

# NEWS RELEASE

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## **GENENTECH DATA HIGHLIGHTS STRENGTH OF OPHTHALMOLOGY PORTFOLIO AND COMMITMENT TO ADVANCING EYE CARE AT ARVO 2023**

- *Vabysmo data suggest rapid and robust drying of retinal fluid in patients with wet age-related macular degeneration and diabetic macular edema –*
- *Real-world studies of Vabysmo demonstrate ability to extend treatment intervals in the first four months while maintaining visual acuity –*
- *Clinical data on an investigational anti-interleukin-6 treatment in uveitic macular edema (UME) will be presented for the first time –*

SOUTH SAN FRANCISCO, Calif. – April 12, 2023 – Genentech, a member of the Roche Group (SIX: RO, ROG; OTCQX: RHHBY), announced today that new data for its approved and investigational medicines will be highlighted in 30 abstracts at the 2023 Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting, which will be held from April 23-27 in New Orleans, LA. The abstracts showcase the strength of Genentech’s Ophthalmology portfolio, including post-hoc data from Phase III Vabysmo® (faricimab-svoa) studies that support its benefit in drying retinal fluid in wet, or neovascular, age-related macular degeneration (AMD) and diabetic macular edema (DME). Real-world data on Vabysmo treatment patterns and outcomes will also be presented, as well as approaches to personalized healthcare that include the use of artificial intelligence (AI) modeling to predict retinal disease progression. Additionally, Phase I data for an investigational anti-interleukin-6 (IL-6) treatment in uveitic macular edema (UME), to be presented for the first time, suggest the monoclonal antibody may improve visual acuity in patients with UME.

“The breadth of data we are presenting at ARVO demonstrates our sustained commitment to preserving vision for people with potentially blinding retinal conditions,” said Levi Garraway, M.D., Ph.D., chief medical officer and head of Global Product Development. “We are particularly encouraged by data indicating that Vabysmo may stabilize blood vessels and reduce fluid in the retina. Fluid control is essential for optimal central vision used for everyday activities such as reading and driving.”

The following data will be presented at ARVO 2023:

### **Vabysmo improves drying for people with wet AMD and DME**

A post-hoc analysis from the head-to-head dosing period of the Phase III TENAYA and LUCERNE studies suggests Vabysmo results in greater drying of retinal fluid compared to aflibercept in people with wet AMD. The data include change in central subfield thickness (CST), absence of subretinal and intraretinal fluid (SRF and IRF) and time to absence of SRF and IRF.

A post-hoc analysis from the head-to-head dosing period of the Phase III YOSEMITE and RHINE studies also supports the positive impact of Vabysmo on macular blood vessel leakage compared to aflibercept in people with DME. Outcomes include macular leakage area and the proportion of patients with minimal to no macular leakage - two important markers of vascular stability. Another analysis from YOSEMITE and RHINE suggests Vabysmo reduces retinal fluid when compared to aflibercept in people with DME. The data include time to absence of DME (CST <325 µm) and time to absence of IRF.

### **Vabysmo extends dosing intervals early in the real-world**

Two Vabysmo real-world studies in wet AMD and DME show patients extended their dosing intervals early in their treatment while maintaining or improving their vision. The majority of patients were able to extend their treatment intervals during the four initial doses. Treatment intervals were categorized as “extended” if any interval was more than six weeks apart.

### **Investigational IL-6 monoclonal antibody may benefit people with UME**

Phase I data on an IL-6 inhibitor that is in development for UME and other retinal conditions suggest that this investigational monoclonal antibody improves visual acuity and CST in patients with UME.

The IL-6 pathway plays an important role in the development and progression of UME by promoting blood vessel leakage and inflammation. UME is a complication of uveitis, a form of eye inflammation. This results in accumulation of fluid in the macula and can lead to significant visual impairment and vision loss. About 750,000 patients have uveitis in the U.S. and approximately one-third are impacted by UME.

Genentech recently launched two Phase III trials in UME based on encouraging Phase I safety and efficacy data. The first patients have been treated in the Meerkat ([NCT05642312](#)) and Sandcat ([NCT05642325](#)) studies, which are evaluating the safety and efficacy of the monoclonal antibody in people with UME. Genentech is also studying the IL-6 inhibitor in DME.

### **AI and machine learning in retina**

Genentech will also present research related to the diagnosis and treatment of retinal conditions. These presentations include new research on the use of AI and machine learning to predict disease progression in geographic atrophy, a progressive and irreversible form of AMD; enable timely and accurate assessment of disease activity in wet AMD or DME; predict treatment response in DME; and investigate new imaging biomarkers in diabetic retinopathy.

Further information on select Genentech abstracts that will be presented at ARVO 2023 can be found in the table below.

