Vamikibart offers a novel non-steroid IVT potential treatment option for patients with UME

Efficacy and Safety of Vamikibart in Patients With Uveitic Macular Edema: Week 16 Results From the Phase 3 MEERKAT and SANDCAT Trials

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Financial Disclosures
- CP: Consultant: AbbVie, Alimera, Allergan, Roche
- RNK: Consultant: AbbVie, Annexon, Genentech, Inc./Roche, Opthhea, Regeneron, Regenxbio; Research Support: Alcon, Annexon, Apellis, Clearside, Genentech, Inc./Roche, Opthea, Regenxbio
- NA: Consultant: Roche
- K-HS: Financial Support: AbbVie, Alcon Japan, Chugai, Eisai, HOYA, Mitsubishi Tanabe, Otsuka, Santen, Senju, Wakamoto; Review Panel Member: Chugai, Japan Tobacco, Riverfield, Sand, Santen, Senju
- CB, ZH: Employee: Genentech, Inc.: Stocks/Stock Options: Roche
- SF, MM: Employee: F. Hoffmann-La Roche AG: Stocks/Stock Options: Roche
- DG, EH, DS, LS: Employee: Roche Products Ltd.: Stock/Stock Options: Roche
- ES: Consultant: AbbVie, Clearside, EyePoint, Gilead, Kriya, Roche; Research Support: AbbVie, Clearside, EyePoint, Gilead, Roche

Acknowledgements
- The authors would like to acknowledge Lachlan McGregor and Mark Lomax, from F. Hoffmann-La Roche Ltd., for contributions to the study

Study and Product Disclosures
- The MEERKAT and SANDCAT trials are funded by F. Hoffmann-La Roche Ltd.
- This study includes research conducted on human subjects
- Institutional Review Board approval was obtained prior to study initiation
- Funding was provided by F. Hoffmann-La Roche Ltd. for the study and third-party writing assistance, which was provided by Nilisha Fernando, PhD, of Envision Pharma Group

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Presented at the Royal College of Ophthalmologists Annual Congress
Manchester, UK | 18–21 May 2026

Introduction

- Uveitic macular edema (UME), the most frequent cause of vision loss in uveitis,[1] affects around one-third of patients,[2] primarily those of working age[3]
- Despite control of inflammation with immunomodulatory therapies, UME did not resolve in ~40–60% of eyes[4–6]
- Intraocular, periocular and systemic corticosteroids are the mainstay of treatment but have recognised side effects and efficacy limitations[7–10]

Currently, there are no approved intravitreal (IVT) biologic therapies for UME

- Interleukin (IL)-6 is a pro-inflammatory cytokine, with dysregulated IL-6 secretion leading to angiogenesis, inflammation and blood–retinal barrier disruption,[11–15] and is elevated in the aqueous humour of patients with UME[a]
- Therefore, there is strong scientific rationale to target IL-6

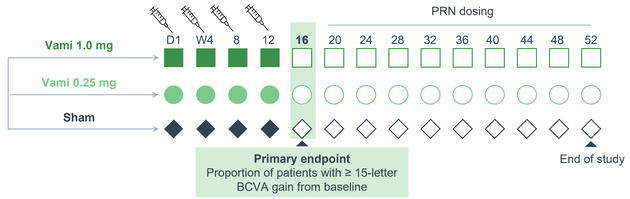
Vamikibart is a first-in-class anti–IL-6 monoclonal antibody engineered for IVT delivery

[a] Presented by Tsui et al at AUS Spring 2025 (DOVETAIL [NCT06771271]).

Methods

MEERKAT and SANDCAT: Identical Phase 3 Trials in UME

- **Key Eligibility Criteria:**
  - Age ≥ 18 years with UME secondary to NIU
  - CST ≥ 325 µm and BCVA 73–19 ETDRS letters
  - Rescue treatment allowed from week 4
  - Prior periocular/IVT treatments allowed with washout periods per protocol criteria
  - Stable systemic IMT allowed per protocol criteria



MEERKAT (NCT05642312) and SANDCAT (NCT05642325). Rescue/prohibited therapies prior to week 16 handled as non-responders. BCVA, best-corrected visual acuity; CST, central subfield thickness; D, day; ETDRS, Early Treatment Diabetic Retinopathy Study; IMT, immunomodulatory therapy; IVT, intravitreal; NIU, non-infectious uveitis; PRN, pro re nata; UME, uveitic macular edema; Vami, vamikibart; W, week.

