



Actemra® (tocilizumab) – New orphan indication

- On August 30, 2017, the FDA approved [Genentech's Actemra \(tocilizumab\)](#) injection, for the treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS) in adults and pediatric patients 2 years of age and older.
- Actemra is also indicated for the following:
 - Treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs.
 - Treatment of giant cell arteritis in adult patients.
 - Treatment of active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older.
 - Treatment of active systemic juvenile idiopathic arthritis in patients 2 years of age and older.
- The efficacy of Actemra for the treatment of CRS was assessed in a retrospective analysis of pooled outcome data from clinical trials of CAR T-cell therapies for hematological malignancies. The study population consisted of 45 patients treated with Actemra with or without additional high-dose corticosteroids for severe or life-threatening CRS.
 - Patients were considered responders if CRS resolved within 14 days of the first dose of Actemra, no more than 2 doses of Actemra were needed, and no drugs other than Actemra and corticosteroids were used for treatment.
 - Thirty-one patients (69%; [95% CI: 53, 82]) achieved a response.
 - Achievement of resolution of CRS within 14 days was confirmed in a second study using an independent cohort that included 15 patients (range: 9 – 75 years old) with CAR T-cell-induced CRS.
- Actemra carries a boxed warning regarding the risk of serious infections.
- The recommended dose of Actemra for the treatment of CRS given as a 60-minute intravenous infusion is 12 mg/kg for patients < 30 kg and 8 mg/kg for patients ≥ 30 kg.
 - Actemra may be administered alone or in combination with corticosteroids.
 - If no clinical improvement in the signs and symptoms of CRS occurs after the first dose, up to 3 additional doses of Actemra may be administered. The interval between consecutive doses should be at least 8 hours.
 - Doses exceeding 800 mg per infusion are not recommended in CRS patients.
 - Subcutaneous administration is not approved for CRS.
 - Refer to the Actemra drug label for the recommended dosing in all other indications.



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