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Regeneron, Sanofi announce positive results for IL-33 antibody for asthma

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REGN3500 monotherapy significantly reduced loss of asthma control and improved lung function compared to placebo



Regeneron Pharmaceuticals and Sanofi have announced that a Phase 2 proof-of-concept trial evaluating the investigational IL-33 antibody REGN3500 (SAR440340) met the primary endpoint of improvement in loss of asthma control when comparing REGN3500 monotherapy to placebo. The trial also met a key secondary endpoint, demonstrating REGN3500 monotherapy significantly improved lung function compared to placebo.

In the trial, the greatest improvement was observed in patients with blood eosinophil levels ?300 cells/microliter. Patients treated with Dupixent® (dupilumab) monotherapy did numerically better than REGN3500 across all endpoints, although the trial was not powered to show differences between active treatment arms. The combination of REGN3500 and Dupixent also did not demonstrate increased benefit compared to Dupixent monotherapy in this trial. More detailed results will be presented at an upcoming medical meeting.

"This trial suggests that REGN3500 may provide an alternative targeted approach for patients suffering from asthma," said George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer at Regeneron. "We look forward to working with Sanofi to advance REGN3500 through our asthma clinical trial program, as well as continuing our ongoing trials in atopic dermatitis and chronic obstructive pulmonary disease."

Adverse events (AEs) occurred in 61.6% of patients who received REGN3500, 66.2% of patients receiving both REGN3500 and Dupixent, 56.8% of patients who received Dupixent and 64.9% of patients who received placebo. The incidence of serious AEs and AEs leading to treatment discontinuations was low.

Despite standard-of-care treatment with inhaled corticosteroid (ICS) and long-acting beta-agonist (LABA) therapy, people with moderate-to-severe asthma often have inadequately controlled, persistent symptoms that may make them suitable for treatment with a biologic therapy. These people live with coughing, wheezing and difficulty breathing, and are at risk of severe asthma attacks that may require emergency room visits or hospitalizations.

"Asthma is a heterogeneous disease and not everyone experiences it in the same way. Therefore, there is value in evaluating new therapies with distinct and novel mechanisms such as anti-IL-33," said Steve Pascoe, M.D., Head of Immuno-Inflammation Development at Sanofi. "We have ongoing studies for REGN3500 in atopic dermatitis and chronic obstructive pulmonary disease. We will evaluate the results of these studies as well as the findings in asthma to determine the best path forward for this therapy."

REGN3500 is a fully-human monoclonal antibody that inhibits interleukin-33 (IL-33), a protein that is believed to play a key role in type 1 and type 2 inflammation. Preclinical research showed REGN3500 blocked several markers of both types of inflammation. In moderate-to-severe asthma, there can be multiple sources of underlying inflammation that new therapies may help address.