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Impact of remibrutinib on dermatology-related quality of life in patients with chronic spontaneous urticaria in the Phase 3 REMIX-1 and REMIX-2 studies

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*Prof. Maurer M sadly passed away during the development of this poster. His invaluable contribution to this study is honoured with his recognition as a co-author in memoriam

KEY FINDINGS AND CONCLUSIONS

- Remibrutinib demonstrated significant improvements in the dermatology-related quality of life of patients in both REMIX-1 and REMIX-2 studies compared with placebo
- Twice as many patients on remibrutinib compared with those on placebo at week 24 reported no impact of CSU on their quality of life (DLQI = 0–1)
- Nearly half of all patients in the remibrutinib group experienced no further impact of CSU on their quality of life (DLQI = 0–1) at week 24, which was sustained until week 52, despite reporting poor quality of life at baseline
- For patients who received placebo and transitioned to receive remibrutinib after week 24, a comparable improvement in DLQI was achieved at week 52

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INTRODUCTION

- Chronic spontaneous urticaria (CSU) is an unpredictable disease characterised by the spontaneous occurrence of itchy wheals (hives) and/or angioedema lasting for more than 6 weeks.[1] Over 50% of patients with CSU experience inadequate disease control with H1-antihistamines (H1-AH), negatively impacting the quality of life (QoL)[2]
- Remibrutinib, a novel, highly selective, oral Bruton's tyrosine kinase inhibitor, has previously shown superior efficacy versus placebo and a favourable safety profile in 52-week pivotal Phase 3 studies (REMIX-1 and REMIX-2) in patients with CSU inadequately controlled with H1-AHs[3]

OBJECTIVE

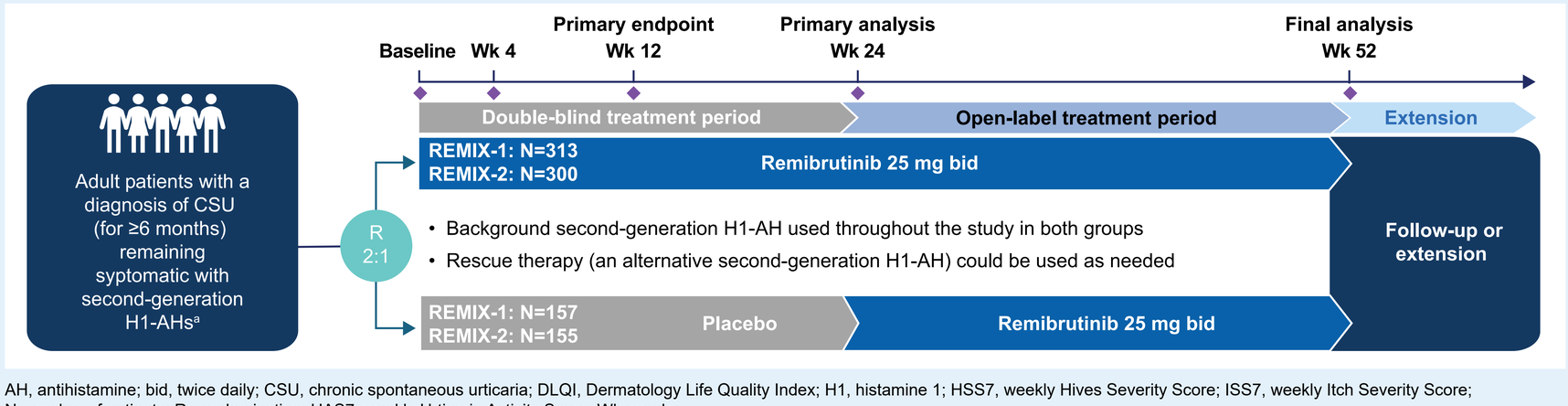
- In this analysis from the REMIX-1 and REMIX-2 studies, we evaluated the effect of long-term remibrutinib treatment up to 52 weeks on dermatology-related QoL

METHODS

Study Design

- REMIX-1 and REMIX-2 are identical, multicentre, randomised, double-blind, placebo-controlled studies assessing the efficacy and safety of remibrutinib in adult patients with CSU remaining symptomatic with second-generation H1-AHs
- Patients were randomised 2:1 to remibrutinib 25 mg twice daily (bid) or placebo over a 24-week double-blind period, followed by a 28-week open-label treatment with remibrutinib 25 mg bid. At week 24, patients on placebo transitioned to remibrutinib (**Figure 1)**

Figure 1. Study design[3]



AH, antihistamine; bid, twice daily; CSU, chronic spontaneous urticaria; DLQI, Dermatology Life Quality Index; H1, histamine 1; HSS7, weekly Hives Severity Score; ISS7, weekly Itch Severity Score; N, number of patients; R, randomisation; UAS7, weekly Urticaria Activity Score; Wk, week.
♦ indicates the time points for DLQI measurements.
[a]Presence of itch and hives for ≥6 consecutive weeks prior to screening despite the use of a second-generation H1-AH; UAS7 ≥16, ISS7 ≥6 and HSS7 ≥6 during the 7 days prior to randomisation (day 1).

