Press Release

FujiPharma

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Fuji Pharma Co., Ltd.

Marketing Approval for new specification of Golimumab Biosimilar
— GOLIMUMAB BS 50mg autoinjector for S.C. injection「F」 —

Tokyo, Japan – Fuji Pharma Co., Ltd. ("Fuji") announced today that it has obtained marketing approval in Japan for one biosimilar product.

The newly approved product, GOLIMUMAB BS 50mg autoinjector for S.C. injection「F」(the "Product"), is indicated for the treatment of rheumatoid arthritis, including inhibition of structural joint damage, in patients who have shown an inadequate response to existing therapies, as well as for the induction and maintenance treatment of moderately to severely active ulcerative colitis in patients who have shown an inadequate response to existing therapies.

Fuji currently markets GOLIMUMAB BS 50mg syringe for S.C. injection「F」. The Product is an auto-injector formulation containing the same active ingredient and dosage strength as the prefilled syringe formulation. With this approval, Fuji has expanded its golimumab biosimilar product lineup. The addition of the auto-injector formulation provides patients and healthcare professionals with a broader range of administration device options, contributing to improved convenience for patients and addressing diverse needs in clinical practice.
Under the agreement between Fuji, Janssen Biotech, Inc. (Pennsylvania, USA), and Alvotech hf. (Iceland), previously announced on November 4, 2025, the Product will be eligible for NHI drug price listing and commercial launch in Japan from May 2027 onward.

In its Mid-Term Business Plan (2025-2029), Fuji positions the biosimilar business as one of its key growth strategies. Going forward, Fuji remains committed to improving patient access to treatment and contributing further to healthcare through the provision of high-quality biosimilars.

Product Information

Therapeutic category	Product name	Original drug in Japan
Human anti-TNFα monoclonal antibody formulation	GOLIMUMAB BS 50mg autoinjector for S.C. injection「F」	Simponi® Subcutaneous Injection autoinjector

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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