Press Release

FujiPharma

September 16, 2026
Fuji Pharma Co., Ltd.

Marketing Approval for new specification of Ustekinumab Biosimilar — USTEKINUMAB BS 130mg intravenous infusion「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, USTEKINUMAB BS 130mg intravenous infusion「F」(the "Product"), is an intravenous formulation indicated for induction therapy in patients with moderately to severely active Crohn's disease who have shown an inadequate response to existing treatments.

Fuji currently markets USTEKINUMAB BS 45mg Syringe for S.C. injection 「F」 and USTEKINUMAB BS 90mg Syringe for S.C. injection 「F」. With the approval of the Product, Fuji has expanded its ustekinumab biosimilar portfolio, enabling the Company to provide treatment options covering both induction and maintenance therapy for moderately to severely active Crohn's disease. Through this expanded lineup, Fuji aims to contribute to the broader adoption of biosimilars in the field of inflammatory bowel disease and to improve patient access to treatment.

Fuji is aiming for NHI drug price listing and product launch in November 2026.

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-human IL-12/23p40 monoclonal antibody preparation	USTEKINUMAB BS 130mg intravenous infusion「F」	Stelara® Intravenous Infusion

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