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Efficacy and Safety of CM326, a Humanized Anti-Thymic Stromal Lymphopoietin (TSLP) Monoclonal Antibody, in Moderate-to-Severe Asthma: A Phase II Randomized, Double-Blind, Placebo-Controlled Trial

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Background: Moderate-to-severe asthma often remains uncontrolled despite medium-to-high-dose inhaled glucocorticoids (ICS) plus long-acting β-agonists, highlighting the need for biologics targeting TSLP.

Aims: To evaluate efficacy and safety of CM326, a recombinant humanized IgG1 mAb against TSLP, in such patients (NCT05774340).

Methods: Patients with mod-to-severe uncontrolled asthma were randomized 1:1:1 to subcutaneous CM326 220 mg Q2W, Q4W, or placebo for 24 weeks. The primary endpoint was annualized asthma exacerbation rates (AAER) over 24 weeks; secondary endpoints included annualized loss of asthma control (LOAC) rates, lung function and safety.

Results: Of 208 treated patients (68 Q2W, 69 Q4W, 71 placebo), baseline characteristics were balanced: 30.8% of all had ≥2 prior exacerbations. CM326 significantly reduced AAER vs placebo by 95.6% (90% CI: 74.3, 99.3; P=0.002) for Q2W and 68.0% (90% CI: 22.1, 86.8; P=0.018) for Q4W, notably in patients on a moderate dose of ICS (94.0% [90% CI: 63.5, 99.0] for Q2W and (69.3% [90% CI: 11.0, 89.4] for Q4W. Annualized LOAC rates decreased by 61.5% (90% CI: 37.6, 76.2; P<0.001) and 62.6% (90% CI: 39.4, 76.9; P<0.001), respectively. Prebronchodilator FEV1 improved by 0.17 L (95% CI: 0.03, 0.31) for Q2W and 0.19 L (95% CI: 0.05, 0.34) for Q4W vs placebo at week 24.

Treatment-emergent adverse events (TEAEs) were similar (72.5%-76.5% CM326 vs 75% placebo), with no discontinuations or deaths. The most common TEAEs (≥5%) were upper respiratory tract infection (26.5%, 26.1%, and 25.4%) and urinary tract infection (13.2%, 8.7%, and 16.9%).

Conclusion: CM326, especially for Q2W, demonstrated rapid, sustained improvements in asthma exacerbation rates and control, with a safety profile comparable to placebo, supporting phase III evaluation.