**INTRODUCTION**

- Chronic spontaneous urticaria (CSU) is characterized by the occurrence of wheals (hives) and/or angioedema for more than 6 weeks and has a dramatic impact on the well-being of patients.
- Remibrutinib is a novel, oral, highly selective Bruton’s tyrosine kinase inhibitor that offers fast disease control in patients with CSU who present with chronic spontaneous urticaria despite treatment with second-generation H\(_1\) antagonists (H\(_1\)AH).
- Patients showed clinical efficacy and a favorable safety profile in the Phase 2b core and extension studies (NCT02925657 and NCT01545331) in patients with CSU inadequately controlled by H\(_1\)AH treatment.
- The Phase 2b core study randomized 249 patients to receive remibrutinib 10 mg q.d, remibrutinib 35 mg q.d, or placebo. Remibrutinib 100 mg q.d was subsequently added to the treatment regimen in the extension study (NCT03512574).

**OBJECTIVE**

- To assess whether patients treated with remibrutinib experience an early clinically meaningful improvement of CSU disease activity, and whether that led to a better overall clinical response in a 12-week Phase 2b study.

**METHODS**

**STUDY DESIGN AND PATIENTS**

- The study was a double-blind, multicenter, randomized, double-blind, placebo-controlled Phase 2b study conducted across 17 countries in patients with CSU.
- The study included patients aged ≥18 years with moderate/severe CSU inadequately controlled by H\(_1\)-AH treatment.
- Patients were randomized to receive remibrutinib 10 mg once daily (q.d.), 35 mg q.d., 100 mg q.d., or placebo.

**RESULTS**

- This post-hoc analysis of the Phase 2b study evaluated data of 309 CSU patients from the full analysis set (311 patients).
- Demographics and baseline characteristics were generally comparable between remibrutinib and placebo in MID-UAS7 early versus late responders (Table 1).
- In patients who achieved MID-UAS7 within the first 2 weeks after randomization, the mean baseline UAS7 was 28.0–33.3 across all remibrutinib doses versus 32.3 for placebo.
- The mean baseline UAS7 for any remibrutinib dose versus placebo was 30.3±6.9 vs 31.0±6.2 at Weeks 0–2 and 28.7±7.1 vs 23.5±6.7 at Weeks 2–12, respectively.
- Higher proportions of patients achieved MID-UAS7 at any time (between Weeks 0–12) and early (Weeks 2) versus placebo.
- The proportion of patients achieving MID-UAS7 not achieved within 12 weeks was higher for all remibrutinib doses versus placebo.
- Of the patients who achieved MID-UAS7 early, the mean time to achieve symptom remission (24–46 weeks) was longer for all remibrutinib doses versus placebo.

**CONCLUSIONS**

- In this post-hoc analysis, the majority of patients with CSU achieved MID-UAS7 during the first 2 weeks of treatment with remibrutinib.
- Patients who achieved MID-UAS7 within the first 2 weeks after randomization had a mean baseline UAS7 score of 28.0–33.3 across all remibrutinib doses versus 32.3 for placebo.
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**REFERENCE:**