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ASIA EDITION

Samsung Bioepis gains marketing approval in Japan for 130mg intravenous infusion of Ustekinumab Biosimilar

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Marks second marketing approval in Japan through partnership with Nipro Corporation

South Korea-based Samsung Bioepis has announced the marketing approval of Ustekinumab BS Intravenous Infusion 130mg, a biosimilar referencing Stelara (ustekinumab), indicated for an induction therapy for moderate-to-severe active Crohn's disease where other treatments are ineffective. This is a second product to be approved in Japan under partnership with Nipro Corporation.

Ustekinumab is a human immunoglobulin G1 kappa (IgG1?) monoclonal antibody that binds to the p40 subunit shared by IL-12 and IL-23, blocking their activity in immune-mediated diseases. Japan's Pharmaceuticals and Medical Devices Agency (PMDA) has granted marketing authorization to Ustekinumab BS Subcutaneous Injection 45mg Syringes in December 2025 which was subsequently launched in May 2026.

In June 2025, Samsung Bioepis announced a strategic partnership with Nipro for the development and commercialisation of multiple biosimilar candidates in Japan, including ustekinumab.

Samsung Bioepis's ustekinumab biosimilar is also available under different brand names across the European Union (EU), Republic of Korea, the United Kingdom (UK), and the United States (US).