**INTRODUCTION**

- Chronic spontaneous urticaria (CSU) is characterized by the occurrence of wheals (hives) and/or angioedema for >6 weeks and has a major detrimental impact on patients’ well-being.1
- Remibrutinib is a novel, oral, highly selective, Bruton’s tyrosine kinase (BTK) inhibitor that has shown clinical efficacy with a fast symptom relief and a favorable safety profile for up to 52 weeks in Phase 2 studies (NCT03926611 and NCT04093535) in patients with CSU inadequately controlled by H1-antihistamines.2
- The Week 24 data from remibrutinib-Phase 3 clinical studies in CSU (REMIX-1: NCT03503031, REMIX-2: NCT03503275)3 recently became available and are being presented at the American College of Allergy, Asthma & Immunology (ACAAI) Annual Scientific Meeting 2023.3
- Histamine release试验 demonstrates that activation of BTK receptors on the mast cell membrane plays a critical role in CSU pathophysiology and BTK enzyme is central to this process.4 BTK signaling also plays an important role in B-cell development and BTK mutation linked to X-linked agammaglobulinemia have been shown to affect serum immunoglobulin (Ig) levels.5

**METHODS**

**STUDY DESIGN AND PATIENTS**

- This was a dose-finding, multicenter, randomized, double-blind, placebo-controlled Phase 2b study conducted across 17 countries in patients with CSU.1
- Eligible patients (having weekly Urticaria Score [UAS7] ≥16 at the end of the treatment period or by the end of the follow-up period of the Phase 2b core study, or by the end of a 12-week observational period of the extension study) were enrolled in the treatment period of the extension study.5

**STUDY OUTCOMES AND STATISTICAL ANALYSIS**

- Total serum Ig levels were assessed at baseline, Week 4 (only IgE) and Week 12 during the core study and at baseline, Week 12 (only IgE), Week 28, and Week 52 during the extension study.
- Data were analyzed using summary statistics based on safety population.

**OBJECTIVE**

- To evaluate the impact of remibrutinib treatment on total serum Ig levels over time in the Phase 2b core and extension studies.

**RESULTS**

**DEMOGRAPHICS AND CLINICAL CHARACTERISTICS**

- Of 309 patients included in the Phase 2b core analysis, 194 rolled-over to the 52-week extension study and were included in the analysis.
- Patient demographics and baseline disease characteristics and serum Ig levels were comparable between the core and extension studies (Table 1).

**CONCLUSIONS**

- Remibrutinib treatment did not have any impact on the total serum Ig levels in patients with CSU in the Phase 2 core study and long-term extension study with 100 mg b.i.d. up to 52 weeks.
- Remibrutinib has shown a favorable safety profile for up to 52 weeks in patients with CSU6.