Tezspire™ (tezepelumab-ekko) – New drug approval

- On December 17, 2021, Amgen and AstraZeneca announced the FDA approval of Tezspire (tezepelumab-ekko), for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma.
    - Tezspire is not indicated for the relief of acute bronchospasm or status asthmaticus.
- Tezspire is a first-in-class monoclonal antibody that blocks thymic stromal lymphopoietin (TSLP). TSLP is a cytokine mainly derived from epithelial cells and occupies an upstream position in the asthma inflammatory cascade.
- The efficacy of Tezspire was established in two randomized, double-blind, placebo-controlled studies in 1,609 patients 12 years of age and older with severe asthma. PATHWAY was a 52-week dose-ranging study in which patients received tezepelumab-ekko 70 mg every 4 weeks, Tezspire 210 mg every 4 weeks, tezepelumab-ekko 280 mg every 2 weeks, or placebo. NAVIGATOR was a 52-week study in which patients received Tezspire 210 mg every 4 weeks or placebo. The primary endpoint in both studies was the rate of clinically significant asthma exacerbations measured over 52 weeks. Asthma exacerbations were defined as worsening of asthma requiring the use of or increase in oral or injectable corticosteroids for at least 3 days, or a single depo-injection of corticosteroids, and/or emergency department visits requiring use of oral or injectable corticosteroids and/or hospitalization.
    - In PATHWAY, the annualized rate of asthma exacerbations was 0.20 with Tezspire vs. 0.72 with placebo (rate ratio 0.29, 95% CI: 0.16, 0.51).
    - In NAVIGATOR, the annualized rate of asthma exacerbations was 0.93 with Tezspire vs. 2.10 with placebo (rate ratio 0.44, 95% CI: 0.37, 0.53).
    - In NAVIGATOR, patients receiving Tezspire experienced fewer exacerbations than those receiving placebo regardless of baseline levels of blood eosinophils or fractional exhaled nitric oxide (FeNO). Similar results were seen in PATHWAY.
- In addition to the studies above, Tezspire was evaluated in a randomized, double-blind, placebo-controlled clinical study in 150 adult patients with severe asthma who required treatment with daily oral corticosteroids (OCS). Patients received Tezspire 210 mg every 4 weeks or placebo. The primary endpoint was categorized percent reduction from baseline of the final OCS dose at week 48 (≥ 90% reduction, ≥ 75% to < 90% reduction, ≥ 50% to < 75% reduction, > 0% to < 50% reduction, and no change or no decrease in OCS), while maintaining asthma control.
    - Tezspire did not demonstrate a statistically significant reduction in maintenance OCS dose vs. placebo (cumulative odds ratio 1.28, 95% CI: 0.69, 2.35).
- Warnings and precautions for Tezspire include hypersensitivity reactions, acute asthma symptoms or deteriorating disease, risk associated with abrupt reduction of corticosteroid dosage, parasitic (helminth) infection, and live attenuated vaccines.
- The most common adverse reactions (≥ 3%) with Tezspire use were pharyngitis, arthralgia, and back pain.
- The recommended dose of Tezspire is 210 mg administered subcutaneously once every 4 weeks. Tezspire is intended for administration by a healthcare provider.

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- Amgen and AstraZeneca's launch plans for Tezspire are pending. Tezspire will be available as a 210 mg/1.91 mL solution in a single-dose vial and solution in a single-dose pre-filled syringe.

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