Avtozma® (tocilizumab-anoh) – New biosimilar approval

- On January 30, 2025, Celltrion announced the FDA approval of Avtozma (tocilizumab-anoh), biosimilar to Genentech's Actemra® (tocilizumab).
    - Avtozma is the third FDA-approved biosimilar to intravenous (IV) Actemra and the second subcutaneous (SC) biosimilar to Actemra.
    - Biogen's Tofidence™ (tocilizumab-bavi) IV and Fresenius Kabi's Tyenne® (tocilizumab-aazg) IV and SC have already launched.
- Avtozma, Tofidence, Tyenne and Actemra share the following indications:
    - Treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs
    - Treatment of active polyarticular juvenile idiopathic arthritis (PJIA) in patients 2 years of age and older
    - Treatment of active systemic juvenile idiopathic arthritis (SJIA) in patients 2 years of age and older.
- Avtozma, Tyenne and Actemra also share the following indication:
    - Treatment of giant cell arteritis (GCA) in adult patients.
- Avtozma and Actemra also share the following indication:
    - Treatment of coronavirus disease 2019 in hospitalized adult patients who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation.
- In addition, Actemra is indicated for the following:
    - Slowing the rate of decline in pulmonary function in adult patients with systemic sclerosis-associated interstitial lung disease
    - Treatment of chimeric antigen receptor T cell-induced severe or life-threatening cytokine release syndrome in adults and pediatric patients 2 years of age and older.
- The approval of Avtozma is based on review of a comprehensive data package and totality of evidence demonstrating a high degree of similarity to its reference product, Actemra.
- Like Actemra, Tofidence and Tyenne, Avtozma carries a boxed warning for risk of serious infections.
- Refer to Avtozma's drug label for additional information about warnings/precautions, adverse reactions and dosing.

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- Celltrion’s launch plans for Avtozma are pending. Avtozma will be available as single-dose vials containing 80 mg/4 mL, 200 mg/10 mL, 400 mg/20 mL solution for IV infusion and as a single-dose prefilled syringe or single-dose prefilled autoinjector containing 162 mg/0.9 mL solution for SC administration.