HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use LUMVOA safely and effectively. See full prescribing information for LUMVOA.

LUMVOA (veligrotug-vvze) injection, for intravenous use
Initial U.S. Approval: 2026

----------INDICATIONS AND USAGE----------
LUMVOA is an insulin-like growth factor-1 receptor inhibitor indicated for the treatment of thyroid eye disease regardless of thyroid eye disease activity or duration. (1)

----------DOSAGE AND ADMINISTRATION----------
- 10 mg/kg every three weeks for a total of 5 infusions (2.1)
- Administer LUMVOA by intravenous infusion over 30 to 45 minutes (2.3)
- See full prescribing information for dose preparation and administration instructions (2.2, 2.3)

----------DOSAGE FORMS AND STRENGTHS----------
Injection: 500 mg/10 mL (50 mg/mL) solution in a single-dose vial (3)

----------CONTRAINDICATIONS----------
None (4)

----------WARNINGS AND PRECAUTIONS----------
- Infusion Reactions: If an infusion reaction occurs, interrupt or slow the rate of infusion and use appropriate medical management (5.1)
- Inflammatory Bowel Disease (IBD): Monitor patients for signs and symptoms of disease, including patients without a history of IBD; discontinue LUMVOA if IBD is suspected (5.2)
- Hyperglycemia: Assess patients for elevated blood glucose and symptoms of hyperglycemia prior to infusion and continue to monitor while on treatment with LUMVOA. Ensure patients with hyperglycemia or preexisting diabetes are under appropriate glycemic control before and while receiving LUMVOA. Continue monitoring after treatment for patients who experience hyperglycemia while on LUMVOA (5.3)
- Hearing Impairment including Hearing Loss: LUMVOA may cause severe hearing impairment including hearing loss, which in some cases may be permanent. Assess patient's hearing before, during, and after treatment with LUMVOA and consider the benefit-risk of treatment with patients (5.4)

----------ADVERSE REACTIONS----------
Most common adverse reactions (incidence of 5% or more) are muscle spasms, headache, hearing impairment, hyperglycemia, fatigue, diarrhea, ear discomfort, infusion-related reaction, nausea, nasopharyngitis, blood creatine phosphokinase increased, dry skin, and hypertension (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Viridian Therapeutics, Inc. at 1-866-321-VRDN (1-866-321-8736) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------USE IN SPECIFIC POPULATIONS----------
Females of Reproductive Potential: Appropriate forms of contraception should be implemented prior to initiation, during treatment and for 6 months following the last dose of LUMVOA (8.3)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 06/2026

FULL PRESCRIBING INFORMATION: CONTENTS*

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

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

LUMVOA is indicated for the treatment of thyroid eye disease regardless of thyroid eye disease activity or duration.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosage

The recommended dosage of LUMVOA is 10 mg/kg administered by intravenous infusion every three weeks for a total of 5 infusions.

2.2 Dose Preparation

Step 1: Calculate the dose (mg) and determine the number of vials needed for the 10 mg/kg dosage based on patient weight. Each LUMVOA vial contains 500 mg of veligrotug antibody.

Step 2: Use a 250 mL 0.9% Sodium Chloride infusion bag to prepare the diluted solution. To maintain a constant volume in the infusion bag, use a sterile syringe and needle to remove the volume equivalent to the amount of the LUMVOA solution to be placed into the infusion bag. Discard the withdrawn volume of 0.9% Sodium Chloride.

Step 3: Withdraw the required volume from the LUMVOA vial(s) based on the patient's weight (in kg) and transfer into the intravenous bag containing 0.9% Sodium Chloride Solution. Mix the diluted solution by gentle inversion to avoid foaming. Do not shake.

LUMVOA does not contain any preservative. The storage time of the diluted solution in the infusion bag containing 0.9% Sodium Chloride Injection is 4 hours at room temperature 20°C to 25°C (68°F to 77°F) or up to 72 hours under refrigerated conditions at 2°C to 8°C (36°F to 46°F), protected from light. If refrigerated prior to administration, allow the diluted solution to reach room temperature prior to infusion.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. The diluted solution should be a colorless, clear liquid, and free of visible particles. Discard the solution if any particulate matter or discoloration are observed.

Do not freeze the diluted solution.

