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News Release

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Eylea™ 8 mg approved for third retinal indication in Japan

- The Ministry of Health, Labour and Welfare (MHLW) in Japan has granted marketing authorization for Eylea™ 8 mg (aflibercept 8 mg) for the treatment of patients with macular edema following retinal vein occlusion (RVO) including branch, central and hemiretinal vein occlusion
 - Approval is based on positive results from Phase III study QUASAR that demonstrated early and robust vision gains and fluid control with Eylea 8 mg with less frequent injections compared to Eylea 2 mg through week 64
 - Eylea 8 mg (after 3 initial monthly injections) showed high durability through week 64 with more than 60% of RVO patients achieving a last assigned treatment interval of four months or longer, and with 40% having a last assigned interval of five months
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Berlin, March 23, 2026 – The Ministry of Health, Labour and Welfare (MHLW) in Japan has granted marketing authorization for Eylea™ 8 mg (aflibercept 8 mg, 114.3 mg/ml solution for injection) for the treatment of patients with visual impairment due to macular edema following retinal vein occlusion (RVO) including branch, central and hemiretinal vein occlusion. RVO is the third indication for Eylea 8 mg in Japan. The approval is based on positive results from the pivotal Phase III study QUASAR.

RVO is the second most common cause of vision loss due to retinal vascular disease.¹ If not diagnosed and treated early, RVO can cause macular edema and retinal ischemia (a lack of blood flow) resulting in abrupt vision loss.

“In patients with macular edema following retinal vein occlusion, where VEGF is known to be significantly elevated, some patients require long-term outpatient care. In the QUASAR trial, Eylea 8 mg demonstrated similar efficacy and safety compared to Eylea 2 mg while

¹ Laouri M, *et al. Eye (Lond)* 2011;25:981–988

reducing the frequency of injections. With the approval of Eylea 8 mg, treatment options will expand, leading to a broader range of treatments that can reduce the burden on patients more than ever before,” said Professor Motohiro Kamei, Department of Ophthalmology, Aichi Medical University, Aichi, Japan, and one of the trial investigators.

“In Japan, retinal vein occlusion ranks as the second most common retinal disease, following age-related macular degeneration.^{2,3} With the introduction of Eylea 8 mg, patients now have access to a more durable treatment option that maintains both efficacy and safety for macular edema associated with retinal vein occlusion,” said Christine Roth, Executive Vice President, Global Product Strategy and Commercialization and Member of the Pharmaceuticals Leadership Team at Bayer.

In the QUASAR trial, Eylea 8 mg achieved non-inferior functional and similar anatomic outcomes compared to Eylea 2 mg at week 36. Patients treated with Eylea 8 mg (after 3 initial monthly injections) not only maintained their visual acuity but required an average of 3 fewer injections than those receiving Eylea 2 mg (8.5 vs. 11.7) by week 64. More than 60% of patients receiving aflibercept 8 mg (after 3 initial monthly injections) were able to achieve a last assigned treatment interval of four months or longer, with 40% having a last assigned interval of five months. Importantly, fluid reduction – an indicator of disease control – was similar with extended dosing intervals of aflibercept 8 mg compared with dosing intervals of Eylea 2 mg at week 64. Eylea 8 mg was well tolerated, and its safety profile was consistent with results from previous clinical trials.

Eylea 8 mg has been recently approved for the treatment of patients with macular edema following RVO in the EU and is approved to date in more than 60 markets for the treatment of neovascular (wet) age-related macular degeneration (nAMD) and visual impairment due to diabetic macular edema (DME). In Japan, for patients experiencing macular edema following RVO, Eylea 8 mg is usually administered with injection intervals of every 4 weeks or longer.

² Miho Yasuda et al., *Invest Ophthalmol Vis Sci*. 2010 Jun;51(6):3205-9. doi: 10.1167/iov.09-4453

³ Japan Statistics Bureau (mid-2023) and Rogers et al. 2010 Feb;117(2):313-9.e1. doi: 10.1016/j.ophtha.2009.07.017.

Eylea 8 mg is the first and only anti-vascular endothelial growth factor-treatment (anti-VEGF) that is approved for extended treatment intervals of up to 6 months both in nAMD and DME in the EU and UK.

Eylea 8 mg (in the United States: Eylea HD) is being jointly developed by Bayer and Regeneron. Regeneron maintains exclusive rights to Eylea 2 mg and Eylea HD in the United States. Bayer has licensed the exclusive marketing rights outside the United States, where the companies share equally the profits from sales of Eylea 2 mg and Eylea 8 mg.

About RVO

Retinal vein occlusion (RVO) is a chronic condition that currently affects 28 million adults globally and can lead to sudden, rapid vision loss. There are two main types of RVO – central retinal vein occlusion (CRVO) and branch retinal vein occlusion (BRVO). CRVO occurs when there is a blockage in the main vein of the retina at the optic nerve. BRVO occurs when the smaller, branch retinal veins are obstructed, and is up to six times more common than CRVO. Hemiretinal vein occlusion (HRVO), a less common subtype, refers to the occlusion of a vein that supplies one half of the retina. RVO can lead to a reduced oxygen supply to the retina, increasing the production of vascular endothelial growth factor (VEGF) and placental growth factor (PIGF). The blocked vein can cause fluid and blood to leak into the retina resulting in swelling and bleeding within the macula, the part of the eye responsible for sharp central vision and seeing fine detail. This swelling is called macular edema, and VEGF plays a major role in driving this pathology.

About Bayer

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