

PRESS RELEASE
FOR IMMEDIATE RELEASE

Global Regulatory Partners Announces MHLW Approval of Aflibercept Biosimilar Prefilled Syringe in Japan

Tokyo, Japan | October 26, 2026

Tokyo, Japan - October 26, 2026 - Global Regulatory Partners GK (GRP) announced today that Japan's Ministry of Health, Labour and Welfare (MHLW) granted marketing approval on **October 13, 2026** for **Aflibercept BS Solution for Intravitreal Injection Kit 40 mg/mL [GRP]** (prefilled syringe (PFS) presentation), a biosimilar to EYLEA®¹ (aflibercept), for ophthalmic use.

The product, also known as SB15, was developed by Samsung Bioepis. In June 2024, the vial presentation, Aflibercept BS Solution for Intravitreal Injection 40 mg/mL [GRP], was approved by MHLW.² The newly approved PFS presentation builds on this earlier approval and represents the continued lifecycle development of SB15 in the Japanese market.

GRP serves as the Marketing Authorization Holder (MAH) in Japan, working in collaboration with Samsung Bioepis to support the regulatory approval, quality oversight, safety, and lifecycle management of SB15 in the Japanese market.

"We are very pleased to achieve this important regulatory milestone for SB15 in Japan. The approval of the prefilled syringe presentation reflects the continued strength of our collaboration with Samsung Bioepis and our shared commitment to expanding access to high-quality biosimilar medicines for patients in Japan."

Dr. Suzan Davis
Chief Executive Officer, Global Regulatory Partners

About Aflibercept BS Solution for Intravitreal Injection Kit 40 mg/mL [GRP]

Aflibercept BS Solution for Intravitreal Injection Kit 40 mg/mL [GRP] (prefilled syringe presentation) is a biosimilar to EYLEA® (aflibercept) developed by Samsung Bioepis.

The PFS presentation contains aflibercept in a prefilled, single-use syringe, providing an additional presentation alongside the previously approved vial presentation, Aflibercept BS Solution for Intravitreal Injection 40 mg/mL [GRP].

Aflibercept BS Solution for Intravitreal Injection Kit 40 mg/mL [GRP] is indicated for the treatment of:

- Age-related macular degeneration with subfoveal choroidal neovascularization
- Macular edema secondary to retinal vein occlusion
- Choroidal neovascularization in pathologic myopia
- Diabetic macular edema

Aflibercept is a recombinant fusion protein that inhibits vascular endothelial growth factor (VEGF)-mediated signaling involved in pathological neovascularization and vascular permeability associated with these approved ophthalmic indications.³

Notes to Editors



About Global Regulatory Partners GK

Global Regulatory Partners GK (GRP) is the Japanese affiliate of Global Regulatory Partners, Inc. and a licensed Marketing Authorization Holder headquartered in Tokyo, Japan. Operating in Japan since 2016, GRP GK provides integrated services and local representation to international pharmaceutical, biotechnology, and healthcare companies seeking to register, launch, commercialize, and maintain products in Japan.

GRP's mission is to accelerate access to innovative healthcare products and technologies for patients in Japan. Through its local expertise and international network, GRP serves as a bridge between innovation and patient access, helping international companies navigate the regulatory and operational requirements necessary to bring their products to the Japanese market.

Trademark and References

¹ EYLEA® is a registered trademark of Regeneron Pharmaceuticals, Inc. and Bayer AG.

² Pharmaceuticals and Medical Devices Agency (PMDA). Approved Biosimilar Products: Aflibercept BS Solution for Intravitreal Injection 40 mg/mL [GRP]. Approval date: June 24, 2024.

³ JAPIC. Package Insert: Aflibercept BS Solution for Intravitreal Injection 40 mg/mL [GRP]. Revised December 2025.