Otulfi™ (ustekinumab-aauz) – New biosimilar approval

- On September 30, 2024, Formycon and Fresenius Kabi announced the FDA approval of Otulfi (ustekinumab-aauz), biosimilar to Janssen's Stelara® (ustekinumab).
    - Wezlana (ustekinumab-auub) is the first FDA-approved biosimilar that is interchangeable to Stelara.
    - Selarsdi (ustekinumab-aekn) is the second biosimilar approved to Stelara. It was only approved as a subcutaneous formulation.
    - Pyzchiva (ustekinumab-ttwe) is the third biosimilar approved to Stelara.
- 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).
- Otulfi, Pyzchiva, 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 Otulfi 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 Otulfi 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 Otulfi use in psoriasis were nasopharyngitis, upper respiratory tract infection, headache, and fatigue.
- The most common adverse reaction (≥ 3%) with Otulfi induction use in CD was vomiting.
- The most common adverse reactions (≥ 3%) with Otulfi maintenance use in CD were nasopharyngitis, injection site erythema, vulvovaginal candidiasis/mycotic infection, bronchitis, pruritus, urinary tract infection, and sinusitis.
- The most common adverse reaction (≥ 3%) with Otulfi induction use in UC was nasopharyngitis.
- The most common adverse reactions (≥ 3%) with Otulfi maintenance use in UC were nasopharyngitis, headache, abdominal pain, influenza, fever, diarrhea, sinusitis, fatigue, and nausea.
- The recommended dosage of Otulfi 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.

Continued . . .

    - The recommended dosage of Otulfi 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 Otulfi that allows weight-based dosing for pediatric patients below 60 kg (132 pounds).

- The recommended dosage of Otulfi 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 Otulfi 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 Otulfi that allows weight-based dosing for pediatric patients below 60 kg (132 pounds).

- The recommended induction dosage of Otulfi 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 Otulfi 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.

- Otulfi is intended for use under the guidance and supervision of a physician. Otulfi 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 Otulfi be administered by a healthcare provider. If a physician determines that it is appropriate, a patient may self-inject, or a caregiver may inject Otulfi after proper training in SC injection technique.

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

- Sandoz's launch plans for Otulfi are pending. Otulfi will be available as single-dose vials 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.

    - Formycin and Fresenius Kabi have signed a settlement agreement with Johnson & Johnson (Janssen) allowing the company to sell Otulfi "beginning on February 22, 2025."