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News Release

First Positive Phase III Results Presented at Japanese Ophthalmological Society Meeting Demonstrated that Vabysmo Sufficiently Improved Vision in Japanese Patients with Angioid Streaks

- The NIHONBASHI study results presented statistically significant and clinically meaningful vision improvement in angioid streaks associated with neovascularization
- Vabysmo was generally well tolerated, with a safety profile consistent with the previous trials
- If approved, Vabysmo will be the first drug for the treatment of angioid streaks associated with neovascularization in Japan

TOKYO, April 17, 2025 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that results from the Phase III clinical trial (NIHONBASHI study) of anti-VEGF/anti-Ang-2 bispecific antibody Vabysmo® Intravitreal Injection 120 mg/mL [generic name: faricimab (genetical recombination)] (Hereafter Vabysmo), for angioid streaks associated with neovascularization were presented at the 129th Annual Meeting of the Japanese Ophthalmological Society on April 17.

“Based on the study results, Vabysmo is expected to become the first drug for angioid streaks, for which there are currently no approved drugs in Japan. The regulatory approval review is currently underway under priority review. Chugai will make every effort to obtain approval in Japan so that we can deliver this drug to patients who are eagerly awaiting treatment as soon as possible,” said Chugai’s President and CEO, Dr. Osamu Okuda.

The NIHONBASHI study is a multicenter, open-label, single-arm phase III study in Japan evaluating the efficacy and safety of Vabysmo for people with angioid streaks associated with neovascularization. In this study, 24 patients with angioid streaks were enrolled and received Vabysmo every 4 weeks for the first three doses, followed by disease activity assessments at 4-week interval visits with Vabysmo administered as needed. In this study, the primary endpoint of mean change in best-corrected visual acuity from baseline at week 12 was +5.8 letters (90% confidence interval: 3.0 to 8.5 letters), with the lower limit of the 90% confidence interval exceeding the pre-specified clinically meaningful threshold of 0 letters, demonstrating statistically significant visual acuity improvement. Retinal fluid, which can be caused by vascular leakage, may lead to retinal edema and blurred vision. For one of the secondary endpoints, the mean change in central retinal thickness from baseline at week 12 was -106.4 µm (90% confidence interval: -123.4 to -89.4).

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

Vabysmo was generally well tolerated. The safety profile was consistent with the known profile, and no new safety concerns were identified. Adverse events in the study eye occurred in 20.8% (5/24) of patients, with no serious ocular adverse events or events leading to study drug discontinuation or study withdrawal. Non-ocular adverse events occurred in 50.0% (12/24) of patients, with events leading to study drug discontinuation or study withdrawal. Serious adverse events occurred in two patients, but none were assessed as related to Vabysmo. None of the ocular or non-ocular adverse events were assessed as related to Vabysmo.

[Reference]
Positive Phase III Results Showed Vabysmo Improved Vision for the First Time in Japanese in Angioid Streaks (Press release by Chugai issued on April 15, 2024)
https://www.chugai-pharm.co.jp/english/news/detail/20240415113000_1064.html

Chugai Files in Japan for Additional Indication of Vabysmo for Angioid Streaks, a Leading Cause of Vision Loss (Press release by Chugai issued on September 6, 2024)
https://www.chugai-pharm.co.jp/english/news/detail/20240906150000_1098.html

About angioid streaks
Angioid streaks is a disease characterized by cracks in parts of the 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 with angioid streaks in Japan is unknown, but approximately 300 patients have pseudoxanthoma elasticum (one of the designated intractable diseases), which is known to be associated with angioid streaks in approximately half of patients.[1,2]

About Vabysmo
Vabysmo is the first bispecific antibody approved for the eye.[3,4,5] 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. By blocking pathways involving Ang-2 and VEGF-A, Vabysmo is designed to stabilize blood vessels.[5,6] Vabysmo is approved in nearly 100 countries around the world, including the United States (US), Japan, the United Kingdom and the European Union, for people living with neovascular or 'wet' age-related macular degeneration and diabetic macular edema, and in several countries, including the US, EU and Japan, for the treatment of macular edema following retinal vein occlusion. Review by other health authorities is ongoing.[3,4,7,8]

Sources

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