

Stegeyma® (ustekinumab-stba) – New biosimilar approval

- On December 18, 2024, <u>Celltrion announced</u> the <u>FDA approval</u> of <u>Steqeyma (ustekinumab-stba)</u>, 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 <u>Selarsdi[™] (ustekinumab-aekn)</u>, <u>Pyzchiva[™] (ustekinumab-ttwe)</u>, <u>Otulfi[™] (ustekinumab-aauz)</u>, <u>Imuldosa[™] (ustekinumab-slrf)</u>, and <u>Yesintek[™] (ustekinumab-kfce)</u>.
- 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 <u>drug label</u> 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.



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