Actemra® (tocilizumab) – New indication

- On December 21, 2022, Genentech announced the FDA approval of Actemra (tocilizumab) intravenous infusion, for treatment of hospitalized adult patients with coronavirus disease 2019 (COVID-19) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).
    - This indication was previously approved under emergency use authorization (EUA).
    - The EUA remains in effect for hospitalized pediatric patients 2 to less than 18 years of age with COVID-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO.
- Actemra is also FDA-approved for the adult patients with moderately to severely active rheumatoid arthritis, giant cell arteritis, and systemic sclerosis-associated interstitial lung disease; and for patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis, active systemic juvenile idiopathic arthritis, and chimeric antigen receptor T cell-induced severe or life-threatening cytokine release syndrome.
- The approval of Actemra for the new indication was based on a randomized, controlled, open-label, platform study (RECOVERY) and supported by the results from a randomized, double-blind, placebo-controlled study (EMPACTA). Results of two other randomized, double-blind, placebo-controlled studies, COVACTA and REMDACTA, were also utilized. About 5,500 hospitalized patients with COVID-19 were included in these four studies.
    - Overall, the results of these four studies showed that Actemra may improve outcomes in patients with COVID-19 receiving corticosteroids and requiring supplemental oxygen or breathing support.
    - Consult the Actemra drug label for more detailed information about the clinical studies.
- Actemra carries a boxed warning for risk of serious infections.
- The recommended dose of Actemra for the treatment of COVID-19 in hospitalized adult patients is 8 mg per kg administered as a single 60-minute intravenous infusion. If clinical signs or symptoms worsen or do not improve after the first dose, one additional infusion of Actemra may be administered at least 8 hours after the initial infusion.
    - Doses exceeding 800 mg per infusion are not recommended in patients with COVID-19.
    - Subcutaneous administration is not approved for COVID-19.
    - Refer to the Actemra drug label for dosing for all its other indications.