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<b>Topic</b>	<b>Abstract Title</b>	<b>Presentation Number /Presentation Details</b>
<b>Vabysmo</b>	Faricimab rapidly improves fluid outcomes in patients with neovascular age-related macular degeneration	Poster Number: C0138 Session: 123 April 24 3:15 PM to 5:15 PM CDT
	Efficacy, durability, and safety of faricimab in diabetic macular edema (DME): 1-year results from China subpopulation of phase 3 RHINE trial	Poster Number: B0522 Session: 148 April 25 8:45 AM to 10:30 AM CDT
	Faricimab causes rapid and sustained intraocular suppression of Ang-2 and VEGF-A for up to 16 weeks in neovascular age-related macular degeneration and diabetic macular edema	Poster Number: B0455 Session: 146 April 25 8:45 AM to 10:30 AM CDT
	Durable vision gains and greater fluid control with extended faricimab dosing versus aflibercept in patients with diabetic macular edema	#2815 oral presentation Session: 153 April 25 12:45 PM to 1:00 PM CDT
	Faricimab reduces macular leakage vs aflibercept in patients with DME	#2816 oral presentation Session: 153 April 25 1:00 PM to 1:15 PM CDT
	Faster time to retinal fluid control with faricimab in patients with DME in the Phase 3 YOSEMITE/RHINE trials	#2817 oral presentation Session: 153 April 25 1:15 PM to 1:30 PM CDT
	Individualized faricimab dosing up to every 16 weeks maintains robust anatomic and vision	#5056 oral presentation Session: 271 April 27 10:45 AM to 11:00 AM CDT

	outcomes through 2 years in nAMD	
<b>Uveitic Macular Edema</b>	A novel intravitreal anti-IL-6 monoclonal antibody for uveitic macular edema (UME): preliminary results from the phase 1 DOVETAIL study	#5100 oral presentation Session: 277 April 27 11:30 AM to 11:45 AM CDT
	A novel anti-IL-6 monoclonal antibody leads to restoration of IL-6-mediated endothelial barrier breakdown	Poster Number: B0163 Session: 284 April 27 10:30 AM to 12:15 PM CDT
<b>Real World Evidence</b>	FARETINA-AMD: Patient characteristics and initial clinical response of patients with neovascular age-related macular degeneration treated with faricimab in the IRIS Registry	Poster Number: C0171 Session: 124 April 24 3:15 PM to 5:00 PM CDT
	FARETINA-DME Patient characteristics and initial clinical response of patients with diabetic macular edema treated with faricimab in the IRIS Registry	Poster Number: B0521 Session: 148 April 25 8:45 AM to 10:30 AM CDT
<b>Susvimo</b>	Port delivery system with ranibizumab in the treatment of diabetic retinopathy without center-involved diabetic macular edema: primary analysis results of the Phase 3 Pavilion trial.	#3754 oral presentation Session: 205 April 26 11:00 AM to 11:15 AM CDT
<b>AI/Personalized Healthcare</b>	Deep learning to predict future region of growth of geographic atrophy from fundus autofluorescence images	Poster Number: C0218 Session: 21 April 23 8:00 AM to 9:45 AM CDT
	Predicting geographic atrophy growth rate with clinical and derived imaging features	Poster Number: C0211 Session: 67 April 23 3:45 PM to 5:30 PM CDT
	Optical coherence tomography segmentation	Poster Number: C0212 Session: 67

	of retinal fluids using deep learning	April 23 3:45 PM to 5:30 PM CDT
	Deep learning segmentation of foveal avascular zone (FAZ) in optical coherence tomography angiography (OCTA) of non-proliferative diabetic retinopathy	Poster Number: C0218 Session: 67 April 23 3:45 PM to 5:30 PM CDT
	A pilot study of machine learning models for prediction of treatment response in patients with diabetic macular edema in a Phase II clinical trial	Poster Number: C0219 Session: 67 April 23 3:45 PM to 5:30 PM CDT

### **About Wet Age-Related Macular Degeneration**

Age-related macular degeneration (AMD) is a condition that affects the macula, the part of the eye that provides sharp, central vision needed for activities like reading, and is a leading cause of blindness for people aged 60 and over in the U.S. Wet, or neovascular, AMD is an advanced form of the disease that can cause rapid and severe vision loss. Approximately 20 million people in the U.S. have some form of AMD, and of those, about 1.5 million have late-stage AMD which includes wet AMD.

Wet AMD is caused by growth of abnormal blood vessels, also referred to as choroidal neovascularization (CNV), into the macula. These vessels leak fluid and blood and cause scar tissue that destroys the central retina. This process results in a deterioration of sight over a period of months to years.

