Actemra® (tocilizumab) – New indication

- On March 4, 2021, Genentech announced the FDA approval of Actemra (tocilizumab), for slowing the rate of decline in pulmonary function in adult patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD).

- Actemra is also approved for rheumatoid arthritis, giant cell arteritis, polyarticular juvenile idiopathic arthritis, systemic juvenile idiopathic arthritis, and cytokine release syndrome.

- Systemic sclerosis (SSc) is an autoimmune disease that causes the tissues of the skin and lungs to thicken and harden. SSc affects up to 75,000 people in the U.S. and approximately 80% have SSc-ILD, which causes inflammation and scarring of the lungs.

- The approval of Actemra for the new indication was based on the focuSSced trial, a Phase 3, randomized, double-blind, placebo-controlled clinical study in 212 adults with SSc. Supportive information was also used from the faSScinate trial, a Phase 2/3, randomized, double-blind, placebo-controlled study in patients with SSc. The primary efficacy endpoint was change from baseline at week 48 in modified Rodnan Skin Score (mRSS). Change from baseline in percent predicted forced vital capacity (ppFVC) at week 48 was a key secondary endpoint.

    - In the overall population of focuSSced, there was not a statistically significant difference in the mean change from baseline to week 48 in mRSS in patients receiving Actemra vs. placebo (difference: -1.73; 95% CI: -3.78, 0.32). There also was not a statistically significant effect on the primary endpoint of mRSS in the faSScinate trial.
    - In the overall population of focuSSced, patients treated with Actemra, as compared to placebo treated patients, were observed to have less decline from baseline in ppFVC and observed FVC at 48 weeks. FVC results from faSScinate were similar.
    - The ppFVC and observed FVC results in the overall population were primarily driven by results in the SSc-ILD subgroup. In the SSc-ILD subgroup, the differences in mean changes from baseline to week 48 for Actemra vs. placebo were 6.47% (95% CI: 3.43, 9.50) and 241 mL (95% CI: 124, 358) for ppFVC and observed FVC, respectively.
    - The results of the key FVC secondary endpoints from focuSSced support a conclusion of effectiveness of Actemra in reducing the rate of progressive loss of lung function in the study population. However, in settings where a trial does not provide evidence of an effect on the primary endpoint, the estimated magnitude of effect on other endpoints should be interpreted with caution, and comparisons to results of other products and studies may be misleading.

- Actemra carries a boxed warning for risk of serious infections.

- The recommended dose of Actemra for adult patients with SSc-ILD is 162 mg given once every week as a subcutaneous injection.

    - Subcutaneous administration with the prefilled ACTPen® autoinjector has not been studied in SSc-ILD.
    - Intravenous administration is not approved for SSc-ILD.
    - Refer to the Actemra drug label for dosing for all its other indications.