News Release

Chugai Obtains First Regulatory Approval in Japan for Vabysmo for Additional Indication of Angioid Streaks, a Cause of Vision Loss

- Choroidal neovascularization associated with angioid streaks is a rare disease with poor prognosis
- Approval based on results from the Japanese phase III study (NIHONBASHI study)

TOKYO, May 19, 2025 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that it obtained regulatory approval from the Ministry of Health, Labour and Welfare (MHLW) for anti-VEGF/anti-Ang-2 bispecific antibody Vabysmo® Intravitreal Injection 120 mg/mL [generic name: faricimab (genetical recombination)], for an additional indication of the treatment of choroidal neovascularization associated with angioid streaks. Vabysmo is the first approved drug in Japan for the treatment of this disease.

“We are very pleased that we can offer Vabysmo as the first approved treatment in Japan for choroidal neovascularization associated with angioid streaks. This disease is known to cause vision impairment and has a poor prognosis. We expect that treatment with Vabysmo will contribute to maintaining and improving vision for patients. We will continue to provide information promptly on the proper use of this medication,” said Dr. Osamu Okuda, Chugai’s President and CEO.

This approval is based on the results from a Japanese phase III NIHONBASHI study for angioid streaks.

Approval Information *Newly added description
Indications:
choroidal neovascularization associated with angioid streaks
Dosage and administrations:
6 mg (0.05 mL) of faricimab (genetical recombination) is administered by intravitreal injection once every 4 weeks or more.

[Reference]
First Positive Phase III Results Presented at Japanese Ophthalmological Society Meeting Demonstrated that Vabysmo Sufficiently Improved Vision in Japanese Patients with Angioid Streaks (Press release by Chugai issued on April 17, 2025)
https://www.chugai-pharm.co.jp/english/news/detail/20250417122000_1150.html

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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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