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Early And Sustained Efficacy Of Remibrutinib In Adult Patients With CSU: Pooled Analysis Of REMIX-1/-2 Studies

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CONCLUSIONS

- In the pooled REMIX-1/-2 studies, remibrutinib showed improvements in urticaria symptoms as early as week 1, with over 50% improvement by week 2, which improved further and was sustained through week 52
- Overall, remibrutinib showed a favorable safety profile across the REMIX-1/-2 studies
- These outcomes indicate that remibrutinib provides fast and sustained symptom relief for patients with CSU who remained symptomatic despite treatment with second-generation H_1-AH

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INTRODUCTION

- Chronic spontaneous urticaria (CSU) is characterized by the spontaneous occurrence of itch, wheals (hives), and/or angioedema lasting for more than 6 weeks, without an identifiable trigger[1]
- Remibrutinib, an oral, highly selective Bruton's tyrosine kinase inhibitor, has shown superior efficacy at week 12 vs placebo and a favorable safety profile in the phase 3 REMIX-1/-2 studies when administered as an add-on medication in patients with CSU who remain symptomatic despite treatment with second-generation H_1-antihistamines (H_1-AH)[2]
- Remibrutinib has been recently approved by the FDA for the treatment of CSU in adult patients who remain symptomatic despite H_1-AH use[3]

OBJECTIVE

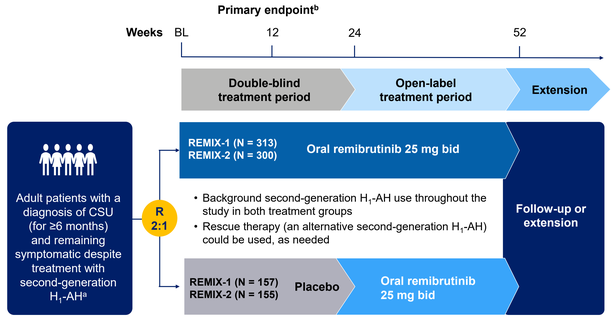
- This pooled analysis of data from the REMIX-1 and REMIX-2 studies assessed the long-term efficacy (52 weeks) of remibrutinib in reducing disease activity

METHODS

Study Design

- REMIX-1 and REMIX-2 were identical, multicenter, randomized, double-blind, placebo-controlled studies assessing the efficacy and safety of remibrutinib in adult patients with CSU who remained symptomatic despite treatment with second-generation H_1-AH
- Patients were randomized 2:1 to oral remibrutinib 25 mg twice daily (bid) or placebo over a 24-week double-blind period, followed by 28-week open-label treatment with oral remibrutinib 25 mg bid. At week 24, patients on placebo transitioned to remibrutinib (**Figure 1**)[2,4]

Figure 1. Study design[4]



[a]Presence of itch and hives for ≥6 consecutive weeks before screening despite the use of a second-generation H_1-AH; weekly Urticaria Activity Score of ≥16, weekly Itch Severity Score of ≥6, and weekly Hives Severity Score of ≥6 during the 7 days before randomization (day 1).
[b]The primary endpoint was the change in UAS7 from baseline to week 12.
bid, twice daily; BL, baseline; CSU, chronic spontaneous urticaria; H_1-AH, H_1-antihistamines; N, number of patients in each treatment group; R, randomization.

Study Assessments and Data Analysis

- Mean percentage change from baseline (CFB; observed data) in weekly Urticaria Activity Score (UAS7), weekly Itch Severity Score (ISS7), and weekly Hives Severity Score (HSS7) over 52 weeks was assessed
- Data were analyzed descriptively and presented as mean ± standard deviation or percentage

RESULTS

- This analysis included 606 and 306 patients receiving remibrutinib and placebo, respectively
- In general, patient demographics and baseline characteristics were well balanced between the remibrutinib and placebo groups in both studies (**Table 1**)

Table 1. Patient demographics and baseline characteristics (pooled full analysis set)

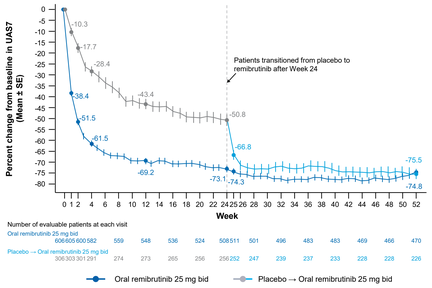
	Oral remibrutinib 25 mg bid (N = 606)	Placebo (N = 303)
Age (years)	**43.3** ± 14.4	**43.7** ± 14.1
Female, n (%)	403 (**66.5**)	204 (**66.7**)
BMI (kg/m^2)	**27.4** ± 6.5	**27.7** ± 6.3[a]
Duration of CSU (years)	**6.2** ± 8.6	**5.3** ± 6.7
UAS7	**30.6** ± 7.8	**29.7** ± 7.6
ISS7	**14.6** ± 4.2	**14.1** ± 4.0
HSS7	**16.0** ± 4.5	**15.6** ± 4.5

[a]n = 305.
Data are presented as mean ± standard deviation unless specified otherwise.
bid, twice daily; BMI, body mass index; CSU, chronic spontaneous urticaria; HSS7, weekly Hives Severity Score; ISS7, weekly Itch Severity Score; N, total number of patients in the treatment group; n, number of patients who satisfied the designated criterion; UAS7, weekly Urticaria Activity Score.

