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Remibrutinib Improves Urticaria Symptoms, Quality Of Life, And Sleep: An Analysis From REMIX-1/-2 Studies

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KEY FINDINGS & CONCLUSIONS

- Improvements in UAS7, observed as early as week 1, with remibrutinib are associated with subsequent enhancements in QoL, sleep, and daily activity when compared with placebo
- Overall, remibrutinib showed a favorable safety profile across the REMIX-1 and REMIX-2 studies
- Remibrutinib has the potential to be an effective oral treatment option with fast action to provide early symptom relief and improved QoL, sleep, and daily activity in patients with CSU inadequately controlled with 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]
- In the REMIX-1 and REMIX-2 studies, remibrutinib, an oral, highly selective Bruton's tyrosine kinase inhibitor, has shown superior efficacy at week 12 versus placebo and a favorable safety profile 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 recently been approved by FDA for the treatment of CSU in adult patients who remain symptomatic despite H_1-AH[3]

OBJECTIVE

- This pooled REMIX-1/-2 analysis assessed the relationship between weekly Urticaria Activity Score (UAS7) and Dermatology Life Quality Index (DLQI), weekly Sleep Interference Score (SIS7), and weekly Activity Interference Score (AIS7)

METHODS

Study Design[2]

- 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

Study Assessments and Data Analysis

- UAS7 ranges from 0 to 42, with UAS7 = 0 indicating complete control (urticaria free), 1–6 = well-controlled, 7–15 = mild; 16–27 = moderate, and 28–42 = severe disease[4]
- DLQI scores range from 0 to 30, with DLQI = 0–1 indicating no effect; 2–5 = small effect, 6–10 = moderate effect, 11-20 = very large effect and 21–30 = extremely large effect on patient's QoL[4]
- SIS7 and AIS7 range from 0 to 21 with higher scores indicating severe impact on patients' sleep, and daily activity, respectively. SIS7 = 0 and AIS7 = 0 indicate no interference on sleep and daily activity, respectively[4]
- DLQI was measured at baseline and weeks 4, 12, 24, and 52. UAS7, SIS7, and AIS7 were measured at baseline and then weekly up to week 52
- Data (observed) were analyzed descriptively and presented as mean ± standard error (SE) or percentage. Correlation between UAS7 and other parameters (DLQI/AIS7/SIS7) was calculated using Spearman's correlation coefficient

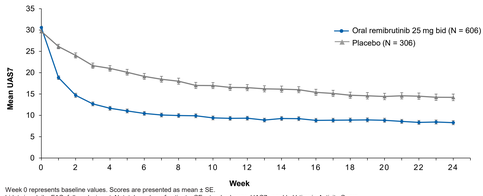
RESULTS

- This analysis included 606 patients in the remibrutinib and 306 patients in the placebo group across the REMIX-1 and REMIX-2 studies, with outcomes assessed over a 24-week period
- Patient demographics and baseline disease characteristics were well-balanced between both the groups in the REMIX-1/-2 studies

Mean UAS7 scores up to week 24

- At baseline, the remibrutinib and placebo group had high UAS7 (mean ± SE: 30.6 ± 0.3 vs 29.7 ± 0.4, respectively) indicating that patients had moderate to severe disease **(Figure 1)**
- Improvements in UAS7 were observed with remibrutinib vs placebo as early as week 1 (18.8 ± 0.4 vs 26.1 ± 0.5) and further improved through week 24 (8.3 ± 0.5 vs 14.2 ± 0.8)
- At week 24, higher proportion of patients in the remibrutinib group vs the placebo group achieved UAS7 = 0 (35.6% [216/606] vs 18% [55/306]) and UAS7 ≤6 (53.3% [323/606] vs 31.4% [96/306])

Figure 1. Mean UAS7 scores up to week 24 (pooled FAS)[a,b]

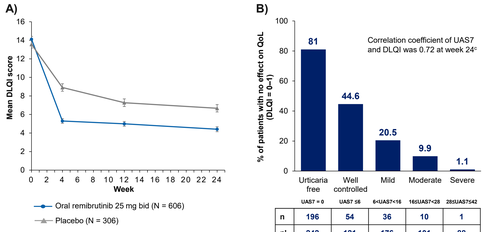


Week 0 represents baseline values. Scores are presented as mean ± SE.
bid, twice daily; FAS, full analysis set; N, total number of patients; SE, standard error; UAS7, weekly Urticaria Activity Score.
[a]Post hoc analysis. [b]Based on descriptive analysis.

Correlation between UAS7 and DLQI

- At baseline, remibrutinib and placebo groups had high mean ± SE DLQI scores (14.1 ± 0.3 and 13.6 ± 0.4), reflecting a very large effect on patients' QoL due to moderate to severe disease
- A greater improvement in DLQI scores was observed with remibrutinib (5.3 ± 0.3) versus placebo (8.9 ± 0.4) at week 4

Figure 2. Mean DLQI scores (A) and percentage of patients with no impact on QoL by disease severity bands independent of treatment (B) at week 24 (pooled FAS)[a,b]



	UAS7 = 0	UAS7 ≤6	6<UAS7<16	16≤UAS7<28	28≤UAS7≤42
n	196	54	36	10	1
n'	242	121	176	101	88

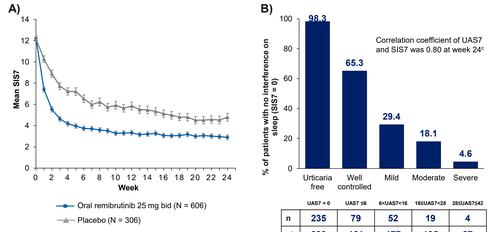
Week 0 represents baseline values. DLQI scores are presented as mean ± SE.
bid, twice daily; DLQI, Dermatology Life Quality Index; FAS, full analysis set; N, total number of patients; n, number of participants with DLQI = 0–1 in the respective UAS7 bands; n', number of participants in each UAS7 band; QoL, quality of life; SE, standard error; UAS7, weekly Urticaria Activity Score.
[a]Post hoc analysis. [b]Based on descriptive analysis. [c]Correlation between UAS7 and DLQI was analyzed using Spearman's correlation coefficient.

