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Late Breaking Abstract - VALIANT: a phase 2 trial of the efficacy and safety of verekitug, a thymic stromal lymphopoietin (TSLP) receptor antagonist, for severe asthma

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Introduction: Verekitug is a novel, fully human monoclonal antibody with extended dosing interval targeting the receptor for TSLP, a key epithelial alarmin in severe asthma.

Aim: Assess verekitug efficacy and safety in participants (pts) with severe asthma.

Methods: VALIANT, a ph2, dose-ranging study, randomized adults with severe asthma 1:1:1:1 to subcutaneous verekitug (100mg every [q] 12 weeks [w]; 400mg q24w; 100mg q24w) or placebo (PBO), with a variable 24–60w treatment period. The primary endpoint was annualized asthma exacerbation rate (AAER) over 60w. Secondary endpoints included w24 and w60 change from baseline in prebronchodilator FEV_1, FeNO and ACQ-6.

Results: 478 pts were randomized. Median treatment duration for efficacy analysis was 37w; 436 (91%) received ≥3 doses of study drug. All verekitug arms reduced AAER vs PBO: rate ratio (95% CI) 0.44 (0.28–0.69), *P*=0.0003 [100mg q12w]; 0.61 (0.40–0.93), *P*=0.02 [400mg q24w]; 0.51 (0.33–0.79), *P*=0.003 [100mg q24w], with up to 87% reduction for pts with high baseline eosinophil counts (Table). All verekitug arms improved w24 FEV_1, FeNO and ACQ-6, and w60 FEV_1 and FeNO vs PBO. Treatment-emergent adverse event incidence was similar with verekitug (58–62%) vs PBO (66%).

Conclusion: In pts with severe asthma on standard background therapy, verekitug q12w or q24w led to statistically significant, clinically meaningful AAER reductions, early lung function and asthma symptom improvements, and a similar safety profile to PBO.

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