Selarsdi™ (ustekinumab-aekn) – New biosimilar approval

- On April 16, 2024, Alvotech and Teva announced the FDA approval of Selarsdi (ustekinumab-aekn), biosimilar to Janssen's Stelara® (ustekinumab).
    - Amgen's Wezlana™ (ustekinumab-auub) was the first FDA-approved biosimilar to Stelara. It also has been granted interchangeability.
- Selarsdi, Wezlana 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).
- Wezlana and Stelara also share the following indications:
    - 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 Selarsdi 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 Selarsdi 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 Selarsdi use in psoriasis were nasopharyngitis, upper respiratory tract infection, headache, and fatigue.
- The recommended dosage of Selarsdi 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 Selarsdi 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 to 100 kg, 45 mg; and > 100 kg, 90 mg. There is no dosage form for Selarsdi that allows weight-based dosing for pediatric patients < 60 kg.
- The recommended dosage of Selarsdi 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 Selarsdi 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, 45 mg. There is no dosage form for Selarsdi that allows weight-based dosing for pediatric patients < 60 kg.
- Selarsdi is intended for use under the guidance and supervision of a physician. Selarsdi 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 Selarsdi be

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administered by a healthcare provider. If a physician determines that it is appropriate, a patient may self-inject, or a caregiver may inject Selarsdi after proper training in SC injection technique.

    - Refer to the Selarsdi drug label for additional dosing details.

- Teva's launch plans for Selarsdi are pending. Selarsdi will be available as single-dose prefilled syringes containing 45 mg/0.5 mL and 90 mg/mL for SC injection.

- Teva/Alvotech has signed a settlement agreement with Johnson & Johnson (Janssen) allowing the company to sell Selarsdi "no later than February 21, 2025."