Efficacy and Safety of MG-K10 in Adult Patients with Moderate-to-Severe Uncontrolled Asthma: Results From The Phase 2 Study

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BACKGROUND/AIMS:MG-K10 is an innovative long-acting mAb that specifically binds to human IL-4Rα, inhibits IL-4 and IL-13 signaling, key drivers of Type 2-mediated inflammation. Following Fc mutation, MG-K10 allows long dosing interval owing to its prolonged half-life. The analysis reports the efficacy and safety of MG-K10 in asthma during 24 weeks'treatment.
MATERIALS AND METHODS:This was a randomized, double-blind, placebo-controlled phase 2 study. Patients (n=187) were randomly assigned (1:1:1) to receive subcutaneous MG-K10 300 mg every 2 weeks (Q2W,n=64) or Q4W(n=60), or placebo(n=63), over a 24-week period. The primary endpoint was change from baseline at week 12 in FEV1 before use of a bronchodilator. Other efficacy endpoints included measures of lung-function (PEF), annualized severe exacerbation rates (AAER), asthma attacks (LOAC), asthma control (ACQ-5), etc.
RESULTS:At week 12, MG-K10 significantly improved Pre-BD FEV1 compared with placebo (P<0.01 for both doses groups), the FEV1 had increased by 0.30 liters in patients assigned to Q4W group (Q2W vs placebo, 0.35 liters; P<0.001). From week 4 to week 24, MG-K10 showed sustained improvement in FEV1 compared to the placebo (P<0.001 for each visit). Both MG-K10 doses led to sustained improvements in lung function and asthma control, and a reduced exacerbation rate. The overall incidence of TRAEs (treatment related adverse event) in Q4W group was lower than Q2W group and placebo (23.3% vs 34.4% vs 27.0%).
DISCUSSION AND CONCLUSION:MG-K10 with extended dosing interval significantly improved lung function and clinical symptoms in patients with moderate-to-severe uncontrolled asthma, with a favorable safety profile.

Keywords: MG-K10,IL-4R,Asthma

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