Study Assessments and Data Analysis

- Improvement of dermatology-related QoL was assessed as change from baseline of Dermatology Life Quality Index (DLQI) score at weeks 4, 12, 24 and 52
- DLQI scores were also assessed by score bands (0–1, no effect at all on patient's life; 2–5, small effect on patient's life; 6–10, moderate effect on patient's life; 11–20, very large effect on patient's life; 21–30, extremely large effect on patient's life) at baseline and at weeks 4, 12, 24 and 52
- Data were analysed using summary statistics

RESULTS

- Patient demographics and baseline characteristics were well balanced between the remibrutinib and placebo groups in both studies
- At baseline, DLQI scores (mean±SD) in patients receiving remibrutinib versus placebo were 14.2±7.0 versus 13.5±6.8 and 14.0±7.5 versus 13.6±6.7 in REMIX 1 and REMIX 2 studies, respectively (**Table 1**)

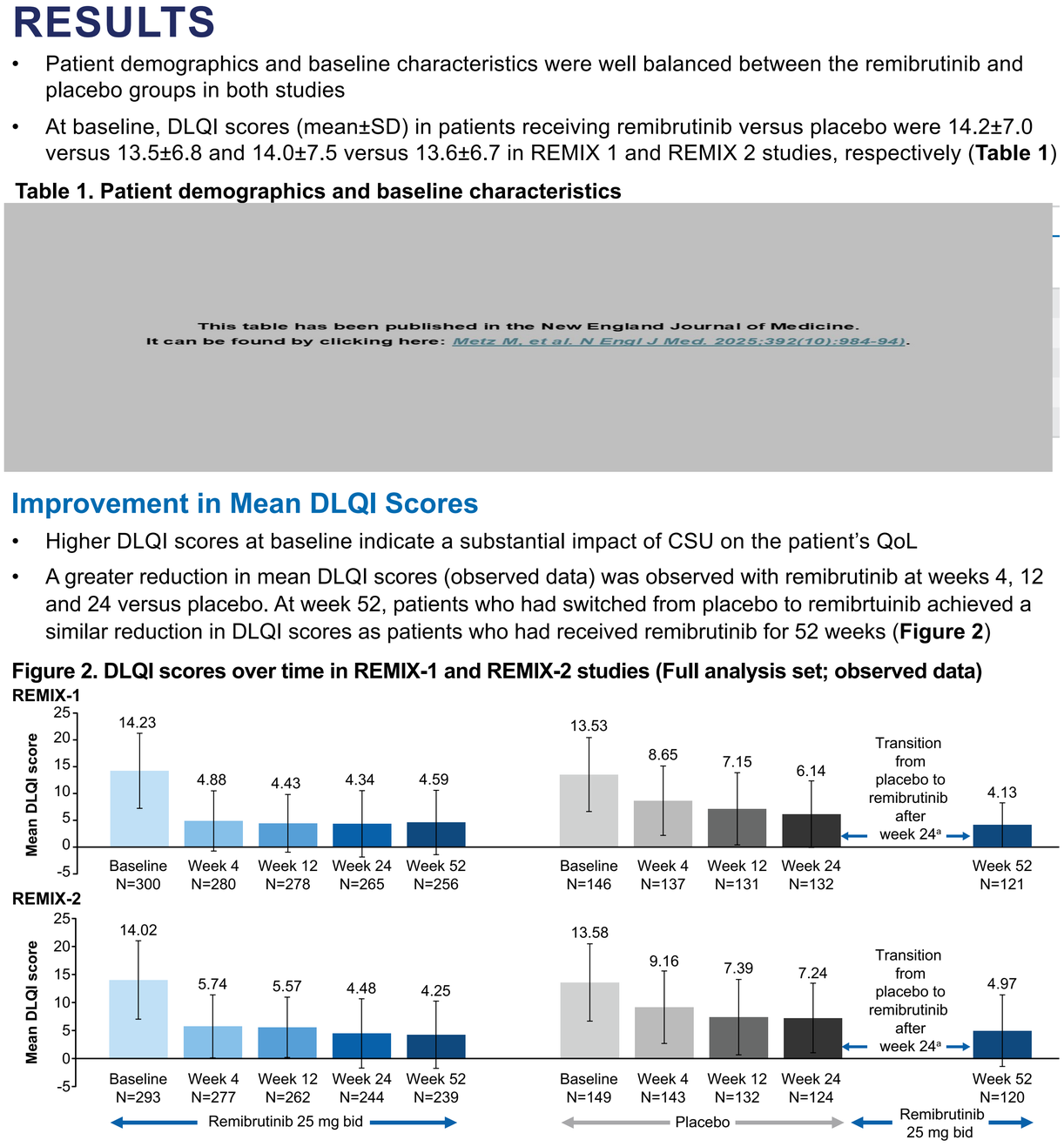
Table 1. Patient demographics and baseline characteristics

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.

