Treatment with ligelizumab achieves a higher complete response rate in chronic spontaneous urticaria patients originally treated with omalizumab

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INTRODUCTION
• Chronic spontaneous urticaria (CSU) is characterised by the occurrence of itchy wheals (hives), angioedema, or both for 6 weeks in the absence of specific external stimuli, and has a significant negative impact on patients' quality of life.1
• Ligelizumab is a next generation, high affinity humanised monoclonal anti-IgE antibody, which has shown greater control of symptoms compared with omalizumab in the Phase 2b core study (NCT02477332).
• Here, we report levels of disease activity measured by the 7-day Urticaria Activity Score (UAS7) for patients who received omalizumab in the core study followed by ligelizumab in the extension study (NCT02649218)10.

METHODS
• Phase 2b core study has been reported previously.9

Endpoints and assessments: UAS7
• In the Phase 2 studies, urticaria was measured using the UAS7, with complete urticaria activity control defined as UAS7=0.
• In this analysis, the change from baseline in UAS7 for patients who received omalizumab: 300 mg in the core study followed by ligelizumab 240 mg in the extension study was evaluated. UAS7 change from baseline as a function of time for each individual patient during the core and the extension study was also evaluated.
• The proportion of patients achieving UAS7=0 for patients treated with omalizumab in the core study were calculated.

RESULTS
• From the core study population, 73.0% (226/310) of patients were eligible based on their disease activity score (UAS7≥12) and willing to enter the extension study after the washout period (as early as Week 32 of the core study). In total, 88.9% of these patients (201/226) completed the extension study. A total of 53 patients on omalizumab switched to ligelizumab in the extension study (Figure 2).
• The mean standard deviation absolute change in UAS7 from Baseline to Week 12 in patients treated with omalizumab 300 mg (n=53) in the core study was -17.4±13.1, whereas re-treatment with ligelizumab 240mg (n=53) showed a -20.9±13.1 change following 12 Weeks of treatment in the extension study (Figure 3).
• The mean standard deviation absolute change in UAS7 from Baseline to Week 20 in patients treated with omalizumab 300 mg in the core study was -17.1±12.6, whereas re-treatment with ligelizumab 240mg showed a -21.3±13.3 change following 20 Weeks of treatment in the extension study, and -22.6±11.8 at the end of the extension study (Week 52) (Figure 3).

CONCLUSIONS
• In the core study, 30.2% (n=16; 95% CI [18.3%, 44.3%]) of patients treated with omalizumab 300 mg achieved UAS7=0 at Week 12, increasing to 43.4% (n=23; 95% CI [28.8%, 57.7%]) upon 12 week re-treatment with ligelizumab 240 mg in the extension study (Figure 5).
• At the end of the core study (Week 20), 32.1% (n=17; 95% CI [19.9%, 46.3%]) of patients treated with omalizumab 300 mg achieved UAS7=0, increasing to 47.2% (n=25; 95% CI [33.3%, 61.4%]) upon re-treatment with ligelizumab 240 mg at (Week 20), and then to 66.5% (n=30; 66.5% [42.3%, 79.7%]), at the end of the extension study (Week 52) (Figure 5).

REFERENCES

Disclosures
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