Starjemza® (ustekinumab-hmny) – New biosimilar approval

- On May 27, 2025, Bio-Thera Solutions and Hikma announced the FDA approval of Starjemza (ustekinumab-hmny), biosimilar to Janssen's Stelara® (ustekinumab).
    - Interchangeable biosimilars to Stelara that have launched include Wezlana™ (ustekinumab-auub), Selarsdi™ (ustekinumab-aekn), Pyzchiva™ (ustekinumab-ttwe), Otulfi™ (ustekinumab-aauz), Steqeyma® (ustekinumab-stba), and Yesintek® (ustekinumab-kfce).
    - An additional biosimilar approved to Stelara is Imuldosa™ (ustekinumab-slrf).

- All of the biosimilars to Stelara share the same indications as Stelara:
    - 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 Starjemza is based on review of a comprehensive data package and totality of evidence demonstrating a high degree of similarity to its reference product, Stelara.

- Warnings and precautions for Starjemza include infections; theoretical risk for vulnerability to particular infections; pre-treatment evaluation for tuberculosis; malignancies; hypersensitivity reactions; posterior reversible encephalopathy syndrome; immunizations; and noninfectious pneumonia.

- The most common adverse reactions (≥ 3%) with Starjemza use in psoriasis were nasopharyngitis, upper respiratory tract infection, headache, and fatigue.

- The most common adverse reaction (≥ 3%) with Starjemza use in CD, induction was vomiting.

- The most common adverse reactions (≥ 3%) with Starjemza use in CD, maintenance were nasopharyngitis, injection site erythema, vulvovaginal candidiasis/mycotic infection, bronchitis, pruritus, urinary tract infection, and sinusitis.

- The most common adverse reaction (≥ 3%) with Starjemza use in UC, induction was nasopharyngitis.

- The most common adverse reactions (≥ 3%) with Starjemza use in UC, maintenance were nasopharyngitis, headache, abdominal pain, influenza, fever, diarrhea, sinusitis, fatigue, and nausea.

- The recommended dosage of Starjemza for adult patients with PsO is 45 mg subcutaneously (SC) initially and 4 weeks later, followed by 45 mg every 12 weeks in those weighing ≤ 100 kg. For those weighing > 100 kg, the dose is 90 mg SC initially and 4 weeks later, followed by 90 mg every 12 weeks.
    - The recommended dosage of Starjemza for PsO in pediatric patients (6 – 17 years old) is administered SC at weeks 0 and 4, then every 12 weeks thereafter and based on body weight as follows: < 60 kg, 0.75 mg/kg; 60 to 100 kg, 45 mg; and > 100 kg, 90 mg.

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- The recommended dosage of Starjemza for adult patients with PsA is 45 mg SC initially and 4 weeks later, followed by 45 mg every 12 weeks.
    - The recommended dosage of Starjemza for PsA in pediatric patients (6 – 17 years old) is administered SC at weeks 0 and 4, then every 12 weeks thereafter and based on body weight as follows: < 60 kg, 0.75 mg/kg; ≥ 60 kg, 45 mg.
- The recommended induction dosage of Starjemza in adult patients with CD and UC is a single intravenous (IV) infusion using the weight-based dosage regimen as follows: ≤ 55 kg, 260 mg; > 55 kg to 85 kg, 390 mg; and > 85 kg, 520 mg.
    - The recommended maintenance dosage of Starjemza in adult patients with CD and UC is a 90 mg dose administered SC 8 weeks after the initial IV dose, then every 8 weeks thereafter.
- Starjemza is intended for use under the guidance and supervision of a physician. Starjemza should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician. The appropriate dose should be determined by a healthcare provider using the patient's current weight at the time of dosing. In pediatric patients, it is recommended that Starjemza be administered by a healthcare provider. If a physician determines that it is appropriate, a patient may self-inject, or a caregiver may inject Starjemza after proper training in SC injection technique.
    - Refer to the Starjemza drug label for additional dosing details.
- Bio-Thera/Hikma's launch plans for Starjemza are pending. Starjemza 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.

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