Erelzi™ (etanercept-szzs) – Indication removals

- On January 26, 2018, the FDA approved the deletion of two indications and related information from Sandoz's Erelzi (etanercept-szzs) drug label:
    - For 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 methotrexate (MTX) in patients who do not respond adequately to MTX alone.
    - For the treatment of adult patients (18 years or older) with chronic moderate to severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy.
    - The FDA has not concluded that these deletions are necessary for reasons of safety or efficacy.

- Erelzi is also indicated for the treatment of rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (JIA) in patients aged 2 years or older, and ankylosing spondylitis (AS).

- Enbrel® (etanercept), the reference product for biosimilar Erelzi, is indicated for the treatment of RA, polyarticular JIA in patients aged 2 years or older, PsA, AS, and PsO in patients 4 years of age and older.

- Erelzi carries a boxed warning for serious infections and malignancies.