



Chugai Files for Additional Indication of Vabysmo for Macular Edema Associated with Retinal Vein Occlusion in Japan

- The application was submitted based on a global phase III clinical study, BALATON study for branch retinal vein occlusion, and COMINO study for central retinal or hemiretinal vein occlusion

TOKYO, April 27, 2023 -- [Chugai Pharmaceutical Co., Ltd.](#) (TOKYO: 4519) announced that it filed for additional application with 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 the treatment of macular edema associated with retinal vein occlusion (RVO) today.

“I’m very pleased that we have filed an additional indication for Vabysmo, the first bispecific antibody in the ophthalmology field for macular edema associated with RVO,” said Chugai’s President and CEO, Dr. Osamu Okuda. “RVO is a disease that can threaten vision and lead to blindness. In addition to existing indications, we will seek approval as soon as possible so that Vabysmo can further contribute to treating patients as a new treatment option for macular edema associated with RVO.”

This application 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.

[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>

About Vabysmo

Vabysmo is the first bispecific antibody approved for the eye.^{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 50 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, and can lead to severe and sudden vision loss.^{8,9} 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.⁸⁻¹⁰ Currently, macular edema due to RVO is typically treated with repeated intravitreal injections of anti-vascular endothelial growth factor therapies.¹¹ There are two main types of RVO: branch retinal vein occlusion, 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, which is less common, affecting more than four million people worldwide, and occurs when the eye’s central retinal vein becomes blocked.^{8,11}

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Sources

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