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Safety and efficacy of IMG-007, a nondepleting anti-OX40 monoclonal antibody, in adult patients with moderate-to-severe atopic dermatitis: results from a phase 2a study

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Introduction & Objectives:

OX40 antagonists have shown efficacy in treating atopic dermatitis (AD). IMG-007 is a nondepleting OX40 antibody with a Fc N297A mutation designed to eliminate ADCC, thereby potentially minimizing safety risks. In a Phase 1 single-dose study in healthy adults, IMG-007 was well-tolerated, without any reports of pyrexia or chills. It also exhibited an extended half-life of 31 days at anticipated therapeutic doses, which would potentially enable less frequent dosing, such as once every 12 weeks (Q12W). Here we are reporting safety and efficacy data from a Phase 2a proof-of concept study in adult patients with moderate-to-severe AD.

Materials & Methods:

In this Phase 2a study, patients with moderate-to-severe AD (≥10% body surface area [BSA], investigator global assessment [IGA] ≥3, and eczema area and severity index [EASI] ≥16) were enrolled and received three intravenous (IV) infusions of 300 mg IMG-007 over 4 weeks, in an open-label fashion. Patients were followed until Week 24 for safety and efficacy including EASI, IGA, BSA, and SCORing atopic dermatitis (SCORAD), pharmacokinetic and pharmacodynamic assessments. The primary endpoint was safety, and key secondary endpoint was EASI percent change from baseline at week 12.

Results:

A total of 13 patients were enrolled from 6 centers in the US and Canada. Baseline characteristics included a mean (standard deviation [SD]) age of 49.8 years (15.0) with 69.2% males, mean EASI of 29.5 (13.7), mean SCORAD of 71.7 (10.6), 61.5% patients with IGA=3 vs 38.5% with IGA=4. As of an interim data cutoff of April 1, 2024, all patients ongoing in the study had completed at least the Week 16 visit. Of these patients, 9 (69.2%) reported a total of 17 adverse events (AEs). There were no serious adverse events (SAEs), treatment-related AEs, or infusion-related reactions, such as pyrexia or chills. All AEs were of mild (grade 1) or moderate (grade 2) intensity, except for one patient who experienced a severe (grade 3) AE of AD flare. Treatment with IMG-007 resulted in a rapid and significant reduction from baseline in EASI score as early as Week 1, with continued improvement sustained through Week 20. Similar improvements were noted for other efficacy variables, such as IGA, SCORAD, and BSA. Final safety and efficacy results up to the end of the study will be presented during the European Academy of Dermatology and Venereology (EADV) 2024 conference.

Conclusion:

IMG-007, a novel nondepleting OX40 mAb, was safe and well tolerated without any reports of pyrexia or chills in patients with moderate-to-severe AD. The favorable safety profile is consistent with a silenced ADCC function. Treatment with IMG-007 for 4 weeks led to rapid and sustained improvements in AD disease activity.