Remibrutinib Achieves Clinically Significant Response in Chronic Spontaneous Urticaria Patients Regardless of Prior Oral Treatments

INTRODUCTION

- Chronic spontaneous urticaria (CSU) is characterized by recurrent wheals (hives) and/or angioedema for more than 6 weeks that can have a major impact on patients' well-being.
- Remibrutinib is a novel, oral, highly selective Bruton's tyrosine kinase inhibitor that offers fast disease control in patients with CSU who remain symptomatic despite treatment with second-generation H1-antihistamines (AH).
- Remibrutinib showed clinical efficacy and a favorable safety profile for up to 52 weeks in the Phase 3 clinical studies (CSU-REMIX1-1 and CSU-REMIX2).
- The Week 24 data from remibrutinib Phase 3 clinical studies (CSU-REMIX1-1, CSU-REMIX2) recently became available and are being presented at the American College of Allergy, Asthma and Immunology (ACAAI) Annual Scientific Meeting 2023.

OBJECTIVE

- Here, we analyzed the efficacy of remibrutinib treatment in the Phase 2b study in patients with CSU who had received prior oral treatments.

RESULTS

- Baseline UAS7 was balanced between any remibrutinib arm and placebo for patients on prior oral treatments except those on dual or triple H1-AH (Table 1).

Table 1. Baseline UAS7 for patients on prior oral treatments in any remibrutinib arm and placebo

<table>
<thead>
<tr>
<th>Prior oral treatments</th>
<th>Any remibrutinib arm</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>SH-AH</td>
<td>30.2±7.0</td>
<td>27.1±7.4</td>
</tr>
<tr>
<td>UH-AH</td>
<td>28.7±7.3</td>
<td>20.6±7.0</td>
</tr>
<tr>
<td>DTH-AH</td>
<td>31.4±7.2</td>
<td>23.1±6.1</td>
</tr>
<tr>
<td>H1-AH/H2-AH</td>
<td>30.6±6.3</td>
<td>28.2±6.2</td>
</tr>
</tbody>
</table>

- At Week 2, 4, and 12, higher change from baseline in the UAS7 was observed in any remibrutinib arm versus placebo (Figure 1).

- Similarly, the proportion of patients achieving UAS7=0 and UAS7≤6 at Week 2 was higher in any remibrutinib arm versus placebo for patients on all prior oral treatments except dual or triple H1-AH (Figure 2).

Discussion

- Remibrutinib results in a fast, consistent, and clinically significant response regardless of prior oral treatment, indicating that treatment escalation to remibrutinib could be beneficial versus remission therapy.

CONCLUSIONS

- Remibrutinib results in a fast, consistent, and clinically significant response regardless of prior oral treatment, indicating that treatment escalation to remibrutinib could be beneficial versus remission therapy.
- Results should be interpreted with caution due to low number of patients in the placebo group.

REFERENCES


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.
- The study included patients aged ≥18 years with moderate/severe CSU for ≥6 months that was inadequately controlled by H1-AH treatment.

STUDY ASSESSMENTS

- Prior oral treatments were categorized as:
  1. Standard dose second-generation H1-AH monotherapy (SH-AH)
  2. Up-dosed second-generation H1-AH monotherapy (UH-AH)
  3. Dual or triple H1-AH (DTH-AH)
  4. Second-generation H1-AH/H2-AH (H1-AH/H2-AH) or second-generation H1-AH/human leukotriene receptor antagonist (LTBA, H1-AH/H2-AH/LTBA) in patients achieving UAS7=0 and UAS7≤6 at Week 2 in any remibrutinib arm and placebo were analyzed.

CONCLUSIONS

- Remibrutinib results in a fast, consistent, and clinically significant response regardless of prior oral treatment, indicating that treatment escalation to remibrutinib could be beneficial versus remission therapy.
- Results should be interpreted with caution due to low number of patients in the placebo group.

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- All authors contributed to the study or article preparation.

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