Discard vial(s) and all unused contents.

LUMVOA compatibility with the infusion solution has been demonstrated in the following intravenous administration materials:

- Intravenous (IV) Bag: polyvinyl chloride (PVC), ethyl vinyl acetate (EVA), polypropylene-styrene-ethylene-butylene-styrene (PP-SEBS), and ethylene-propylene copolymer (polyolefin (PO)).
- Inline 0.2- or 0.22-micron filters: polyethersulfone solution filter (PES) and polyvinylidene fluoride air filter (PVDF).
- Infusion sets: polyvinyl chloride/bis (2-ethylhexyl) phthalate (PVC/DEHP), polyurethane (PUR), and polyethylene (without DEHP).

2.3 Administration Instructions

Administer the diluted solution intravenously over 45 minutes for the first infusion. If well tolerated, subsequent infusions can be administered over a minimum of 30 minutes. If not well tolerated, the minimum time for subsequent infusions should remain at 45 minutes.

Do not administer LUMVOA as an intravenous push or bolus. LUMVOA should not be infused concomitantly with other agents.

3 DOSAGE FORMS AND STRENGTHS

Injection: 500 mg/10 mL (50 mg/mL) yellowish to brown, slightly opalescent solution in a single-dose vial.

4 CONTRAINDICATIONS

None

5 WARNINGS AND PRECAUTIONS

5.1 Infusion Reactions

LUMVOA may cause infusion reactions. Infusion reactions have been reported in approximately 9% of patients treated with LUMVOA. Signs and symptoms of infusion-related reactions include transient increases in blood pressure, fever, chills, headache, and fatigue. Infusion reactions may occur during or soon after an infusion. Reported infusion reactions are usually mild or moderate in severity and can usually be successfully managed with corticosteroids, antihistamines, and antipyretics. In patients who experience an infusion reaction, consideration should be given to standard premedication and/or administering infusions at a slower infusion rate.

5.2 Inflammatory Bowel Disease

LUMVOA may cause an exacerbation of inflammatory bowel disease (IBD). IBD has been reported in some patients receiving insulin-like growth factor-1 receptor inhibitors without a prior diagnosis of IBD. Monitor patients for signs and symptoms of IBD, including patients without a history of IBD. If IBD is suspected, discontinue use of LUMVOA.

5.3 Hyperglycemia

Hyperglycemia or increased blood glucose may occur in patients treated with LUMVOA. In clinical trials, 12% of patients, of whom one half had pre-existing diabetes or impaired glucose tolerance, experienced hyperglycemia. Hyperglycemic events should be controlled with medications for glycemic control, if necessary.

Assess patients for elevated blood glucose and symptoms of hyperglycemia prior to infusion and continue to monitor while on treatment with LUMVOA. Ensure patients with hyperglycemia or preexisting diabetes are under appropriate glycemic control before and while receiving LUMVOA. Continue monitoring after treatment for patients who experience hyperglycemia while on LUMVOA.

5.4 Hearing Impairment Including Hearing Loss

LUMVOA may cause severe hearing impairment including hearing loss, which in some cases may be permanent. Assess patients' hearing before, during, and after treatment with LUMVOA and consider the benefit-risk of treatment with patients.

6 ADVERSE REACTIONS

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

- Infusion Reactions [*see Warnings and Precautions (5.1)*]
- Inflammatory Bowel Disease [*see Warnings and Precautions (5.2)*]
- Hyperglycemia [*see Warnings and Precautions (5.3)*]
- Hearing Impairment [*see Warnings and Precautions (5.4)*]

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.

The safety of LUMVOA was evaluated in two randomized, double-masked, placebo-controlled clinical studies (Study 1 [NCT05176639] and Study 2 [NCT06021054]) consisting of 113 patients with active thyroid eye disease (75 received LUMVOA and 38 received placebo) and 188 patients with chronic thyroid eye disease (125 received LUMVOA and 63 received placebo). Patients were treated with LUMVOA 10 mg/kg or placebo given as an intravenous infusion every 3 weeks for a total of 5 infusions. The majority of patients completed 5 infusions (94% of LUMVOA patients and 99% of placebo patients).

