## **Positioning of Tezepelumab in Severe Asthma**

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## **CME Items**

- In the anti-TSLP proof-of-concept study, the use of AMG 157 reduced allergen-induced bronchoconstriction. Which of the following was the primary endpoint on day 42 and on day 84?
  - a. The primary endpoint was the immediate asthma response. The FeNO levels did not change after the use of AMG 157.
  - b. The primary endpoint was the late asthma response. The maximum percentage decrease in FEV<sub>1</sub> during the late response with AMG 157 was 34% smaller in the AMG 157 group than in the placebo group on day 42 and 45.9% smaller on day 84.
  - c. The primary endpoint was the change in blood and sputum eosinophils, which decreased to a higher extent from higher initial levels.
  - d. The primary endpoint was the difference between the effect of anti-TSLP depending on whether the challenge was performed with allergens or methacholine.
- 2. The NAVIGATOR study concluded that tezepelumab reduced asthma exacerbations compared with placebo. Which of the following statements indicates better results?
  - a. Patients with levels of eosinophils  $<150/\mu L$  experienced greater effects than patients with  $\geq 300/\mu L$ .
  - b. ACQ-6 scores increased, although the ASD score remained similar compared with placebo.
  - c. There was a more marked effect in patients with ≥300/µL, FeNO ≥25 ppb, and positive sensitization to perennial allergens. However, there was a lower AAER in the group of subcutaneous tezepelumab 210 mg/4 wk compared with placebo, regardless of blood eosinophil counts at inclusion.
  - d. The AQLQ(S)+12 score and ACQ-6 scores did not improve in the active group.
- 3. Which of the following primary endpoints was assessed in the SOURCE trial?
  - a. The difference in terms of ACQ-6 scores, which was not clinically significant.
  - b. The difference in terms of AQLQ(S)+12 scores, which was not clinically significant.
  - c. The AAER (events per patient-year) at week 52.
  - d. The categorized percentage reduction from baseline in daily oral corticosteroid dose at week 48 without the loss of asthma control. Although there were no significant differences between groups, after grouping by baseline eosinophil count, reductions in oral corticosteroid use were greater in patients with >150/µL.
- 4. Regarding the role of tezepelumab in patients with asthma and CRSwNP, which of the following is false?
  - Patients with concomitant asthma and CRSwNP responded much better than those without nasal polyps to tezepelumab in a post hoc analysis from the pivotal phase 2b PATHWAY study.
  - b. At baseline, patients with CRSwNP had higher blood eosinophil counts and FeNO levels than those without nasal polyps.
  - c. The benefits of tezepelumab were observed in the post hoc analysis of the phase 3 NAVIGATOR study, irrespective of nasal polyp status.
  - d. In 2023, an ongoing multicenter, randomized, doubleblind, placebo-controlled, parallel-group study is evaluating the efficacy and safety of tezepelumab in adults with severe CRwNP.

- According to the algorithm included in Figure 2, which of the following biologic drugs would not be indicated in an allergic patient with an eosinophil count of 250/μL in peripheral blood and a FeNO of 10 ppb?
  - a. Benralizumab
  - b. Dupilumab
  - c. Tezepelumab
  - d. They are all indicated
- 6. In clinical trials, tezepelumab reduced all common biomarkers of inflammation from baseline compared with placebo. For which biomarker is the decrease smaller?
  - a. Eosinophils
  - b. FeNO
  - c. IgE
  - d. The decrease is similar for all biomarkers
- 7. Which of the following adverse effects was reported least frequently in the pivotal studies with tezepelumab?
  - a. Infections and infestations
  - b. Injection site reactions
  - c. Pharyngitis
  - d. Arthralgia
- 8. A subanalysis of the NAVIGATOR study evaluated the effect of tezepelumab in patients with and without sensitization to aeroallergens and in patients eligible for omalizumab. Which of the following was the main finding for tezepelumab?
  - a. A 58% decrease in the AAER compared with placebo in patients sensitized to perennial aeroallergens and in patients with both perennial and seasonal allergy.
  - b. A 60% decrease in the AAER in patients with confirmed symptomatic perennial allergy.
  - c. In patients who were candidates for omalizumab (European Union label), tezepelumab reduced the AAER by 68% compared with placebo.
  - d. All the above answers are correct.
- 9. What role does TSLP play in bronchial inflammation in patients with asthma?
  - a. TSLP increases the expression of the OX40 ligand in dendritic cells in the presence of IL-12.
  - b. TSLP induces the differentiation of naïve T lymphocytes into  $T_H2$  or  $T_H17$  lymphocytes and activates ILC-2 cells.
  - c. TSLP inhibits the production of cytokines IL-13 and IL-5.
  - d. TSLP induces the production of IL-17, which directly recruits neutrophils to the bronchial epithelium.
- 10. Which of the following statements is correct regarding TSLP?
  - a. TSLP is an epithelial cytokine, together with IL-33 and IL-27.
  - b. It is secreted by very few cells.
  - c. It always has a proinflammatory action when it has a long isoform.
  - d. It has only been found in lung cells.