Angioedema control with ligelizumab in patients with chronic spontaneous urticaria correlates with improvement of health-related quality of life

**INTRODUCTION**

- Chronic spontaneous urticaria (CSU) is characterized by the spontaneous occurrence of urticaria, angioedema, or both, lasting for 6 weeks or more and can adversely affect health-related quality of life (HRQoL).
- Angioedema is characterized by a sudden pronounced edematous or puffy swelling of the lower dermis and subcutis or mucous membranes, and occurs mostly on the face and inside the mouth.
- Angioedema has an independent negative impact on Dermatology Life-Quality Index (DLQI) and CSU patients with angioedema experience higher impacts on dermatology quality of life (QoL) and greater severity than those without angioedema.
- Here, we analyzed the impact of angioedema on HRQoL as assessed using DOLQ in CSU patients with data from the ligelizumab Phase 2b core and extension studies.

**METHODS**

**Study design**

- The ligelizumab Phase 2b trial was a multicenter, randomized, double-blind, active- placebo-controlled study and included treatments with ligelizumab 72 mg or 240 mg, omalizumab 300 mg, or placebo every 4 weeks (q4w) for 20 weeks.
- Adult patients (aged ≥18 to ≤75 years), diagnosed with refractory CSU who remained symptomatic despite treatment with H1- receptor antagonists at approved or increased doses, alone or in combination with H2-antihistamines and/or a leukotriene receptor antagonist, were enrolled in the study.

**RESULTS**

**Baseline demographics and disease characteristics**

- In the core study (n=226), 55% of patients had a baseline DLQI score of ≥12, indicating severe disease. Among patients with angioedema at baseline (n=128), 71% had a baseline DLQI score of ≥12.
- The overall mean change from baseline in AAS7 over time was 3.1 ± 7.1 points at 24 weeks, with 24% of patients achieving a complete resolution of symptoms (AAS7 = 0) in the ligelizumab 240 mg group.

**Assessments**

- **LS mean change from baseline (CFB) in the 4.84**
- **Placebo (n=28)**
- **Data across treatment arms and timepoints were pooled for the Urticaria Center of Reference and Excellence (UCARE), Institute of Allergology, Corporate member of Freie Universität Berlin, Berlin, Germany; 2Fraunhofer Institute for Translational Medicine and Pharmacology ITMP, Allergology and Immunology, Berlin, Germany; 3Department of Dermatology, Hospital del Mar -IMIM, Universitat Pompeu Fabra, Barcelona, Spain; 4Department of Dermatology, Hiroshima University, Hiroshima, Japan; 5Department of Dermatology, Hiroshima City Hospitals, Hiroshima, Japan; 6Little Rock Allergy and Asthma Clinic, Little Rock, United States; 7Novartis Pharma AG, Basel, Switzerland**

**CONCLUSIONS**

- Angioedema has a significant negative impact on the health-related quality of life of patients with CSU.
- Patients with more severe angioedema are more likely to achieve a DOLQ 0-1 status (no disease impact) compared with patients without angioedema at baseline.
- Angioedema has a significant negative impact on quality of life compared with patients without angioedema at baseline.
- Angioedema remains a challenge in patients with CSU, which correlates with improved health-related quality of life outcomes.

**References**

- 1. Zuberbier T, et al. 2018;73:1724-32. 2. Martin Metz,1,2 Ana Giménez-Arnau,3 Marcus Maurer,1,2 Michihiro Hide,4,5 Karl Sitz,6 Christine-Elke Ortmann,7 Maria-Magdalena Balp,7 Thomas Severin7

**Figure 1. Study design of the Phase 2b core and extension ligelizumab studies in patients with CSU inadequately controlled with H1-antihistamines**

**Figure 2. A mixed model for repeated measures was used to compare AAS7 between adjacent DOLQ categories**

**Figure 4. Dermatology QoL by angioedema status at baseline:**

- Median (IQR) range, meanSD in the Phase 2b core and extension studies. AAST comparison by DOLQ categories among patients with angioedema at baseline (Figure 2 in the Phase 2b core study, and c) in the extension study**