Poster L28

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Efficacy of Remibrutinib in Patients With Chronic Spontaneous Urticaria With or Without Prior Exposure to Biologics in the Phase 3 REMIX-1 and REMIX-2 Studies

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CONCLUSIONS

- In the primary analysis of the phase 3 REMIX-1 and REMIX-2 studies, remibrutinib had greater efficacy than placebo, demonstrating significant improvements in UAS7 at week 12 in patients with CSU with inadequate disease control with second-generation H_1-AH treatment, regardless of prior exposure to anti-IgE biologics at baseline
- More patients treated with remibrutinib than placebo achieved complete absence of itch and hives at week 12, with well-controlled disease as early as week 2 that was sustained to week 12, regardless of prior exposure to anti-IgE biologics at baseline
- Remibrutinib showed a favorable safety profile across REMIX studies during the 24-week double-blind period
- Remibrutinib demonstrated greater efficacy than placebo, regardless of prior exposure to anti-IgE biologics at baseline

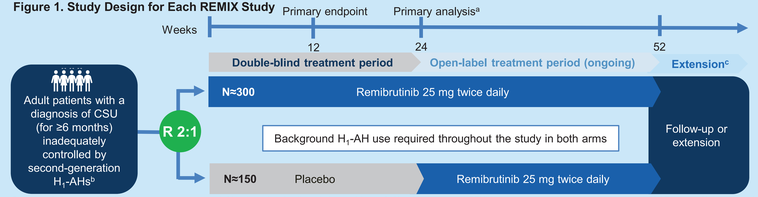
INTRODUCTION

- Remibrutinib is a novel, highly selective, oral BTK inhibitor that demonstrated superiority in change from baseline in UAS7 vs placebo at week 12 in the phase 3 REMIX-1 (NCT05030311) and REMIX-2 (NCT05032157) studies in patients with CSU inadequately controlled with H_1-AHs[1-4]
- Guidelines recommend the use of an anti-IgE monoclonal antibody as an add-on therapy for patients with inadequately controlled CSU receiving up to 4 times the label-approved dose of H_1-AHs[5]
- Here, we present primary analysis results from the phase 3 REMIX studies evaluating the efficacy of remibrutinib 25 mg twice daily in patients with CSU with or without prior anti-IgE biologic treatment at baseline compared with placebo and pooled safety of remibrutinib 25 mg twice daily vs placebo

Study Design

- REMIX-1 and REMIX-2 are 2 phase 3, randomized, placebo-controlled studies of remibrutinib 25 mg twice daily administered orally (**Figure 1**)
- Patients were stratified by prior exposure to anti-IgE biologics (exposed vs naive) at baseline and region
- The proportion of patients with prior exposure to anti-IgE biologics at baseline was limited to approximately 30% of the total study population
- Primary endpoints included change from baseline in UAS7 (scenario 1) and ISS7 and HSS7 (scenario 2) at week 12
- Secondary endpoints included percentages of patients with UAS7≤6 and UAS7=0 at week 12, UAS7≤6 at week 2, and occurrence of treatment-emergent and serious AEs during the study

Figure 1. Study Design for Each REMIX Study



[a] Primary analysis was conducted after all patients completed week 24 or discontinued earlier and when a minimum of 150 patients across both REMIX studies completed the treatment period at week 52. [b] Presence of itch and hives for ≥6 consecutive weeks prior to screening despite the use of a second-generation H_1-AH; UAS7 of ≥16, ISS7 of ≥6, and HSS7 of ≥6 during the 7 days prior to randomization (day 1). [c] Patients may continue receiving remibrutinib in a separate extension study.

RESULTS

Patient Demographics and Baseline Characteristics

- The number of patients with previous exposure to anti-IgE biologics at baseline was well balanced between the remibrutinib and placebo arms in both studies (**Table 1**)

Table 1. Patient Demographics and Baseline Characteristics[a]

This table has been published in the New England Journal of Medicine.

