUC basis.

14 CLINICAL STUDIES

14.1 Adults with gMG

The efficacy of IMAAVY for the treatment of gMG in adults who are anti-AChR or anti-MuSK antibody positive was established in a 24-week, multicenter, randomized, double-blind, placebo-controlled study (gMG Study 1; NCT04951622). Patients were treated with IMAAVY with the recommended dosage regimen *[see Dosage and Administration (2.1)]*.

gMG Study 1 enrolled patients with gMG who met the following criteria:

- Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV
- Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score of at least 6
- On stable dose of standard of care MG therapy prior to baseline that included acetylcholinesterase (AChE) inhibitors, steroids or non-steroidal immunosuppressive therapies (NSISTs), either in combination or alone.

In gMG Study 1, a total of 196 patients were randomized 1:1 to receive IMAAVY (n=98) or placebo (n=98). Baseline characteristics were similar between treatment groups. For the primary efficacy analysis population (n=153), patients had a median age of 52 years at screening (range 20 to 81 years) and a median time since diagnosis of 6 years. Sixty percent of patients were female; 63% were White; 32% were Asian; 1% were Black or African-American; and <1% were American Indian or Alaskan Native. At baseline, median MG-ADL total score was 9, and median Quantitative Myasthenia Gravis (QMG) total score was 15. Eighty-eight percent (n=134) of patients were positive for AChR antibodies and 10% (n=16) were positive for MuSK antibodies.

At baseline, in each group, 85% of patients received AChE inhibitors, 66% of patients received steroids, and 54% of patients received NSISTs at stable doses.

The efficacy of IMAAVY was measured using the MG-ADL scale, which assesses the impact of gMG on daily functions of 8 signs and symptoms that are typically affected in gMG. Each item is assessed on a 4-point scale, where a score of 0 represents normal function and a score of 3 represents loss of ability to perform that function. A total score ranges from 0 to 24, with the higher scores indicating more impairment.

The primary efficacy endpoint was the comparison of the mean change from baseline to Weeks 22, 23, and 24 between treatment groups in the MG-ADL total score. A statistically significant difference favoring IMAAVY was observed in MG-ADL total score change from baseline (p=0.002; see Table 5 and Figure 1).

The efficacy of IMAAVY was also measured using the QMG total score, which is a 13-item categorial grading system that assesses muscle weakness. Each item is assessed on a 4 -point scale, where a score of 0 represents no weakness, and a score of 3 represents severe weakness. A total possible score ranges from 0 to 39, where higher scores indicate more severe impairment.

The secondary endpoint was the comparison of the mean change from baseline to Weeks 22 and 24 between treatment groups in the QMG total score. A statistically significant difference favoring IMAAVY was observed in the QMG total score change from baseline (p<0.001; see Table 5).

The results are presented shown in Table 5.

Table 5: Least Squares Mean Change from Baseline to Week 24 in MG-ADL and QMG Total Scores in gMG Study 1

Efficacy Endpoints	IMAAVY N = 77 LS Mean (SE)	Placebo N = 76 LS Mean (SE)	IMAAVY Change Relative to Placebo LS Mean Difference (95% CI)	p-value
Primary Endpoint				
MG-ADL Total Score[1]	-4.7 (0.33)	-3.3 (0.34)	-1.5 (-2.4, -0.5)	0.002
Secondary Endpoint				
QMG Total Score[2]	-4.9 (0.5)	-2.1 (0.5)	-2.8 (-4.2, -1.4)	<0.001

