News Release

Vamikibart Filed for Regulatory Approval in Japan for Uveitic Macular Edema Associated with Non-Infectious Uveitis

- If approved, vamikibart is expected to become the first anti-IL-6 antibody therapy in Japan for uveitic macular edema associated with non-infectious uveitis
- Aims to contribute to long-term vision preservation as a non-steroid local ocular treatment option

TOKYO, August 25, 2026 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that it has filed a regulatory application with Japan's Ministry of Health, Labour and Welfare for vamikibart, an anti-IL-6 monoclonal antibody, for the treatment of uveitic macular edema (UME) associated with non-infectious uveitis. Vamikibart was granted orphan drug designation by the Ministry of Health, Labour and Welfare for this indication on June 23, 2026.

“Uveitic macular edema associated with non-infectious uveitis can lead to visual impairment and have a long-term impact on patients' lives. While corticosteroids have been the mainstay of treatment, we hope that vamikibart, an anti-IL-6 antibody, will enable patients to continue treatment with confidence and help preserve vision over the long term. We remain committed to obtaining approval as soon as possible so that patients can gain access to vamikibart at the earliest opportunity,” said Chugai's President and CEO, Dr. Osamu Okuda.

This filing is based on results from the global Phase III MEERKAT and SANDCAT studies, among others, in patients with uveitic macular edema associated with non-infectious uveitis. Development of vamikibart in Japan is conducted by Chugai, and Japan participated in the SANDCAT study.

[Reference]
Roche’s Announcement Regarding Vamikibart (Presentation of New Data in Noninfectious Uveitic Macular Edema) (Oct.20, 2025 news release)
https://www.chugai-pharm.co.jp/english/news/detail/20251020083000_1193.html

About the MEERKAT and SANDCAT Studies
The MEERKAT and SANDCAT studies are identically designed global Phase III, randomized, double-masked, sham-controlled clinical trials evaluating the efficacy and safety of vamikibart in patients with uveitic macular edema associated with non-infectious uveitis.[1-3] Patients were randomized to receive vamikibart 0.25 mg, vamikibart 1 mg, or sham intravitreal injection every four weeks for four doses, followed by dosing according to disease status.[1-3]

CHUGAI PHARMACEUTICAL CO., LTD. Corporate Communications Dept.
1-1 Nihonbashi-Muromachi 2-chome, Chuo-ku, Tokyo 103-8324 Japan
Media Relations Group TEL: +81-(0)3-3273-0881 E-mail: pr@chugai-pharm.co.jp
Investor Relations Group TEL: +81-(0)3-3273-0554 E-mail: ir@chugai-pharm.co.jp

The primary endpoint of both studies was the proportion of patients achieving an improvement of at least 15 letters from baseline in best corrected visual acuity (BCVA) at Week 16.[1-3] Key secondary endpoints included mean change from baseline in BCVA and mean change from baseline in central subfield thickness (CST), a measure of macular edema, at Week 16.[1-3]

About Vamikibart

Vamikibart is an anti-IL-6 monoclonal antibody specifically engineered for intravitreal administration.[1,4] It targets interleukin-6 (IL-6), a cytokine that plays an important role in the inflammatory pathway in uveitic macular edema associated with non-infectious uveitis.[5,6] Vamikibart has received orphan drug designation in Japan and the United States.

About Uveitic Macular Edema*

Uveitic macular edema is characterised by the buildup of fluid in the macula, the centre of the retina, due to uveitis, an inflammatory condition of the eye.[7] Although rare compared with other eye diseases, uveitic macular edema has a disproportionate impact on vision loss and blindness globally.[7-13] It is the leading cause of moderate to severe vision loss in people with uveitis and the most frequent sight-threatening complication in uveitis.[10-15] Uveitis accounts for 10% to 20% of blindness in the United States and Europe, and up to 25% of blindness in the developing world.[16]

Uveitic macular edema 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.[15,17,18] Steroid therapy is the current standard of care for uveitic macular edema associated with non-infectious uveitis, and the estimated number of patients in Japan is approximately 26,000.[19]

* The proposed indication for vamikibart is uveitic macular edema associated with non-infectious uveitis.

