

Roche presents new phase III pivotal data for vamikibart in uveitic macular edema (UME), a serious cause of vision loss

- **Vamikibart is the first non-steroid targeted therapy designed to address inflammation driving UME and may offer a potential new treatment option for patients**
- **Vision improvements were seen in both pivotal studies, achieving statistical significance in MEERKAT and nominal significance in SANDCAT**
- **The MEERKAT and SANDCAT trials are ongoing and the data will be discussed with health authorities globally**

Basel, 17 October 2025 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today results from two phase III studies evaluating the efficacy and safety of two doses of investigational vamikibart (0.25 and 1 mg) compared with a sham procedure that mimics intravitreal (IVT) injections in people with uveitic macular edema (UME).¹ UME is characterised by the buildup of fluid in the macula due to uveitis, an inflammatory condition of the eye, that can result in vision loss.² Across both studies, the primary and secondary endpoint data support the potential for rapid improvements in vision and reductions in macular thickness (swelling in the back of the eye due to retinal fluid) with vamikibart treatment.¹ The data were presented at the American Academy of Ophthalmology annual meeting (AAO 2025) in Orlando, Florida, United States.

“The totality of data from these pivotal vamikibart studies represent an important step towards addressing a clear unmet need for people with uveitic macular edema,” said Levi Garraway, MD, PhD, Roche’s Chief Medical Officer and Head of Global Product Development. “UME is a major cause of vision loss and blindness in people of working age. We look forward to discussing the data for this potential first-in-class treatment with regulatory authorities.”

“UME is most commonly treated with steroids that, when injected in the eye, are associated with significant side effects such as increased pressure in the eye, which can lead to glaucoma and cataract formation,” said study investigator Eric Suhler MD, MPH, Professor of Ophthalmology at the Casey Eye Institute, Oregon Health & Science University, Portland, United States. “These data seen across multiple endpoints in both phase III studies, along with the overall low rate of treatment-related ocular adverse events, suggest that vamikibart could provide a clinically relevant, locally injectable non-steroid treatment option for people with UME.”

In both trials, a numerically higher proportion of patients treated with vamikibart gained vision, with primary endpoint data demonstrating statistically significant superiority over sham in MEERKAT, though not in SANDCAT.¹ Consistently across both trials, key secondary endpoints showed rapid and clinically meaningful improvements in average change from

baseline in best corrected visual acuity (BCVA), and average change from baseline in central subfield thickness (CST), a key measure of macular edema, supporting the overall efficacy profile of vamikibart.¹

The underlying variability of BCVA as an endpoint, along with variations in patient baseline characteristics and concomitant medications, may have influenced the differences in trial primary outcomes and further analyses are currently underway.¹

Vamikibart was generally well tolerated in both studies, with a low incidence of treatment-related ocular adverse events (AEs) and intraocular inflammation (IOI) events, and no events of retinal occlusive vasculitis.¹ The most common AEs (≥5%) in either trial in patients receiving vamikibart were conjunctival hemorrhage and raised intraocular pressure.¹

Key data from the pivotal vamikibart phase III MEERKAT and SANDCAT studies:¹

	MEERKAT (n=245)			SANDCAT (n=256)		
	Sham (n=80)	0.25 mg vamikibart (n=74)	1 mg vamikibart (n=78)	Sham (n=82)	0.25 mg vamikibart (n=85)	1 mg vamikibart (n=86)
Primary endpoint: proportion of patients with a 15 letter or more improvement from baseline in best corrected visual acuity (BCVA) at week 16						
Difference compared with sham IVT injections	-	19.9% (95% CI: 8.1, 31.4; P=0.0008)	36.9% (95% CI: 23.7, 48.5; P<0.0001)	-	20.7% (95% CI: 7.6, 32.8; P=NS*)	10.9% (95% CI: -1.4, 22.6; P=0.0699)
Secondary endpoint: average change from baseline in BCVA at week 16						
Average BCVA change, letters	+3.5	+9.6 (P=0.0002)	+12.8 (P<0.0001)	+5.0	+11.9 (P=NS)	+9.2 (P=NS)
Secondary endpoint: average change from baseline in central subfield thickness (CST) at week 16						
Average CST change, µm	-58.5	-187.5 (P<0.0001)	-196.1 (P<0.0001)	-43.5	-209.7 (P=NS)	-194.7 (P=NS)

Tolerability: incidence of treatment-related ocular AEs and IOI events						
Proportion of patients experiencing one or more treatment-related ocular AEs	0%	4.1%	1.3%	3.7%	4.7%	3.5%
Proportion of patients experiencing one or more IOI events	0%	4.1%	1.3%	1.2%	3.5%	1.2%

