



# Committed to Helping You Get Your **Genentech Ophthalmology** **Treatment**, Right From the Start

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There may be options that may help you afford your Genentech Ophthalmology treatments, no matter what type of health insurance you have.

## GENENTECH OPHTHALMOLOGY CO-PAY PROGRAM

If you have commercial health insurance, and have been prescribed VABYSMO® (faricimab-svoa), SUSVIMO™ (ranibizumab injection) or LUCENTIS® (ranibizumab injection) for an FDA-approved indication, you maybe eligible for the Genentech Ophthalmology Co-pay Program.\*

### WITH THIS PROGRAM, YOU PAY AS LITTLE AS

\$0 per drug co-pay,<sup>†</sup> up to \$15,000 per calendar year,  
for **VABYSMO**, **SUSVIMO** and **LUCENTIS**

\$0 per drug administration co-pay,<sup>†</sup> up to \$1,000 per calendar year:

Surgical procedure and  
refill co-pay for **SUSVIMO**

Injection co-pay for  
**VABYSMO** and **LUCENTIS**

There are no income requirements for this program.

### Make sure you have the following information on hand:

- ☐ Your doctor's name, address and phone number
- ☐ The disease you are being treated for and the Genentech Ophthalmology treatment you have been prescribed
- ☐ Commercial insurance information (insurance type, group number and member ID)
- ☐ Your insurance card (if you have more than one insurer, please have all information available)

### The Genentech Ophthalmology Co-pay Program Is Flexible

- You can enroll into the program up to **180 days** after your injection or prescription fill occurred
- Claims can be submitted within **365 days** from the date of service to be eligible

**To enroll or learn more, visit [EyeOnCopoly.com](https://www.EyeOnCopoly.com) or call (855) 218-5307.**

\*The Product and Administration Co-pay Programs are valid ONLY for patients with commercial (private or non-governmental) insurance who have a valid prescription for a Food and Drug Administration (FDA)-approved indication of a Genentech medicine. Patients using Medicare, Medicaid or any other federal or state government program (collectively, "Government Programs") to pay for their Genentech medicine and/or administration services are not eligible. (continued on next page)

## REFERRALS TO INDEPENDENT CO-PAY ASSISTANCE FOUNDATIONS

If you have public or commercial health insurance, you may qualify for help from an independent co-pay assistance foundation.



**Genentech can refer you to a foundation that might help you pay for your treatment.**

Foundations have their own rules for eligibility and how much they will pay.

- For example, some foundations only support patients with Medicare Part D

There might be a few foundations that can help you. If one can't help, another one might be able to.

**You can visit [VABYSMO.com](http://VABYSMO.com), [SUSVIMO.com](http://SUSVIMO.com) or [LUCENTIS.com](http://LUCENTIS.com) to view a list of independent co-pay assistance foundations or call (833) EYE-GENE/(833) 393-4363 to get help.**

Under the Programs, the patient may pay a co-pay for drug costs and a co-pay for administration costs. The final amount owed by a patient may be as little as \$0 for the Genentech medicine or administration of the Genentech medicine (see Program specific details). The total patient out-of-pocket cost is dependent on the patient's health insurance plan. The Programs assist with the cost of the Genentech medicine and the Genentech medicine administration only. It does not assist with the cost of other administrations, medicines, procedures or office visit fees. After reaching the maximum Programs' benefit amounts, the patient will be responsible for all remaining out-of-pocket expenses. The amount of the Programs' benefits cannot exceed the patient's out-of-pocket expenses for the cost of the Genentech medicine or administration fees associated with the Genentech medicine.

All participants are responsible for reporting the receipt of all Programs' benefits as required by any insurer or by law. The Programs are only valid in the United States and U.S. Territories and are void where prohibited by law. The Drug Co-pay Program shall follow state restrictions in relation to AB-rated generic equivalents (e.g., MA, CA) where applicable. The Administration Co-pay Program is not valid for Massachusetts or Rhode Island residents. No party may seek reimbursement for all or any part of the benefit received through the Programs. The Programs are intended for the patient. Only the patient using the Programs may receive the funds made available through the Programs. The Programs are not intended for third parties who reduce the amount available to the patient or take a portion for their own purposes. Patients with health plans that redirect Genentech Program assistance intended for patient out-of-pocket costs may be subject to alternate Program benefit structures. Genentech reserves the right to rescind, revoke or amend the Programs without notice at any time.

Additional terms and conditions apply. Please visit the co-pay Program website for the full list of Terms and Conditions.

<sup>†</sup>The final amount owed by patients may be as little as \$0, but may vary depending on the patient's health insurance plan. Eligible commercially insured patients who are prescribed VABYSMO, SUSVIMO or LUCENTIS for an FDA-approved use can receive up to \$15,000 in assistance per calendar year for drug costs and/or up to \$1,000 in administration assistance per calendar year for SUSVIMO surgical procedure and refill costs and VABYSMO and LUCENTIS injection costs. The program benefit does not reset if a patient switches from one Genentech Ophthalmology treatment to another. It does not help with facility fees. See terms and conditions for each program. Program limits apply.

Independent co-pay assistance foundations have their own rules for eligibility. Genentech has no involvement or influence in independent foundation decision-making or eligibility criteria and does not know if a foundation will be able to help you. We can only refer you to a foundation that supports your disease state. Genentech does not endorse or show preference for any particular foundation. The foundations we refer you to may not be the only ones that might be able to help you.

# GENENTECH PATIENT FOUNDATION

If you don't have insurance coverage or have financial concerns and meet eligibility criteria, you may be able to get free treatments from the Genentech Patient Foundation.

## ELIGIBILITY CRITERIA<sup>‡</sup>

### UNINSURED PATIENTS

With incomes under \$150,000

OR

### INSURED PATIENTS WITHOUT COVERAGE for a Genentech medicine

With incomes under \$150,000

OR

### INSURED PATIENTS WITH COVERAGE for a Genentech medicine<sup>§</sup>

- With unaffordable out-of-pocket costs
- With household size and income within certain guidelines, available at [GenentechPatientFoundation.com](https://www.GenentechPatientFoundation.com)

**For more information, visit [GenentechPatientFoundation.com](https://www.GenentechPatientFoundation.com) or call a Foundation Specialist at (888) 941-3331.**

<sup>‡</sup>For all patient types, add \$25,000 for each extra person in households larger than 4 people.





<sup>§</sup>We encourage insured patients to try other financial assistance options prior to applying for help from the Genentech Patient Foundation, if possible.

Genentech reserves the right to modify or discontinue the program at any time and to verify the accuracy of information submitted.

GENENTECH OPHTHALMOLOGY ACCESS SOLUTIONS

Genentech Ophthalmology Access Solutions is dedicated to helping you understand your insurance coverage and assistance options. This can help you access the ophthalmology treatment your doctor prescribed.

We work with your doctor, surgical coordinator, health insurance company and specialty pharmacy to help you get your Genentech Ophthalmology treatment. We have programs that can help based on your unique needs.

	COMMERCIAL Insurance	PUBLIC Insurance	NO Insurance
Genentech Ophthalmology Co-pay Program*			
Genentech Patient Foundation†			

If you have public or commercial health insurance, you may qualify for help from an independent co-pay assistance foundation.‡

**Commercial insurance** is a health insurance plan from your employer, a plan you bought yourself or a plan from the health insurance marketplace (for example, from HealthCare.gov).

**Public insurance** is a health insurance plan you get from the federal or state government. This includes Medicare, Medicaid, TRICARE and DoD/VA insurance.

\*Eligibility criteria apply. Not valid for patients using federal or state government programs to pay for their medications and/or administration of their Genentech medication. Patient must be taking the Genentech medication for an FDA-approved indication. See full Terms and Conditions at EyeOnCopay.com.

†If you have health insurance, you should try to get other types of financial assistance, if available. You also need to meet income requirements. If you do not have insurance, or if your insurance does not cover your Genentech treatment, you must meet a different set of income requirements. Genentech reserves the right to modify or discontinue the program at any time and to verify the accuracy of information submitted.

‡Independent co-pay assistance foundations have their own rules for eligibility. Genentech has no involvement or influence in independent foundation decision-making or eligibility criteria and does not know if a foundation will be able to help you. We can only refer you to a foundation that supports your disease state. Genentech does not endorse or show preference for any particular foundation. The foundations we refer you to may not be the only ones that might be able to help you.

