Media & Investor Release

Ad hoc announcement pursuant to Art. 53 LR

Roche provides update on astegolimab in chronic obstructive pulmonary disease

- **The pivotal phase IIb ALIENTO study met the primary endpoint of a statistically significant reduction in the annualised exacerbation rate (AER) at 52 weeks when astegolimab was given every two weeks**
- **The phase III ARNASA study did not meet the primary endpoint of a statistically significant reduction in the AER at 52 weeks**
- **The safety profile of astegolimab was consistent with previously reported data, with no new safety signals identified**
- **Analysis of the ALIENTO and ARNASA data will be discussed with regulatory authorities and shared at an upcoming medical meeting**

Basel, 21 July 2025 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today topline results from the pivotal phase IIb ALIENTO (n=1,301) and the phase III ARNASA (n=1,375) trials investigating astegolimab compared to placebo, on top of standard of care maintenance therapy in people with moderate to very severe chronic obstructive pulmonary disease (COPD). The studies included a broad population: both former and current smokers, regardless of blood eosinophil count, who have a history of frequent exacerbations.

The pivotal phase IIb ALIENTO study met its primary endpoint and showed that astegolimab reduced the annualised exacerbation rate (AER) by a statistically significant 15.4% at 52 weeks, when given every two weeks. However, the phase III ARNASA study did not meet its primary endpoint of a statistically significant reduction in the AER, demonstrating a numerical 14.5% reduction, at 52 weeks when astegolimab was given every two weeks. The results were generally consistent across secondary endpoints in both studies. The total number of exacerbations was lower than prospectively anticipated in both trials. The safety profile of astegolimab was consistent with previously reported data, with no new safety signals identified.

"While COPD remains the third leading cause of death worldwide, patients and families have limited treatment options for managing this debilitating and complex disease," said Levi Garraway, MD, PhD, Roche's Chief Medical Officer and Head of Global Product Development. "This was the first set of studies in an 'all-comers' COPD population, and we will discuss these data with regulatory authorities to evaluate next steps for astegolimab."

Detailed results from ALIENTO and ARNASA will be shared at an upcoming medical meeting.

About the ALIENTO and ARNASA studies[1,2]

Astegolimab is an investigational, fully human anti-ST2 monoclonal antibody designed to bind with high affinity to the ST2 receptor, thereby blocking the signalling of IL-33.[3] The astegolimab COPD pivotal programme consists of two registrational studies, the phase IIb ALIENTO (NCT05037929) and phase III ARNASA (NCT05595642) studies. Both ALIENTO and ARNASA are double-blinded, placebo-controlled, multicentre studies that evaluate the efficacy and safety of astegolimab administered every two or every four weeks in patients with COPD on top of standard of care maintenance therapy. Patients in the studies included former and current smokers, regardless of blood eosinophil count, who have a history of frequent exacerbations. The primary analysis is based on the initial phase of the study, which consisted of 1,301 patients for ALIENTO and 1,375 patients for ARNASA. The primary endpoint is the reduction in the annualised rate of moderate and severe COPD exacerbations (AER) over the 52-week treatment period. AER is the total number of exacerbations (a sudden worsening in airway function and respiratory symptoms) occurring over the relevant treatment period, divided by the total number of patient years. Standard of care maintenance therapy for both studies was one of the following combinations – inhaled corticosteroid (ICS) plus long-acting beta-agonist (LABA); long-acting muscarinic antagonist (LAMA) plus LABA; ICS plus LAMA plus LABA.

About Roche

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded medicines, Roche has grown into the world's largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalised healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each person we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

For over 125 years, sustainability has been an integral part of Roche's business. As a science-driven company, our greatest contribution to society is developing innovative medicines and diagnostics that help people live healthier lives. Roche is committed to the Science Based Targets initiative and the Sustainable Markets Initiative to achieve net zero by 2045.

Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan.

For more information, please visit www.roche.com.

References

[1] A Study to Evaluate Astegolimab in Participants With Chronic Obstructive Pulmonary Disease (ARNASA). [Internet; cited March 2025]. Available from: https://clinicaltrials.gov/study/NCT05595642.
[2] A Study to Evaluate the Efficacy and Safety of Astegolimab in Participants With Chronic Obstructive Pulmonary Disease. [Internet; cited March 2025]. Available from: https://clinicaltrials.gov/study/NCT05037929.
[3] Kelsen SG, Agache O, Soong W, Israel E, Chupp GL, Cheung DS, et al. Astegolimab (anti-ST2) efficacy and safety in adults with severe asthma: A randomized clinical trial. Journal of Allergy and Clinical Immunology. 2021 Sep;148(3):790–8.

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