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

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Abstract

Introduction: MG-K10 is an innovative long-acting mAb that specifically binds to human IL-4Rα, and efficiently blocks theTh2 inflammatory signaling of IL-4 and IL-13. Following Fc mutation, MG-K10 allows long dosing interval owing to its prolonged half-life. We report the efficacy and safety of MG-K10 in moderate-to-severe AD with 16 weeks' treatment.
Methods: This was a randomized, double-blind, placebo-controlled phase 2 study. Patients with moderate-to-severe AD were randomized 1:1:1:1 to subcutaneous dosing of MG-K10 150 mg every 4 weeks (Q4W) or 300 mg Q4W or 300 mg Q2W or placebo, all with two fold loading in first dose. Primary endpoints was EASI change from baseline at week 16. Other efficacy endpoints included EASI-75, EASI-90, IGA response(clear/almost clear [0/1] with ≥2-grade improvement), pruritus NRS improvement, etc. Safety was assessed via AE and laboratory monitoring.
Results: 163 patients were randomized. At Week 16, least squares mean percent change in EASI were –58.9%/–81.6%/–69.8%/–42.7%, respectively (P=0.071/P<0.001/ P=0.003vs placebo). 53.8%/79.5%/66.7%/28.9% of patients receiving 150mg Q4W/300mg Q4W/300mg Q2W/placebo achieved EASI-75; 46.2%/51.3%/46.2%/15.8% of patients achieved IGA response. The overall adverse event rate was similar among all groups over 16 weeks. Serious adverse events and AE-related treatment discontinuations were rare. No injection-site reactions or conjunctivitis.
Conclusion: MG-K10 300 mg Q4W was highly efficacious in the treatment of moderate-to-severe AD, with a favorable safety profile. The long-acting merit of the MG-K10 will benefit greatly to the AD patients during the long-term treatment.

References

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