## HELPING YOU GET THE TREATMENT YOU NEED SO YOU CAN FOCUS ON WHAT MATTERS MOST

To learn how we can help:

 Visit **VABYSMO.com**, **SUSVIMO.com** or **LUCENTIS.com**

 Call **(833) EYE-GENE**/(833) 393-4363

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M-US-00012737(v3.0) 11/22 Printed in USA

## HIGHLIGHTS OF PRESCRIBING INFORMATION

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

**VABYSMO® (faricimab-svoa) injection, for intravitreal use**

**Initial U.S. Approval: 2022**

### RECENT MAJOR CHANGES

Indications and Usage, Macular Edema Following Retinal Vein Occlusion (RVO) (1.3)	10/2023
Dosage and Administration, General Dosing Information (2.1)	7/2024
Dosage and Administration, Macular Edema Following Retinal Vein Occlusion (2.4)	10/2023
Dosage and Administration, Preparation for Administration - Prefilled Syringe (2.5)	7/2024
Dosage and Administration, Injection Procedure (2.7)	7/2024
Warnings and Precautions, Retinal Vasculitis and/or Retinal Vascular Occlusion (5.4)	10/2023

### INDICATIONS AND USAGE

VABYSMO is a vascular endothelial growth factor (VEGF) and angiopoietin-2 (Ang-2) inhibitor indicated for the treatment of patients with:

- Neovascular (Wet) Age-Related Macular Degeneration (nAMD) (1.1)
- Diabetic Macular Edema (DME) (1.2)
- Macular Edema Following Retinal Vein Occlusion (RVO) (1.3)

### DOSAGE AND ADMINISTRATION

For intravitreal injection. (2.1)

- **Neovascular (Wet) Age-Related Macular Degeneration (nAMD)**
  - The recommended dose for VABYSMO is 6 mg (0.05 mL of 120 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 ± 7 days, monthly) for the first 4 doses, followed by optical coherence tomography and visual acuity evaluations 8 and 12 weeks later to inform whether to give a 6 mg dose via intravitreal injection on one of the following three regimens: 1) Weeks 28 and 44; 2) Weeks 24, 36 and 48; or 3) Weeks 20, 28, 36 and 44. Although additional efficacy was not demonstrated in most patients when VABYSMO was dosed every 4 weeks compared to every 8 weeks, some patients may need every 4 week (monthly) dosing after the first 4 doses. Patients should be assessed regularly. (2.2)
- **Diabetic Macular Edema (DME)**
  - VABYSMO is recommended to be dosed by following one of these two dose regimens: 1) 6 mg (0.05 mL of 120 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 days ± 7 days, monthly) for at least 4 doses. If after at least 4 doses, resolution of edema based on the central subfield thickness

(CST) of the macula as measured by optical coherence tomography is achieved, then the interval of dosing may be modified by extensions of up to 4 week interval increments or reductions of up to 8 week interval increments based on CST and visual acuity evaluations; or 2) 6 mg dose of VABYSMO can be administered every 4 weeks for the first 6 doses, followed by 6 mg dose via intravitreal injection at intervals of every 8 weeks (2 months). Although additional efficacy was not demonstrated in most patients when VABYSMO was dosed every 4 weeks compared to every 8 weeks, some patients may need every 4 week (monthly) dosing after the first 4 doses. Patients should be assessed regularly. (2.3)

- **Macular Edema Following Retinal Vein Occlusion (RVO)**
  - The recommended dose for VABYSMO is 6 mg (0.05 mL of 120 mg/mL) administered by intravitreal injection every 4 weeks (approximately every 28 ± 7 days, monthly) for 6 months. (2.4)

### DOSAGE FORMS AND STRENGTHS

- Injection: 6 mg (0.05 mL of 120 mg/mL solution) in a single-dose prefilled syringe (3)
- Injection: 6 mg (0.05 mL of 120 mg/mL solution) in a single-dose vial (3)

### CONTRAINDICATIONS

- Ocular or periocular infection (4.1)
- Active intraocular inflammation (4.2)
- Hypersensitivity (4.3)

### WARNINGS AND PRECAUTIONS

- Endophthalmitis and retinal detachments may occur following intravitreal injections. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay, to permit prompt and appropriate management. (5.1)
- Increases in intraocular pressure have been seen within 60 minutes of an intravitreal injection. (5.2)
- There is a potential risk of arterial thromboembolic events (ATEs) associated with VEGF inhibition. (5.3)

### ADVERSE REACTIONS

The most common adverse reactions (≥ 5%) reported in patients receiving VABYSMO were cataract (15%) and conjunctival hemorrhage (8%). (6.1)

**To report SUSPECTED ADVERSE REACTIONS, contact Genentech at 1-888-835-2555 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

**See 17 for PATIENT COUNSELING INFORMATION.**

**Revised: 7/2024**

## FULL PRESCRIBING INFORMATION: CONTENTS\*

### 1 INDICATIONS AND USAGE

- 1.1 Neovascular (Wet) Age-Related Macular Degeneration (nAMD)
- 1.2 Diabetic Macular Edema (DME)
- 1.3 Macular Edema Following Retinal Vein Occlusion (RVO)

### 2 DOSAGE AND ADMINISTRATION

- 2.1 General Dosing Information
- 2.2 Neovascular (Wet) Age-Related Macular Degeneration (nAMD)
- 2.3 Diabetic Macular Edema (DME)
- 2.4 Macular Edema Following Retinal Vein Occlusion (RVO)
- 2.5 Preparation for Administration - Prefilled Syringe
- 2.6 Preparation for Administration - Vial
- 2.7 Injection Procedure

### 3 DOSAGE FORMS AND STRENGTHS

### 4 CONTRAINDICATIONS

- 4.1 Ocular or Periocular Infections
- 4.2 Active Intraocular Inflammation
- 4.3 Hypersensitivity

### 5 WARNINGS AND PRECAUTIONS

- 5.1 Endophthalmitis and Retinal Detachments
- 5.2 Increase in Intraocular Pressure
- 5.3 Thromboembolic Events
- 5.4 Retinal Vasculitis and/or Retinal Vascular Occlusion

### 6 ADVERSE REACTIONS

- 6.1 Clinical Trials Experience
- 6.2 Postmarketing Experience

### 8 USE IN SPECIFIC POPULATIONS

- 8.1 Pregnancy
- 8.2 Lactation
- 8.3 Females and Males of Reproductive Potential
- 8.4 Pediatric Use
- 8.5 Geriatric Use

### 11 DESCRIPTION

### 12 CLINICAL PHARMACOLOGY

- 12.1 Mechanism of Action
- 12.2 Pharmacodynamics
- 12.3 Pharmacokinetics
- 12.6 Immunogenicity

### 13 NONCLINICAL TOXICOLOGY

- 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

### 14 CLINICAL STUDIES

- 14.1 Neovascular (Wet) Age-Related Macular Degeneration (nAMD)
- 14.2 Diabetic Macular Edema (DME)
- 14.3 Macular Edema Following Retinal Vein Occlusion (RVO)

### 16 HOW SUPPLIED/STORAGE AND HANDLING

- 16.1 How Supplied
- 16.2 Storage and Handling

### 17 PATIENT COUNSELING INFORMATION

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

## **FULL PRESCRIBING INFORMATION**

### **1 INDICATIONS AND USAGE**

VABYSMO is a vascular endothelial growth factor (VEGF) and angiopoietin 2 (Ang-2) inhibitor indicated for the treatment of patients with:

#### **1.1 Neovascular (wet) Age-Related Macular Degeneration (nAMD)**

#### **1.2 Diabetic Macular Edema (DME)**

#### **1.3 Macular Edema Following Retinal Vein Occlusion (RVO)**

### **2 DOSAGE AND ADMINISTRATION**

#### **2.1 General Dosing Information**

For intravitreal injection. VABYSMO must be administered by a qualified physician.

VABYSMO is available as:

- Prefilled syringe: A sterile injection filter needle (30-gauge x ½-inch, Extra Thin Wall) with an integrated filter in the hub is provided. Each prefilled syringe should only be used for the treatment of a single eye.
- Vial: A sterile 5-micron, blunt transfer filter needle (18-gauge x 1½-inch) is provided. Each vial should only be used for the treatment of a single eye.

*[see How Supplied/Storage and Handling (16)]*

#### **2.2 Neovascular (wet) Age-Related Macular Degeneration (nAMD)**

The recommended dose for VABYSMO is 6 mg (0.05 mL of 120 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every  $28 \pm 7$  days, monthly) for the first 4 doses, followed by optical coherence tomography and visual acuity evaluations 8 and 12 weeks later to inform whether to give a 6 mg dose via intravitreal injection on one of the following three regimens: 1) Weeks 28 and 44; 2) Weeks 24, 36 and 48; or 3) Weeks 20, 28, 36 and 44. Although additional efficacy was not demonstrated in most patients when VABYSMO was dosed every 4 weeks compared to every 8 weeks, some patients may need every 4 week (monthly) dosing after the first 4 doses. Patients should be assessed regularly.

#### **2.3 Diabetic Macular Edema (DME)**

VABYSMO is recommended to be dosed by following one of these two dose regimens: 1) 6 mg (0.05 mL of 120 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every  $28 \pm 7$  days, monthly) for at least 4 doses. If after at least 4 doses, resolution of edema based on the central subfield thickness (CST) of the macula as measured by optical coherence tomography is achieved, then the interval of dosing may be modified by extensions of up to 4 week interval increments or reductions of up to 8 week interval increments based on CST and visual acuity evaluations; or 2) 6 mg dose of VABYSMO can be administered every 4 weeks for the first 6 doses, followed by 6 mg dose via intravitreal injection at intervals of every 8 weeks (2 months). Although additional efficacy was not demonstrated in most patients when VABYSMO was dosed every 4 weeks compared to every 8 weeks, some patients may need every 4 week (monthly) dosing after the first 4 doses. Patients should be assessed regularly.

#### **2.4 Macular Edema Following Retinal Vein Occlusion (RVO)**

The recommended dose for VABYSMO is 6 mg (0.05 mL of 120 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every  $28 \pm 7$  days, monthly) for 6 months.

## 2.5 Preparation for Administration - Prefilled Syringe

### Before you start

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Read all the instructions carefully before using VABYSMO.

The VABYSMO carton includes:



A sterile prefilled syringe in a sealed tray. The prefilled syringe is for treatment of a single eye.



A sterile injection filter needle (30-gauge x 1/2 inch, Extra Thin Wall) with an integrated filter in the hub. The injection filter needle is for single use only.

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**Only use the provided injection filter needle for the administration.**

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VABYSMO should be refrigerated at temperatures between 2°C to 8°C (36°F to 46°F).

**Do not** freeze.



Allow VABYSMO to reach room temperature, 20°C to 25°C (68°F to 77°F) before proceeding with the administration.



Prior to use, keep the sealed tray in the original carton to **protect the prefilled syringe from light**. The prefilled syringe may be kept at room temperature in the original carton for up to **24 hours**.



VABYSMO should be inspected visually prior to administration.