### **About Diabetic Macular Edema**

Affecting approximately 750,000 people in the U.S., diabetic macular edema (DME) is a vision-threatening retinal condition associated with blindness and decreased quality of life when left untreated. DME occurs when damaged blood vessels in the retina leak into and cause swelling in the macula – the central area of the retina responsible for the sharp vision needed for reading and driving. The number of people with DME is expected to grow as the prevalence of diabetes increases.

### **About the Vabysmo® (faricimab-svoa) Clinical Development Program**

Genentech has a robust Phase III clinical development program for Vabysmo. The program includes AVONELLE-X, an extension study of TENAYA and LUCERNE evaluating the long-term safety and tolerability of Vabysmo in wet, or neovascular, macular degeneration (AMD), and RHONE-X, an extension study of YOSEMITE and RHINE evaluating the long-term safety and tolerability of Vabysmo in diabetic macular edema (DME). In addition, Genentech is investigating the efficacy and safety of Vabysmo in people with macular edema following retinal vein occlusion in two Phase III studies, BALATON and COMINO. Genentech has also initiated several Phase IV studies, including the Elevatum study of Vabysmo in underrepresented patient populations with DME, the SALWEEN study of Vabysmo in a subpopulation

of wet AMD highly prevalent in Asia, as well as the VOYAGER study, a global real-world data collection platform. Genentech also supports several other independent studies to further understand retinal conditions with a high unmet need.

### **About Vabysmo® (faricimab-svoa)**

Vabysmo (faricimab-svoa) is the first bispecific antibody approved for the eye. It targets and inhibits two disease pathways linked to a number of vision-threatening retinal conditions by neutralizing angiopoietin-2 (Ang-2) and vascular endothelial growth factor-A (VEGF-A). While research is underway to better understand the role of the Ang-2 pathway in retinal disease, Ang-2 and VEGF-A are thought to contribute to vision loss by destabilizing blood vessels, which may cause new leaky blood vessels to form and increase inflammation. By blocking pathways involving Ang-2 and VEGF-A, Vabysmo is designed to stabilize blood vessels.

### **Vabysmo U.S. Indications**

Vabysmo (faricimab-svoa) is a prescription medicine given by injection into the eye, used to treat adults with neovascular (wet) age-related macular degeneration (AMD) and diabetic macular edema (DME).

### **Important Safety Information**

#### **Contraindications**

Vabysmo is contraindicated in patients who have an infection in or around their eye, have active swelling around their eye that may include pain and redness, or are allergic to Vabysmo or any of the ingredients in Vabysmo.

#### **Warnings and Precautions**

- Injections like the one for Vabysmo can cause an eye infection (endophthalmitis) or separation of layers of the retina (retinal detachment). Patients should seek medical care if they experience increasing eye pain, vision loss, sensitivity to light, or redness in the white of the eye.
- Vabysmo may cause a temporary increase in pressure in the eye (intraocular pressure), which occurs 60 minutes after the injection.
- Although not common, Vabysmo patients have had serious, sometimes fatal, problems related to blood clots, such as heart attacks or strokes (thromboembolic events). In clinical studies for wet AMD during the first year, 7 out of 664 patients treated with Vabysmo reported such an event. In DME studies from baseline to week 100, 64 out of 1,262 patients treated with Vabysmo reported such an event.

#### **Adverse Reactions**

The most common adverse reactions ( $\geq 5\%$ ) reported in patients receiving Vabysmo were cataract (15%) and blood on the white of the eye (conjunctival hemorrhage, 7%). These are not all the possible side effects of Vabysmo.

#### **Pregnancy, Lactation, Females and Males of Reproductive Potential**

- Based on how Vabysmo interacts with your body, there may be a potential risk to an unborn baby. Patients should use birth control before their first injection, during their treatment with Vabysmo, and for 3 months after their last dose of Vabysmo.

- It is not known if Vabysmo passes into breast milk. Patients should talk to their healthcare provider about the best way to feed their baby if they receive Vabysmo.

**Patients may report side effects to the FDA at (800) FDA-1088 or <http://www.fda.gov/medwatch>. Patients may also report side effects to Genentech at (888) 835-2555.**

**Please see additional Important Safety Information in the full Vabysmo [Prescribing Information](#) or visit <https://www.Vabysmo.com>.**

### **About Genentech in Ophthalmology**

Genentech is researching and developing new treatments for people living with a range of eye diseases that cause significant visual impairment and blindness, including wet age-related macular degeneration (AMD), diabetic macular edema (DME), diabetic retinopathy (DR), geographic atrophy (GA) and other retinal diseases.

### **About Genentech**

Founded more than 40 years ago, Genentech is a leading biotechnology company that discovers, develops, manufactures and commercializes medicines to treat patients with serious and life-threatening medical conditions. The company, a member of the Roche Group, has headquarters in South San Francisco, California. For additional information about the company, please visit <http://www.gene.com>.

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