Results

1. Baseline Patient Demographics and Ocular Characteristics Were Balanced Across Treatment Arms

	MEERKAT			SANDCAT		
n (%)[a]	Sham n = 80	Vami 0.25 mg n = 74	Vami 1.0 mg n = 78	Sham n = 82	Vami 0.25 mg n = 85	Vami 1.0 mg n = 86
Age, mean (SD), years	52.5 (17.5)	52.7 (16.1)	53.0 (15.6)	57.5 (16.3)	55.9 (15.6)	56.1 (16.5)
Sex, female	53 (66.3)	48 (64.9)	48 (61.5)	50 (61.0)	54 (63.5)	61 (70.9)
Race						
Asian	30 (37.5)	29 (39.2)	31 (39.7)	19 (23.2)	22 (25.9)	19 (22.1)
White	41 (51.3)	37 (50.0)	36 (46.2)	54 (65.9)	53 (62.4)	58 (67.4)
Other[b]	9 (11.3)	8 (10.8)	11 (14.1)	9 (11.0)	10 (11.8)	9 (10.5)
Region						
Asia	29 (36.3)	29 (39.2)	30 (38.5)	19 (23.2)	19 (22.4)	19 (22.1)
North America	19 (23.8)	16 (21.6)	18 (23.1)	19 (23.2)	21 (24.7)	21 (24.4)
Rest of the world	32 (40.0)	29 (39.2)	30 (38.5)	44 (53.7)	45 (52.9)	46 (53.5)
BCVA, mean (SD), letters	60.9 (10.9)	61.3 (10.7)	59.2 (12.6)	60.7 (10.7)	61.1 (10.4)	59.0 (12.3)
CST, mean (SD), µm	526.9 (185.8)	499.5 (135.2)	522.1 (173.4)	519.5 (142.1)	531.0 (136.3)	527.1 (157.8)
Lens status, pseudophakic	36 (45.0)	38 (51.4)	34 (43.6)	41 (50.0)	45 (52.9)	42 (48.8)
Glaucoma/raised IOP history	18 (22.5)	24 (32.4)	18 (23.1)	21 (25.6)	24 (28.2)	18 (20.9)
Uveitis anatomical type, non-anterior[b]	71 (88.8)	62 (83.8)	71 (91.0)	67 (81.7)	75 (88.2)	69 (80.2)
Uveitis activity (SUN grade)[c]						
Inactive	49 (61.3)	48 (64.9)	40 (51.3)	56 (68.3)	50 (58.8)	54 (62.8)
Active	31 (38.8)	26 (35.1)	38 (48.7)	26 (31.7)	35 (41.2)	32 (37.2)
Systemic immunosuppression	38 (47.5)	31 (41.9)	31 (39.7)	30 (36.6)	27 (31.8)	28 (32.6)

[a] Unless stated. [b] Non-anterior types include intermediate, panuveitis and posterior. [c] Inactive: ACC and VH < 1+; active: ACC and/or VH ≥ 1+. ACC, anterior chamber cells; BCVA, best-corrected visual acuity; CST, central subfield thickness; IOP, intraocular pressure; SD, standard deviation; SUN, Standardization of Uveitis Nomenclature; Vami, vamikibart; VH, vitreous haze.

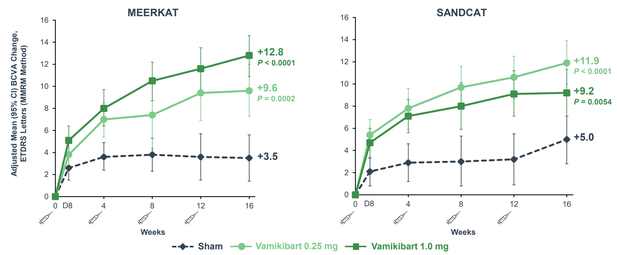
2. A Higher Proportion of Patients Receiving Vamikibart Had ≥ 15-Letter BCVA Gains

Primary Endpoint: Proportion of Patients With ≥ 15-Letter BCVA Gain From Baseline in the Study Eye at Week 16

	MEERKAT			SANDCAT		
	Sham n = 80	Vami 0.25 mg n = 74	Vami 1.0 mg n = 78	Sham n = 82	Vami 0.25 mg n = 85	Vami 1.0 mg n = 86
Adjusted proportion of patients	**6.3%**	**26.1%**	**43.2%**	**13.3%**	**34.0%**	**24.2%**
Adjusted treatment difference vs sham		19.9%	36.9%		20.7%	10.9%
95% CI		(8.1, 31.4)	(23.7, 48.5)		(7.6, 32.8)	(−1.4, 22.6)
P value		**0.0008**	**< 0.0001**		**0.0019**	**0.0699**