*NS = Nominally Significant

About the MEERKAT and SANDCAT studies

MEERKAT and SANDCAT are identical phase III, global, parallel, multicentre, randomised, double-masked, sham comparator-controlled trials of intravitreal (IVT) vamiKibart in uveitic macular edema (UME).^{1,3,4} In both trials, patients were randomised and received treatment every four weeks with either 0.25 mg vamiKibart, 1 mg vamiKibart or sham IVT injection, for up to 16 weeks.^{1,3,4} The primary endpoint of both phase III trials was the proportion of participants with a 15 letter or more improvement from baseline in best corrected visual acuity (BCVA) at week 16.^{1,3,4} Key secondary endpoints included the average change from baseline in BCVA and CST at week 16.^{1,3,4} The safety of vamiKibart was assessed through adverse events (AEs) such as treatment related ocular AEs, intraocular inflammation (IOI) and retinal occlusive vasculitis.^{1,3,4} The studies included participants with and without prior IVT treatment history and included patients with history of raised IOP and glaucoma.^{1,3,4}

About uveitic macular edema (UME)

UME is characterised by the buildup of fluid in the macula due to uveitis, an inflammatory eye condition.² Although rare compared to other eye diseases, UME has a disproportionate impact on vision loss and blindness globally.^{2,5-10} It is the leading cause of moderate and severe vision loss in people with uveitis, and the most frequent sight threatening complication in uveitis.⁷⁻¹² Uveitis accounts for 10% to 20% of blindness in the United States and Europe, and up to 25% of blindness in the developing world.¹³ UME has a significant negative impact on people's quality of life, including physical and mental health, social functioning, and visual function for day-to-day activities such as driving and reading.^{12,14,15} Steroids, the current standard of care for UME, are associated with significant serious side

effects such as increased pressure in the eye, glaucoma and cataracts, and have recognised efficacy limitations.¹⁶⁻²¹

About vamikibart

Vamikibart is an investigational monoclonal antibody that has been specifically engineered for IVT administration.^{1,22} It targets interleukin-6 (IL-6), a key cytokine in the inflammatory pathway in UME.^{1,22} In the phase I DOVETAIL study, vamikibart provided rapid vision improvements and resolution of macular edema in people with UME.^{1,22} Vamikibart was also well tolerated, with no treatment-related serious adverse events reported.²² Based on the promising phase I DOVETAIL data, Roche initiated the two identical phase III vamikibart studies MEERKAT and SANDCAT. Vamikibart is being investigated in retinal diseases with recognised inflammatory pathways, including in people with UME. Vamikibart has orphan drug designation in the United States and European Union.

About Roche in Ophthalmology

Roche is focused on saving people's eyesight from the leading causes of vision loss through pioneering therapies. Through our innovation in the scientific discovery of new potential drug targets, personalised healthcare, molecular engineering, biomarkers and continuous drug delivery, we strive to design the right therapies for the right patients.

We have the broadest retina pipeline in ophthalmology, which is led by science and informed by insights from people with eye diseases. Our pipeline includes innovative treatments across different modalities, such as antibodies, and gene and cell therapies targeting multiple vision-threatening conditions, including retinal vascular and diabetic eye diseases, geographic atrophy, and autoimmune conditions, such as thyroid eye disease and uveitic macular edema.

Applying our extensive experience, we have already brought breakthrough ophthalmic treatments to people living with vision loss. Susvimo® (previously called Port Delivery System with ranibizumab) 100 mg/mL for intravitreal use via ocular implant is the first United States Food and Drug Administration-approved refillable eye implant for neovascular age-related macular degeneration (nAMD) that continuously delivers a customised formulation of ranibizumab over a period of months. Vabysmo® (faricimab) is the first bispecific antibody approved for the eye, which targets and inhibits two signalling pathways linked to a number of vision-threatening retinal conditions by neutralising angiopoietin-2 and vascular endothelial growth factor-A. Vabysmo is approved around the world for people living with nAMD, diabetic macular edema (DME) and macular edema following retinal vein occlusion (RVO). Lucentis® (ranibizumab injection) was the first treatment approved to improve vision in people with certain retinal conditions.

About Roche

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded medicines, Roche has grown into the world's largest biotechnology company and the global

leader in in-vitro diagnostics. The company pursues scientific excellence to discover and develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalised healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each person we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

For over 125 years, sustainability has been an integral part of Roche's business. As a science-driven company, our greatest contribution to society is developing innovative medicines and diagnostics that help people live healthier lives. Roche is committed to the Science Based Targets initiative and the Sustainable Markets Initiative to achieve net zero by 2045.

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