Chronic spontaneous/idiopathic urticaria (CSU/CIU)

Omalizumab, a humanized anti-IgE monoclonal antibody

Data were obtained from three 2

Regardless of the measure used, clinicians will have comparable information about

Figure 3

16-week follow-up

CU-QoL

2

The results provide evidence that any of the three PRO measures are suitable to

DLQI – a 10-item PRO, measures impact of skin disease

CSU/CIU adversely impacts patients’ HRQoL.

2

Data were analyzed using latent growth modeling

To assess whether three PRO measures (UAS7, DLQI

Figure 1. Design of Phase III studies with omalizumab

- Chronic spontaneous/idiopathic urticaria (CSU/CIU) is defined by the latest European Academy of Allergy and Clinical Immunology (EAACI)/Global Allergy and Asthma European Network (GA/LEN/EAACI) European Dermatology Forum (EDF)/World Allergy Organization (WAO) guidelines as the occurrence of hives, angioedema or both for 6 weeks or longer due to known or unknown causes. 1, 2

Omalizumab, a humanized anti-IgE monoclonal antibody is the first and only therapy approved by the European Medicines Agency (EMA) and US Food and Drug Administration (FDA) for the treatment of CSU/CIU in adult and adolescent (<12 years) patients refractory to H1-antihistamines. 1, 2

CSU/CIU adversely impacts patients’ HRQoL. 1 The progression of disease and its burden can be assessed with PRO measures for symptoms and HRQoL.

OBJECTIVE

To assess whether three PRO measures (UAS7, DLQI

RESULTS

Figure 2. Trajectories of change in UAS7 and DLQI

A near perfect association was found between UAS7 and DLQI in all three trials, the correlations between the UAS7 and DLQI ranged between 0.88 and 0.94 (Figure 2).

PROCedures and outcomes: PRO instruments are equally informative about response to treatment with CSU/CIU patients

METHODS

PRO data used for the analysis come from baseline and Weeks 4, 12, 24 and 40 in ASTERIA I and GLACIAL, and at baseline and Weeks 4, 12 and 28 in ASTERIA II (Figure 1). UAS7 – daily diary measuring urticaria signs (wheals) and symptoms (itching), weekly scores range from 0–42, with higher scores meaning more severe urticaria.

Correlation: 0.93

Baseline* Week 4* Week 12* Week 24 Week 40

0 5 10 15 20 25 30 35 40 45

PRO scale score

40 weeks

Baseline* Week 4* Week 12* Week 24 Week 40

0 5 10 15 20 25 30 35 40 45

PRO scale score

300 mg/placebo

28 weeks

300 mg/placebo

28 weeks

Figure 3. Trajectories of change in UAS7 and CU-QoL

A near perfect association was found between UAS7 and CU-QoL in all three trials, the correlations between the UAS7 and CU-QoL ranged between 0.90 and 0.94 (Figure 3).

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REFERENCES


A positive correlation between changes in urticaria symptoms (UAS7) and dermatologic-related quality of life (DLQI) was evident (4–15 scale range). The progression of disease and its burden can be assessed with PRO measures for symptoms and HRQoL.

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Figure 1. Design of Phase III studies with omalizumab

CONCLUSIONS

The results provide evidence that any of the three PRO measures are suitable to evaluate a patient’s severity of urticaria and response to treatment.

Regardless of the measure used, clinicians will have comparable information about the evolution of a patient’s symptoms and signs, and the changes in their HRQoL.

Improvements in symptoms, as measured by the UAS7, are reflected in improvements in HRQoL, as measured by the DLQI and the CU-QoL.

Any of the three PRO measures could be implemented in a clinical setting to allow assessment of patient severity and response to treatment.

CU-QoL and CU-QoL may be easier to use in-clinic than a daily diary as they require only one administration.

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