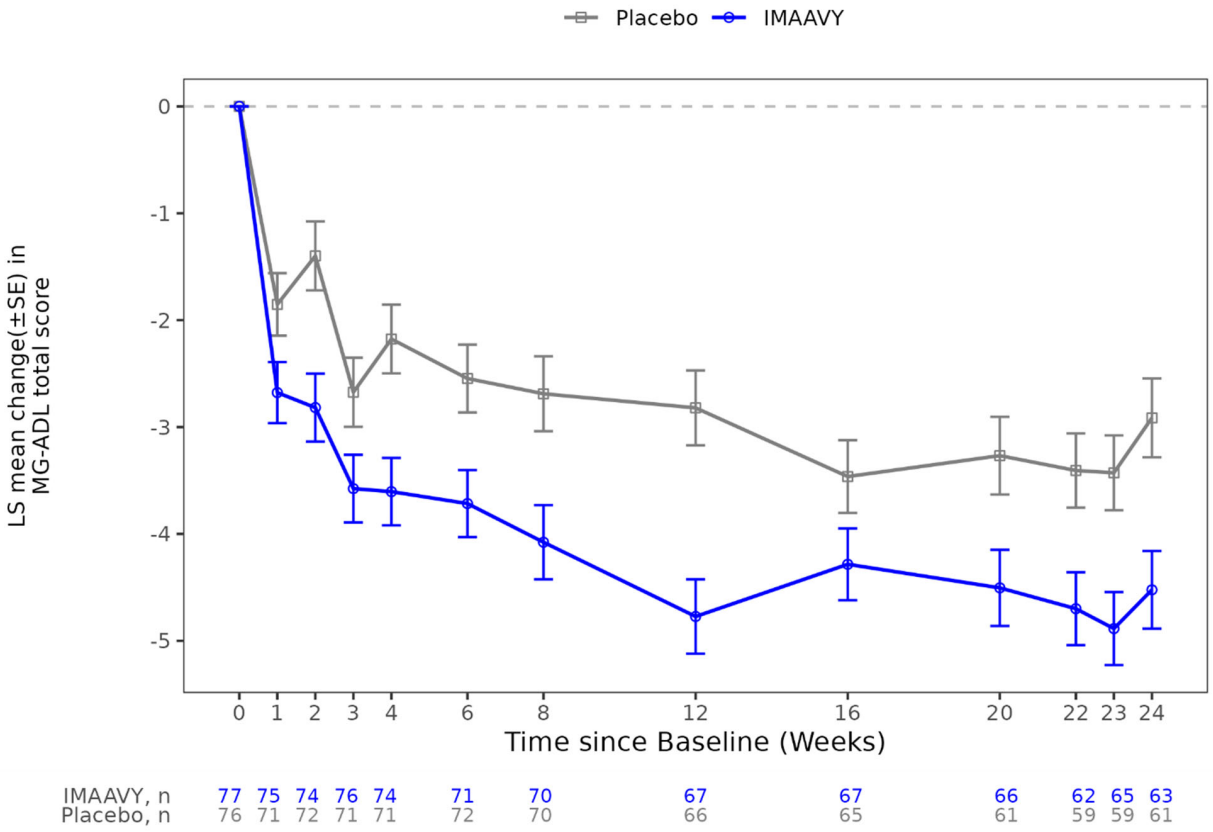
Key: CI=confidence interval; MG-ADL = Myasthenia Gravis – Activities of Daily Living; QMG = Quantitative Myasthenia Gravis; LS mean = Least squares mean; SE = standard error

