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Japan approves Bayer's EYLEA Injection

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Regeneron Pharmaceuticals Inc. has announced that Bayer HealthCare's Japanese subsidiary, Bayer Yakuhin Ltd, has received approval for EYLEA (aflibercept) Injection by the Ministry of Health, Labour and Welfare (MHLW) in Japan for the treatment of patients with macular edema secondary to retinal vein occlusion (RVO).

This new indication includes macular edema secondary to branch retinal vein occlusion (BRVO) in addition to the previously-approved indication of macular edema secondary to central retinal vein occlusion (CRVO).

The approval is based on positive results from the double-masked, randomized, active-controlled phase 3 VIBRANT study in patients with visual impairment due to macular edema secondary to BRVO. The primary endpoint was the proportion of subjects who gained at least 15 letters in best corrected visual acuity (BCVA) from baseline at week 24, as measured on the Early Treatment Diabetic Retinopathy Scale (ETDRS) eye chart, a standard chart used in research to measure visual acuity. More than half of the patients who were treated with aflibercept solution for injection gained at least three lines of vision.

Bayer HealthCare and Regeneron are collaborating on the global development of EYLEA. Regeneron maintains exclusive rights to EYLEA in the United States. Bayer HealthCare licensed the exclusive marketing rights outside the United States, where the companies share equally the profits from sales of EYLEA, except for Japan where Regeneron receives a percentage of net sales.