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Positive Phase III Results Showed Vabysmo Improved Vision for the First Time in Japanese in Angioid Streaks

- Vabysmo showed statistically significant and clinically meaningful vision improvement in angioid streaks associated with neovascularization
- Vabysmo was generally well tolerated, with a safety profile consistent with previous trials
- Vabysmo is the first and only treatment that targets and inhibits two signalling pathways involving Ang-2 and VEGF-A, linked to a number of vision-threatening retinal conditions
- Detailed results will be presented at an upcoming medical meeting and submitted to health authorities

TOKYO, April 15, 2024 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that Japanese phase III study (NIHONBASHI study), evaluating the first and only bispecific antibody for the eye, Vabysmo® (faricimab), for angioid streaks associated with neovascularization, met its primary endpoint, which demonstrated statistically significant and clinically meaningful vision improvement at 12 weeks. Vabysmo was generally well-tolerated and no new safety signal of this combination were observed.

“I am very pleased that Vabysmo demonstrates good vision improvement for the first time in Japanese in clinical study for angioid streaks, a rare disease with no approved drugs in Japan. We will make efforts for filing for approval to deliver this drug to patients as soon as possible,” said Chugai’s President and CEO, Dr. Osamu Okuda.

The data will be submitted to health authorities in Japan, where the study was conducted, and will be presented at an upcoming medical meeting.

About angioid streaks

Angioid streaks is a disease characterized by a crack in a part of retina, causing-discoloration (pigmented streak) of the fundus. The disease is often asymptomatic, and when choroidal neovascularization extends to the macula region of the fundus, it causes symptoms such as decreased or distorted vision. People with neovascularization have a poor prognosis, but conventional treatments such as surgery and laser are not sufficiently effective, and new treatment options are needed. The number of patients in Japan is unknown, and approximately 300 patients with pseudoxanthoma elasticum (one of the designated intractable diseases), which is known to be associated with angioid streaks in about half of patients.[1,2]

About NIHONBASHI study

NIHONBASHI study is a multicenter, single-arm phase III study in Japan evaluating the efficacy and safety of Vabysmo for the people with angioid streaks associated with neovascularization. 24 people were enrolled into this study. The primary endpoint is the change in best-corrected visual acuity (BCVA) score (the best distance vision a person can achieve – including with correction such as glasses – when reading

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letters on an eye chart) from baseline at 12 weeks. Secondary endpoints include the mean change in BCVA score at 52 weeks, change in central subfield thickness from baseline over time, and safety.

About Vabysmo

Vabysmo is the first bispecific antibody approved in the ophthalmology field.[3,4] It targets and inhibits two signaling pathways linked to a number of vision-threatening retinal conditions by neutralizing angiopoietin-2 (Ang-2) and vascular endothelial growth factor-A (VEGF-A). Ang-2 and VEGF-A contribute to vision loss by destabilizing blood vessels, causing new leaky blood vessels to form and increasing inflammation.[5,6] By blocking pathways involving Ang-2 and VEGF-A, Vabysmo is designed to stabilize blood vessels.[5,6] Vabysmo is approved in more than 90 countries around the world, including the United States, Japan, the United Kingdom, and the European Union, for people living with neovascular or 'wet' age-related macular degeneration and diabetic macular edema. Vabysmo is also approved for people living with macular edema associated with retinal vein occlusion on March 26, 2024. Review by other regulatory authorities is ongoing.[3,4,7-9]

Sources

1. Chatziralli I, Saitakis G, Dimitriou E, Chatzirallis A, Stoungioti S, Theodossiadis G, et al. ANGIOID STREAKS: A Comprehensive Review From Pathophysiology to Treatment. Retina. 2019;39(1):1-11.
2. Japan Intractable Diseases Information Center. Pseudoxanthoma elasticum (designated intractable disease 166) [Internet; cited April 2024]. Available from: https://www.nanbyou.or.jp/entry/4580. (Japanese only)
3. United States Food and Drug Administration (U.S. FDA). Highlights of prescribing information, Vabysmo. 2022 [Internet; cited April 2024]. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761235s000lbl.pdf.
4. Medicines and Healthcare products Regulatory Agency (MHRA). MHRA approves faricimab through international work-sharing initiative [Internet; cited April 2024]. Available from: https://www.gov.uk/government/news/mhra-approves-faricimab-through-international-work-sharing-initiative.
5. Heier JS, et al. Efficacy, durability, and safety of intravitreal faricimab up to every 16 weeks for neovascular age-related macular degeneration (nAMD) (TENAYA and LUCERNE): two randomised, double-masked, phase III, non-inferiority trials. The Lancet. 2022; 399:729-740.
6. Wykoff C, et al. Efficacy, durability and safety of intravitreal faricimab with extended dosing up to every 16 weeks in patients with diabetic macular edema (DME) (YOSEMITE and RHINE): two randomised, double-masked, phase III trials. The Lancet. 2022; 399:741-755.
7. European Medicines Agency. Summary of Product Characteristics, Vabysmo, 2022 [Internet; cited April 2024]. Available from: https://www.ema.europa.eu/en/documents/product-information/vabysmo-epar-product-information_en.pdf.
8. Roche data on file.
9. Chugai Pharmaceutical Co. Ltd. Chugai obtains regulatory approval for Vabysmo, the first bispecific antibody in ophthalmology, for nAMD and DME [Internet; cited April 2024]. Available from: https://www.chugai-pharm.co.jp/english/news/detail/20220328160002_909.html.

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