- DLQI scores improved through week 24 with remibrutinib (4.4 ± 0.3, small impact) vs placebo (6.7 ± 0.4, moderate impact), indicating an improvement in patients' dermatology-related QoL **(Figure 2A)**
- A reduction in UAS7 was associated with an improvement in patient's dermatology-related QoL **(Figure 2B)**. The correlation between UAS7 and DLQI at week 24 was 0.72, indicating a strong association between the two measures

Correlation between UAS7 and SIS7

- At baseline, patients in the remibrutinib and placebo groups had high mean ± SE SIS7 (12.2 ± 0.2 vs 12.2 ± 0.3), reflecting a high interference on sleep due to moderate to severe disease
- A greater reduction in SIS7 was observed with remibrutinib versus placebo as early as week 1 (7.4 ± 0.2 vs 10.3 ± 0.3), which continued to reduce through week 24 (2.9 ± 0.2 vs 4.8 ± 0.4), indicating sustained improvements in patients' sleep **(Figure 3A)**
- A reduction in UAS7 was associated with an improvement in patient's sleep **(Figure 3B)**. The correlation between UAS7 and SIS7 at week 24 was 0.80, indicating a strong association between the two measures

Figure 3. Mean SIS7 scores (A) and percentage of patients with no impact on sleep by disease severity bands independent of treatment (B) at week 24 (pooled FAS)[a,b]



	UAS7 = 0	UAS7 ≤6	6<UAS7<16	16≤UAS7<28	28≤UAS7≤42
n	235	79	52	19	4
n'	239	121	177	105	87

Week 0 represents baseline values. SIS7 scores are presented as mean ± SE.
bid, twice daily; FAS, full analysis set; N, total number of patients; n, number of participants with SIS7 = 0 in the different UAS7 bands; n', number of participants in the respective UAS7 bands; SE, standard error; SIS7, weekly Sleep Interference Score; UAS7, weekly Urticaria Activity Score.
[a]Post hoc analysis. [b]Based on descriptive analysis. [c]Correlation between UAS7 and AIS7 was analyzed using Spearman's correlation coefficient.

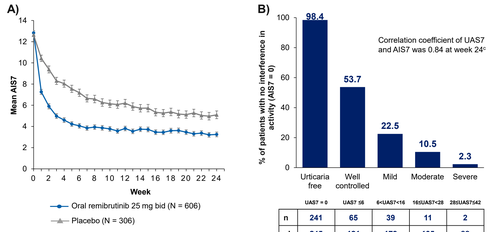
Correlation between UAS7 and AIS7

- At baseline, patients in both groups showed high mean ± SE AIS7 (12.8 ± 0.2 vs 12.6 ± 0.3), indicating high interference in performing daily activities due to moderate to severe disease **(Figure 4A)**
- A greater reduction in AIS7 was observed with remibrutinib vs placebo as early as week 1 (7.3 ± 0.2 vs 10.4 ± 0.3) that continued to reduce through week 24 (3.3 ± 0.2 vs 5.1 ± 0.4), showing improvements in patients' ability to perform daily activities
- A reduction in UAS7 was associated with an improvement in the patients' ability to perform daily activities **(Figure 4B)**. The correlation between UAS7 and AIS7 at week 24 was 0.84, indicating a strong association between the two measures

Overall Safety Profile[2]

- 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 AE up to week 24 was comparable between the remibrutinib (64.9% of patients) and placebo (64.7% of patients) groups

Figure 4. Mean AIS7 scores (A) and percentage of patients with no impact on daily activities by disease severity bands independent of treatment (B) at week 24 (pooled FAS)[a,b]

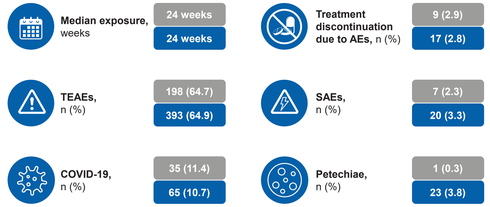


	UAS7 = 0	UAS7 ≤6	6<UAS7<16	16≤UAS7<28	28≤UAS7≤42
n	241	65	39	11	2
n'	245	121	173	105	88

Week 0 represents baseline values. AIS7 scores are presented as mean ± SE.
AIS7, weekly Activity Interference Score; bid, twice daily; FAS, full analysis set; N, total number of patients; n, number of participants with AIS7 = 0 in the respective UAS7 bands; n', number of participants in each UAS7 band; SE, standard error; UAS7, weekly Urticaria Activity Score.
[a]Post hoc analysis. [b]Based on descriptive analysis. [c]Correlation between UAS7 and AIS7 was analyzed using Spearman's correlation coefficient.

- No deaths were reported, and discontinuation of study treatment due to adverse events (AEs) was infrequent. No serious AEs were considered related to study medication by the investigator (**Figure 5**)

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



AE, adverse event; bid, twice daily; COVID-19, coronavirus disease 2019; n, number of patients in each treatment arm; SAE, serious adverse event; TEAE, treatment-emergent adverse event.

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Disclosures

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