

October 31, 2025
Fuji Pharma Co., Ltd.

Notice of Settlement Agreement Regarding Denosumab BS (Biosimilar)

Fuji Pharma Co., Ltd. (Head Office: Chiyoda-ku, Tokyo; hereinafter “Fuji”) is pleased announces that its entered into an agreement (hereinafter “the Agreement”) with Daiichi Sankyo co., Ltd. (Head Office: Chuo0ku, Tokyo; hereinafter “Daiichi Sankyo”) Regarding Denosumab BS, a biosimilar product.

Daiichi Sankyo holds the marketing approval for RANMARK®, a medication containing Denosumab as its active ingredient, and exclusive license for patents related to denosumab products in Japan.

Fuji has partnered with Alvotech, which developed and manufactures Denosumab BS. Fuji received marketing approval on September 19, 2025, for Denosumab BS Subcutaneous Injection 120mg RM “F” ([Denosumab biosimilar 1]), and is preparing for NHI price listing and product launch within CY2026. 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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