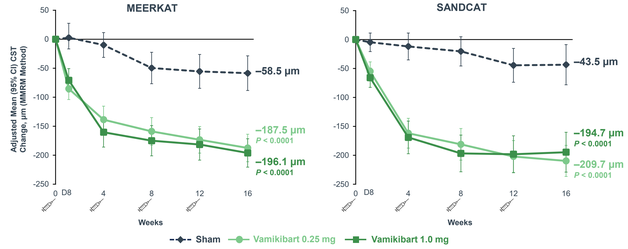
Patients are set as non-responders after the receipt of rescue/prohibited treatment. Analysis was performed using the CMH method stratified by baseline BCVA (≥ 55 vs ≤ 54 ETDRS letters) and region (North America vs the rest of the world). BCVA, best-corrected visual acuity; CI, confidence interval; CMH, Cochran-Mantel-Haenszel; ETDRS, Early Treatment Diabetic Retinopathy Study; Vami, vamikibart.

3. Rapid and Clinically Meaningful Improvements in BCVA



P values vs sham. BCVA, best-corrected visual acuity; CI, confidence interval; D, day; ETDRS, Early Treatment Diabetic Retinopathy Study; MMRM, mixed-effect model with repeated measures.

4. Rapid and Clinically Meaningful Improvements in CST



P values vs sham. CI, confidence interval; CST, central subfield thickness; D, day; MMRM, mixed-effect model with repeated measures.

5. Low Incidence of Ocular AEs Leading to Treatment Discontinuation

	MEERKAT			SANDCAT		
Patients Experiencing AEs Through Week 16, n (%)	Sham n = 80	Vami 0.25 mg n = 74	Vami 1.0 mg n = 78	Sham n = 82	Vami 0.25 mg n = 85	Vami 1.0 mg n = 86
Ocular AEs in the study eye						
≥ 1 AE	17 (21.3)	20 (27.0)	20 (25.6)	24 (29.3)	32 (37.6)	33 (38.4)
≥ 1 SAE	1 (1.3)	2 (2.7)	0	1 (1.2)	0	1 (1.2)
≥ 1 treatment-related AE	0	3 (4.1)	1 (1.3)	3 (3.7)	4 (4.7)	3 (3.5)
≥ 1 treatment-related SAE	0	1 (1.4)	0	0	0	0
≥ 1 ocular AE leading to treatment discontinuation	1 (1.3)	3 (4.1)	2 (2.6)	2 (2.4)	3 (3.5)	3 (3.5)
Non-ocular AEs						
≥ 1 AE	20 (25.0)	24 (32.4)	24 (30.8)	27 (32.9)	30 (35.3)	31 (36.0)
≥ 1 SAE	3 (3.8)	1 (1.4)	2 (2.6)	5 (6.1)	5 (5.9)	1 (1.2)

AE, adverse event; SAE, serious adverse event; Vami, vamikibart.

6. Low Rates of Intraocular Inflammation

	MEERKAT			SANDCAT		
Patients Experiencing Selected Ocular AEs Through Week 16, n (%)[a]	Sham n = 80	Vami 0.25 mg n = 74	Vami 1.0 mg n = 78	Sham n = 82	Vami 0.25 mg n = 85	Vami 1.0 mg n = 86
Intraocular inflammation (IOI)	0	3 (4.1)	1 (1.3)	1 (1.2)	3 (3.5)	1 (1.2)
Anterior chamber inflammation	0	0	1 (1.3)	0	1 (1.2)	0
Eye inflammation	0	0	1 (1.3)	0	0	1 (1.2)
Iridocyclitis	0	1 (1.3)	0	1 (1.2)	0	0
Retinal occlusive vasculitis	0	0	0	0	0	0
Uveitis	0	2 (2.7)	0	0	2 (2.4)	0
Endophthalmitis	0	0	0	0	0	0
Cataract	2 (2.5)	1 (1.4)	2 (2.6)	2 (2.4)	3 (3.5)	4 (4.7)
Glaucoma/raised IOP	4 (5.0)	4 (5.4)	5 (6.4)	4 (4.9)	7 (8.2)	6 (7.0)

[a] Protocol-defined selected ocular AEs (pre-specified AE groups capturing similar or synonymous terms in single categories). MedDRA Preferred Terms. AE, adverse event; IOI, intraocular inflammation; IOP, intraocular pressure; MedDRA, Medical Dictionary for Regulatory Activities; Vami, vamikibart.

Conclusions

- Efficacy: In MEERKAT and SANDCAT, vamikibart treatment led to rapid improvements in vision and macular edema
- Safety: Vamikibart was well tolerated, with a low incidence of IOI and ocular AEs leading to treatment discontinuation
- Targeted therapeutic strategy: Vamikibart is a novel non-steroid IVT option that may change the treatment paradigm for patients with UME