Actemra® (tocilizumab) – New indication

- On September 13, 2018, Genentech announced the FDA approval of the subcutaneous (SC) formulation of Actemra (tocilizumab), for the treatment of active systemic juvenile idiopathic arthritis (SJIA) in patients 2 years of age and older.
    - In 2011, FDA approved the intravenous (IV) formulation of Actemra for this same indication.
- Actemra SC and IV are also approved for moderately to severely active rheumatoid arthritis (RA) and polyarticular juvenile idiopathic arthritis (PJIA). In addition, Actemra SC is approved for giant cell arteritis and Actemra IV is approved for cytokine release syndrome.
- SJIA is the rarest form of juvenile idiopathic arthritis (JIA), a chronic arthritic disease affecting children. JIA affects nearly 300,000 children in the U.S., of which SJIA accounts for around 10%.
- The approval of Actemra SC was based on data from the JIGSAW-118 study, a 52-week, open-label, phase 1b pharmacokinetic/pharmacodynamic bridging study designed to determine the appropriate dosing regimen of Actemra SC across a range of body weights in children with SJIA.
    - The efficacy of Actemra SC in children 2 to 17 years of age is based on pharmacokinetic exposure and extrapolation of the established efficacy of Actemra IV in systemic JIA patients.
    - In general, the safety observed for Actemra SC was consistent with the known safety profile of Actemra IV, with the exception of injection site reactions.
- Actemra carries a boxed warning for increased risk for developing serious infections that may lead to hospitalization or death.
- The recommended dose of Actemra SC for the treatment of SJIA is 162 mg once every two weeks for patients less than 30 kg weight and 162 mg once every week for patients at or above 30 kg weight.
    - For RA, PJIA and SJIA, Actemra may be used alone or in combination with methotrexate. In RA, Actemra may be used with other disease modifying anti-rheumatic drugs. The dose of Actemra should not be changed based solely on a single visit body weight measurement, as weight may fluctuate.
    - When transitioning from Actemra IV therapy to SC administration, the first SC dose should be administered when the next scheduled IV dose is due.
    - Refer to the Actemra drug label for dosing for all other indications.