1 Mean change from baseline over weeks 22, 23, and 24

2 Mean change from baseline over weeks 22 and 24

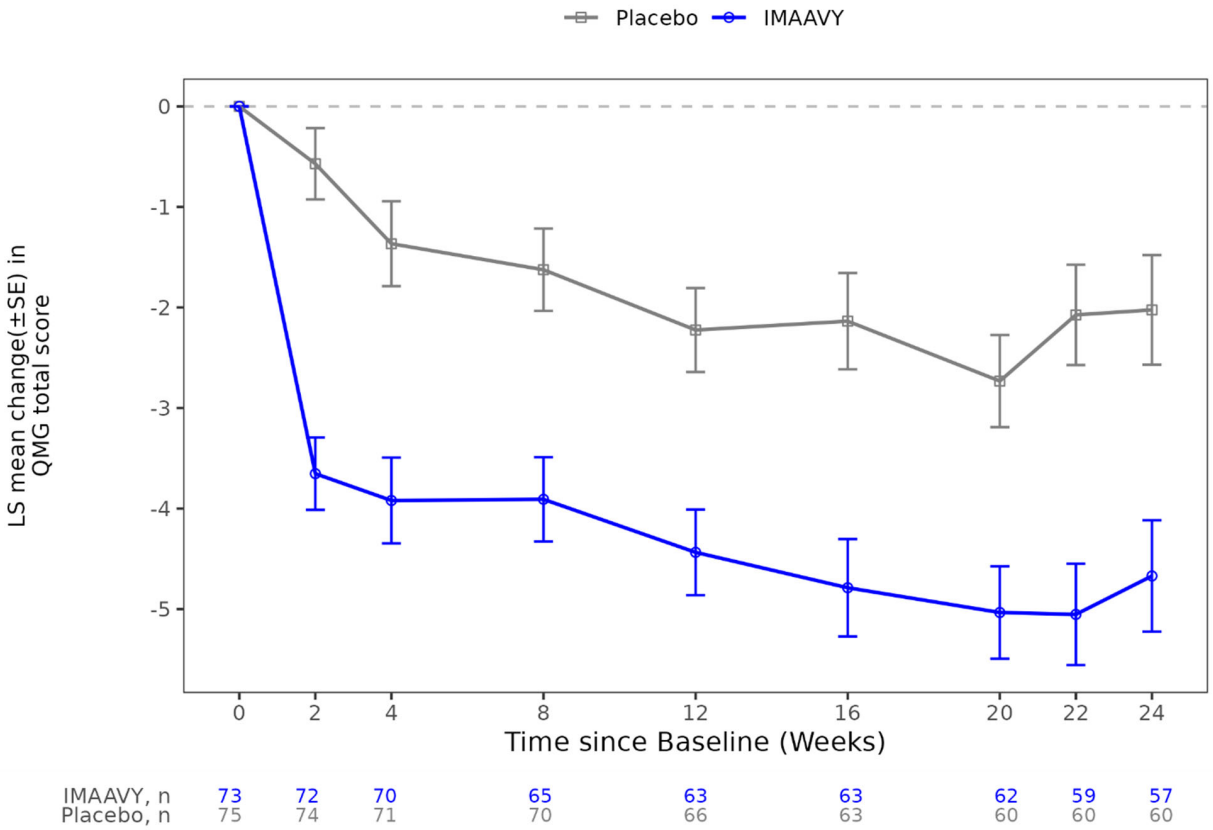
Figure 1 shows the mean change from baseline to Week 24 in MG-ADL total score in gMG Study 1, and Figure 2 shows the mean change from baseline to Week 24 in QMG total score in gMG Study 1.

Figure 1: Least Squares Mean Change from Baseline in MG-ADL Total Score Over 24 Weeks in gMG Study 1



LS = least squares, SE = standard error, MG-ADL = Myasthenia Gravis Activities of Daily Living

Figure 2: Least Squares Mean Change from Baseline in QMG Total Score Over 24 Weeks in gMG Study 1



LS = least squares, SE = standard error, QMG = Quantitative Myasthenia Gravis.

14.2 Adults with wAIHA

The wAIHA Study (NCT04119050) was a randomized, double-blind, placebo-controlled study evaluating IMAAVY in patients with a confirmed diagnosis of wAIHA for at least 3 months, who were either receiving or had previously received treatment for wAIHA. In addition, patients had a hemoglobin level <10 g/dL and evidence of hemolysis and positive monospecific direct antiglobulin test (DAT).

Efficacy was established based on a randomized comparison of IMAAVY 30 mg/kg intravenously every 4 weeks (n=38) and placebo (n=39) for a double-blind period of 24 weeks. Stable concomitant wAIHA therapy was allowed during the study.

Demographics and baseline disease characteristics for all randomized patients were similar between treatment groups. Patients had a median age of 59 years at screening (range 24 to 86 years) and a median time since diagnosis of 2 (0 to 16) years. 53.2% of patients were female; 46.8% were White; 33.8% were Asian; 1.3% were Black or African-American; 18.2% other race or race not reported. 5.2% were Hispanic or Latino, 87.0% were not Hispanic or Latino, and 7.8% were not reported. Baseline disease characteristics are presented in Table 6.

Table 6: Baseline Disease Characteristics of Patients in the wAIHA Study

Parameter	IMAAVY 30 mg/kg every 4 weeks	Placebo
N	**38**	**39**
wAIHA Type		
Primary wAIHA (%)	92.1	82.1
Monospecific Direct Antiglobulin Test (DAT)[1]		
Only IgG positive (%)	41.7	63.2
IgG and C3d positive (%)	58.3	36.8
Baseline Hemoglobin (g/dL)		
Median (range)	9.3 (5; 12)	9.1 (5; 12)
Baseline FACIT-Fatigue total score[2]		
Median (range)	36.0 (14; 52)	32.0 (8; 49)
Concomitant corticosteroids and/or immunosuppressants		
Corticosteroids[3] (%)	89.5	87.2
Immunosuppressants[3,4] (%)	23.7	25.6
Corticosteroids and immunosuppressants (%)	18.4	20.5
Previous Treatment for wAIHA		
Corticosteroid use only (%)	47.4	59.0
Rituximab (%)	42.1	48.7
Immunosuppressant use only (%)	0	0

1 DAT screening results are missing for two patients in the IMAAVY 30 mg/kg IV every 4 weeks group and one patient in the placebo group due to an operational issue. All three patients met the inclusion criteria and were eligible to enroll in the study.

