Tyenne® (tocilizumab-aazg) – New biosimilar approval

- On March 6, 2024, Fresenius Kabi announced the FDA approval of Tyenne (tocilizumab-aazg), biosimilar to Genentech's Actemra (tocilizumab).
    - Tyenne is the second FDA-approved biosimilar to intravenous (IV) Actemra and the first FDA-approved biosimilar to subcutaneous (SC) Actemra.
    - Biogen's Tofidence™ (tocilizumab-bavi) was the first FDA-approved biosimilar to IV Actemra, approved on September 23, 2023. It has not yet launched.

- Tyenne, Tofidence 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.

- Tyenne and Actemra also share the following indication:
    - Treatment of giant cell arteritis (GCA) in adult patients.

- 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
    - 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.

- The approval of Tyenne 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 and Tofidence, Tyenne carries a boxed warning for risk of serious infections.

- Warnings and precautions for Tyenne include gastrointestinal perforations; hepatoxicity; changes in laboratory parameters; immunosuppression; hypersensitivity reactions, including anaphylaxis; demyelinating disorders; active hepatic disease and hepatic impairment; and vaccinations.

- The most common adverse reactions (≥ 5%) with Tyenne use were upper respiratory tract infections, nasopharyngitis, headache, hypertension, and increased alanine transaminase (ALT).

- The recommended dosage of Tyenne for adult patients with RA given as a 60-minute single IV drip infusion is 4 mg/kg every 4 weeks followed by an increase to 8 mg/kg every 4 weeks based on clinical response.

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- The recommended dosage of Tyenne for PJIA patients given once every 4 weeks as a 60-minute single IV drip infusion in patients < 30 kg: 10 mg/kg and ≥ 30 kg: 8 mg/kg.
- The recommended dosage of Tyenne for SJIA patients given once every 2 weeks as a 60-minute single IV drip infusion in patients < 30 kg: 12 mg/kg and ≥ 30 kg: 8 mg/kg.
- The recommended dosage of Tyenne for GCA patients given as a 60-minute single IV drip infusion is 6 mg/kg every 4 weeks in combination with tapering course of glucocorticoids.
    - Doses exceeding 600 mg per infusion are not recommended in GCA patients.
- For the treatment of RA, PJIA, SJIA, and GCA when transitioning from IV therapy with Tyenne to SC therapy with Tyenne, the first SC dose should be administered instead of the next scheduled IV dose.
- For the treatment of RA, the SC dose is 162 mg administered every other week, followed by an increase to every week based on clinical response in patients < 100 kg and 162 mg administered every week for patients ≥ 100 kg.
- For the treatment of PJIA, the SC dose is 162 mg administered every 3 weeks for patients < 30 kg and 162 mg every 2 weeks for patients ≥ 30 kg.
- For the treatment of SJIA, the SC dose is 162 mg administered every 2 weeks for patients < 30 kg and 162 mg every 1 week for patients ≥ 30 kg.
- For the treatment of GCA, the SC dose 162 mg given once every week in combination with a tapering course of glucocorticoids.
- Fresenius' launch plans for Tyenne are pending. Tyenne 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 ACTPen® autoinjector containing 162 mg/0.9 mL solution for SC administration.