

Roche presents new Phase III one-year data for vamiKibart in uveitic macular edema (UME), a serious cause of vision loss

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In the MEERKAT and SANDCAT studies, vamiKibart demonstrated sustained improvements in vision and reductions in macular thickness in patients with UME at 52 weeks^{1,2} UME is the leading cause of moderate and severe vision loss in patients with uveitis, posing a significant risk of blindness if left untreated^{3,4} The FDA has accepted Roche's Biologics License Application (BLA), with an approval decision expected by July 2027

Basel, 10 October 2026 - Roche (SIX: RO, ROP; OTCQX: RHHBY) announced today new one-year data from the Phase III MEERKAT and SANDCAT studies evaluating investigational vamiKibart compared with a sham procedure that mimics intravitreal (IVT) injections in adults with uveitic macular edema (UME). Across both studies, data continue to support the potential for rapid and sustained improvements in vision and reductions in macular thickness (swelling in the back of the eye due to retinal fluid) with vamiKibart treatment. The data were presented at the American Academy of Ophthalmology 2026 Annual Meeting (AAO 2026) in New Orleans, LA.¹

Additionally, the U.S. Food and Drug Administration (FDA) has accepted Roche's Biologics License Application (BLA) for vamiKibart for the treatment of UME. The filing acceptance is based on the results from the MEERKAT and SANDCAT studies. The FDA is expected to make a decision on approval by July 2027. If approved, vamiKibart would be the first non-steroid targeted treatment for UME, with potential to establish a new standard of care. Regulatory submissions have also been filed and accepted in the European Union, China and Japan.

"These one-year results strengthen vamiKibart's clinical profile, confirming that initial visual and anatomical improvements are maintained over 52 weeks," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "The acceptance of our application by the FDA and other regulatory bodies around the world brings us closer to offering a transformative, non-steroid therapy for people living with this sight-threatening condition."

"Currently, UME is commonly treated with off-label therapies or ocular steroids, the latter carrying significant long-term side effects like glaucoma and cataract formation," said Nisha Acharya, M.D.,

M.S., Distinguished Professor of Ophthalmology at UCSF and Director of the Uveitis and Ocular Inflammatory Disease Service. “Vamikibart is the first non-steroid targeted therapy to demonstrate meaningful and sustained visual and anatomical improvements in people with UME, offering a potential new treatment option that directly targets the inflammation driving this sight-threatening condition.”

The 16-week primary analysis results were presented at the AAO meeting in October 2025.² In both MEERKAT and SANDCAT at 52 weeks, a numerically higher proportion of vamikibart-treated patients achieved vision gains compared to sham treatment on the primary endpoint. Key secondary endpoints showed this benefit was maintained, with sustained 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. Vamikibart demonstrated durable clinical benefit with a low treatment burden: approximately two-thirds of eligible patients required no retreatment after 16 weeks, while the majority of those who did required only one additional injection. Vamikibart was well tolerated, maintaining a favourable safety profile, with a low incidence of treatment-related ocular adverse events (AEs) and intraocular inflammation (IOI) events.¹

UME is the leading cause of moderate-to-severe vision loss in individuals with uveitis, predominantly affecting working-age adults.^{3,4} Approximately 20% of UME patients progress to sustained blindness within three years of diagnosis.⁵ Standard-of-care treatments, primarily high-dose or local corticosteroids, carry substantial long-term risks, including secondary cataracts and elevated intraocular pressure leading to glaucoma.⁶⁻¹¹ As a targeted anti-IL-6 monoclonal antibody, vamikibart is being developed to address these clinical unmet needs and deliver sustained visual preservation.^{1,12}

About the MEERKAT and SANDCAT studies

MEERKAT (NCT05642312) and SANDCAT (NCT05642325) are identical Phase III, global, parallel, multicentre, randomised, double-masked, sham comparator-controlled, 52-week trials of intravitreal (IVT) vamikibart in uveitic macular edema (UME). 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, followed by PRN treatment through week 52. 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. Key secondary endpoints included the average change from baseline in BCVA and CST at week 16. The safety of vamikibart was assessed through adverse events (AEs) such as treatment related ocular AEs, intraocular inflammation (IOI) and retinal occlusive vasculitis. The studies included participants with and without prior IVT treatment history and included patients with history of raised IOP and glaucoma.^{2,13,14}

About uveitic macular edema (UME)

UME is characterised by the buildup of fluid in the macula due to uveitis, an inflammatory eye condition.³ Although rare compared to other eye diseases, UME has a disproportionate impact on vision loss and blindness globally.^{3,15-20} It is the leading cause of moderate and severe vision loss in people with uveitis, and the most frequent sight threatening complication in uveitis.¹⁷⁻²² Uveitis accounts for 10% to 20% of blindness in the United States and Europe, and up to 25% of blindness in the developing world.²³ 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.^{22,24,25} 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.⁶⁻¹¹

About vamikibart

Vamikibart is an investigational monoclonal antibody that has been specifically engineered for IVT administration.^{1,2,12} It targets interleukin-6 (IL-6), a key cytokine in the inflammatory pathway in UME.^{1,2,12} In the Phase I DOVETAIL study, vamikibart provided rapid vision improvements and resolution of macular edema in people with UME.¹² Vamikibart was also well tolerated, with no treatment-related serious adverse events reported.¹² Based on the promising Phase I DOVETAIL data, Roche initiated the two identical Phase III vamikibart studies MEERKAT and SANDCAT.^{1,2,12} Vamikibart is being investigated in retinal diseases with recognised inflammatory pathways. Vamikibart has orphan drug designation in the United States and European Union.

About Roche in Ophthalmology

At Roche, we are on a mission to save and restore eyesight. Over 330 million people around the world are blind, or living with vision loss, creating a profound personal and socioeconomic burden. With the broadest pipeline in Ophthalmology, we continue to invest at scale to redefine what is medically possible in eye care.

Our comprehensive ophthalmology pipeline integrates diverse targets, advanced delivery systems, cell and gene therapies, and AI-augmented imaging capabilities, 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.

About Roche

Roche (SIX: RO, ROP; OTCQX: RHHBY) is a healthcare company uniquely placed to prevent, stop and cure diseases by uniting leading science and technology across diagnostics, medicines and digital solutions.

Roche was founded in Basel, Switzerland in 1896 and today is a leading provider of transformative medicines and diagnostics for millions of people in over 150 countries around the world. It is dedicated to tackling healthcare challenges that place the greatest strain on patients, families, communities and healthcare systems. Across its Diagnostics and Pharmaceutical divisions, Roche focuses on areas including oncology, neurology, cardiovascular and metabolic diseases, ophthalmology, infectious diseases and immunology with the aim of providing real and positive change for patients, the people they love and the professionals who care for them.

Genentech in the United States is a fully owned subsidiary in the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, a major innovator in the Japanese therapeutic antibody market.

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