safety, tolerability, pharmacokinetics, pharmacodynamics of mg-zg122, a long-acting humanized anti-thymic stromal lymphopoietic mab, in healthy subjects

Wei Hu[1], Xuan Zhang[1], Qian Zhang[1], Liang Zheng[1], Jinlin Guo[2], Qiuling Zou[2], Rui Yan[2], Di Qin[3], Lingqiao Zhu[2], Chenghai Zhang[2]

[1]Department of Respiratory,The Second Affiliated Hospital of Anhui Medical University,Hefei, China

[2]R&D Department,Shanghai Mabgeek Therapeutics Co., LTD,Shanghai,China

[3]Medical Management Department,Shanghai Mabgeek Therapeutics Co., LTD,Shanghai,China

BACKGROUND/AIMS:Thymic stromal lymphopoietin (TSLP) is associated with the initiation and persistence of inflammatory pathways in asthma. MG-ZG122 is a humanized anti-TSLP monoclonal antibody that effectively blocks TSLP binding to its receptor complex. This first-in-human, Phase I study aimed to investigate the safety, tolerability, pharmacokinetics, and pharmacodynamics of MG-ZG122 in healthy Chinese subjects.
MATERIALS AND METHODS:A randomized, double-blind, placebo-controlled, and single ascending dose design was used in this study. Four planned dose cohorts (52.5, 105, 210, and 420 mg) with 10 subjects (8:2) each were randomized to receive subcutaneously a single dose of MG-ZG122 or placebo, except for the 52.5 mg cohort with 4 subjects (MG-ZG122 vs. placebo=2:2). The primary endpoint was to determine the safety and tolerability of MG-ZG122.
RESULTS:Of the 34 randomized subjects, 26 received different doses of MG-ZG122, and 8 received placebo. Most treatment-emergent adverse events (TEAEs) in subjects receiving MG-ZG122 were grade 1 or 2, and no dose dependence was observed for either TEAEs or treatment-related adverse events. A single dose of MG-ZG122 exhibited a dose-dependent increase in the exposure ranging from 52.5 to 420 mg.It had a half-life of up to 80 days, and may be sufficient to support a biannual administration.. A dose-dependent reduction in peripheral blood eosinophil count was observed with 210 mg and 420 mg of MG-ZG122, with sustained responses through day 211.
DISCUSSION AND CONCLUSION:MG-ZG122 was safe and well-tolerated with favorable pharmacokinetic profiles, can reduce the peripheral blood eosinophil count, suggests a potential benefit in patients with asthma.

Keywords: TSLP,MG-ZG122,asthma

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