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Tezepelumab Significantly Reduced Asthma Exacerbations Requiring Hospitalization in Phase 3 NAVIGATOR Trial

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ATS 2021, New York, NY – Results from the NAVIGATOR study of tezepelumab showed that the new biologic therapy significantly reduced exacerbations requiring hospital stays and emergency department (ED) visits for adults and adolescents with severe, uncontrolled asthma, according to research presented at the ATS 2021 International Conference. NAVIGATOR (NCT03347279) is a recently completed randomized, placebo-controlled double-blind multicenter phase 3 clinical trial.

"Tezepelumab offers new therapeutic opportunities for patients who are currently ineligible for biologic treatments," said study author/investigator Arnaud Bourdin, MD, professor, Département de Pneumologie et Addictologie, PhyMedExp, University of Montpellier, CNRS, INSERM, CHU Montpellier, Montpellier, France. "It may also challenge the current mandatory step of biomarker assessment before initiating a biologic."

Biologics are drugs that are derived from living cells.

"Tezepelumab is the first and only asthma biologic to consistently demonstrate in randomized trials clinically meaningful exacerbation reductions irrespective of key biomarkers, including blood eosinophil counts, allergic status and FeNO (fractional exhaled nitric oxide)," stated the study authors.

Eosinophils (EOS) are a type of white blood cell that can cause lung inflammation in people with asthma. FeNO is a measure of airway inflammation.

One thousand fifty-nine patients, age 12-80 years old, with severe, uncontrolled asthma who were being treated with medium- or high-dose inhaled corticosteroids and at least one other asthma controller medication were recruited for the study. Approximately half of the study participants received 210 mg. of tezepelumab subcutaneously (under the skin) while the other half received a placebo every 4 weeks for 52 weeks. Patients were assigned to the two groups randomly, and researchers were blinded to which participants were receiving the treatment and which were receiving the placebo. The investigators calculated the annualized rate of asthma exacerbations that required hospitalization or an ED visit for the two groups over the year, and also assessed the time to first evaluation that required hospitalization or ED visit. They also evaluated the proportion of patients who required asthma-related health care resources over the 52 weeks.

Tezepelumab demonstrated significant and clinically meaningful reductions in annualized asthma exacerbation rates (AAER) across all eosinophil level subgroups: 70 percent AAER reduction in EOS ≥300; 41 percent AAER reduction in EOS <300 ($p<0.001$); 39 percent AAER reduction in EOS <150.

Tezepelumab also reduced the rate of exacerbations that required hospitalization or an emergency room visit by 79 percent, compared with placebo. The investigational therapy prolonged the time to first exacerbation that required hospitalization or an ED visit (compared with placebo), with a risk reduction of 65 percent.

A lower proportion of patients in the tezepelumab group than in the placebo group required asthma-related hospitalizations (3.2 percent vs. 7.0 percent), ED visits (4.4 percent vs. 9.4 percent), unscheduled visits to a specialist (35.4 percent vs. 43.5 percent), telephone calls with a health care provider (19.1 percent vs. 25.0 percent) or ambulance transport (0.8 percent vs. 2.3 percent).

In addition, tezepelumab demonstrated statistically significant improvements in key secondary endpoints compared to placebo in lung function, asthma control and health-related quality of life. The researchers observed improvements in tezepelumab-treated patients as early as the second week of treatment or at the first time point assessment. These improvements were sustained throughout the treatment period.

Tezepelumab is the first thymic stromal lymphoprotein blocker designed to treat asthma. Thymic stromal lymphoprotein is an inflammatory cytokine (small protein involved in cell signaling) that controls other inflammatory cells involved in asthma. It can cause severe pathological airway inflammation and, ultimately, structural changes in the airways.

“Patients with severe asthma are at an increased risk of mortality and, compared to patients with persistent asthma, have twice the risk of asthma-related hospitalizations,” stated the authors. “Reductions in hospitalizations are particularly important at this critical time.”

In a separate exploratory analysis from NAVIGATOR of exacerbations requiring hospitalizations, tezepelumab showed an 85 percent reduction over 52 weeks compared to placebo when added to current standard of care treatment.

The authors conclude, "These results show that tezepelumab has the potential not only to treat a broad population of severe asthma patients but also to reduce the burden severe asthma places on health care systems. Once on the market, this therapy presents the real possibility that severe asthma patients will no longer have to be hospitalized."

This study was funded by AstraZeneca and AMGEN.

*Full results from the NAVIGATOR clinical trial will be published in a peer-reviewed medical journal at the time of the ATS conference. Results from a related study were presented at the 2021 American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting.

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