

January 30, 2026
Fuji Pharma Co., Ltd.

Notice of Licensing and Settlement Regarding Aflibercept 2mg BS (Biosimilar)

Fuji Pharma Co., Ltd. (Head Office: Chiyoda-ku, Tokyo; hereinafter “Fuji”) announces that Alvotech hf. (Head Office: Iceland, hereinafter “Alvotech”) and Regeneron and Bayer have entered into a global licensing and settlement agreement (“the Agreement”) to resolve all patent disputes worldwide related to the biosimilar candidate of aflibercept (2 mg).

Regeneron is the developer of the drug containing aflibercept as its active ingredient and holds several related patents. Fuji had received a petition for a provisional disposition order concerning patent rights from Regeneron, but Alvotech and Regeneron executed the Agreement to dismiss all pending litigation. The settlement agreement allows Fuji and its sales partner Nitto Medic Co., Ltd. (“Nitto”) to market and sell the biosimilar from January 1, 2026 in Japan without the diabetic macular edema indication, and from November 1, 2026 with all approved indications. The remaining terms of the agreement remain confidential.

After execution of the agreement, Alvotech now has rights in Japan to supply to Fuji with Aflibercept BS solution 40mg/mL for IVT injection “NIT” and Aflibercept BS kit 40mg/mL for IVT injection “NIT” (Aflibercept biosimilar 2) — for which Fuji hold manufacturing and marketing approval in Japan and which began sales through our sales partner Nitto Medic Co., Ltd. on January 7, 2026. Fuji’s marketing and sales of its Aflibercept BS products are part of its ongoing commitment to providing new treatment options for patients in Japan who require biosimilars.

As part of its five-year medium-term management plan ending in September 2029, Fuji aims to become the No.1 biosimilar company in Japan by the fiscal year ending September 2029. Fuji will continue to expand our biosimilar lineup, provide new treatment options to patients and healthcare professionals, and further contribute to medical economics. Guided by its corporate philosophy of “contributing to people’s healthy lives through excellent pharmaceuticals,” we will continue to strive to improve the well-being of as many patients as possible.

Note

The financial forecasts and other projections provided in this release are based on information available at the time of its compilation and it therefore contains an element of uncertainty and potential risks. Actual results may differ significantly from these forecasts for a number of reasons. It should also be noted that the views and/or facts presented here may be altered or deleted without prior notification. Information in this release about pharmaceuticals (including items in the pipeline) is not provided for the purpose of marketing or advertising or of supplying medical advice.

For further information, contact

Fuji Pharma Co., Ltd.

Corporate Communication Section, Corporate Planning Department, Corporate Strategy Division

fsks@fujipharma.jp