EFFICACY AND SAFETY OF OMALIZUMAB IN JAPANESE AND KOREAN PATIENTS WITH CHRONIC IDIOPATHIC/SPOONTANEOUS URTICARIA (CIU/CSU): RESULTS FROM THE PHASE 3 POLARIS STUDY

Michihide Hide, 1,2 Hae-Sim Park, 1 Asuysyu Igarashi, 1,2 Young-Min Ye, 1,3 Tae-Bum Kim, 1 Akiko Yamagi 5,6 JooYoung Roh, 1,4 Jae-Hyun Lee, 8 Atsuyuki Igarashi, 3 Atsushi Fukunaga, 9 Sam Khalil, 2 on behalf of the POLARIS Study Group

1Department of Dermatology, Institute of Biomedical and Health Sciences, Hiroshima University, Hiroshima, Japan; 2Department of Allergy and Clinical Immunology, Asan Medical Center, University of Ulsan College of Medicine, Seoul, Korea; 3Department of Dermatology, Fujita Health University Second Educational Hospital, Nagoya, Japan; 4Department of Dermatology, Gachon University Gil Medical Center, Incheon, Korea; 5Department of Internal Medicine, Institute of Allergy, Yonsei University College of Medicine, Seoul, Korea; 6Department of Internal Related, Kobe University Graduate School of Medicine, Kobe, Japan; 7Novartis Pharma AG, Basel, Switzerland

INTRODUCTION

• Chronic idiopathic/spontaneous urticaria (CIU/CSU) is a prevalent skin condition, characterized by the spontaneous appearance of wheals (hives) or exanthemas of unknown etiology for ≥6 weeks per year.
• For patients who do not respond to H1-AHs, omalizumab (OMA) – a monoclonal antibody that targets IgE – is an effective treatment option.
• Three placebo-controlled, randomized Phase II studies (IPOLARIS, 12; NCT01300127; ASTERIA II [NCT01292473]; and GLACIAL [NCT01264939]) have established the efficacy and safety of omalizumab in Japanese and Korean populations.

OBJECTIVE

The objective of the POLARIS study was to evaluate the efficacy and safety of omalizumab in Japanese and Korean CIU/CSU patients who remain symptomatic despite H1-AH therapy.

METHODS

Study design

• POLARIS was a 26-week, randomized, double-blind, placebo-controlled, parallel group multicenter Phase III study, conducted in 43 sites in Japan and Korea.

• The study comprised 2-week screening period, 12-week randomized treatment period, and 12-week follow-up conducted between December 2014 to June 2016.

• Patients were randomized (1:1) to omalizumab 150 mg or placebo, administered subcutaneously every 4 weeks for a total of three doses.

RESULTS

Baseline characteristics

• Most disease characteristics were well balanced across treatment arms (Table 1).

• A slight imbalance in duration of CIU/CSU was observed between placebo (86.4%) and omalizumab 150 mg (91.0%).

Study population

• The study population consisted of men and women, aged 12–75 years, with CIU/CSU who were refractory to conventional H1-AH treatment during the time of randomization.

• Eligible patients had:
  • ≥2 hives or 10 outdoor concomitant wheals at any time prior to enrollment.
  • ≥2 hives at most visit during placebo run-in period.
  • ≥2 hives at most visit during placebo run-in period (Day 1; 14 - Day 1 – 7; 14; 1 Day 1).

• Patients were randomized to either the placebo or omalizumab 150 mg group (1:1), administered subcutaneously every 4 weeks for a total of three doses.

• The median time to achieve UAS7 ≤6 response was 7 weeks in the placebo group.

Efficacy

Primary outcome

• Change from baseline in ISS7 was the primary outcome and Week 12 was the primary analysis time point.

• Patients treated with omalizumab experienced greater mean decreases in UAS7 at all time points from Week 1 to Week 12 compared with patients in the placebo group (Figure 2).

• Omalizumab 150 mg versus placebo, respectively: −8.55 (−12.05, −5.05), unadjusted P<0.001 (adjusted P<0.05) and −3.70 (−5.31, −2.10), unadjusted P<0.001 (adjusted P<0.05)

Secondary outcomes

• Change from baseline in UAS7 in the omalizumab 150 mg group versus placebo was significantly greater compared with placebo (Figure 3).

• Significantly greater treatment effect was observed in the omalizumab 300 mg group than with omalizumab 150 mg (P<0.001).

• The median time to achieve ISS7 ≤7 response was 7 weeks in the placebo group.

• 9 weeks in the omalizumab 150 mg group.

Safety and tolerability

• Overall incidence of AEs was similar across treatment arms (34.8%, 37.7%, and 30.8% in the omalizumab 150 mg, 300 mg, and placebo groups, respectively).

• The most common AEs were nasopharyngitis (30.2%, 28.4%, and 18.9%, respectively) and upper respiratory tract infection (7.9%, 11.4%, and 4.1%

• No deaths were reported in this study.

• No serious AEs were reported in this study.

• No clinically relevant changes were observed in laboratory parameters in any treatment group.

• No clinically relevant changes were observed in vital signs in any treatment group.

• The median body weight at Week 12 was 58.9 kg in the omalizumab 150 mg group and 58.8 kg in the placebo group.

• Overall incidence of AEs was similar across treatment arms (54.8%, 57.7%, and 55.9% in the omalizumab 150 mg, 300 mg, and placebo groups, respectively).

• Only 3.5% of patients treated with omalizumab experienced at least one treatment-emergent AE leading to discontinuation (Figure 5).

• The most common AEs were nasopharyngitis (20.2%, 22.4%, and 12.6%, respectively) and upper respiratory tract infection (6.8%, 11.4%, and 3.9% respectively).

• These findings suggest that ethnic differences do not affect omalizumab treatment outcomes in Japanese and Korean patients with CIU/CSU.

CONCLUSIONS

• POLARIS met all Phase III endpoints with omalizumab 150 mg producing significantly greater treatment effects than placebo, with omalizumab 300 mg producing even greater treatment effects than omalizumab 150 mg.

• The results demonstrate that omalizumab treatment results in significant clinical benefit with omalizumab treatment across all treatment groups compared with placebo.

• Overall incidence of AEs was similar across treatment arms (54.8%, 57.7%, and 55.9% in the omalizumab 150 mg, 300 mg, and placebo groups, respectively).

• No deaths were reported in this study.

• The median time to achieve ISS7 ≤7 response was 7 weeks in the placebo group.

• Nine weeks in the omalizumab 150 mg group.

• These findings suggest that ethnic differences do not affect CIU/CSU treatment outcomes with omalizumab.

REFERENCES


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DISCLOSURES

MH, HI, AI, YHL, TK, THY, JR, HL, and AF have nothing to disclose. NY is an employee of Novartis Pharmaceuticals Corporation.