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Effect of Remibrutinib on Disease Activity in Patients with Chronic Spontaneous Urticaria: Post hoc Analysis of Phase 3 REMIX-1 and REMIX-2 Studies

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2 Introduction

- **Remibrutinib,** a **novel, oral, highly selective Bruton's tyrosine kinase inhibitor** has demonstrated **superior efficacy** versus placebo and a **favourable safety** profile with up to **24-weeks** of treatment in the **pivotal** double-blind, placebo-controlled **Phase 3** studies **(REMIX-1 and REMIX-2)**[1]
- In previous post hoc analysis of the **Phase 2b** study, **remibrutinib** was associated with a **decrease in CSU disease activity** within **2 weeks** in **>80%** of patients who had **moderate or severe CSU disease activity** at baseline[2]

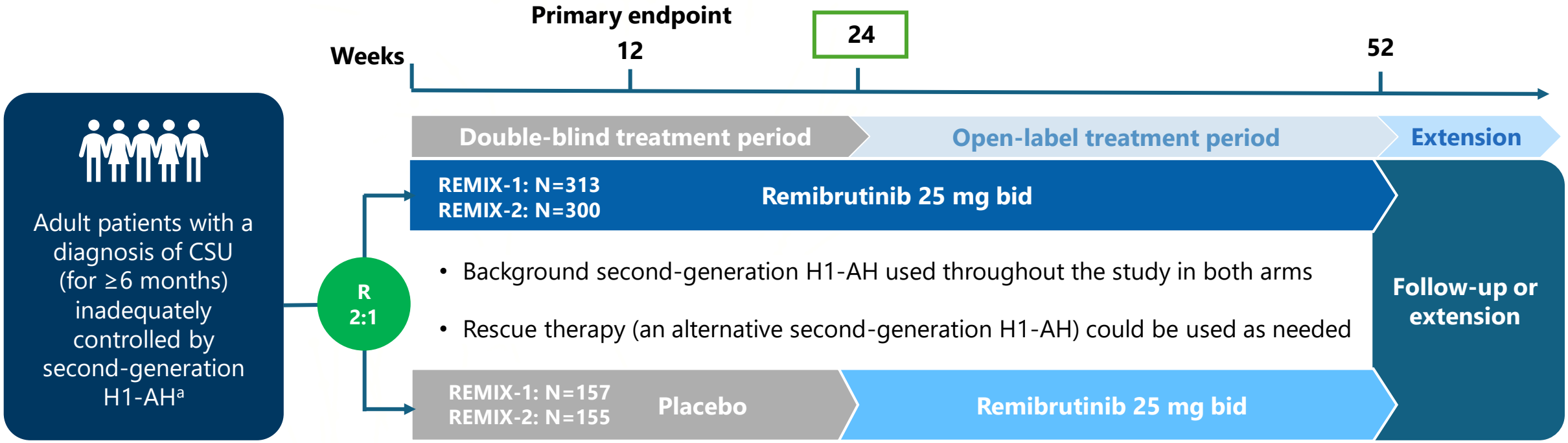
Here, we assess the **shift** in **disease activity** following treatment with **remibrutinib** versus placebo using a post-hoc analysis of the **pooled REMIX-1 & -2** studies in the target patients with **moderate** to **severe CSU disease activity** at baseline

CSU, chronic spontaneous urticaria

1. Saini S, et al. ACAAI 2023. Oral Presentation LB001 – Late-breaker; November 12, 2023; Anaheim, CA. 2. Giménez-Arnau AM, et al. EADV 2023. Oral Presentation FC07.8 – October 11-14, 2023; Berlin, Germany.

2 Study Design

REMIX-1 and REMIX-2 are two Phase 3, randomised, placebo-controlled studies of remibrutinib 25 mg bid administered orally



AH, antihistamine; bid, twice daily; CSU, chronic spontaneous urticaria; H1, histamine 1; HSS7, weekly Hives Severity Score; ISS7, weekly Itch Severity Score; N, number of randomized patients; R, randomisation; UAS7, weekly Urticaria Activity Score.