**Do not** use if the carton seals have been tampered with.

**Do not** use if the packaging, prefilled syringe, injection filter needle is expired, damaged, or have been tampered with.

**Do not** use if the injection filter needle is missing.

**Do not** remove the finger grip from the syringe.

**Do not** use if the syringe cap is detached from the Luer lock.

**Do not** use if particulates, cloudiness, or discoloration are visible.

VABYSMO is a clear to opalescent and colorless to brownish-yellow liquid solution.

## Prefilled Syringe Description

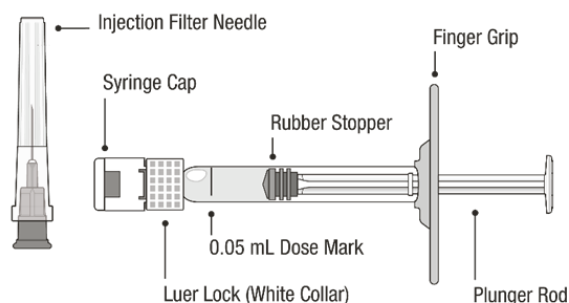


Figure A

**Note: the dose must be set to the 0.05 mL dose mark.**

Use aseptic technique to carry out the following preparation steps:

### Open Tray and Remove Syringe Cap

- 1 Peel the lid off the syringe tray and aseptically remove the prefilled syringe.
- 2 Hold the syringe by the white collar; snap off the syringe cap (see **Figure B**).

**Do not** twist off the cap.

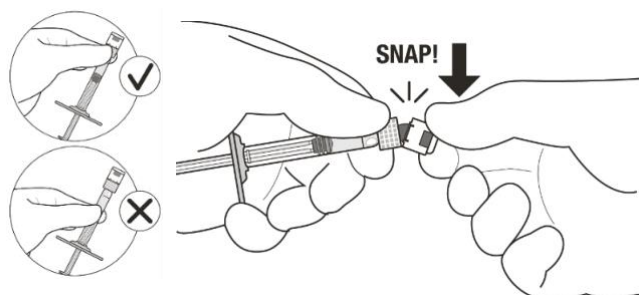


Figure B

### Attach Injection Filter Needle

- 3 Aseptically remove the provided injection filter needle from its packaging.
- 4 Aseptically and firmly attach the injection filter needle onto the syringe Luer lock (see **Figure C**).

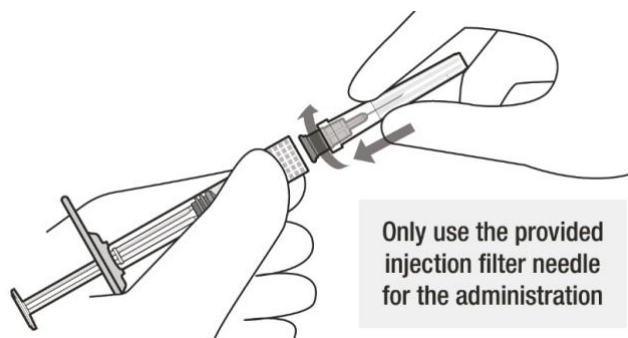


Figure C

- 5 Carefully remove the needle cap by pulling it straight off.

### Dislodge Air Bubbles

- 6 Hold the syringe with the injection filter needle pointing up. Check the syringe for air bubbles.
- 
- 7 If there are any air bubbles, gently tap the syringe with your finger until the bubbles rise to the top (see **Figure D**).

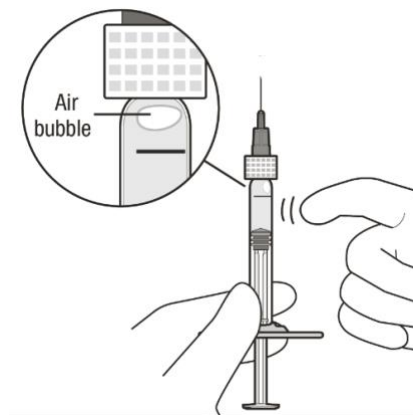


Figure D

### Expel Air and Adjust the Dose

- 8 Hold the syringe at eye level and **slowly** push the plunger rod until the **lower edge of the rubber stopper's dome** is aligned with the 0.05 mL dose mark (see **Figure E**). This will expel the air and the excess solution and set the dose to 0.05 mL.
- Ensure that the injection is given **immediately** after preparation of the dose.

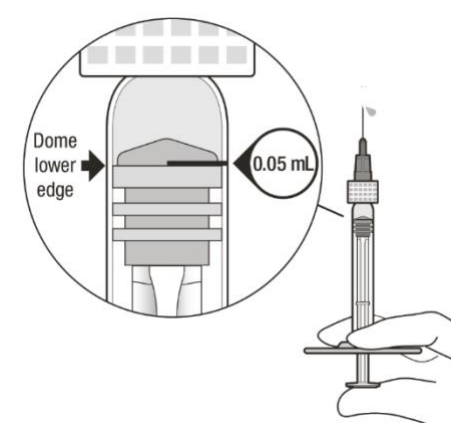


Figure E

## 2.6 Preparation for Administration - Vial

### Before you start

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Read all the instructions carefully before using VABYSMO.



The VABYSMO kit includes a glass vial and transfer filter needle. The glass vial is for a single dose only. The filter needle is for treatment of a single eye.



VABYSMO should be stored refrigerated at temperatures between 2°C to 8°C (36°F to 46°F).

**Do not** freeze.

**Do not** shake.



Allow VABYSMO to reach room temperature, 20°C to 25°C (68°F to 77°F) before proceeding with the administration. Keep the vial in the original carton to **protect from light**.

The VABYSMO vial may be kept at room temperature for up to **24 hours**.



The VABYSMO vial should be inspected visually for particulate matter and discoloration prior to administration. VABYSMO is a clear to opalescent and colorless to brownish-yellow liquid solution.

**Do not** use if particulates, cloudiness, or discoloration are visible.

**Do not** use if the packaging, vial and/or transfer filter needle are expired, damaged, or have been tampered with (see **Figure F**).



Figure F

Use aseptic technique to carry out the preparation of the intravitreal injection.

**1** Gather the following supplies:

- One VABYSMO vial (included)
- One sterile 5-micron blunt transfer filter needle 18-gauge x 1½ inch (included)
- One sterile 1 mL Luer lock syringe with a 0.05 mL dose mark (**not included**)
- One sterile injection needle 30-gauge x ½ inch (**not included**)  
**Note** that a 30-gauge injection needle is recommended to avoid increased injection forces that could be experienced with smaller diameter needles.
- Alcohol swab (**not included**).

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**2** To ensure all liquid settles at the bottom of the vial, place the vial upright on a flat surface (for about 1 minute) after removal from packaging (see **Figure G**). Gently tap the vial with your finger (see **Figure H**), as liquid may stick to the top of the vial.

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Figure G



Figure H

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- 3** Remove the flip-off cap from the vial (see **Figure I**) and wipe the vial septum with an alcohol swab (see **Figure J**).

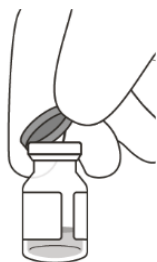


Figure I

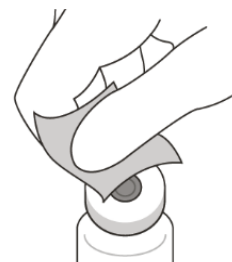


Figure J

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- 4** Aseptically and firmly attach the included 18-gauge x 1½ inch transfer filter needle onto a 1 mL Luer lock syringe (see **Figure K**).

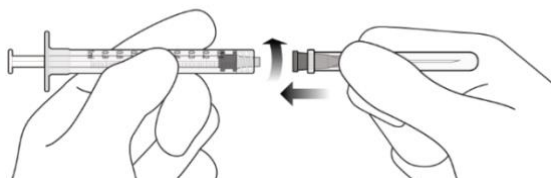


Figure K

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- 5** Using aseptic technique, push the transfer filter needle into the center of the vial septum (see **Figure L**), push it all the way in, then tilt the vial slightly so that the needle touches the bottom edge of the vial (see **Figure M**).

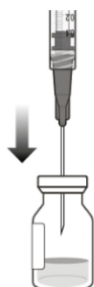


Figure L

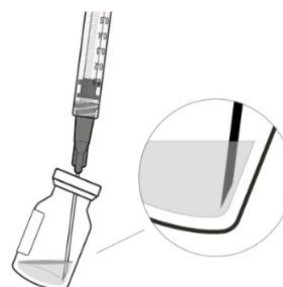


Figure M

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- 6** Hold the vial slightly inclined and **slowly** withdraw all the liquid from the vial (see **Figure N**). Keep the bevel of the transfer filter needle submerged in the liquid, to avoid introduction of air.



Figure N

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**7** Ensure that the plunger rod is drawn sufficiently back when emptying the vial, in order to completely empty the transfer filter needle (see **Figure N**).

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**8** Disconnect the transfer filter needle from the syringe and dispose of it in accordance with local regulations.

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**Do not use the transfer filter needle for the intravitreal injection.**

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**9** Aseptically and firmly attach a 30-gauge x ½ inch injection needle onto the Luer lock syringe (see **Figure O**).

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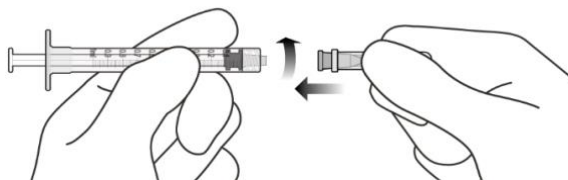


Figure O

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**10** Carefully remove the plastic needle shield from the needle by pulling it straight off.