The most common adverse reactions (≥5%) that occurred at greater incidence in the LUMVOA group than in the control group during the treatment period of Studies 1 and 2 are summarized in Table 1. In addition, menstrual disorders (amenorrhea, menstruation irregular, dysmenorrhea, menstruation delayed, intermenstrual bleeding, and menstrual disorder) were reported in approximately 29% (24/82) of menstruating women treated with LUMVOA compared to 6% (2/33) of patients treated with placebo in the clinical trials.

Table 1: Adverse Reactions Occurring in 5% or More of Patients Treated with LUMVOA and Greater Incidence than Placebo in Study 1 and Study 2

Adverse Reactions	LUMVOA N=200 N (%)	Placebo N=101 N (%)
Muscle spasms	79 (40%)	7 (7%)
Headache	34 (17%)	14 (14%)
Hearing impairment[1]	29 (15%)	6 (6%)
Hyperglycemia[2]	25 (13%)	5 (5%)
Fatigue[3]	25 (13%)	11 (11%)
Diarrhea	22 (11%)	7 (7%)
Ear discomfort[4]	19 (10%)	3 (3%)
Infusion-related reaction	18 (9%)	2 (2%)
Nausea	15 (8%)	6 (6%)
Nasopharyngitis	14 (7%)	1 (1%)
Blood creatine phosphokinase increased	12 (6%)	1 (1%)
Dry skin	12 (6%)	2 (2%)
Hypertension	11 (6%)	5 (5%)

[1] Hearing impairment includes tinnitus, hypoacusis, deafness, and autophony.
[2] Hyperglycemia includes blood glucose increased, glucose tolerance impaired, glycosylated hemoglobin increased, diabetes mellitus, glucose urine present, and impaired fasting glucose.
[3] Fatigue includes asthenia.
[4] Ear discomfort includes ear feels clogged or blocked, ear plugging, sensation of ear pressure, and ear popping.

During the follow-up period, the most common adverse reactions in patients treated with LUMVOA were alopecia and onychoclasis (5%). Immune thrombocytopenia was also reported in one patient.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Because inhibiting insulin-like growth factor-1 receptor (IGF-1R) signaling impacts embryonic development and placental development and function, LUMVOA may cause fetal harm when administered to a pregnant woman *[see Clinical Pharmacology (12.1)]*.

There is insufficient data with LUMVOA use in pregnant women to inform any drug associated risks for adverse developmental outcomes. Animal reproductive and developmental toxicity studies have not been conducted with LUMVOA. Advise pregnant women and females of reproductive potential of the potential risk to a fetus.

LUMVOA should not be used during pregnancy, and appropriate forms of contraception should be implemented prior to initiation, during treatment and for 6 months after the last dose of LUMVOA. Women of childbearing potential should have a pregnancy test performed by their doctor before starting treatment with

LUMVOA. If the patient becomes pregnant during treatment, LUMVOA should be discontinued and the patient advised of the potential risk to the fetus.

The background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

8.2 Lactation

Risk Summary

There is no information regarding the presence of LUMVOA in human milk, the effects on the breast-fed infant or the effects on milk production.

8.3 Females and Males of Reproductive Potential

Contraception

Females

Because inhibiting IGF-1R signaling impacts normal embryonic development and placental development and function, LUMVOA may cause fetal harm when administered to a pregnant woman *[see Use in Specific Populations (8.1)]*. Advise females of reproductive potential to use effective contraception prior to initiation, during treatment with LUMVOA and for 6 months after the last dose of LUMVOA.

8.4 Pediatric Use

The safety and effectiveness of LUMVOA have not been established in pediatric patients.

8.5 Geriatric Use

Of the 301 patients in Study 1 and Study 2, 12% were 65 years of age or older, with a similar proportion of patients 65 years of age or older between treatment groups. No overall differences in safety or effectiveness of LUMVOA have been observed between patients 65 years of age or older and younger adult patients.

10 OVERDOSAGE

No information is available for patients who have received an overdosage.

11 DESCRIPTION

Veligrotug-vvze, an insulin-like growth factor-1 receptor inhibitor (IGF-1R), is a humanized IgG1κ monoclonal antibody produced in Chinese hamster ovary (CHO-K1) cells. It has a molecular weight of approximately 150 kilodaltons.

