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Samsung Bioepis launches Ustekinumab biosimilar in Japan

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Marks first launch in Japan through partnership with Nipro Corporation



South Korea-based Samsung Bioepis has announced the launch of **Ustekinumab BS 45 mg Syringe for S.C. Injectionã?? *NIPRO*ã?•**, a biosimilar referencing Stelara (ustekinumab), marking its first product launch in Japan under partnership with Nipro Corporation. The launch follows the Official Gazette announcement on May 19 regarding the product's listing under the National Health Insurance (NHI) Drug Price Standard, which became effective today.

Ustekinumab is a human immunoglobulin G1 kappa (IgG1?) monoclonal antibody that prevents abnormal regulation of IL-12 and IL-23 associated with immune-mediated diseases. Japan's Pharmaceuticals and Medical Devices Agency (PMDA) has granted marketing authorisation to Ustekinumab BS 45 mg Syringe for S.C. Injectionã??NIPROã?• for the treatment of plaque psoriasis and psoriatic arthritis in December 2025.

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

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