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RCT Abstract - Lunsekimig for patients with moderate-to-severe asthma: results from the AIRCULES trial

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INTRODUCTION: Lunsekimig (SAR443765), a novel pentavalent, bispecific NANOBODY[®] molecule, blocks thymic stromal lymphopoietin (TSLP) and IL-13.

AIM: Evaluate the efficacy and safety of lunsekimig in adults with moderate-to-severe asthma.

METHODS: AIRCULES (NCT06102005) was a phase 2b, randomized, double-blind, dose-ranging trial. Adults (18-80 yrs; N=685) on medium-to-high dose inhaled corticosteroids with 1-2 controllers, ≥ 1 exacerbation in the past year, and ACQ-5 ≥ 1.5 were randomized 2:1:2:2 to placebo (pbo; n=152), subcutaneous lunsekimig 60mg every 8 weeks (Q8W; n=75), 60mg Q4W (n=154), 300mg Q8W (n=151), or 300mg Q4W (n=153) for 48W. Efficacy endpoints included AAER (primary), FEV₁ (key secondary), time to first exacerbation, and ACQ-5.

RESULTS: The 300mg Q4W arm showed statistically significant and clinically meaningful improvements vs pbo in AAER and FEV₁ (Figure). These results were supported by numerically longer time to first exacerbation and ACQ-5 improvement. Other doses showed improvements in efficacy endpoints, though not statistically significant. Numerically greater effect sizes with lunsekimig were observed in frequent exacerbators (prespecified subgroup of ≥ 2 prior exacerbations; Figure). Lunsekimig was well tolerated at all doses.

CONCLUSIONS: Lunsekimig, a first-in-class molecule, demonstrated clinically meaningful improvements in exacerbations, lung function, and asthma control, and was well tolerated. These findings support dual TSLP and IL-13 targeting to address unmet need in asthma.

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