LUMVOA (veligrotug-vvze) injection is supplied as a sterile, preservative-free, yellowish to brown, slightly opalescent solution, and free of visible particles, for intravenous infusion. Each single-dose vial contains 500 mg of veligrotug-vvze, histidine (6.50 mg), L-histidine hydrochloride monohydrate (33.1 mg), methionine (14.9 mg), polysorbate 80 (2.0 mg), sucrose (800 mg), and Water for Injection (quantity sufficient to 10 mL). The final concentration is 50 mg/mL with a pH of 5.5.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Veligrotug-vvze's mechanism of action in patients with thyroid eye disease has not been fully characterized. Veligrotug-vvze is a humanized IgG1 monoclonal antibody that binds to IGF-1R and inhibits IGF-1R signaling by blocking ligand-induced receptor autophosphorylation.

12.2 Pharmacodynamics

No formal pharmacodynamic studies have been conducted with veligrotug-vvze.

12.3 Pharmacokinetics

The pharmacokinetics (PK) of veligrotug-vvze were described by a two-compartment population PK model based on data from 298 patients with thyroid eye disease receiving 10 mg/kg LUMVOA every 3 weeks in 4 clinical trials. Following this dose regimen, the geometric mean estimates for steady-state area under the concentration curve (AUC), peak (C_{max}), and trough (C_{trough}) concentrations of veligrotug-vvze were 3450 mcg·day/mL, 363 mcg/mL, and 97.8 mcg/mL, respectively.

Distribution

The population PK estimated mean central and peripheral volume of distribution of veligrotug-vvze were 2.80 L and 2.50 L, respectively.

Elimination

The population PK estimated mean (% relative standard error) linear clearance of veligrotug-vvze was 0.216 (2.7) L/day with a corresponding half-life of approximately 18 days.

Metabolism

Metabolism of veligrotug-vvze has not been fully characterized. However, veligrotug-vvze is expected to undergo metabolism via proteolysis.

Specific Populations

No clinically meaningful differences in the pharmacokinetics of veligrotug-vvze were observed following administration of LUMVOA based on patient's age (20 - 79 years), sex (216 female and 82 male), race/ethnicity (224 White, 22 Black, and 13 Asian), or weight (41 - 161 kg). Neither renal nor hepatic impairment is expected to influence the pharmacokinetics of veligrotug-vvze.

Drug Interaction Studies

No studies evaluating the drug interaction potential of LUMVOA have been conducted.

12.6 Immunogenicity

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

In controlled clinical studies with veligrotug, ADA sampling was conducted during the 15-week treatment period, as well as during the post treatment follow-up period 12 weeks after the final infusion. Two hundred and ninety (290) of 361 patients (80.3%) had evaluable samples for ADA assessment, in which treatment emergent anti-veligrotug antibodies were detected in 20% (58/290) of patients. In general, there was no apparent

correlation of anti-veligrotug antibody development with changes in the pharmacokinetics, safety, and/or effectiveness of veligrotug.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

The carcinogenic potential of LUMVOA has not been evaluated in long-term animal studies.

Mutagenesis

The genotoxic potential of LUMVOA has not been evaluated.

Impairment of Fertility

Dedicated fertility studies have not been performed with LUMVOA. In the repeat-dose toxicology studies in sexually mature male and female cynomolgus monkeys, no effects on the reproductive system were observed at exposure higher (7-fold) than the human exposure (AUC) at the maximum recommended human dose.

14 CLINICAL STUDIES

LUMVOA was evaluated in 301 patients across 2 randomized, double-masked, placebo-controlled studies: active thyroid eye disease (Study 1: NCT05176639) and chronic thyroid eye disease (Study 2: NCT06021054). Patients were randomized to receive LUMVOA or placebo in a 2:1 ratio. Patients were given intravenous infusions of LUMVOA 10 mg/kg every 3 weeks for a total of 5 infusions. Patients in Study 1 had a clinical diagnosis of thyroid eye disease with onset within 15 months and a clinical activity score of 3 or more. Patients in Study 2 had a clinical diagnosis of thyroid eye disease with onset greater than 15 months and any clinical activity score (0-7). Prior orbital decompression surgery was permitted in either study if surgery was limited to bone. Patients with abnormal baseline audiometry Pure Tone Average (PTA) assessment or history of significant (as determined by the investigator) ear pathology, relevant ear surgery, or hearing loss were excluded. Patients with biopsy proven or clinical evidence of inflammatory bowel disease (IBD) were also excluded.