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**11** To check for air bubbles, hold the syringe with the needle pointing up. If there are any air bubbles, gently tap the syringe with your finger until the bubbles rise to the top (see **Figure P**).

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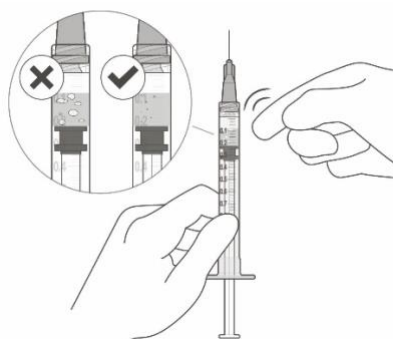


Figure P

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**12** Carefully expel the air from the syringe and needle, and **slowly** depress the plunger to align the rubber stopper tip to the 0.05 mL dose mark. The syringe is ready for the injection (see **Figure Q**). Ensure that the injection is given **immediately** after preparation of the dose.

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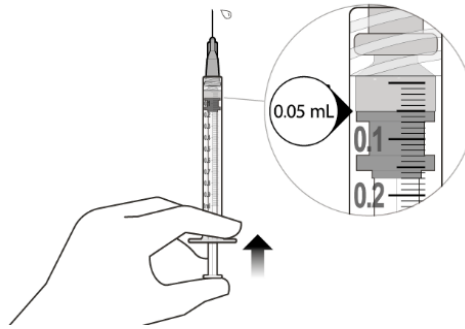


Figure Q

## 2.7 Injection Procedure

The intravitreal injection procedure must be carried out under aseptic conditions, which includes the use of surgical hand disinfection, sterile gloves, a sterile drape and a sterile eyelid speculum (or equivalent), and the availability of sterile paracentesis equipment (if required). Adequate anesthesia and a broad-spectrum microbicide should be administered prior to the injection.

Inject **slowly** until the rubber stopper reaches the end of the syringe to deliver the volume of 0.05 mL.

Note for the prefilled syringe: **Do not** recap or detach the injection filter needle from the syringe.

Any unused drug product or waste material should be disposed of in accordance with local regulations.

Immediately following the intravitreal injection, patients should be monitored for elevation in intraocular pressure. Appropriate monitoring may consist of a check for perfusion of the optic nerve head or tonometry. If required, a sterile paracentesis needle should be available. Following intravitreal injection, patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment (e.g., vision loss, eye pain, redness of the eye, photophobia, blurring of vision) without delay [see *Patient Counseling Information (17)*].

Each syringe should only be used for the treatment of a single eye. If the contralateral eye requires treatment, a new syringe should be used and the sterile field, syringe, gloves, drapes, eyelid speculum, filter, and injection needles should be changed before VABYSMO is administered to the other eye.

## 3 DOSAGE FORMS AND STRENGTHS

VABYSMO is a clear to opalescent, colorless to brownish-yellow solution available as:

- Injection: 6 mg (0.05 mL of 120 mg/mL solution) in a single-dose prefilled glass syringe
- Injection: 6 mg (0.05 mL of 120 mg/mL solution) in a single-dose glass vial

## 4 CONTRAINDICATIONS

### 4.1 Ocular or Periocular Infections

VABYSMO is contraindicated in patients with ocular or periocular infections.

## 4.2 Active Intraocular Inflammation

VABYSMO is contraindicated in patients with active intraocular inflammation.

## 4.3 Hypersensitivity

VABYSMO is contraindicated in patients with known hypersensitivity to faricimab or any of the excipients in VABYSMO. Hypersensitivity reactions may manifest as rash, pruritus, urticaria, erythema, or severe intraocular inflammation.

# 5 WARNINGS AND PRECAUTIONS

## 5.1 Endophthalmitis and Retinal Detachments

Intravitreal injections, including Vabysmo, have been associated with endophthalmitis and retinal detachments [*see Adverse Reactions (6.1)*]. Proper aseptic injection techniques must always be used when administering VABYSMO. Patients should be instructed to report any signs or symptoms suggestive of endophthalmitis or retinal detachment without delay, to permit prompt and appropriate management [*see Dosage and Administration (2.6) and Patient Counseling Information (17)*].

## 5.2 Increase in Intraocular Pressure

Transient increases in intraocular pressure (IOP) have been seen within 60 minutes of intravitreal injection, including with VABYSMO [*see Adverse Reactions (6.1)*]. IOP and the perfusion of the optic nerve head should be monitored and managed appropriately [*see Dosage and Administration (2.6)*].

## 5.3 Thromboembolic Events

Although there was a low rate of arterial thromboembolic events (ATEs) observed in the VABYSMO clinical trials, there is a potential risk of ATEs following intravitreal use of VEGF inhibitors. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause).

The incidence of reported ATEs in the nAMD studies during the first year was 1% (7 out of 664) in patients treated with VABYSMO compared with 1% (6 out of 662) in patients treated with aflibercept [*see Clinical Studies (14.1)*].

The incidence of reported ATEs in the DME studies from baseline to week 100 was 5% (64 out of 1,262) in patients treated with VABYSMO compared with 5% (32 out of 625) in patients treated with aflibercept [*see Clinical Studies (14.2)*].

The incidence of reported ATEs in the RVO studies during the first 6 months was 1.1% (7 out of 641) in patients treated with VABYSMO compared with 1.4% (9 out of 635) in patients treated with aflibercept [*see Clinical Studies (14.3)*].

## 5.4 Retinal Vasculitis and/or Retinal Vascular Occlusion

Retinal vasculitis and/or retinal vascular occlusion, typically in the presence of intraocular inflammation, have been reported with the use of VABYSMO [*see Adverse Reactions (6.2)*]. Discontinue treatment with VABYSMO in patients who develop these events. Patients should be instructed to report any change in vision without delay.

# 6 ADVERSE REACTIONS

The following potentially serious adverse reactions are described elsewhere in the labeling:

- Hypersensitivity [*see Contraindications (4)*]
- Endophthalmitis and retinal detachments [*see Warnings and Precautions (5.1)*]

- Increase in intraocular pressure [see Warnings and Precautions (5.2)]
- Thromboembolic events [see Warnings and Precautions (5.3)]
- Retinal Vasculitis and/or Retinal Vascular Occlusion [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 other clinical trials of the same or another drug and may not reflect the rates observed in practice.

The data described below reflect exposure to VABYSMO in 2,567 patients, which constituted the safety population in six Phase 3 studies [see Clinical Studies (14.1, 14.2, 14.3)].

**Table 1: Common Adverse Reactions (≥ 1%)**

Adverse Reactions	VABYSMO			Active Control (aflibercept)		
	AMD N=664	DME N=1,262	RVO N=641	AMD N=662	DME N=625	RVO N=635
Cataract	3%	15%	< 1%	2%	12%	1%
Conjunctival hemorrhage	7%	8%	3%	8%	7%	4%
Vitreous detachment	3%	5%	2%	3%	4%	2%
Vitreous floaters	3%	4%	2%	2%	3%	2%
Retinal pigment epithelial tear <sup>a</sup>	3%			1%		
Intraocular pressure increased	3%	4%	1%	2%	3%	3%
Eye pain	3%	3%	< 1%	3%	3%	< 1%
Intraocular inflammation <sup>b</sup>	2%	1%	1%	1%	1%	< 1%
Eye irritation	1%	< 1%	< 1%	< 1%	1%	< 1%
Lacrimation increased	1%	1%	0	1%	< 1%	< 1%
Ocular discomfort	1%	1%	< 1%	< 1%	< 1%	< 1%
<sup>a</sup> AMD only						
<sup>b</sup> Including iridocyclitis, iritis, uveitis, vitritis						

Less common adverse reactions reported in < 1% of the patients treated with VABYSMO were corneal abrasion, eye pruritus, ocular hyperemia, blurred vision, sensation of foreign body, endophthalmitis, conjunctival hyperaemia, visual acuity reduced, visual acuity reduced transiently, vitreous hemorrhage, retinal tear and rhegmatogenous retinal detachment.

## 6.2 Postmarketing Experience

The following adverse reactions have been identified during postapproval use of VABYSMO. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

*Eye disorders:* retinal vasculitis with or without retinal vascular occlusion.

## 8 USE IN SPECIFIC POPULATIONS

### 8.1 Pregnancy

#### Risk Summary

There are no adequate and well-controlled studies of VABYSMO administration in pregnant women.

Administration of VABYSMO to pregnant monkeys throughout the period of organogenesis resulted in an increased incidence of abortions at intravenous (IV) doses 158 times the human exposure (based on C<sub>max</sub>) of the maximum recommended human dose [see Animal Data]. Based on the mechanism of action of VEGF and Ang-2 inhibitors, there is a potential risk to female

reproductive capacity, and to embryo-fetal development. VABYSMO should not be used during pregnancy unless the potential benefit to the patient outweighs the potential risk to the fetus.

All pregnancies have a background risk of birth defect, loss, and other adverse outcomes. 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 is 2%-4% and of miscarriage is 15%-20% of clinically recognized pregnancies.

#### Data

##### *Animal Data*

An embryo fetal developmental toxicity study was performed on pregnant cynomolgus monkeys. Pregnant animals received 5 weekly IV injections of VABYSMO starting on day 20 of gestation at 1 or 3 mg/kg. A non-dose dependent increase in pregnancy loss (abortions) was observed at both doses evaluated. Serum exposure ( $C_{max}$ ) in pregnant monkeys at the low dose of 1 mg/kg was 158 times the human exposure at the maximum recommended intravitreal dose of 6 mg once every 4 weeks. A no observed adverse effect level (NOAEL) was not identified in this study.

## **8.2 Lactation**

### Risk Summary

There is no information regarding the presence of faricimab in human milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production. Many drugs are transferred in human milk with the potential for absorption and adverse reactions in the breastfed child.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for VABYSMO and any potential adverse effects on the breastfed child from VABYSMO.