Sources:

1. Khurana RN, et al. Efficacy and Safety of Vamikibart in Patients With Uveitic Macular Edema: First Report of Phase 3 MEERKAT/SANDCAT Trials. Presented at: the American Academy of Ophthalmology annual meeting (AAO 2025); 2025 October 17; Orlando, Florida, United States.
2. Hoffmann-La Roche. A Phase III, Multicenter, Randomized, Double-Masked, Sham-Controlled Study to Investigate the Efficacy, Safety, Pharmacokinetics and Pharmacodynamics of Vamikibart Administered Intravitreally in Patients With Uveitic Macular Edema. clinicaltrials.gov; 2025. Accessed August, 2026. https://clinicaltrials.gov/study/NCT05642312
3. Hoffmann-La Roche. A Phase III, Multicenter, Randomized, Double-Masked, Sham-Controlled Study to Investigate the Efficacy, Safety, Pharmacokinetics and Pharmacodynamics of Vamikibart Administered Intravitreally in Patients With Uveitic Macular Edema. clinicaltrials.gov; 2025. Accessed August, 2026. https://clinicaltrials.gov/study/NCT05642325

4. Sharma S, Suhler E, Lin P, et al. A novel intravitreal anti-IL-6 monoclonal antibody for uveitic macular edema (UME): preliminary results from the phase 1 DOVETAIL study. Invest Ophthalmol Vis Sci. 2023;64(8):5100.
5. Mesquida M, Molins B, Llorenç V, de la Maza MS, Adán A. Targeting interleukin-6 in autoimmune uveitis. Autoimmun Rev. 2017;16(10):1079-1089.
6. Yang JY, Goldberg D, Sobrin L. Interleukin-6 and macular edema: a review of outcomes with inhibition. Int J Mol Sci. 2023;24(5):4676.
7. Massa H, Pipis SY, Adewoyin T, Vergados A, Patra S, Panos GD. Macular edema associated with non-infectious uveitis: pathophysiology, etiology, prevalence, impact and management challenges. OPTH. 2019;Volume 13:1761-1777. doi:10.2147/OPTH.S180580
8. Teper SJ. Update on the Management of Uveitic Macular Edema. J Clin Med. 2021;10(18):4133. doi:10.3390/jcm10184133
9. Fardeau C, Champion E, Massamba N, LeHoang P. Uveitic macular edema. Eye. 2016;30(10):1277-1292. doi:10.1038/eye.2016.115
10. Smith JR, Thorne JE, Flaxel CJ, et al. Treatment of Noninfectious Uveitic Macular Edema with Periocular and Intraocular Corticosteroid Therapies: A Report by the American Academy of Ophthalmology. Ophthalmology. 2024;131(9):1107-1120. doi:10.1016/j.ophtha.2024.02.019
11. Sood G, Patel BC. Uveitic Macular Edema. In: StatPearls. StatPearls Publishing; 2025. Accessed August, 2026. https://www.ncbi.nlm.nih.gov/books/NBK562158/
12. Tomkins-Netzer O, Lightman SL, Burke AE, et al. Seven-Year Outcomes of Uveitic Macular Edema: The Multicenter Uveitis Steroid Treatment Trial and Follow-up Study Results. Ophthalmology. 2021;128(5):719-728. doi:10.1016/j.ophtha.2020.08.035
13. Matas J, Llorenç V, Fonollosa A, et al. Systemic Regulatory T Cells and IL-6 as Prognostic Factors for Anatomical Improvement of Uveitic Macular Edema. Front Immunol. 2020;11. doi:10.3389/fimmu.2020.579005
14. Tomkins-Netzer O, Talat L, Bar A, et al. Long-Term Clinical Outcome and Causes of Vision Loss in Patients with Uveitis. Ophthalmology. 2014;121(12):2387-2392. doi:10.1016/j.ophtha.2014.07.007
15. Tallouzi MO, Moore DJ, Bucknall N, et al. Outcomes important to patients with non-infectious posterior segment-involving uveitis: a qualitative study. BMJ Open Ophth. 2020;5(1). doi:10.1136/bmjophth-2020-00048
16. Cunningham ET, Zierhut M. Vision Loss in Uveitis. Ocular Immunology and Inflammation. 2021;29(6):1037-1039. doi:10.1080/09273948.2021.2017152
17. Tomkins-Netzer O, Lightman S, Drye L, et al. Outcome of Treatment of Uveitic Macular Edema: The Multicenter Uveitis Steroid Treatment Trial 2-Year Results. Ophthalmology. 2015;122(11):2351-2359. doi:10.1016/j.ophtha.2015.07.036
18. Frick KD, Drye LT, Kempen JH, et al. Associations among Visual Acuity and Vision- and Health-Related Quality of Life among Patients in the Multicenter Uveitis Steroid Treatment Trial. Invest Ophthalmol Vis Sci. 2012;53(3):1169. doi:10.1167/iovs.11-8259

19. Real-world treatment patterns for patients with non-infectious uveitis in Japan: a descriptive study using a large-scale claims database (J-CAT study). Journal of Ophthalmic Inflammation and Infection (2025) 15:56

###