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Chugai Obtains Regulatory Approval for Vabysmo, the Only Bispecific Antibody in the Ophthalmology Field, for Additional Indication of Macular Edema Associated with Retinal Vein Occlusion

- Vabysmo is a treatment with a novel mode of action in patients with macular edema associated with retinal vein occlusion
- The approval was based on global phase III clinical studies, BALATON study for branch retinal vein occlusion, and COMINO study for central retinal or hemiretinal vein occlusion

TOKYO, March 26, 2024 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that it obtained regulatory approval today 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 macular edema associated with retinal vein occlusion (RVO). Vabysmo is the first bispecific antibody in Japan for the treatment of this disease.

“I’m very pleased to have obtained approval for Vabysmo, the only bispecific antibody in the ophthalmology field, for additional indication of macular edema associated with RVO. Treatment with Vabysmo is expected to improve and maintain vision in patients with RVO, a disease that can severely affect vision and lead to blindness. We will continue to provide information on the proper use of Vabysmo in order to contribute to the treatment of patients with macular edema associated with RVO,” said Chugai’s President and CEO, Dr. Osamu Okuda.

This approval is based on the results of the BALATON and COMINO studies for branch retinal vein occlusion and central retinal or hemiretinal vein occlusion, respectively. Both are global phase III clinical studies, and Chugai participated in both studies from Japan.

Approval Information *Newly added description
Indications:
Macular edema associated with retinal vein occlusion

Dosage and administrations:
6 mg (0.05 mL) of faricimab (genetical recombination) is administered by intravitreal injection once every 4 weeks or more.

[Reference]
・BALATON and COMINO studies
New phase III data show Roche’s Vabysmo rapidly improved vision and reduced retinal fluid in people with retinal vein occlusion (RVO) (Press release by Roche issued on February 10, 2023)
https://www.roche.com/media/releases/med-cor-2023-02-10

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About Vabysmo

Vabysmo is the first bispecific antibody approved in the ophthalmology field.[1,2] 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.[3,4] By blocking pathways involving Ang-2 and VEGF-A, Vabysmo is designed to stabilize blood vessels.[3,4] 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. Review by other regulatory authorities is ongoing.[1,2,5-7]

About retinal vein occlusion (RVO)

RVO is the second most common cause of vision loss due to retinal vascular diseases.[8] It affects an estimated 28 million adults globally, mainly those aged 60 or older, an estimated 1.66 million adults in Japan, and can lead to severe and sudden vision loss.[8-10] RVO typically results in sudden, painless vision loss in the affected eye because the vein blockage restricts normal blood flow in the affected retina, resulting in ischemia, bleeding, fluid leakage, and retinal swelling called macular edema.[8,9,11] Currently, macular edema due to RVO is typically treated with intravitreal injections of anti-vascular endothelial growth factor therapies.[12] There are two main types of RVO: branch retinal vein occlusion (BRVO), which affects more than 23 million people globally and occurs when one of the four smaller 'branches' of the main central retinal vein becomes blocked; and central retinal vein occlusion (CRVO), which is less common, affecting more than four million people worldwide, and occurs when the eye's central retinal vein becomes blocked.[8,12]

Sources

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