2 Fatigue-related symptoms and impacts were assessed using a patient reported outcome instrument, FACIT-Fatigue (score range from 0 to 52 with higher scores indicating less fatigue).

3 Alone or in combination with the other treatment.

4 Immunosuppressants included azathioprine, mycophenolate mofetil/mycophenolic acid, methotrexate, cyclosporine, tacrolimus, danazol, and cyclophosphamide.

Efficacy was based on the proportion of patients who achieved a durable hemoglobin response, defined as a hemoglobin level of ≥10 g/dL and an increase from baseline of ≥2 g/dL for at least three consecutive visits (with a minimum duration of 28 days, where criteria was met starting by Week 16 of the double-blind period), without the need of rescue therapy. Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-Fatigue) total score was included in this study.

Efficacy results from the wAIHA Study for the recommended dose of IMAAVY 30 mg/kg every 4 weeks are shown in Table 7.

Table 7: Efficacy Results for the wAIHA Study

	IMAAVY 30 mg/kg every 4 weeks	Placebo
N	38	39
Proportion of patients with durable hemoglobin response[3,4]	9 (23.7%)	3 (7.7%)
Difference in proportions (95% CI)	16.0 (0.1, 31.9)	
One-sided p-value[1,2]	0.015	

Key: CI = Confidence Interval

1 The one-sided p-values use an alpha level of 0.02499.

2 Statistically significant based on equal weight multiple comparison testing procedure.

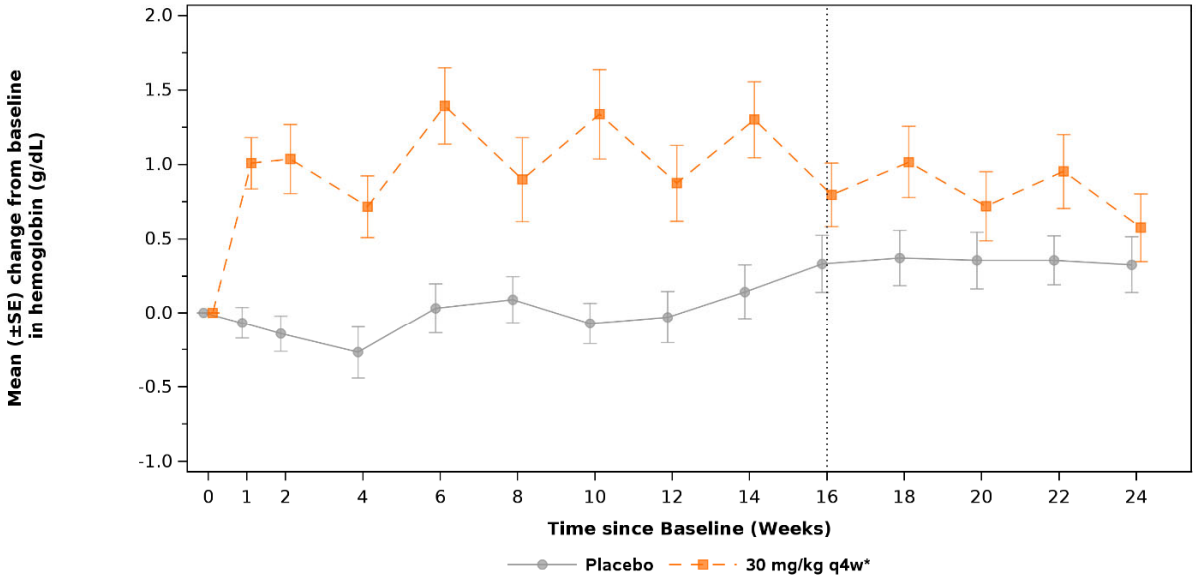
3 Durable hemoglobin response is defined as a hemoglobin level of ≥10 g/dL and an increase from baseline of ≥2 g/dL for at least three consecutive visits (with a minimum duration of 28 days, where criteria were met starting by Week 16 of the double-blind period).

