OBJECTIVES

• PRIMARY: To assess the effect of optimized retreatment after relapse (defined as weekly urticaria activity score [UAS7] ≥16) in patients with chronic idiopathic/spontaneous urticaria (CIU/CSU) who were clinically well controlled (UAS7 ≤6) following their first course of treatment with omalizumab

• SECONDARY: Evaluation of dose step-up therapy in those who do not respond (UAS7 >6) to an initial dose of omalizumab 150 mg; assessment of the time to relapse in patients who initially were well controlled (UAS7 ≤6); and to evaluate the benefit of extending study treatment with omalizumab 300 mg in patients who are not yet clinically well controlled (UAS7 ≤6) after 24 weeks

• EXPLORATORY: Evaluation of quality of life and occurrence of angioedema episodes

STUDY DESIGN

• OPTIMA is an international, multicenter, randomized, open-label, noncomparator study of two doses of omalizumab treatment (150 mg and 300 mg) across two dosing periods

• In the initial dosing period, patients receive omalizumab by subcutaneous injection, at the randomized dose, every 4 weeks (Figure 1)

• Subsequent dosing is determined based on the patient’s UAS7 response (Figures 2 and 3)

• Patients are eligible for the OPTIMA study if they are adults diagnosed with CIU/CSU and have been exhibiting symptoms for at least 6 months prior to the study despite concurrent nonselecting H1-antihistamine therapy

• Refractory to antihistamine therapy is defined as UAS7 ≥16 (scale 0–42) and itch component of UAS7 ≥8 (scale 0–21) despite treatment with an approved dose of nonselecting H1-antihistamine and no other concomitant CIU/CSU treatment for at least 7 consecutive days

SAMPLE SIZE AND ANALYSIS

Sample size

• The study has been planned to enroll and randomize a total of 320 patients, in a ratio of 4:3, to the doses of omalizumab 150 mg or 300 mg. The sample size is estimated on the basis of assessing the effect of retreatment following relapse (primary endpoint)

Primary endpoint

• Proportion of patients who achieved a UAS7 ≤6 at the end of the second dosing period, after being clinically well controlled (UAS7 ≤6) in the initial dosing period followed by relapse (UAS7 ≥16) when treatment was discontinued

Secondary endpoints

• Difference in the UAS7 between the start and the end of the second dosing period in patients who stepped up treatment from omalizumab 150 mg to 300 mg

• The proportion of patients who were clinically well controlled (UAS7 ≤6) at the end of the second dosing period in patients who stepped up treatment from omalizumab 150 mg to 300 mg

• The time to relapse (UAS7 ≥16) after withdrawal of omalizumab in patients who were clinically well controlled following their first course of omalizumab treatment

• Difference in the UAS7 between the end of the initial dosing period and the end of the second dosing period in patients who extended treatment with omalizumab 300 mg

• The UAS7 change from baseline measured at the end of the initial dosing period in patients who received omalizumab 300 mg

• The UAS7 change from baseline measured at the end of the second dosing period in all patients

• The proportion of patients who remain well controlled (UAS7 ≤6) or who have achieved a UAS7 =0 at Week 8 of the initial dosing period versus Week 8 of the second dosing period

• The proportions of patients who remain clinically well controlled (UAS7 ≤6) at any visit starting at Week 8 of the initial dosing period until the end of the first dosing period

CONCLUSIONS

• The OPTIMA study will allow better characterization of the appropriate omalizumab treatment regimen in patients with CIU/CSU who relapse or are not well controlled after initial treatment, by answering the following questions:

  • If a patient is well controlled and therefore treatment is stopped, will the patient relapse? How long will it take to relapse?

  • If treatment is restarted, will the patient respond to retreatment?

  • If the patient does not respond to omalizumab 150 mg, will step-up therapy help?

  • If the patient does not respond to omalizumab 300 mg, will treatment extension help?

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DISCLOSURES

Authors declare the following real or perceived conflicts of interest: GS, JPG, JS, and DWD received honoraria as investigators and consultants. GS received honoraria as speaker of this corresponding study. JS, FMT, and AP are employees of Novartis Pharmaceuticals.

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