It can be found by clicking here: Metz M, et al. N Engl J Med. 2025;392(10):984-94.

[a] All randomized patients. [b] Patients who experienced inadequate response to anti-IgE biologics or did not tolerate anti-IgE biologics could be included.

Change From Baseline in UAS7 With Remibrutinib at Week 12 Was Comparable Between Patients With or Without Prior Exposure to Anti-IgE Biologics at Baseline

- Change from baseline in UAS7 (**Figure 2**) was greater with remibrutinib vs placebo at week 12 regardless of prior exposure to anti-IgE biologics at baseline

Figure 2. Change From Baseline in UAS7 at Week 12

This figure has been published in the New England Journal of Medicine.

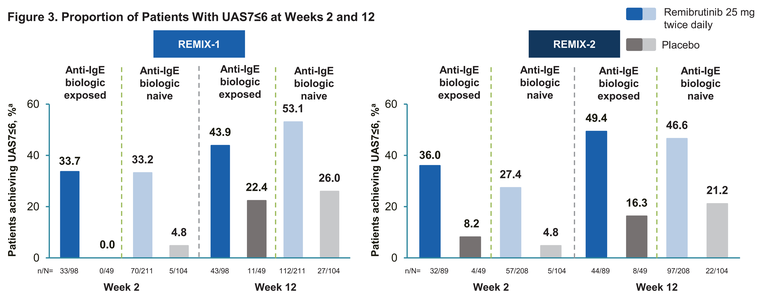
It can be found by clicking here: Metz M, et al. N Engl J Med. 2025;392(10):984-94.

[a] Full analysis set using a linear mixed model with repeated measures; imputed data. [b] Treatment difference in LS mean (95% CI).

The Proportions of Patients Achieving UAS7≤6 and UAS7=0 at Week 12 Were Comparable Between Patients With or Without Prior Exposure to Anti-IgE Biologics at Baseline

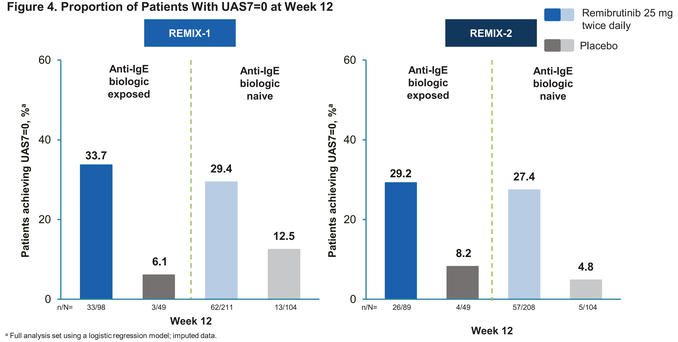
- More patients achieved well-controlled disease (UAS7 ≤6; **Figure 3**) with remibrutinib than placebo as early as week 2, regardless of prior exposure to anti-IgE biologics at baseline, with responses sustained at week 12, with more patients achieving complete absence of itch and hives at week 12 (UAS7 = 0; **Figure 4**)

Figure 3. Proportion of Patients With UAS7≤6 at Weeks 2 and 12



[a] Full analysis set using a logistic regression model; imputed data.

Figure 4. Proportion of Patients With UAS7=0 at Week 12



[a] Full analysis set using a logistic regression model; imputed data.

Overview of Safety During the 24-Week Double-Blind Period From a Pooled Analysis of the REMIX-1 and REMIX-2 Studies

- Overall safety of remibrutinib was comparable to that of placebo (**Table 2**)
- No serious AEs were considered related to the study drug by the investigator

Table 2. Overview of Safety

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Abbreviations

AE, adverse event; AH, antihistamine; BTK, Bruton's tyrosine kinase; CSU, chronic spontaneous urticaria; HSS7, weekly Hives Severity Score; IgE, immunoglobulin E; ISS7, weekly Itch Severity Score; LS, least square; R, randomized; UAS7, weekly Urticaria Activity Score.

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