4 Patients were considered non-responders following discontinuation or if rescue therapy was received.

The least squares (LS) mean change in FACIT-Fatigue score from baseline to Week 24 in patients treated with IMAAVY 30 mg/kg IV every 4 weeks was 2.95 (95% CI: 0.84; 5.07); LS mean difference (95% CI): 3.51 (0.64; 6.39), compared to -0.56 (95% CI: -2.57; 1.46) in the placebo group.

Figure 3 shows the mean change from baseline in hemoglobin values by visit through Week 24.

Figure 3: Mean Change from Baseline in Hemoglobin Values by Visit Through Week 24



* IMAAVY dose; SE=Standard Error
At or after Week 16, all patients had the opportunity to discontinue in the double-blind phase and crossover to IMAAVY if they were not meeting the protocol-defined criteria.
For patients discontinuing treatment or receiving rescue therapy before Week 24, change from baseline was set to zero for all subsequent visits.

16 HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

IMAAVY® (nipocalimab-aahu) injection is a sterile, preservative-free, colorless to slightly brownish, clear to slightly opalescent solution for intravenous use after dilution.

IMAAVY is supplied in cartons containing a single-dose vial per carton as:

- 300 mg/1.62 mL (185 mg/mL) NDC 57894-800-01
- 1,200 mg/6.5 mL (185 mg/mL) NDC 57894-801-01

Storage and Handling

Unopened Vials

Store vials refrigerated at 2 ºC to 8 ºC (36 ºF to 46 ºF) in the original carton to protect from light until the time of use. Do not freeze. Do not shake.

Diluted Solution

For storage of the diluted IMAAVY solution, *see Dosage and Administration (2.5)*.

17 PATIENT COUNSELING INFORMATION

Advise the patient and/or caregiver to read the FDA-approved patient labeling (Patient Information).

Infections

Instruct patients to communicate any history of infections to the healthcare provider and to contact their healthcare provider if they develop any symptoms of an infection *[see Warnings and Precautions (5.1)]*.

Administration of Vaccines

Advise patients to complete all age-appropriate vaccines according to immunization guidelines prior to initiation of treatment with IMAAVY. Administration of live vaccines is not recommended during treatment with IMAAVY. Instruct patients to inform the healthcare provider that they are being treated with IMAAVY prior to a potential vaccination *[see Warnings and Precautions (5.1)]*.

Hypersensitivity Reactions

Inform patients that hypersensitivity reactions, including anaphylaxis, angioedema, rash, urticaria, and eczema have occurred in patients treated with IMAAVY. Inform patients about the signs and symptoms of hypersensitivity reactions. Advise patients to contact their healthcare provider immediately if these occur *[see Warnings and Precautions (5.2)]*.

Infusion-Related Reactions

Advise patients that administration of IMAAVY may result in infusion-related reactions *[see Warnings and Precautions (5.3)]*.

Pregnancy

Advise patients that there is a pregnancy safety study that monitors pregnancy outcomes in women exposed to IMAAVY during pregnancy, and they can be enrolled by calling 1-800-526-7736 or www.IMAAVY.com *[see Use in Specific Populations (8.1)]*.

Manufactured by:
Janssen Biotech, Inc.
Horsham, PA 19044, USA
U.S. License Number 1864

For patent information: www.janssenpatents.com

PATIENT INFORMATION
IMAAVY® (im-AH-vee)
(nipocalimab-aahu)
injection, for intravenous use

What is IMAAVY?

IMAAVY is a prescription medicine used to treat adults and children 12 years of age and older with:

- generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.
- warm Autoimmune Hemolytic Anemia (wAIHA) currently or previously treated with corticosteroids.

It is not known if IMAAVY is safe and effective in children under 12 years of age.

Do not receive IMAAVY if you

have a history of a severe allergic reactions to nipocalimab-aahu or any of the ingredients in IMAAVY. See the end of this Patient Information leaflet for a complete list of ingredients in IMAAVY.

