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Late Breaking Abstract - Lunsekimig for chronic rhinosinusitis with nasal polyps: results from the DUET trial

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INTRODUCTION: Lunsekimig (SAR443765), a first-in-class, pentavalent, bispecific NANOBODY® molecule, blocks thymic stromal lymphopoietin (TSLP) and IL-13, key drivers of chronic rhinosinusitis with nasal polyps (CRSwNP).

AIM: Evaluate the efficacy and safety of lunsekimig in adults with CRSwNP.

METHODS: DUET (NCT06454240) was a phase 2, randomized, double-blind, placebo-controlled trial. Adults (18–70 yrs) with inadequately controlled CRSwNP and bilateral endoscopic nasal polyp score (NPS) ≥5 were randomized 1:1 to lunsekimig 300mg (n=39) or placebo (pbo; n=40) every-4-weeks (W) as an add-on therapy to mometasone furoate nasal spray for 24W. Primary endpoint was change (Δ) from baseline (BL) in NPS at W24. Key secondary endpoints were Δ from BL in nasal congestion (NC) and Lund-Mackay computed tomography (LMK CT) score at W24.

RESULTS: Lunsekimig showed statistically significant Δ in NPS (LS mean difference vs pbo [95% CI]: -1.5 [-2.2,-0.7], *P*<.0001), NC (-0.8 [-1.1,-0.4]; *P*<.0001) and LMK CT score (-6.3 [-8.5,-4.1]; *P*<.0001) vs pbo at W24. Results were generally consistent for key subgroups, including those with comorbid asthma (n=49/79). Incidence of treatment-emergent adverse events (TEAEs) was 61.5% with lunsekimig vs 42.5% with pbo; common TEAEs (≥5%) were injection site reaction, viral upper respiratory tract infection, nasopharyngitis, epistaxis, ear pain, and increased creatine phosphokinase.

CONCLUSIONS: Lunsekimig, a bispecific NANOBODY® molecule, showed statistically significant and clinically meaningful improvements in objective and patient-reported outcomes in adults with CRSwNP including polyp burden, NC, and sinus opacification, and was well tolerated. These findings support the strategy of dual inhibition of key drivers of CRSwNP with this first-in-class molecule.