INTRODUCTION

Chronic spontaneous/idiopathic urticaria (CSU/CIU) is defined as the spontaneous occurrence of daily or almost daily hives and itching for at least 6 weeks without an obvious cause.

CSU/CIU has significant detrimental effects on patient health-related quality of life (HRQoL).

The Chronic Urticaria Quality of Life Questionnaire (CU-Q2L) is a disease-specific tool used to assess HRQoL in patients suffering from CSU/CIU.

The current guidelines recommend maintaining in first-line therapy for CSU/CIU.

Omalizumab, a monoclonal antibody that targets immunoglobulin E, has been approved in Europe for the treatment of CSU in adults and adolescents 12 years of age and older. In the US, omalizumab is approved for the treatment of CSU in adults and adolescents 12 years of age and older with persistent symptoms despite treatment with H1-antihistamines and/or leukotriene receptor antagonists (LTRAs).

ASTERIA I, ASTERIA II and GLACIAL were phase 3, international, multicenter, randomized, placebo-controlled clinical trials designed to assess the efficacy and safety of omalizumab in patients with CSU/CIU.

OBJECTIVE

To report the post-hoc analysis of improvement in quality of life in patients with CSU/CIU from baseline to Week 12 using the CU-Q2L scores from ASTERIA I, ASTERIA II and GLACIAL trials.

METHODS

Study Design and Subjects

ASTERIA I/ASTERIA II/ASTERIA III included patients aged 12–75 years (18–75 years in Germany) with CSU/CIU who remained symptomatic despite treatment with H1-antihistamines and were randomized to placebo or omalizumab 150 mg or 300 mg subcutaneously every 4 weeks.

OMALIZUMAB included patients aged 12–75 years (18–75 years in Germany) with CSU/CIU who remained symptomatic despite treatment with H1-antihistamines plus H2-antihistamines and/or leukotriene receptor antagonists (LTRAs).

Patients were randomized 3:1 to receive omalizumab 150 mg or placebo subcutaneously every 4 weeks to Week 24 (Figure 1).

Figure 1. Study Design of the 3 Phase 3 Trials

ASTERIA I

12-week treatment period

Week 12 follow-up

16-week follow-up

OMALIZUMAB

12-week treatment period

Week 16 follow-up

OMALIZUMAB

16-week follow-up

GLACIAL

16-week treatment period

Week 24 follow-up

16-week follow-up

CU-Q2L Questionnaire

The impact of urticaria symptoms on patients was measured using the CU-Q2L questionnaire. The CU-Q2L instrument was validated using MRAID. An ANCOVA model was run for the comparison of each treatment arm versus placebo.

Statistical Method

The change in CU-Q2L, overall score and individual domain scores were calculated as percent change from Baseline to Week 12.

The change in CU-Q2L from Baseline to Week 12 was compared using ANCOVA t-test. An ANCOVA model was run for the comparison of each treatment arm versus placebo.

RESULTS

Table 1. CU-Q2L Domain Scores

Table 2. Baseline Demographics and Clinical Characteristics

CONCLUSION

Omalizumab significantly improved QoL, as measured by CU-Q2L, in patients with CSU/CIU who have persistent symptoms despite treatment with H1-antihistamines.

For all CSU/CIU patients assessed, the greatest improvements were seen in patients treated with omalizumab 150 mg versus placebo for all the 4 phases in Week 12 (Figure 2).

This was a post hoc analysis and there was no adjustment made for multiple comparisons.

REFERENCE


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