In Study 1, 75 patients with active thyroid eye disease were randomized to LUMVOA and 38 patients were randomized to placebo. The median age was 50 years (range 23 to 79 years), 77% were female, 62% were White, 6% were Black or African-American, 8% were Asian and 13% identified as Other. At baseline, 17% of patients were current users of tobacco. Proptosis ranged from 13.7 to 33.3 mm and 76 patients (67%) had diplopia at baseline.

In Study 2, 125 patients with chronic thyroid eye disease were randomized to LUMVOA and 63 patients were randomized to placebo. The median age was 52 years (range 20 to 77 years), 75% were female, 76% were White, 10% were Black or African-American, 3% were Asian and 4% identified as Other. At baseline, 26% of patients were current users of tobacco. Proptosis ranged from 14.1 to 35.0 mm and 102 patients (54%) had diplopia at baseline. Clinical activity scores ranged from 0 to 7 with 66 patients (35%) having a clinical activity score of 0 or 1 at baseline.

The proptosis responder rate at Week 15 was defined as the percentage of patients with ≥2 mm reduction in proptosis in the study eye from baseline, without deterioration in proptosis (≥2 mm increase) in the non-study eye. Additional evaluations included signs and symptoms of thyroid eye disease including diplopia, retrobulbar pain, gaze evoked orbital pain, eyelid swelling, eyelid erythema, conjunctival redness, chemosis, inflammation, clinical activity score, and assessments of quality of life (functional vision and patient appearance).

The proptosis results at Week 15 as measured by exophthalmometer in Studies 1 and 2 are provided in Table 2. Similar proptosis results were observed when measured by magnetic resonance imaging (MRI)/computed tomography (CT).

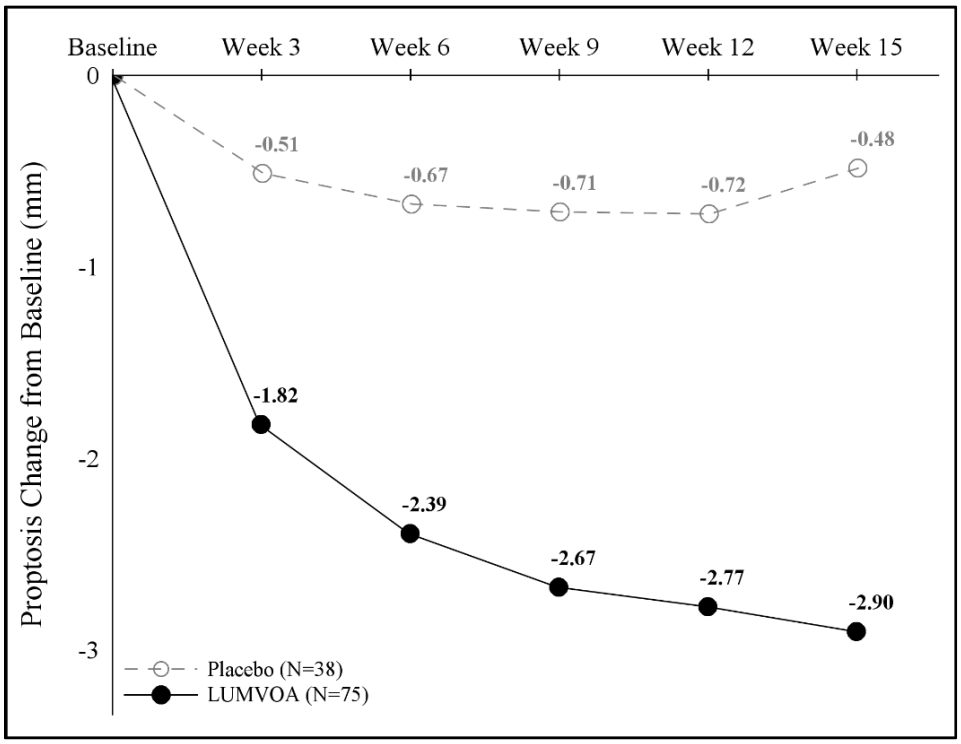
Table 2: Efficacy Results in Patients with Active Thyroid Eye Disease (Study 1) or Chronic Thyroid Eye Disease (Study 2)

