**INTRODUCTION**

Chronic spontaneous urticaria (CSU) reduces patients’ health-related quality of life (HRQoL), impacting daily activities, sleep, and work. Many patients with CSU do not achieve complete control of signs and symptoms despite using standard of care treatments (H1-antihistamines and omalizumab). Ligelizumab, a next-generation high-affinity humanised monoclonal anti-IgE antibody, has been shown to be effective in patients with CSU inadequately controlled by H1-antihistamines alone or in combination with an oral antihistamine and/or leucotriene receptor antagonist during a 20-week core Phase 2b study (NCT02473327). Here, the relationship between complete urticaria control (weekly Urticaria Activity Score 0 [UAS0]) and patient-reported outcomes (PROs) using the Phase 2b core study data were analysed.

**METHODS**

The study design of the dose-finding, multicentre, randomised, double-blind, active- and placebo-controlled Phase 2b core study was previously reported. The present analysis includes all patients in the study who were randomised to receive ligelizumab 24 mg, 72 mg, 120 mg (single-dose arm), or 240 mg, or omalizumab 300 mg, or placebo. Patients received treatment every 4 weeks (q4w) with a total of 5 injections over 20 weeks and a follow-up period of 4 weeks.

The percentage of evaluations achieving Dermaology Life Quality Index (DLQI) 0-1 response was included in this analysis. DLQI 0-1 response is defined as a patient’s quality of life (QoL) was not affected by Urticaria. The least-square (LS) mean and 95% confidence interval (CI) were calculated. All analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC, USA).

**RESULTS**

Data from all 382 patients who were randomised in this study were used in the current analysis. Pooled phase 2b trial data from patients treated with ligelizumab 72 mg or 240 mg, omalizumab 300 mg, or placebo. The percentage of evaluations of each response among consecutive UAS7 bands was compared using odds ratios (OR) and p-values.

**Table 1**

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Ligelizumab (N=84)</th>
<th>Ligelizumab (N=85)</th>
<th>Omalizumab (N=370)</th>
<th>Placebo (N=382)</th>
<th>Study total (N=552)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)*</td>
<td>44.3±12.4</td>
<td>44.8±11.5</td>
<td>41.8±15.1</td>
<td>44.6±11.2</td>
<td>43.3±12.5</td>
</tr>
<tr>
<td>Female (%)</td>
<td>65 (73.2)</td>
<td>67 (78.3)</td>
<td>69 (68.9)</td>
<td>74 (70.8)</td>
<td>71.1±5.1</td>
</tr>
<tr>
<td>BMI**</td>
<td>28.0±7.1</td>
<td>27.9±6.2</td>
<td>27.9±6.9</td>
<td>27.9±6.6</td>
<td>27.9±6.5</td>
</tr>
<tr>
<td>Since (%)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0.0±0.0</td>
</tr>
<tr>
<td>Asians</td>
<td>20 (23.8)</td>
<td>19 (22.6)</td>
<td>12 (14.5)</td>
<td>13 (25.8)</td>
<td>12.0±5.0</td>
</tr>
<tr>
<td>Time since diagnosis of CSU (years)</td>
<td>3.9±4.1</td>
<td>4.1±5.0</td>
<td>4.1±5.7</td>
<td>4.4±3.2</td>
<td>4.3±3.6</td>
</tr>
<tr>
<td>IEL level (months)</td>
<td>10.1±4.1</td>
<td>7.4±4.0</td>
<td>11.1±8.4</td>
<td>8.7±2.5</td>
<td>9.2±5.5</td>
</tr>
</tbody>
</table>

**Figure 3. Percentage of evaluations achieving a AIS7=0 per UAS7 band**

- The least square (LS) mean total score of DLQI in patients with completely controlled disease vs patients with well-controlled disease was 4.5±9.2 (P=0.0036), making the clinical relevant.
- In patients with UAS7=0, 96.9% (n=2,895 associated evaluations) reached SIS7=0 simultaneously, with a 137 times higher (95% CI 37.2 to 502.8) likelihood of having a SIS7=0 (P<0.0001).
- In patients with UAS7=1, a 10.1% difference in the OR 5.11 (P<0.0001) of achieving SIS7=0 between adjacent UAS7 disease bands.
- Urticaria free patients also have a high likelihood of achieving no impact on sleep, productivity, and activity interference, highlighting the importance of achieving complete urticaria control.

**CONCLUSIONS**

- Control of the signs and symptoms of CSU improves overall HRQoL.
- Higher SIS7 and DLQI scores were associated with disease activity and were reduced with decreased disease activity, showing clinically relevant differences in the percentage of patients achieving SIS7=0 and DLQI=0 between adjacent UAS7 disease bands.
- Patients who were urticaria free (according to the UAS7 bands) were those most likely to have no impact on QoL (DLQI score 0-1), emphasizing the importance of complete disease control.
- Urticaria free patients also have a high likelihood of achieving no impact on sleep, productivity, and activity interference, highlighting the importance of achieving complete urticaria control.

**References**


**Conflicts of Interest**

JAB reports grants and personal fees from Novartis, Allergan, Akcea, Dr Reddy’s, GSK, ALK, Galderma, and Ferrosan. MA reports grants from Novartis. AstraZeneca, Merck, Amgen, and Sanofi. KKA reports personal fees from Novartis and AstraZeneca. JEP reports grants from Novartis and AstraZeneca, and has served as a speaker for AstraZeneca. VBG reports personal fees from AstraZeneca, has served as a speaker for AstraZeneca, and has received research funding from AstraZeneca, Merck Sharp & Dohme, Galderma, and Merck. MA reports personal fees from Investigator-initiated clinical trials with AstraZeneca and Merck. JKA reports personal fees from Novartis, Allergan, and Dr Reddy’s. EJC reports grants and personal fees from Novartis. EJC was the medical advisor for uitoxim (Imubla) and Allergan. MA reports personal fees from Janssen, Merck, Vifor, and Novartis. MA has served as a speaker and/or advisor for several companies including Allergan, Akcea, Dr Reddy’s, Galderma, and others. MA has received research funding from several companies, including AstraZeneca, Merck, Novartis, MSD, Janssen, Boehringer Ingelheim, Teva, and Galderma. MA has received research funding and/or compensation for travel or lodging from Novartis, AstraZeneca, Galderma, Dr Reddy’s, Boehringer Ingelheim, Teva, and Vifor. The present analysis was sponsored by Novartis Pharma AG, Basel, Switzerland, and was conducted in accordance with the Good Publication Practice (GPP) guidelines. This investigation was sponsored by Novartis Pharma AG, Basel, Switzerland.

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