Remibrutinib Treatment Has No Impact on Blood Counts in Patients With Chronic Spontaneous Urticaria

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CONCLUSIONS

- Overall, remibrutinib treatment did not result in clinically meaningful changes in counts of any blood cell type evaluated.
- The results further add to the favorable safety profile of remibrutinib reported in the Phase 2 and extension studies.

INTRODUCTION

- Chronic spontaneous urticaria (CSU) is characterized by the occurrence of wheals (hives) and/or angioedema for more than 6 weeks and has a major detrimental impact on patients’ well-being.
- Remibrutinib is a novel, oral, highly selective oral Bruton’s tyrosine kinase (BTK) inhibitor that offers fast disease control in patients with CSU who remain symptomatic despite treatment with second-generation BTK-inhibitors (8).
- Remibrutinib showed clinical efficacy and a favorable safety profile for up to 52 weeks in the Phase 2b core and extension studies (NCT03926611; NCT04059335) in patients with CSU inadequately controlled by BTK inhibitors (8).
- The Week 24 data from remibrutinib Phase 3 clinical trials in CSU (REMELIX-1: NCT01503133, REMELIX-2: NCT01523574) recently became available and are being presented at the American College of Allergy, Asthma & Immunology (ACAAI) Annual Scientific Meeting 2023.
- Bruton’s tyrosine kinase is expressed broadly in hematopoietic cells including myeloid cells. This analysis aimed to examine the impact of remibrutinib treatment on complete blood count parameters.

OBJECTIVE

- To evaluate the effect of remibrutinib compared to placebo with respect to change from baseline in blood cell counts at Week 12 in the Phase 2b core study.

METHODS

- This was a dose-finding, multicenter, randomized, placebo-controlled, Phase 2b study conducted across 17 countries in patients with CSU (Figure 1).
- Patients were equally randomized to receive remibrutinib (10 mg q.d.; 25 mg b.i.d.; 100 mg b.i.d.) or placebo.
- Pooled data of remibrutinib treatment arms versus placebo were presented.
- Summary statistics were provided by treatment and visit.
- Weekly blood counts were performed.

RESULTS

- This post hoc analysis of the Phase 2b study evaluated data of 309 patients with CSU from the full analysis set (ITT patients).
- The absolute mean (SD) baseline blood cell counts were comparable between any remibrutinib arm and placebo. Overall, mean blood cell counts remained within normal limits throughout the treatment (Figure 2).
- No clinically meaningful differences were observed for the CB parameters in blood cell counts for any remibrutinib arm and placebo, at Week 12 (Table 1).

Table 1. Change from baseline in hematopoietic parameters by treatment group at Week 12

<table>
<thead>
<tr>
<th>Laboratory parameter</th>
<th>Mean±SD Baseline</th>
<th>Remibrutinib any arm</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leukocytes (x10^9/L)</td>
<td>3.9±0.8</td>
<td>4.0±0.8</td>
<td>3.9±0.8</td>
</tr>
<tr>
<td>Neutrophils (x10^9/L)</td>
<td>2.0±0.8</td>
<td>2.0±0.8</td>
<td>2.0±0.8</td>
</tr>
<tr>
<td>Eosinophils (x10^9/L)</td>
<td>0.05±0.01</td>
<td>0.05±0.01</td>
<td>0.05±0.01</td>
</tr>
<tr>
<td>Basophils (x10^9/L)</td>
<td>0.00±0.00</td>
<td>0.00±0.00</td>
<td>0.00±0.00</td>
</tr>
<tr>
<td>Lymphocytes (x10^9/L)</td>
<td>1.1±0.5</td>
<td>1.1±0.5</td>
<td>1.1±0.5</td>
</tr>
<tr>
<td>Erythrocytes (x10^12/L)</td>
<td>4.2±0.6</td>
<td>4.2±0.6</td>
<td>4.2±0.6</td>
</tr>
<tr>
<td>Platelets (x10^9/L)</td>
<td>249±65</td>
<td>249±65</td>
<td>249±65</td>
</tr>
</tbody>
</table>

No meaningful changes in counts of any blood cell type were observed.

CONCLUSIONS

Overall, remibrutinib treatment did not result in clinically meaningful changes in counts of any blood cell type evaluated.

The results further add to the favorable safety profile of remibrutinib reported in the Phase 2 core and extension studies.


DISCLOSURES:

- All authors participated in the development of the poster for presentation. The American College of Allergy, Asthma & Immunology (ACAAI) awarded travel support to physician investigators in the top 25% of an annual research award competition. See the ACAAI website (https://www.acaai.org) for more information. The views expressed are those of the authors and do not reflect any policies of the ACAAI or the American Academy of Allergy, Asthma & Immunology. The authors have no conflicts of interest to disclose; Alexandre Bonadonna is an employee of Sanofi, Bridgewater, New Jersey, USA, and at the time of analyses was an employee of Novartis Pharmaceuticals Corporation, East Hanover, New Jersey, USA; Mohammad Fahad Haroon is an employee of Novartis Healthcare Pvt. Limited, Mumbai, India.

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Figure 1. Study design

Figure 2. Baseline (Mean [SD], Week 0), and Week 12 absolute blood cell counts for any remibrutinib arm (n=267) or placebo (n=42)