	Study 1 (Active Thyroid Eye Disease)			Study 2 (Chronic Thyroid Eye Disease)		
	LUMVOA (N=75)	**Placebo (N=38)**	**Difference (95% CI) p-value**	**LUMVOA (N=125)**	**Placebo (N=63)**	**Difference (95% CI) p-value**
Proptosis responder rate at Week 15 – exophthalmometer, %[1]	70%	5%	65% (52, 78) <0.01	57%	8%	49% (38, 60) <0.01
Proptosis (mm) average change from baseline at Week 15 – exophthalmometer, LS Mean (SE)[2]	-2.9 (0.2)	-0.5 (0.2)	-2.4 (-3.0, -1.8) <0.01	-2.4 (0.2)	-0.5 (0.2)	-1.9 (-2.4, -1.4) <0.01

[1] Proptosis responder rate (PRR) results via exophthalmometer were analyzed based on a generalized estimating equation (GEE) model of baseline through Week 15 data.
[2] Results were obtained from a mixed model for repeated measures (MMRM) with an unstructured covariance matrix and included treatment, baseline value, visit, treatment by visit, and visit by baseline value interaction as fixed effects. A change from Baseline of 0 was imputed at the first post-Baseline visit for any subject without a post-Baseline value.

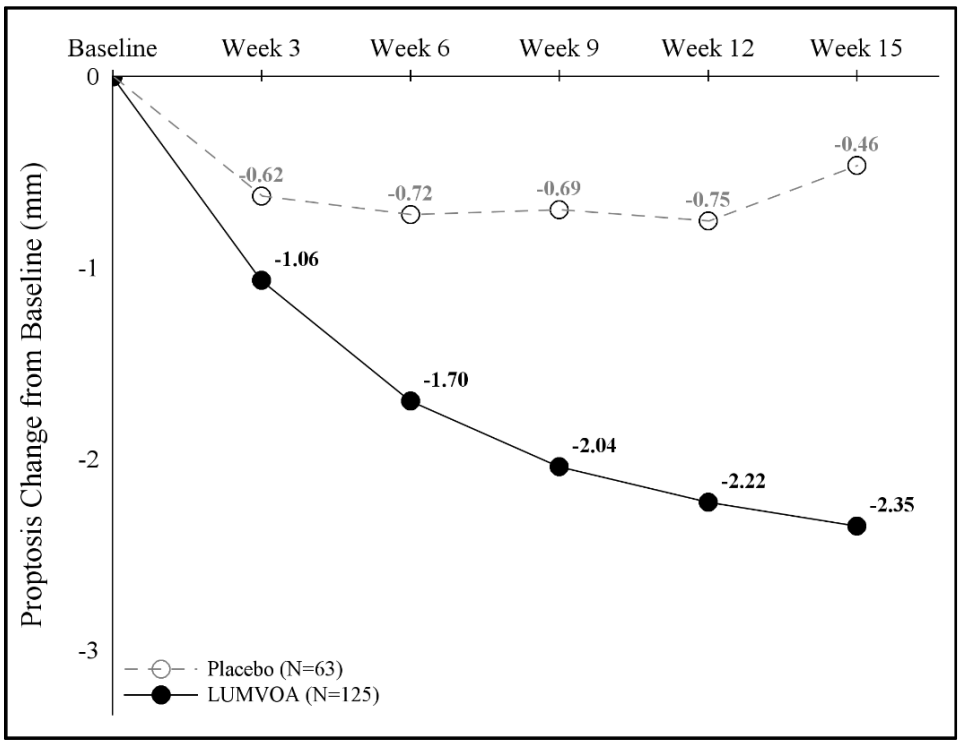
In Studies 1 and 2, improvement of proptosis as measured by mean change from baseline was observed as early as 3 weeks and proptosis continued to improve through Week 15 in both active thyroid eye disease (Figure 1) and chronic thyroid eye disease (Figure 2).

Figure 1: Change from Baseline in Proptosis by Exophthalmometer over 15 Weeks for Patients with Active Thyroid Eye Disease (Study 1)



P<0.01 at each timepoint.