## **8.3 Females and Males of Reproductive Potential**

### Contraception

Females of reproductive potential are advised to use effective contraception prior to the initial dose, during treatment and for at least 3 months following the last dose of VABYSMO.

### Infertility

No studies on the effects of faricimab on human fertility have been conducted and it is not known whether faricimab can affect reproduction capacity. Based on the mechanism of action, treatment with VABYSMO may pose a risk to reproductive capacity.

## **8.4 Pediatric Use**

The safety and efficacy of VABYSMO in pediatric patients have not been established.

## **8.5 Geriatric Use**

In the six clinical studies, approximately 58% (1,496/2,571) of patients randomized to treatment with VABYSMO were  $\geq 65$  years of age. No significant differences in efficacy or safety of faricimab were seen with increasing age in these studies. No dose adjustment is required in patients 65 years and above.

## 11 DESCRIPTION

Faricimab-svoa is a humanized bispecific immunoglobulin G1 (IgG1) antibody that binds both vascular endothelial growth factor A (VEGF-A) and angiopoietin-2 (Ang-2). The fragment crystallizable (Fc) region of faricimab was engineered by selected point mutations to abolish binding interactions with Fcγ and FcRn receptors. Faricimab-svoa has a total molecular weight of approximately 149 kDa and is produced by recombinant DNA technology using mammalian Chinese Hamster Ovary (CHO) cell culture.

VABYSMO (faricimab-svoa) injection is a sterile, clear to opalescent, colorless to brownish-yellow solution in a single-dose prefilled glass syringe or glass vial for intravitreal administration. Each single-dose prefilled syringe or single-dose vial is designed to deliver 0.05 mL (50 microliters) of solution containing 6 mg faricimab-svoa, L-histidine (155 mcg), L-methionine (52.2 mcg), polysorbate 20 (20 mcg), sodium chloride (73.1 mcg), D-sucrose (2.74 mg) and Water for Injection, adjusted to pH 5.5 with acetic acid. The product does not contain an anti-microbial preservative.

## 12 CLINICAL PHARMACOLOGY

### 12.1 Mechanism of Action

Faricimab is a humanized bispecific antibody that acts through inhibition of two pathways by binding to VEGF-A and Ang-2. By inhibiting VEGF-A, faricimab suppresses endothelial cell proliferation, neovascularization and vascular permeability. By inhibiting Ang-2, faricimab is thought to promote vascular stability and desensitize blood vessels to the effects of VEGF-A. Ang-2 levels are increased in some patients with nAMD, DME, and RVO. The contribution of Ang-2 inhibition to the treatment effect and clinical response for nAMD, DME, and RVO has yet to be established.

### 12.2 Pharmacodynamics

Increased retinal thickness, assessed by optical coherence tomography (OCT), is associated with nAMD, DME and macular edema following RVO. Leakage of blood and fluid from choroidal neovascularization, assessed by fluorescein angiography, is associated with nAMD. Reductions in CST were observed across all treatment arms throughout the six Phase 3 studies in nAMD, DME, and RVO.

### 12.3 Pharmacokinetics

#### *Absorption/Distribution*

Maximum faricimab plasma concentrations (C<sub>max</sub>) are estimated to occur approximately 2 days post-dose. Mean (±SD) free faricimab (unbound to VEGF-A and Ang-2) plasma C<sub>max</sub> are estimated to be 0.23 (0.07) mcg/mL and 0.22 (0.07) mcg/mL in nAMD and in DME patients, respectively. After repeated intravitreal administrations, mean plasma free faricimab trough concentrations are predicted to be 0.002-0.003 mcg/mL for every 8 weeks (Q8W) dosing and 0.021-0.029 mcg/mL for every 4 weeks (Q4W) dosing. Although not directly measured in the vitreous, no accumulation of faricimab is expected in the vitreous and no accumulation has been observed in plasma when faricimab has been administered as repeat doses in the vitreous.

#### *Metabolism/Elimination*

Metabolism and elimination of faricimab has not been fully characterized. Faricimab is expected to be catabolized in lysosomes to small peptides and amino acids, which may be excreted renally, in a similar manner to the elimination of endogenous IgG. The estimated mean apparent systemic half-life of faricimab is approximately 7.5 days.

### *Specific Populations*

The systemic pharmacokinetics of faricimab were not influenced by gender, race, or mild to severe renal impairment (i.e., estimated normalized creatinine clearance by Cockcroft-Gault equation: 15 to 89 mL/min/1.73 m<sup>2</sup>). The effect of severe renal impairment or any degree of hepatic impairment on the pharmacokinetics of VABYSMO is unknown. No special dosage modification is required for any of the populations that have been studied (e.g., elderly, gender, race).

Population pharmacokinetic analysis indicated that the pharmacokinetics of faricimab are comparable in nAMD, DME, and RVO patients.

## **12.6 Immunogenicity**

The immunogenicity of VABYSMO was evaluated in plasma samples. The immunogenicity data reflect the percentage of patients whose test results were considered positive for antibodies to VABYSMO in immunoassays. The detection of an immune response is highly dependent on the sensitivity and specificity of the assays used, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to VABYSMO with the incidence of antibodies to other products may be misleading.

There is a potential for an immune response in patients treated with VABYSMO. In the nAMD, DME, and RVO studies, the pre-treatment incidence of anti-faricimab antibodies was approximately 0.8 to 1.8%. After initiation of dosing, the incidence of anti-faricimab antibodies was approximately 8% to 10.4% in patients treated with VABYSMO across studies. As with all therapeutic proteins, there is a potential for immunogenicity with VABYSMO.

## **13 NONCLINICAL TOXICOLOGY**

### **13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility**

No carcinogenicity or mutagenicity data are available for VABYSMO injection in animals or humans.

Based on the anti-VEGF and Ang-2 mechanisms of action, treatment with VABYSMO may pose a risk to reproductive capacity [*see Females and Males of Reproductive Potential (8.3)*].

## **14 CLINICAL STUDIES**

### **14.1 Neovascular (wet) Age-Related Macular Degeneration (nAMD)**

The safety and efficacy of VABYSMO were assessed in two randomized, multi-center, double-masked, active comparator-controlled, 2-year studies (TENAYA – NCT03823287 and LUCERNE – NCT03823300) in patients with nAMD.

A total of 1,329 newly diagnosed, treatment-naïve patients were enrolled in these studies, and 664 patients received at least one dose of VABYSMO. Patient ages ranged from 50 to 99 with a mean of 75.9 years. The studies were identically designed two year studies. Patients were randomized in a 1:1 ratio to one of two treatment arms: 1) aflibercept 2 mg administered fixed every 8 weeks (Q8W) after three initial monthly doses; and VABYSMO 6 mg (0.05 mL of 120 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 ± 7 days, monthly) for the first 4 doses, followed by optical coherence tomography and visual acuity evaluations 8 and 12 weeks later to determine whether to give a 6 mg (0.05 mL of 120 mg/mL solution) dose via intravitreal injection on one of the following three regimens: 1) Weeks 28 and 44; (also referred to as Q16W dosing); 2) Weeks 24, 36 and 48 (also referred to as Q12W dosing); or 3) Weeks 20, 28, 36 and 44 (also referred to as Q8W dosing). However, the utility of these criteria to guide dosing intervals has not been established.

At week 48, after 4 initial monthly doses in the VABYSMO arm, 45% of patients received the Weeks 28 and 44 dosing, 33% of patients received the Weeks 24, 36 and 48 dosing, and the remaining 22% of patients received dosing every 8 weeks. These percentages are reflective of what happened within the conduct of these trials and indicate that some patients did well on two (2) doses spaced 16 weeks apart, or three (3) doses spaced 12 weeks apart, but the percentages may not be generalizable to a broader nAMD population for a variety of reasons. The inclusion/exclusion criteria limited enrollment to a select subset of treatment-naïve, newly diagnosed nAMD patients and there is no empirical data that a similar magnitude would be observed if eligibility criteria allowed for broader enrollment. The disease activity criteria, which was instrumental in determining dose frequency, is unvalidated. Stricter criteria would have changed how patients were treated resulting in different percentages of subjects in each dose interval cohort. There was not a similarly dosed aflibercept arm for comparison, which makes the percentages difficult to interpret.

Both studies demonstrated non-inferiority to the comparator control (aflibercept) at the primary endpoint, defined as the mean change from baseline in Best Corrected Visual Acuity (BCVA) when averaged over the week 40, 44, and 48 visits and measured by the Early Treatment Diabetic Retinopathy Study (ETDRS) letter chart. The primary endpoint analysis was a non-inferiority comparison for the mean change in BCVA between the aflibercept and the VABYSMO arm. The lower bound of the 95% confidence interval for the mean change in BCVA could not be lower than minus 4 letters to declare non-inferiority. In both studies, VABYSMO treated patients had a non-inferior mean change from baseline in BCVA compared to patients treated with aflibercept. Detailed results of both studies are shown in Table 2, Figure 1, and Figure 2 below. The clinical efficacy for the second year of the study has not been reviewed.