[a] Presence of itch and hives for ≥6 consecutive weeks prior to screening despite the use of a second-generation H1-antihistamines; UAS7 score ≥16, ISS7 score ≥6, and HSS7 score ≥6 during the 7 days prior to randomization (day 1).

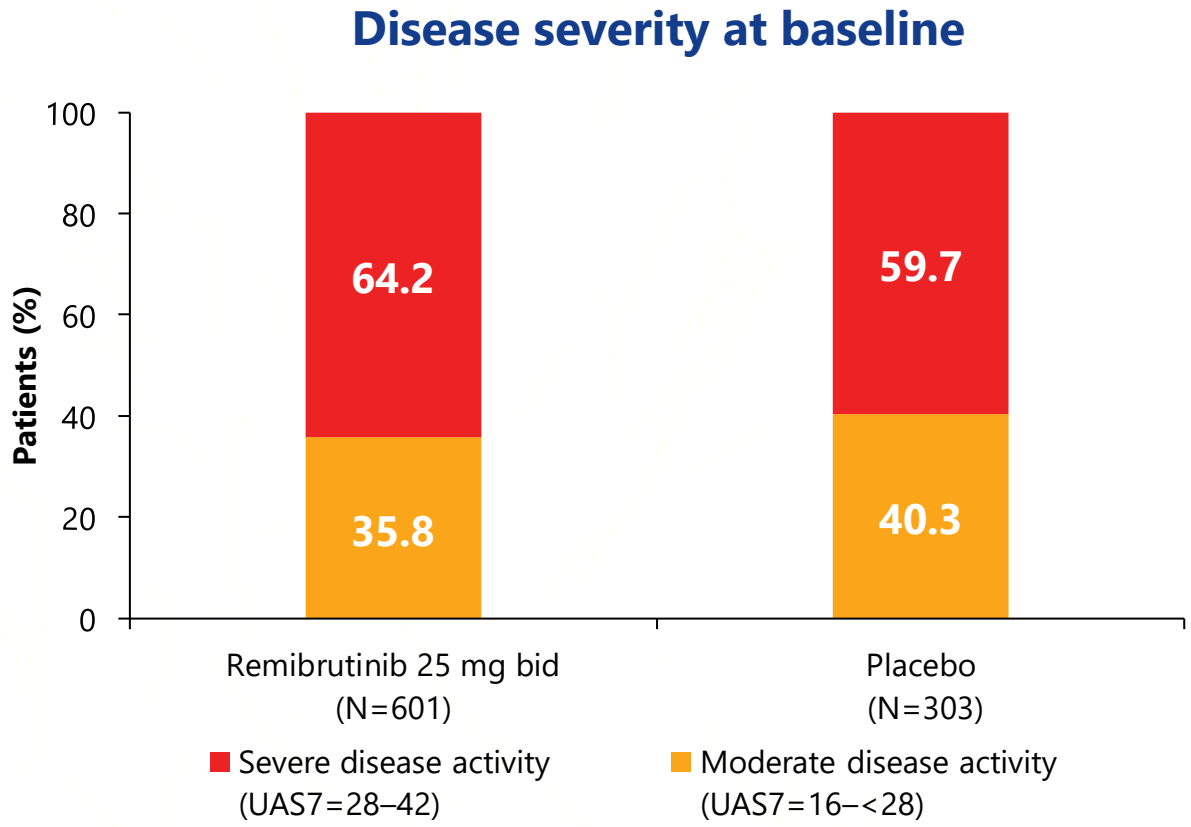
3 CSU Disease Activity was Categorized Into 5 Bands (According to UAS7)

CSU disease activity was defined based on five standard UAS7 bands

The proportion of **patients** with **a shift in CSU disease activity** from **baseline** to **Week 24** in **patients with moderate or severe CSU disease activity** was analysed

CSU, chronic spontaneous urticaria; UAS7, weekly Urticaria Activity Score.
D Stull D, et al. *Br J Dermatol* 2017;177(4):1093-1101.