Figure 2: Change from Baseline in Proptosis by Exophthalmometer over 15 Weeks for Patients with Chronic Thyroid Eye Disease (Study 2)



P<0.01 at each timepoint.

In both studies, LUMVOA also led to improvement in the less severely impacted non-study eye and a reduction in extraocular muscle volume in both eyes.

Diplopia (double vision) was evaluated in patients who had diplopia at baseline in Studies 1 and 2. Results are shown in Table 3. Diplopia resolution was observed as early as 3 weeks in active thyroid eye disease and 6 weeks in chronic thyroid eye disease.

Table 3: Diplopia in Patients with Active Thyroid Eye Disease (Study 1) or Chronic Thyroid Eye Disease (Study 2)

	Study 1 (Active Thyroid Eye Disease)			Study 2 (Chronic Thyroid Eye Disease)		
	LUMVOA N=50	**Placebo N=26**	**Difference (95% CI) p-value**	**LUMVOA N=65**	**Placebo N=37**	**Difference (95% CI) p-value**
Diplopia responder rate at Week 15, %[1,2]	59%	20%	39.2 (18.8, 59.6) <0.01	56%	25%	30.9 (12.3, 49.5) <0.01
Diplopia resolution rate at Week 15, %[1,3]	49%	12%	37.7 (18.9, 56.6) <0.01	32%	14%	17.7 (1.6, 33.9) 0.02

[1] Diplopia was evaluated on a 4-point scale where scores ranged from 0 for no diplopia to 3 for constant diplopia. Diplopia results were analyzed based on a GEE model of baseline through Week 15 data.
[2] Diplopia response in a patient was defined as having a diplopia score >0 at baseline and achieving a reduction of at least 1 point on the diplopia scale at Week 15.
[3] Diplopia resolution in a patient was defined as having a diplopia score >0 at baseline and a score of 0 at Week 15.

In Study 1, 71% of patients who were proptosis responders at Week 15 maintained proptosis response at 52 weeks and 50% of patients who achieved diplopia resolution at Week 15 maintained resolution at Week 52.

In Study 2, 57% of patients who were proptosis responders at Week 15 maintained proptosis response at 52 weeks and 80% of patients who achieved diplopia resolution at Week 15 maintained resolution at Week 52.

Subgroups

Examination of age and sex subgroups did not identify differences in response to LUMVOA among these subgroups. Reduction in proptosis and diplopia was similar between smokers and non-smokers in both studies.

16 HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

LUMVOA (veligrotug-vvze) injection is a sterile, preservative-free, yellowish to brown, slightly opalescent solution available as follows:

Carton containing one 500 mg/10 mL (50 mg/mL) single-dose vial	NDC 85166-001-01

Storage and Handling

Store refrigerated at 2°C to 8°C (36°F to 46°F) in original carton to protect from light. Do not freeze. Do not shake.

17 PATIENT COUNSELING INFORMATION

Embryo-Fetal Toxicity

- Advise females of reproductive potential that LUMVOA may cause harm to a fetus and to inform their healthcare provider of a known or suspected pregnancy.
- Educate and counsel females of reproductive potential about the need to use effective contraception prior to initiation of, during treatment with LUMVOA and for 6 months after the last dose of LUMVOA.

Infusion Reactions

Advise patients that LUMVOA may cause infusion reactions that can occur during or soon after an infusion. Instruct patients to recognize the signs and symptoms of infusion reactions and to contact their healthcare provider immediately for signs or symptoms of potential infusion-related reactions.

Inflammatory Bowel Disease

Advise patients on the risk of inflammatory bowel disease (IBD), including patients with or without a prior diagnosis of IBD. Advise patients to seek medical advice immediately if they experience diarrhea, with or without blood, or rectal bleeding, associated with abdominal pain or cramping/colic, fecal urgency, tenesmus or incontinence.

Hyperglycemia

Advise patients on the risk of hyperglycemia and, if diabetic, discuss with healthcare provider to adjust glycemic control measures including medications as appropriate. Encourage compliance with glycemic control.

Hearing Impairment Including Hearing Loss

Advise patients that LUMVOA may cause severe hearing impairment including hearing loss, which in some cases may be permanent. Instruct patients to contact their healthcare provider if they experience any signs or symptoms of hearing impairment or any changes in hearing.

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