Steqeyma® (ustekinumab-stba) – New biosimilar approval

- On December 18, 2024, Celltrion announced the FDA approval of Steqeyma (ustekinumab-stba), the **7th 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), Imuldosa™ (ustekinumab-slrf), and Yesintek™ (ustekinumab-kfce).
- Steqeyma, 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)
    - Adult patients with moderately to severely active **ulcerative colitis** (UC).
- The approval of Steqeyma is based on review of a comprehensive data package and totality of evidence demonstrating a high degree of similarity to its reference product, Stelara.
- Steqeyma is biosimilar to Stelara and shares the same recommended dosing instructions and safety profile including warnings, precautions, and adverse reactions.
    - Refer to the Steqeyma drug label for additional details.
- **Celltrion plans to launch Steqeyma in February 2025**. Steqeyma 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 for SC injection.