Mean Percentage Change From Baseline in UAS7, ISS7, and HSS7

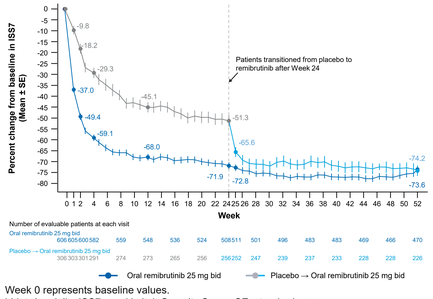
- At baseline, patients in both remibrutinib and placebo groups had high mean UAS7 (30.6 ± 7.8 and 29.7 ± 7.6, respectively), mean ISS7 (14.6 ± 4.2 and 14.1 ± 4.0, respectively), and mean HSS7 (16.0 ± 4.5 and 15.6 ± 4.5, respectively), which reduced substantially by week 1 and continued to reduce further up to week 52 in all remibrutinib-treated patients
- The corresponding percentage change from baseline in UAS7 were (**Figure 2**);
  - Week 1 (remibrutinib vs placebo): 38.4% vs 10.3%
  - Week 24 (remibrutinib vs placebo): 73.1% vs 50.8%
  - Week 52 (patients randomized to remibrutinib): 74.8%
- Similarly, percentage change from baseline in ISS7 (**Figure 3**) and HSS7 (**Figure 4**) were
  - Week 1 (remibrutinib vs placebo): ISS7 = 37.0% vs 9.8%; HSS7 = 39.8% vs 10.1%
  - Week 24 (remibrutinib vs placebo): ISS7 = 71.9% vs 51.3%; HSS7 = 73.8% vs 50.0%
  - Week 52 (patients randomized to remibrutinib): ISS7 = 73.6% and HSS7 = 75.2%
- Patients who transitioned from placebo to remibrutinib at week 24 also showed a substantial reduction in mean UAS7, ISS7, and HSS7 as early as week 25 and were further sustained up to week 52. The subsequent percentage improvements at week 25 were UAS7 = 66.8%, ISS7 = 65.6%, and HSS7 = 67.5%, and those at week 52 were UAS7 = 75.5%, ISS7 = 74.2%, and HSS7 = 75.9%

Figure 2. Mean percentage change from baseline in UAS7 by visit up to week 52 (observed data; pooled full analysis set)



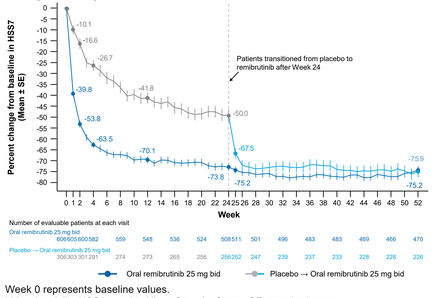
Week 0 represents baseline values.
bid, twice daily; SE, standard error; UAS7, weekly Urticaria Activity Score.

Figure 3. Mean percentage change from baseline in ISS7 by visit up to week 52 (observed data; pooled full analysis set)



Week 0 represents baseline values.
bid, twice daily; ISS7, weekly Itch Severity Score; SE, standard error.

Figure 4. Mean percentage change from baseline in HSS7 by visit up to week 52 (observed data; pooled full analysis set)



Week 0 represents baseline values.
bid, twice daily; HSS7, weekly Hives Severity Score; SE, standard error.

Overall Safety Profile

- In the pooled safety analysis, remibrutinib showed favorable safety and tolerability across the REMIX-1 and REMIX-2 studies
- The incidence of at least one adverse event (AE) up to week 24 was comparable between remibrutinib (64.9%) and placebo (64.7%) patients (**Table 2**)
- The exposure-adjusted incidence rates of AEs, serious AEs, and AEs leading to treatment discontinuation over the 52-week treatment period were consistent with those observed in the double-blind treatment period
- No deaths were reported, and discontinuation of the study treatment due to AEs was infrequent. No serious AEs were considered related to the study medication by the investigator

Table 2. Overview of safety in the REMIX-1/-2 studies (safety analysis set)[5]

n (%) EAIR [95% CI]	Double-blind period (weeks 0–24)		Entire study period (up to week 52)	Open-label period (weeks 24–52)
	Oral remibrutinib 25 mg bid N = 606	Placebo N = 306	Oral remibrutinib 25 mg bid N = 606	Placebo → oral remibrutinib 25 mg bid[a] N = 262
Median duration of exposure, weeks	**24.0**	**24.0**	**52.1**	**28.1**
Participants with AE(s)	393 (**64.9**) **276.4** [249.7–305.1]	198 (**64.7**) **273.5** [236.8–314.4]	446 (**73.6**) **199.8** [181.7–219.3]	133 (**50.8**) **144.8** [121.2–171.6]
SAE(s)	20 (**3.3**) **7.7** [4.7–11.9]	7 (**2.3**) **5.3** [2.2–11.0]	25 (**4.1**) **4.7** [3.0–6.9]	3 (**1.1**) **2.1** [0.4–6.2]
Treatment discontinuation due to AE(s)	17 (**2.8**) **6.5** [3.8–10.3]	9 (**2.9**) **6.8** [3.1–13.0]	28 (**4.6**) **5.1** [3.4–7.4]	4 (**1.5**) **2.8** [0.8–7.2]
COVID-19	65 (**10.7**) **26.0** [20.1–33.2]	35 (**11.4**) **28.0** [19.5–38.9]	94 (**15.5**) **19.0** [15.4–23.3]	19 (**7.3**) **14.1** [8.5–22.1]
Petechiae	23 (**3.8**) **8.9** [5.7–13.4]	1 (**0.3**) **0.8** [0.0–4.2]	24 (**4.0**) **4.5** [2.9–6.7]	7 (**2.7**) **5.0** [2.0–10.4]

[a]Transitioned from placebo to remibrutinib after week 24.
AE, adverse event; bid, twice daily; CI, confidence interval; COVID-19, coronavirus disease 2019; EAIR, exposure-adjusted incidence rate; N, total number of patients in each treatment group; n, number of patients; SAE, serious adverse event.

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Disclosures

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