Complete control of urticaria symptoms with ligelizumab helps normalize quality of life

Jonathan A Bernstein1, Marcus Maurer2, Ana Giménez-Arnau3, Weily Soong4, Martin Metz2, Nathalie Barbier5, Avantika Barve6, Thomas Severin5, Maria-Magdalena Balp5, Reinhold Janocha5

1University of Cincinnati College of Medicine and Bernstein Clinical Research Center, Cincinnati, OH, USA; 2Dermatological Allergology, Department of Dermatology and Allergy, Charité - Universitätsmedizin Berlin, Germany; 3Dermatology Department, Hospital del Mar-Parc de Salut Mar, IMIM, Universitat Autònoma, Barcelona, Spain; 4Alabama Allergy and Asthma Center, Clinical Research Center of Alabama, Birmingham, Alabama, USA; 5Novartis Pharma AG, Basel, Switzerland; 6Novartis Pharmaceuticals Corporation, East Hanover, NJ, United States.

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Introduction

- **Chronic spontaneous urticaria (CSU)** is characterized by the occurrence of *itchy wheals* (hives), angioedema, or both for 6 weeks or more in the absence of specific external stimuli and has a significant negative effect on dermatology-quality of life (QoL)\(^1,2\)

- **CSU disease activity and dermatology-QoL impairment** can be assessed by the Urticaria Activity Score (UAS) and the Dermatology Life Quality Index (DLQI), respectively

- **Ligelizumab**, a *next generation anti-IgE antibody*, has demonstrated to **improve symptom control in patients with CSU**, who remain symptomatic despite the use of H\(_1\)-antihistamines. Here, we describe the **change in dermatology-QoL with decreasing disease activity** using data from the ligelizumab Phase 2b study

Methods

Study design

▪ In this Phase 2b dose-finding, multicenter, randomized, double-blind, active and placebo-controlled study, adult patients with CSU inadequately controlled by an H₁-antihistamine with moderate to severe disease activity (UAS7≥16) were randomized to receive subcutaneous ligelizumab 24, 72 or 240 mg, omalizumab 300 mg, or placebo every 4 weeks for 20 weeks or a single dose of ligelizumab 120 mg.¹

DLQI, UAS7 assessment

▪ For this analysis, the weekly UAS (UAS7) and DLQI scores, from the ligelizumab 72 mg and 240 mg, omalizumab 300 mg and placebo arms were analyzed. Patients were categorized based on their UAS7 response (UAS7=0, UAS7=1–6, UAS7≥7) at Weeks 12 and 20 of the study.


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A substantial proportion of patients achieved DLQI 0–1 as early as Week 4 in ligelizumab 72 mg and 240 mg, and omalizumab 300 mg vs placebo

- A total of 258 patients at Week 12 and 256 patients at Week 20 with patient reported outcome (PRO) data available were used for the analysis. Baseline UAS7 and DLQI scores were comparable for all treatment arms reflecting moderate/severe urticaria.

- Patients achieving DLQI 0–1 (no impact on QoL) maintained the effect throughout the 20 week treatment period in active treatment arms.

DLQI, dermatology life quality index; n, number of patients in each treatment arm; q4w, every 4 weeks.

 Patients with UAS7≥7 were less likely to achieve a DLQI 0–1 compared with patients who were completely controlled or well controlled

- At Week 12,
  - A higher proportion of patients with UAS7=0 achieved DLQI 0–1 in all active treatment arms compared with patients who did not achieve complete symptom control, including even those with well-controlled disease (UAS7=1–6) A much smaller proportion of patients with DLQI 0–1 outcomes were observed within the UAS7≥7 response category

- At Week 20,
  - Majority of patients in the ligelizumab 72 mg and 240 mg arms and the omalizumab 300 mg arm who achieved DLQI 0–1 were patients who had UAS7 of 0-6
More patients in active treatment arms achieve complete control of urticaria and DLQI 0–1 versus placebo.

Percentages may not add up to 100% because of subjects discontinuing the study or missing UAS7 or DLQI assessment data. Results from the very small number of patients in response categories should be interpreted with caution. DLQI, Dermatology Life Quality Index; n, number of patients; N, total number of patients; QoL, quality of life; UAS7, weekly urticaria activity score.

Conclusion

- Overall, a **numerically greater proportion** of patients who had **complete control of symptoms**, achieved DLQI 0–1 compared with patients who did not achieve complete control.

- **Improvement in UAS7** is associated with **improvement in DLQI**, and complete control of disease can help achieve **complete normalization** of patients’ lives.

- The ongoing **Phase III studies (PEARL 1 and PEARL 2)** will provide **additional insights** into the **clinical benefits of ligelizumab** for patients with CSU.

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CSU, chronic spontaneous urticaria; DLQI, Dermatology Life Quality Index; UAS7, weekly Urticaria Activity Score