Before receiving IMAAVY, tell your healthcare provider about all of your medical conditions, including if you:

- have had an allergic reaction to IMAAVY. Ask your healthcare provider if you are not sure.
- have or had any recent infections or have any symptoms of infection.
- have or had shingles (herpes zoster) or mono (mononucleosis caused by Epstein-Barr virus).
- have recently received or are scheduled to receive an immunization (vaccine). You should not receive live vaccines during treatment with IMAAVY.
- are pregnant or plan to become pregnant. It is not known if IMAAVY will harm your unborn baby.
    - **Pregnancy Safety Study.** There is a pregnancy safety study for IMAAVY. If IMAAVY is given during pregnancy or you become pregnant while receiving IMAAVY, your healthcare provider should report IMAAVY exposure by contacting Janssen at 1-800-526-7736 or www.IMAAVY.com.
- are breastfeeding or plan to breastfeed. IMAAVY can pass into your breast milk. It is not known if IMAAVY will harm your baby. Talk to your healthcare provider about the best way to feed your baby during treatment with IMAAVY.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. IMAAVY may affect the way that some medicines work.

How will I receive IMAAVY?

- Your healthcare provider will give you IMAAVY through a needle placed into your vein (intravenous [IV] infusion).
- **For gMG,** you will receive a starting dose of IMAAVY infusion lasting at least 30 minutes. Two weeks later you will receive your next dose of IMAAVY infusion lasting at least 15 minutes. You will receive your following doses every 2 weeks.
- **For wAIHA,** you will receive a starting dose of IMAAVY infusion lasting at least 30 minutes. Four weeks later you will receive your next dose of IMAAVY infusion lasting at least 15 minutes. You will receive your following doses every 4 weeks.
- Your healthcare provider should monitor you for reactions to IMAAVY during the infusion and for 30 minutes after each infusion. If you have a reaction during your IMAAVY infusion, your healthcare provider may infuse IMAAVY more slowly, or give you medicine before your infusion, or stop your infusion if your reaction is severe.
- If you miss a scheduled IMAAVY infusion, you should receive your next dose as soon as possible.

What should I avoid while receiving IMAAVY?

- You should not receive live vaccines during treatment with IMAAVY.

What are the possible side effects of IMAAVY?
IMAAVY can cause serious side effects, including:

- **Infections.** IMAAVY may increase your risk of infections, including serious infections. If you have an infection, your healthcare provider will treat your infection or delay your infusion until your infection is gone. Tell your healthcare provider right away if you get any of the following symptoms of infection:
  - fever
  - chills
  - shivering
  - cough
  - sore throat
  - fever blisters
  - burning when you urinate
  - trouble breathing
- **Allergic (hypersensitivity) reactions.** Allergic reactions can happen during or up to a few weeks after your IMAAVY infusion. Tell your healthcare provider and get emergency medical help right away if you get any of these symptoms during or after your IMAAVY infusion:
  - swelling of your face, lips, mouth, tongue, or throat
  - trouble swallowing or breathing
  - hives
  - itchy rash
  - chest pain or tightness
- **Infusion-related reactions.** Tell your healthcare provider right away if you get any of the following symptoms during or within a few days after your infusion of IMAAVY:
  - headache
  - rash
  - nausea
  - fatigue
  - dizziness
  - chills
  - flu-like symptoms
  - redness of skin

The most common side effects in people with gMG treated with IMAAVY include:

- infection in parts of your body that you use for breathing (respiratory tract infection)
- swelling in your hands, ankles, or feet (peripheral edema)
- muscle spasms

The most common side effects in people with wAIHA treated with IMAAVY include:

- swelling in your hands, ankles, or feet (peripheral edema)
- diarrhea
- fever (pyrexia)

These are not all of the possible side effects of IMAAVY.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of IMAAVY.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet.

You can ask your pharmacist or healthcare provider for information about IMAAVY that is written for health professionals.

What are the ingredients in IMAAVY?
Active ingredient: nipocalimab-aahu

Inactive ingredients: arginine hydrochloride, histidine, L-histidine monohydrochloride monohydrate, methionine, polysorbate 80, sucrose, and water for injection.

Manufactured by: Janssen Biotech, Inc., Horsham, PA 19044, USA
U.S. License Number 1864
For patent information: www.janssenpatents.com

For more information, call 1-800-526-7736 or go to www.IMAAVY.com

This Patient Information has been approved by the U.S. Food and Drug Administration Revised: 08/2026