**Table 2: Primary Endpoint Results<sup>a</sup> in the TENAYA and LUCERNE Studies**

	TENAYA		LUCERNE	
	VABYSMO N = 334	Aflibercept N = 337	VABYSMO N = 331	Aflibercept N = 327
Mean change in BCVA as measured by ETDRS letter score from baseline (95% CI)	5.8 (4.6, 7.1)	5.1 (3.9, 6.4)	6.6 (5.3, 7.8)	6.6 (5.3, 7.8)
Difference in LS mean (95% CI)	0.7 (-1.1, 2.5)		0.0 (-1.7, 1.8)	

<sup>a</sup> Average of weeks 40, 44 and 48

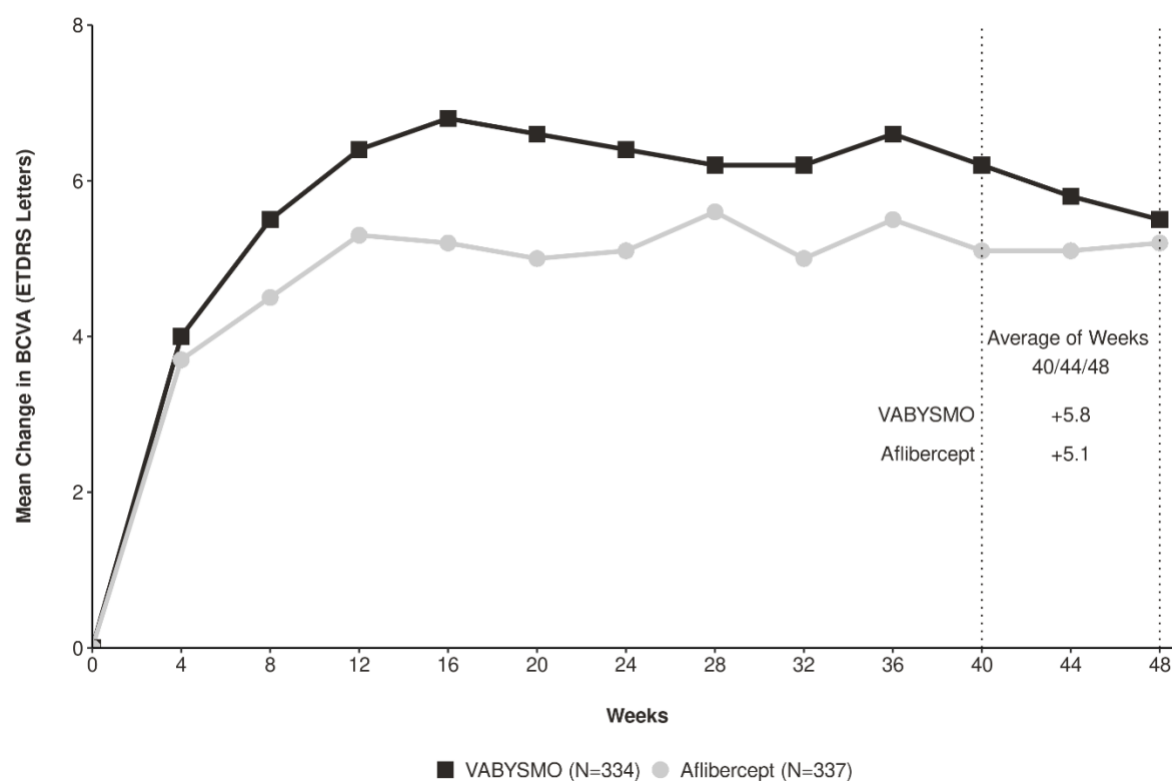
BCVA: Best Corrected Visual Acuity

ETDRS: Early Treatment Diabetic Retinopathy Study

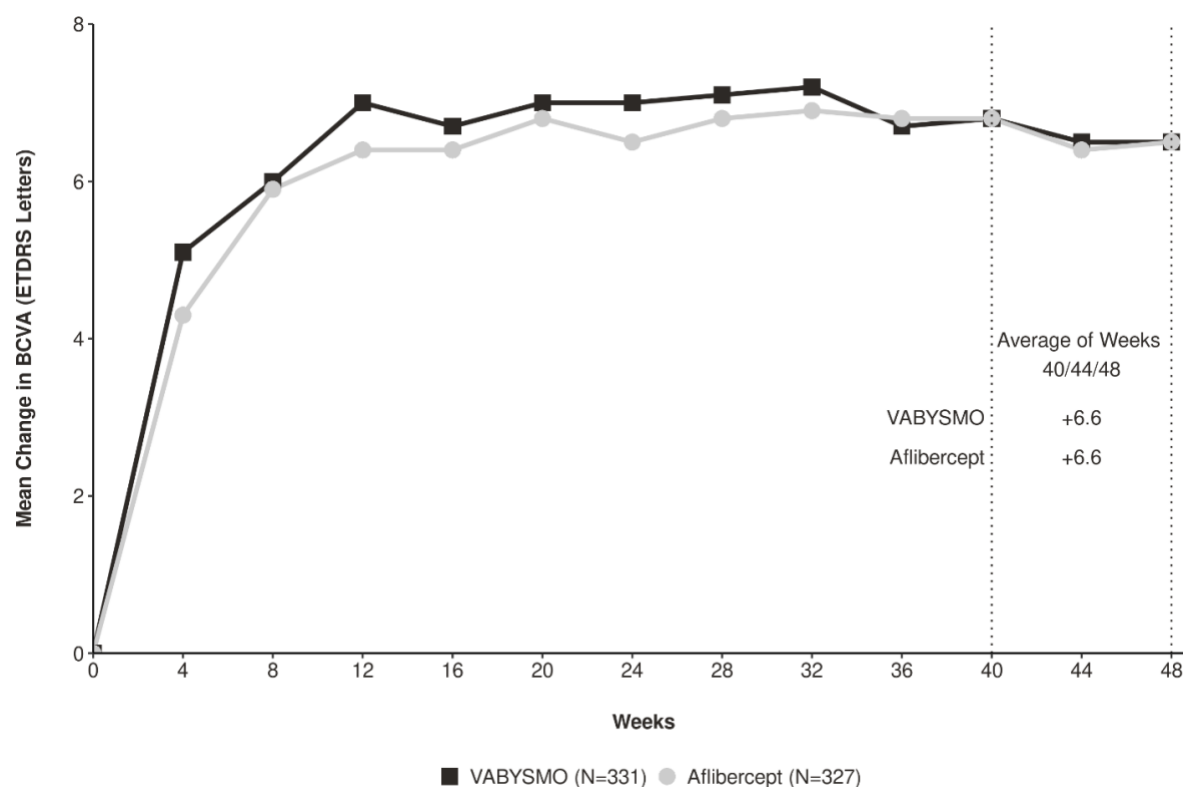
CI: Confidence Interval

LS: Least Square

**Figure 1: Mean Change in Visual Acuity from Baseline to Week 48 in TENAYA**



**Figure 2: Mean Change in Visual Acuity from Baseline to Week 48 in LUCERNE**



Treatment effects in evaluable subgroups (e.g., age, gender, race, baseline visual acuity) in each study were consistent with the results in the overall population.

## 14.2 Diabetic Macular Edema (DME)

The safety and efficacy of VABYSMO were assessed in two randomized, multi-center, double-masked, active comparator-controlled 2-year studies (YOSEMITE – NCT03622580 and RHINE – NCT03622593) in patients with DME.

A total of 1,891 diabetic patients were enrolled in the two studies with a total of 1,262 patients treated with at least one dose of VABYSMO. Patient ages ranged from 24 to 91 with a mean of 62.2 years. The overall population included both anti-VEGF naïve patients (78%) and patients who had been previously treated with a VEGF inhibitor prior to study participation (22%).

The studies were identically designed two year studies. Patients were randomized in a 1:1:1 ratio to one of three treatment regimens: 1) aflibercept Q8W, patients received fixed aflibercept 2 mg administered every 8 weeks (Q8W) after the first five monthly doses; 2) VABYSMO Q8W, patients received fixed VABYSMO 6 mg administered Q8W after the first six monthly doses; and 3) VABYSMO Variable, patients received VABYSMO 6 mg administered every 4 weeks for at least 4 doses and until the central subfield thickness (CST) of the macula measured by optical coherence tomography was less than approximately 325 microns, then the interval of dosing was modified by up to 4 week interval extensions or reductions of up to 8 week interval increments based on CST and visual acuity disease activity criteria at study drug dosing visits.

After 4 initial monthly doses, the patients in the VABYSMO Variable arm received between a minimum of 1 and a maximum of 21 total injections (median of 7 injections) through Week 96 inclusive. At Week 56, 32% of patients had completed at least one Q12W interval followed by one full Q16W interval. Seventeen percent (17%) of patients were treated on Q8W and/or Q4W dosing intervals through Week 56 (7% only on Q4W). These percentages are reflective of what happened within the conduct of these trials, but the percentages may not be generalizable to a broader DME population.

The inclusion/exclusion criteria limited enrollment to a select subset of DME patients and there is no empirical data that a similar magnitude would be observed if eligibility criteria allowed for broader enrollment. The disease activity criteria, which were instrumental in determining dose frequency, are unvalidated. Different criteria would have changed how patients were treated resulting in different percentages of subjects in each dose interval cohort. There was not a similarly dosed aflibercept arm for comparison which makes the percentages difficult to interpret.