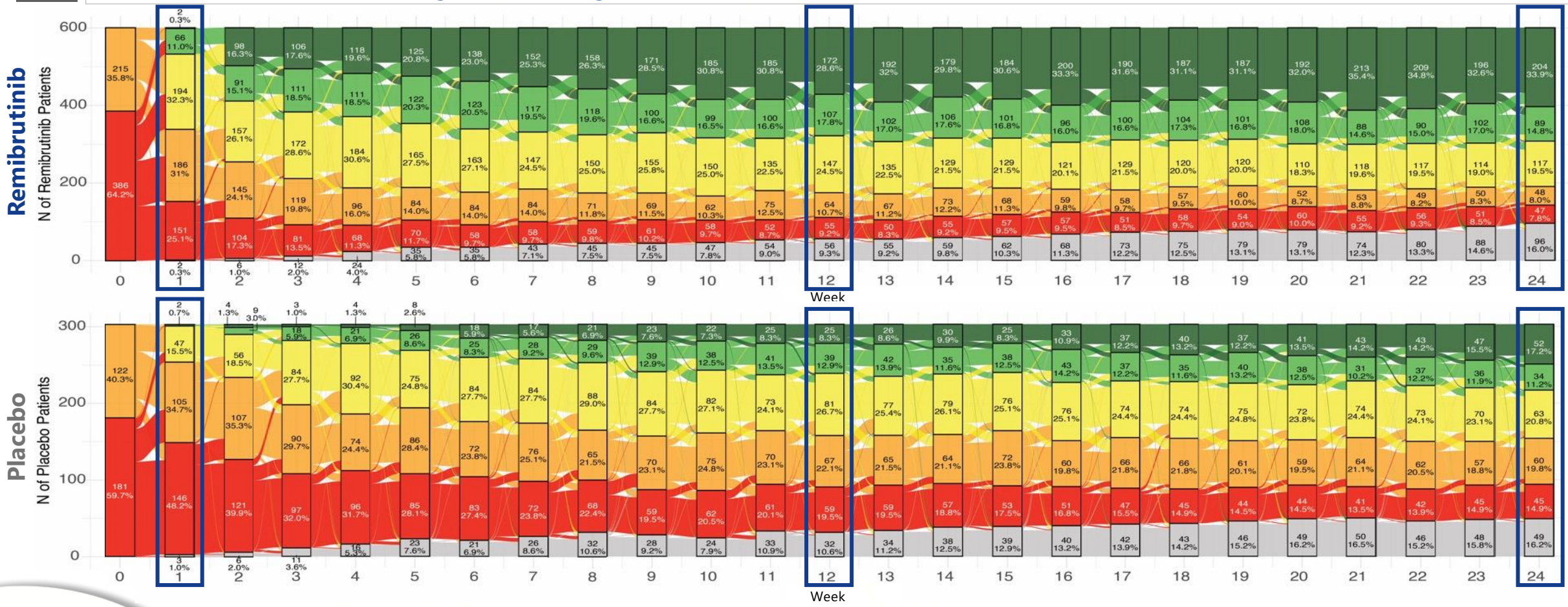
3 The Majority of Patients had Severe CSU Activity at Baseline



bid, twice daily; CSU, chronic spontaneous urticaria; N, number of patients; UAS7, weekly Urticaria Activity Score.

4

Remibrutinib Demonstrated Substantial Improvement (measured by UAS7) in Disease Activity as Early as Week 1



N, number of patients based on full analysis set; UAS7, weekly Urticaria Activity Score.

5 Conclusions

- Following treatment with **remibrutinib,** a **reduction in CSU disease activity** was observed **as early as Week 1, sustained to 24 weeks** of **treatment** in patients with CSU
- Treatment with **remibrutinib** led to **fast improvement** in **symptom control, as early as Week 1** and sustained up to **Week 24**
- **More patients** treated with **remibrutinib** achieved **complete response** (UAS7=0) at **any time point** from **Week 2** up to **Week 24** as compared to placebo

CSU, chronic spontaneous urticaria.