Tezepelumab significantly reduced asthma exacerbations: Phase 3 NAVIGATOR trial

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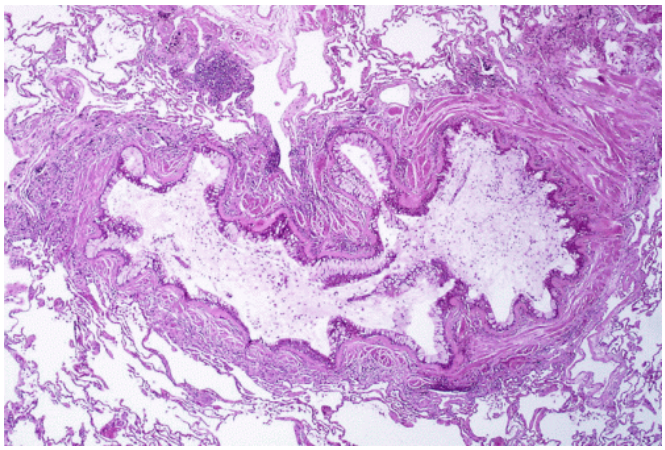

Obstruction of the lumen of a bronchiole by mucoid exudate, goblet cell metaplasia, and epithelial basement membrane thickening in a person with asthma. Credit: Yale Rosen/Wikipedia/CC BY-SA 2.0

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