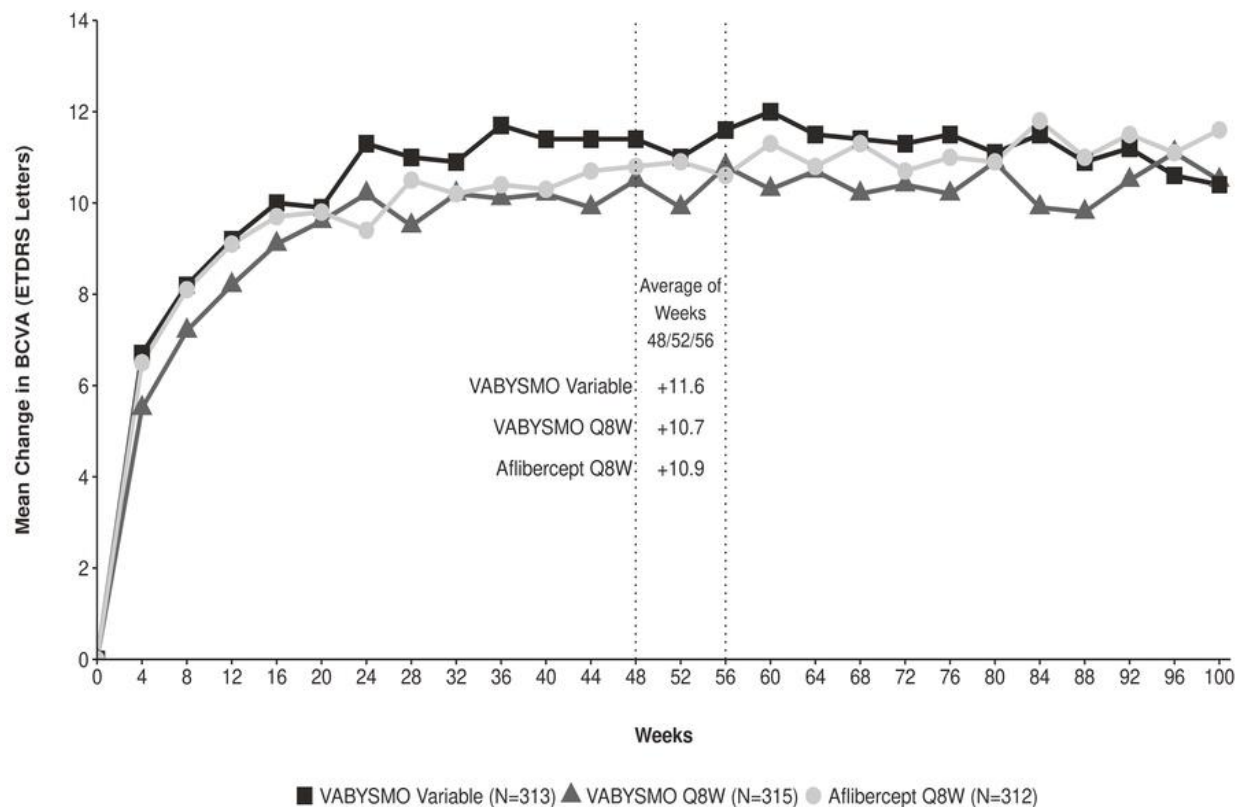
Both studies demonstrated non-inferiority to the comparator control (aflibercept) at the primary endpoint, defined as the mean change from baseline in BCVA at year 1 (average of the Week 48, 52, and 56 visits), measured by the ETDRS Letter Score. The primary endpoint analysis was a non-inferiority comparison for the mean change in BCVA between the aflibercept and VABYSMO arms. The lower bound of the 97.5% confidence interval for the mean change in BCVA could not be lower than minus 4 letters to declare non-inferiority. In both studies, VABYSMO Q8W and VABYSMO Variable treated patients had a non-inferior mean change from baseline in BCVA to the patients treated with aflibercept Q8W at the year 1 primary endpoint. Detailed results of both studies are shown in Table 3, Figure 3, and Figure 4 below.

Table 3: Efficacy Results at Year 1<sup>a</sup> and at Year 2<sup>b</sup> in the YOSEMITE and RHINE Studies

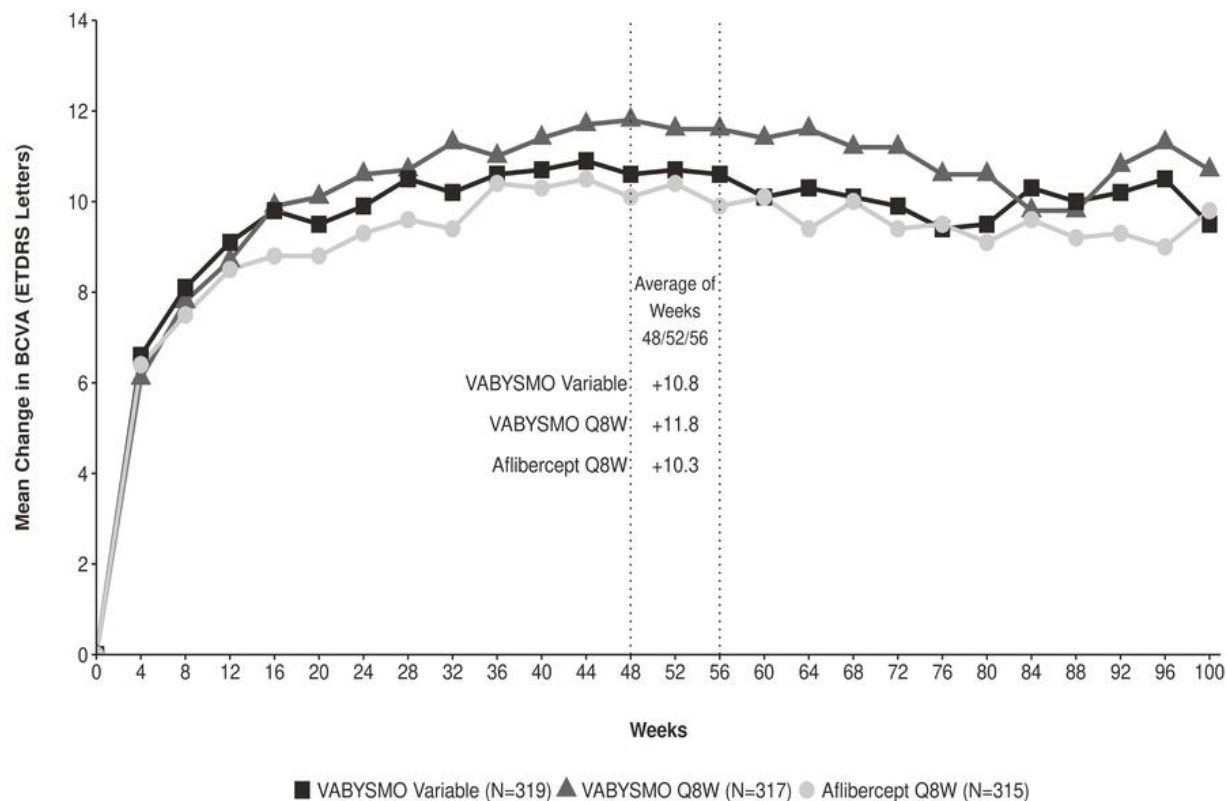
	YOSEMITE						RHINE					
	Year 1			Year 2			Year 1			Year 2		
	VABYSMO Q8W N = 315	VABYSMO Variable N = 313	Aflibercept Q8W N = 312	VABYSMO Q8W N = 262	VABYSMO Variable N = 270	Aflibercept Q8W N = 259	VABYSMO Q8W N = 317	VABYSMO Variable N = 319	Aflibercept Q8W N = 315	VABYSMO Q8W N = 259	VABYSMO Variable N = 282	Aflibercept Q8W N = 254
Mean change in BCVA as measured by ETDRS letter score from baseline (97.5% CI year 1 and 95% CI year 2)	10.7 (9.4, 12.0)	11.6 (10.3, 12.9)	10.9 (9.6, 12.2)	10.7 (9.4, 12.1)	10.7 (9.4, 12.1)	11.4 (10.0, 12.7)	11.8 (10.6, 13.0)	10.8 (9.6, 11.9)	10.3 (9.1, 11.4)	10.9 (9.5, 12.3)	10.1 (8.7, 11.5)	9.4 (7.9, 10.8)
Difference in LS mean (97.5% CI year 1 and 95% CI year 2)	-0.2 (-2.0, 1.6)	0.7 (-1.1, 2.5)		-0.7 <sup>c</sup>	-0.7 <sup>c</sup>		1.5 (-0.1, 3.2)	0.5 (-1.1, 2.1)		1.5 <sup>c</sup>	0.7 <sup>c</sup>	

<sup>a</sup>Average of Weeks 48, 52, 56  
<sup>b</sup>Average of Weeks 92, 96, 100  
<sup>c</sup>A non-inferiority margin was not available for year 2  
BCVA: Best Corrected Visual Acuity  
ETDRS: Early Treatment Diabetic Retinopathy Study  
CI: Confidence Interval  
LS: Least Square

**Figure 3: Mean Change in Visual Acuity from Baseline to Year 2 (Week 100) in YOSEMITE**



**Figure 4: Mean Change in Visual Acuity from Baseline to Year 2 (Week 100) in RHINE**



Treatment effects in the subgroup of patients who were anti-VEGF naïve prior to study participation were similar to those observed in the overall population. Treatment effects in evaluable subgroups (e.g., by age, gender, race, baseline HbA1c, baseline visual acuity) in each study were generally consistent with the results in the overall population.

### 14.3 Macular Edema Following Retinal Vein Occlusion (RVO)

The safety and efficacy of VABYSMO were assessed in two randomized, multicenter, double-masked, studies (BALATON – NCT04740905 in patients with macular edema following branch retinal vein occlusion, and COMINO – NCT04740931 in patients with macular edema following central retinal vein occlusion/hemiretinal vein occlusion). Active comparator-controlled data are available through month 6.

A total of 1,282 newly diagnosed, treatment-naïve patients were enrolled in these studies, of which 641 patients received at least one dose of VABYSMO through 6 months. Patient ages ranged from 28 to 93 with a mean of 64 years, and 22 to 100 with a mean of 65 years in BALATON and COMINO, respectively.

In both studies, patients were randomized in a 1:1 ratio to either 6 mg VABYSMO administered every 4 weeks, or the control arm receiving aflibercept 2 mg injections every 4 weeks for a total of 6 injections.

