Yesintek™ (ustekinumab-kfce) – New biosimilar approval

- On December 1, 2024, Biocon announced the FDA approval of Yesintek (ustekinumab-kfce), biosimilar to Janssen's Stelara® (ustekinumab).
    - Wezlana™ (ustekinumab-auub) was the first FDA-approved biosimilar that is interchangeable to Stelara.
    - Additional biosimilars approved to Stelara include Selarsdi™ (ustekinumab-aekn), Pyzchiva™ (ustekinumab-ttwe), Otulfi™ (ustekinumab-aauz) , and Imuldosa™ (ustekinumab-slrf).
- Yesintek, Imuldosa, Otulfi, Pyzchiva, Wezlana, Selarsdi and Stelara share the following indications:
    - Adults and pediatric patients 6 years and older with moderate to severe plaque psoriasis (PsO), who are candidates for phototherapy or systemic therapy
    - Adults and pediatric patients 6 years and older with active psoriatic arthritis (PsA).
    - Adult patients with moderately to severely active Crohn's disease (CD), and
    - Adult patients with moderately to severely active ulcerative colitis (UC).
- The approval of Yesintek is based on review of a comprehensive data package and totality of evidence demonstrating a high degree of similarity to its reference product, Stelara.
- Yesintek is biosimilar to Stelara and shares the same recommended dosing instructions and safety profile including warnings, precautions, and adverse reactions.
    - Refer to the Yesintek drug label for additional details.
- Biocon plans to launch Yesintek no later than February 22, 2025. Yesintek will be available as a single-dose vial containing 130 mg/26 mL (5 mg/mL) for IV infusion, and single-dose prefilled syringes containing 45 mg/0.5 mL and 90 mg/mL and a single-dose vial containing 45 mg/0.5 mL for SC injection.