Selarsdi™ (ustekinumab-aekn) – New indications and formulation approval

- On October 22, 2024, Alvotech and Teva announced the FDA approval of Selarsdi (ustekinumab-aekn), biosimilar to Janssen's Stelara® (ustekinumab), for the treatment of adult patients with moderately to severely active Crohn's disease (CD) and moderately to severely active ulcerative colitis (UC).
    - Alvotech/Teva also received approval for a single-dose vial of 130 mg/26 mL solution for intravenous (IV) infusion.
- Selarsdi was previously approved for the treatment of:
    - Adults and pediatric patients 6 years and older with moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy
    - Adults and pediatric patients 6 years and older with active psoriatic arthritis.
- The most common adverse reaction (≥ 3%) with Selarsdi use for induction therapy of CD was vomiting.
- The most common adverse reactions (≥ 3%) with Selarsdi use for maintenance therapy of CD were nasopharyngitis, injection site erythema, vulvovaginal candidiasis/mycotic infection, bronchitis, pruritus, urinary tract infection, and sinusitis.
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- The most common adverse reaction (≥ 3%) with Selarsdi use for induction therapy of UC was nasopharyngitis.
- The most common adverse reactions (≥ 3%) with Selarsdi use for maintenance therapy of UC were nasopharyngitis, headache, abdominal pain, influenza, fever, diarrhea, sinusitis, fatigue, and nausea.
- The recommended induction dosage of Selarsdi in adult patients with CD and UC is a single 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 Selarsdi 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.
    - Refer to the Selarsdi drug label for dosing for its other indications.
- 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. If a physician determines that it is appropriate, a patient may self-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.

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