In both studies, the VABYSMO 6 mg Q4W arm demonstrated non-inferiority to the comparator control (aflibercept) arm for the primary endpoint, which was defined as the change from baseline in BCVA at week 24, measured by the ETDRS Letter Score. The primary endpoint analysis was a non-inferiority comparison for the mean change in BCVA between the aflibercept and VABYSMO arms, where the lower bound of the 95% confidence interval for the mean change in BCVA could not be lower than minus 4 letters to declare non-inferiority.

Detailed results for both BALATON and COMINO studies are shown in Table 4, Figure 5, and Figure 6 below.

**Table 4: Primary Endpoint Results at Week 24 in the BALATON and COMINO Studies**

	BALATON		COMINO	
	VABYSMO N = 276	Aflibercept N = 277	VABYSMO N = 366	Aflibercept N = 363
Mean change in BCVA as measured by ETDRS letter score from baseline (95% CI)	16.9 (15.7, 18.1)	17.5 (16.3, 18.6)	16.9 (15.4, 18.3)	17.3 (15.9, 18.8)
Difference in LS mean (95% CI)	-0.6 (-2.2, 1.1)		-0.4 (-2.5, 1.6)	

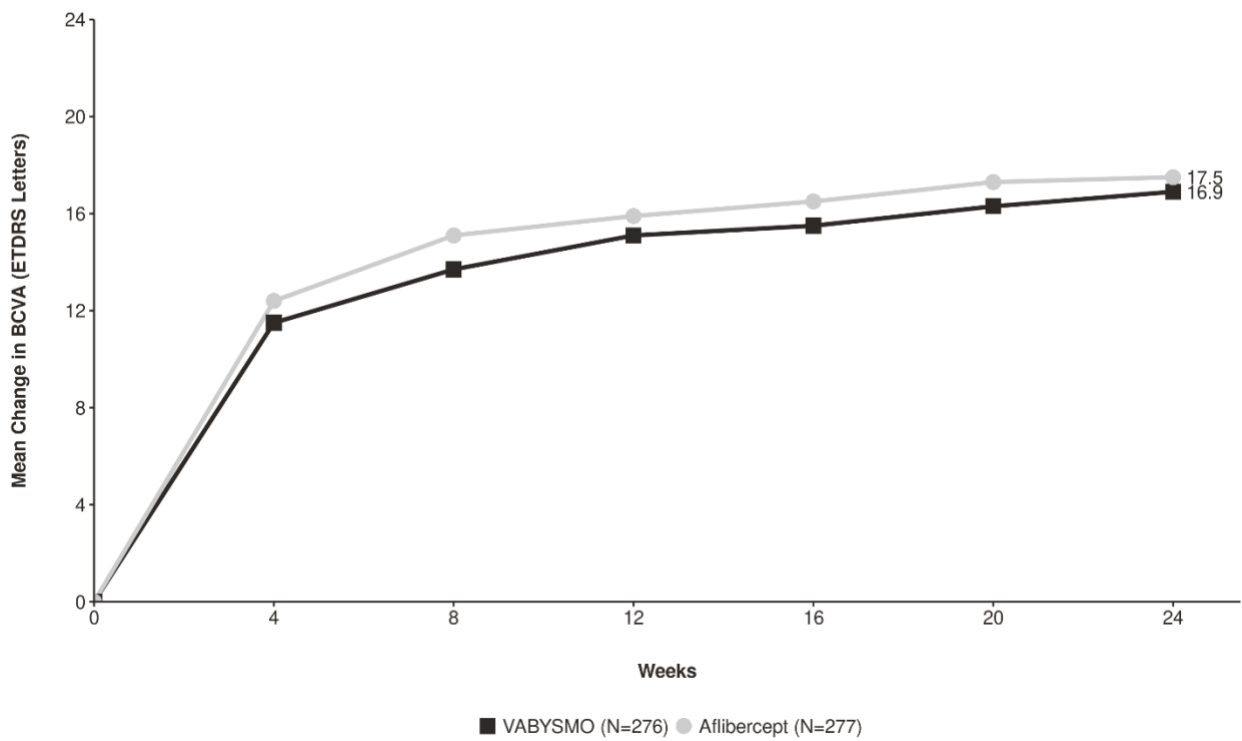
BCVA: Best Corrected Visual Acuity

ETDRS: Early Treatment Diabetic Retinopathy Study

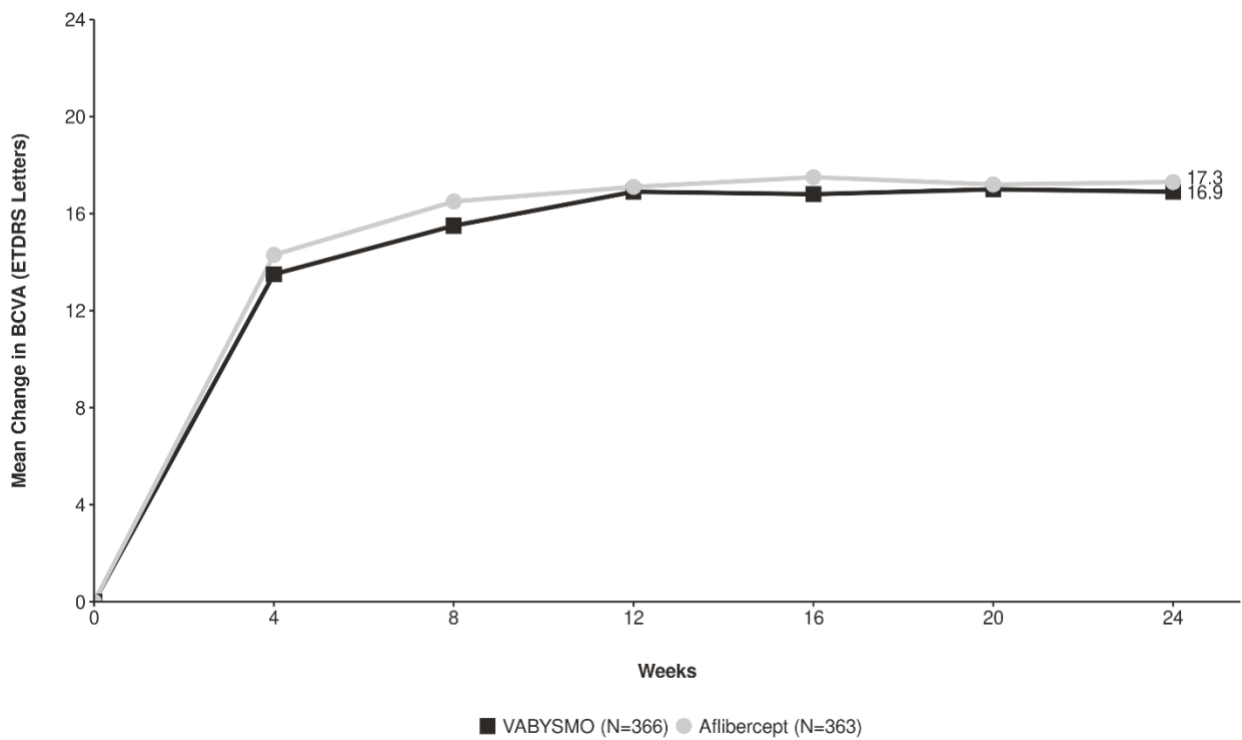
CI: Confidence Interval

LS: Least Square

**Figure 5: Mean Change in Visual Acuity from Baseline to Week 24 in BALATON**



**Figure 6: Mean Change in Visual Acuity from Baseline to Week 24 in COMINO**



## 16 HOW SUPPLIED/STORAGE AND HANDLING

### 16.1 How Supplied

VABYSMO (faricimab-svoa) injection is supplied as a clear to opalescent, colorless to brownish-yellow solution as 6 mg (0.05 mL of 120 mg/mL solution) in a single-dose prefilled syringe or single-dose vial. Each prefilled syringe or vial is for treatment of a single eye.

VABYSMO is supplied in the following presentations:

NDC NUMBER	CARTON TYPE	CARTON CONTENTS
50242-096-06	Prefilled Syringe	one 6 mg (0.05 mL of 120 mg/mL solution) single-dose prefilled glass syringe, in a sealed tray  one sterile injection filter needle (30-gauge x ½ inch, 0.30 mm x 12.7 mm, Extra Thin Wall)  one Prescribing Information
50242-096-01	Vial	one 6 mg (0.05 mL of 120 mg/mL solution) single-dose glass vial  one sterile 5-micron blunt transfer filter needle (18-gauge x 1½ inch, 1.2 mm x 40 mm)  one Prescribing Information

### 16.2 Storage and Handling

Store VABYSMO in the refrigerator between 2°C to 8°C (36°F to 46°F). Do not freeze. Do not shake. Keep the sealed tray containing the prefilled syringe or the vial in the original carton to protect from light.

Prior to use, the unopened prefilled syringe or glass vial of VABYSMO may be kept at room temperature, 20°C to 25°C (68°F to 77°F), for up to 24 hours. Ensure that the injection is given immediately after preparation of the dose.

## 17 PATIENT COUNSELING INFORMATION

Advise patients that in the days following VABYSMO administration, patients are at risk of developing endophthalmitis, retinal detachment, intraocular inflammation and retinal vasculitis with or without retinal vascular occlusion. If the eye becomes red, sensitive to light, painful, or develops a change in vision, advise the patient to seek immediate care from an ophthalmologist [see *Warnings and Precautions* (5)].

Patients may experience temporary visual disturbances after an intravitreal injection with VABYSMO and the associated eye examinations [see *Adverse Reactions* (6)]. Advise patients not to drive or use machinery until visual function has recovered sufficiently.

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VABYSMO® [faricimab-svoa]

Manufactured by:

**Genentech, Inc.**

A Member of the Roche Group

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