

Press Release



November 4, 2025
Fuji Pharma Co., Ltd.

Notice of Settlement and License Agreement Regarding Golimumab BS (Biosimilar)

Fuji Pharma Co., Ltd. (Head Office: Chiyoda-ku, Tokyo; hereinafter “Fuji”) hereby announces that it and Alvotech hf. (Head Office: Iceland, hereafter “Alvotech”) have entered into a settlement and license agreement (hereinafter “the Agreement”) with Janssen Biotech Inc. (Head Office: Pennsylvania, USA; hereinafter “Janssen”) Regarding “Golimumab BS,” a biosimilar product.

Janssen holds the marketing approval for SIMPONI®, a medication containing golimumab as its active ingredient, and owns patents related to golimumab products in Japan.

Alvotech develops and manufactures Golimumab BS and has licensed marketing rights in Japan to Fuji Pharma.

Under the terms of the Agreement, Fuji and Alvotech have obtained a license to market Golimumab BS in Japan. As a result, Golimumab BS Subcutaneous Injection 50mg Syringe “F” ([Golimumab biosimilar 1]), which received marketing approval on September 19, 2025, is now eligible for NHI price listing and market entry in May 2026. This marks a significant step forward in 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.

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