Erelzi™ (etanercept-szzs) – New Biosimilar Approval

- On August 30, 2016, the FDA announced the approval of Sandoz's Erelzi (etanercept-szzs) injection, the third biosimilar product approved in the United States. Erelzi is biosimilar to Enbrel® (etanercept) and shares the same indications.

- Both Erelzi and Enbrel are approved for:

    - Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis (RA). Erelzi can be initiated in combination with methotrexate (MTX) or used alone.
    - Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) in patients ages 2 and older.
    - Reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in patients with psoriatic arthritis (PsA). Erelzi can be used in combination with MTX in patients who do not respond adequately to MTX alone.
    - Reducing signs and symptoms in patients with active ankylosing spondylitis (AS).
    - Treatment of adult patients (18 years or older) with chronic moderate to severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy.

- A biosimilar product is a biological agent that is considered highly similar to an already-approved biological drug, known as the reference product. Biological products are generally derived from a living organism and can come from many sources, including humans, animals, microorganisms or yeast.

    - A biosimilar product must show no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products.
    - In addition, a biosimilar product may only be approved for the indication(s) and condition(s) that have been FDA approved for the reference product, and must have the same mechanism(s) of action, route(s) of administration, dosage form(s) and strength(s) as the reference product.
    - The facilities where biosimilars are manufactured must also meet the FDA's standards.

- The approval of Erelzi is based on a review of analytical, non-clinical, pharmacokinetic and clinical data confirming that Erelzi is highly similar to the reference product. A confirmatory efficacy and safety similarity study was conducted in patients with chronic PsO.

    - The FDA approval follows a unanimous (20-0) vote by the FDA's Arthritis Advisory Committee to recommend use of Erelzi in all indications of Enbrel.

- Erelzi is approved as a biosimilar to Enbrel, ***not*** as an interchangeable product.

- Similar to Enbrel, Erelzi carries a boxed warning for serious infections and malignancies.

- Erelzi is contraindicated in patients with sepsis.

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- Other warnings and precautions of Erelzi include neurologic events, patients with heart failure, hematologic events, hepatitis B reactivation, allergic reactions, immunizations, autoimmunity, immunosuppression, use in Wegener's granulomatosis patients, use with Kineret® (anakinra) or Orencia® (abatacept), and use in patients with moderate to severe alcoholic hepatitis.

- The most common adverse reactions (> 5%) with Erelzi use were infections and injection site reactions.

- The recommended dose of Erelzi administered by subcutaneous injection is as follows:

Indication	Recommended Dose
Adult RA, AS, and PsA	50 mg weekly
Adult PsO	Starting Dose: 50 mg twice weekly for 3 months Maintenance Dose: 50 mg once weekly
JIA (weight ≥ 63 kg)	50 mg weekly
JIA (weight < 63 kg)	There is no dosage form for Erelzi that allows weight based dosing for pediatric patients below 63 kg

- The launch plans for Erelzi are pending due to ongoing patent litigation. Upon launch, Erelzi will be available as 25 mg/0.5 mL and 50 mg/mL single-dose prefilled syringes and as a 50 mg/mL single-dose prefilled Sensoready® pen.

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