High proportion of patients with moderate to severe chronic spontaneous urticaria achieved complete response with ligelizumab: data from the phase 2b study

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INTRODUCTION

• Ligelizumab is a next-generation high-affinity humanised monoclonal anti-IgE antibody that has demonstrated good efficacy and safety in patients with chronic spontaneous urticaria (CSU) inadequately controlled by H1-antihistamines

• In the core Phase 2b study, ligelizumab exhibited a dose-dependent response in terms of complete control of hives (HSS7=0) at Week 12 (primary endpoint) and achieved improved control of symptoms compared with omalizumab and placebo

• Here, we present an exploratory analysis of the efficacy of ligelizumab 72 mg and 240 mg vs. omalizumab at Weeks 4 and 12 in patients with moderate or severe CSU

METHODS

• Data from the Phase 2b trial (NCT02477332), a randomised, double-blind study of ligelizumab (24, 72 or 240 mg every 4 weeks [q4w] or 120 mg single dose) vs. omalizumab 300 mg q4w or placebo in adult patients with moderate to severe CSU (UAS7≥16). CSU, chronic spontaneous urticaria; q4w, every 4 weeks; UAS, weekly Urticaria Activity Score

• The ligelizumab 24 and 120 mg SD arms are not presented further as they were not relevant to outcomes presented in this analysis

• Data from Phase 2b trial (NCT02477332), a randomised, double-blind study of ligelizumab (24, 72 or 240 mg q4w or 120 mg single dose) vs. omalizumab 300 mg q4w or placebo in adult patients with moderate to severe CSU (UAS7≥16).

RESULTS

• At baseline, the distribution of patients in moderate or severe CSU activity was similar across treatment arms (moderate: 23.8%–37.6%; severe: 58.8%–75%). However, ligelizumab arms had slightly higher proportion of severe patients than the omalizumab arm (Figure 3)

• For patients with moderate CSU at baseline, 35.0% and 25.9% vs. 12.5% achieved UAS7=0 at Week 4 with ligelizumab 72 and 240 mg vs. omalizumab 300 mg q4w, respectively. At Week 12, 60.0% and 40.7% vs. 34.4% of patients achieved UAS7=0 with ligelizumab 72 and 240 mg vs. omalizumab 300 mg, respectively (Figure 4A)

• In patients with moderate CSU activity at baseline, up to 90% of patients treated with ligelizumab decreased by at least 1 activity band, and up to 70% of patients at Week 4 and 80% of patients at Week 12 were well controlled with ligelizumab (Figure 4A)

• For patients with severe CSU at baseline, 28.6% and 32.1% vs. 22.0% of patients achieved UAS7=0 at Week 4 with ligelizumab 72 and 240 mg vs. omalizumab 300 mg, respectively. At Week 12, 38.1% and 41.1% of these patients respectively achieved complete control of their symptoms (UAS7=0) at Weeks 4 and 12 in the ligelizumab (72 mg and 240 mg) and omalizumab 300 mg arms are reported here

CONCLUSIONS

• In the Phase 2b core study, ligelizumab achieved numerically higher response rates in patients with moderate or severe CSU compared with omalizumab, and a numerically higher rate of complete response compared with omalizumab

• As early as Week 4, in moderate CSU at baseline, up to 90% of patients decreased by at least 1 activity band, after ligelizumab treatment

• As early as Week 4, in severe CSU at baseline, up to ~70% of patients decreased by 1 activity band or more, after ligelizumab treatment

These results will be explored further in the ongoing Phase 3 pivotal trials of ligelizumab in CSU

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