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Late Breaking Abstract - Tozorakimab to prevent COPD exacerbations: results from the replicate OBERON and TITANIA phase 3 studies

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Background: Increased IL-33 expression is associated with COPD pathobiology including exacerbation risk. Tozorakimab is an anti-IL-33 mAb.

Aim: To evaluate the efficacy and safety of add-on tozorakimab vs placebo in patients with COPD and a history of exacerbations on optimized inhaled SoC therapy.

Methods: OBERON (NCT05166889) and TITANIA (NCT05158387) were 52-week, double-blind, replicate studies. Patients were randomized to tozorakimab 300mg Q4W, Q8W or placebo SC. The annualized rate of moderate/severe exacerbations was assessed in the Q4W arm in former smokers (primary endpoint) and in current and former smokers (overall population; key secondary endpoint).

Results: Overall, 1118 and 1165 patients in OBERON and TITANIA, respectively, were randomized and received treatment. In both studies, tozorakimab 300mg Q4W significantly reduced the annualized rate of moderate/severe exacerbations vs placebo by 29–34% in former smokers and 29–30% in the overall population (Figure). In a pooled analysis, rate reductions were observed in all pre-specified subgroups with tozorakimab Q4W, including screening blood eosinophil counts, baseline airflow limitation and smoking status. The Q8W arm was used to characterize dose-response and showed smaller reductions than Q4W. Tozorakimab was well tolerated with AEs generally similar across treatment groups.

Conclusion: Tozorakimab significantly reduced the rate of moderate/severe exacerbations in a broad population of current and former smokers with COPD and was well tolerated.