Improvement in Mean DLQI Scores

- Higher DLQI scores at baseline indicate a substantial impact of CSU on the patient's QoL
- A greater reduction in mean DLQI scores (observed data) was observed with remibrutinib at weeks 4, 12 and 24 versus placebo. At week 52, patients who had switched from placebo to remibrtuinib achieved a similar reduction in DLQI scores as patients who had received remibrutinib for 52 weeks (**Figure 2**)

Figure 2. DLQI scores over time in REMIX-1 and REMIX-2 studies (Full analysis set; observed data)



All values are presented as mean±standard deviation. For each post-baseline week, only subjects with a value at both baseline and the respective week were included. [a]Patients received placebo up to week 24 and were then reassigned to receive remibrutinib between week 24 and week 52. bid, twice daily; DLQI, Dermatology Life Quality Index. Error bars represent standard deviation.

Proportion of Patients Achieving DLQI Scores of 0–1

- During the double-blind treatment period, the remibrutinib group had consistently higher proportions of patients reporting no impact of CSU on QoL (DLQI=0–1) compared to placebo. Similar DLQI improvements after 24 weeks were seen in patients switched to remibrutinib and patients who recevied remibrutinib for 52 weeks
- In the REMIX-1 study, at week 24, 50.2% of patients in the remibrutinib group achieved DLQI=0–1 compared with 29.9% in the placebo group. At week 52, DLQI=0–1 was achieved by 48.5% of the patients in the remibrutinib group and 45.2% of the patients in the remibrutinib group who had been switched from placebo after week 24
- In the REMIX-2 study, at week 24, 44.5% of patients in the remibrutinib group achieved DLQI=0–1 compared with 22.8% in the placebo group. At week 52, DLQI=0–1 was achieved by 49.0% of patients in the remibrutinib group and 42.6% of the patients in the remibrutinib group who had been switched from placebo after week 24 (**Figure 3**)

Figure 3. Proportion of patients at different DLQI bands in REMIX-1 and REMIX-2 studies (Observed data)[a]

[a]Full analysis set. bid, twice daily; DLQI, Dermatology Life Quality Index.

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Disclosures

John Reed reports role as a medical advisor and has participated in educational activities for Novartis. **Martin Metz** is or recently was a speaker and/or advisor for AbbVie, Almirall, ALK-Abello, Amgen, AstraZeneca, Argenx, Bayer, Beiersdorf, Celldex, Celltrion, Escient, Galderma, GlaxoSmithKline, Incyte, Jasper, Novartis, Pharvaris, Pfizer, Regeneron, Sanofi, Teva, Third Harmonic Bio and Vifor. **Sarbjit Saini** has received grant/research/clinical trial support from the National Institutes of Health, Novartis, Sanofi, Amgen and Regeneron and is a consultant/advisory board member for Allakos, Granular Therapeutics, Novartis, Aquestive, Regeneron, Escient, Innate, Celltrion and Sanofi. **Robert Szalewski** serves as a speaker for AstraZeneca and Pharming and has received clinical trial support and/or consulting fees from Genentech, Sanofi, Arcutis, AstraZeneca, GlaxoSmithKline, AbbVie, Amgen, Novartis, Areteia and Regeneron. **Mark Lebwohl** is an employee of Mount Sinai and receives research funds from AbbVie, Amgen, Arcutis, Avotres, Boehringer Ingelheim, Dermavant Sciences, Eli Lilly, Incyte, Janssen Research & Development, LLC, Ortho Dermatologics, Regeneron and UCB Inc. and is a consultant for Aditum Bio, Almirall, AltruBio Inc., AnaptysBio, Arcutis, Aristea Therapeutics, Arrive Technologies, Avotres Therapeutics, BiomX, Boehringer Ingelheim, Bristol Myers Squibb, Cara Therapeutics, Castle Biosciences, Corrona, Dermavant Sciences, Dr Reddy's Laboratories, Evelo Biosciences, Evommune Inc., Facilitation of International Dermatology Education, Forte Biosciences, Foundation for Research and Education in Dermatology, Helsinn Therapeutics, Hexima Ltd, LEO Pharma, Meiji Seika Pharma, Mindera, Pfizer, Seanergy and Verrica. **Gordon Sussman** has received research support from Aimmune, Amgen, AstraZeneca, DBV Technologies, Genentech, Kedrion S.p.A., LEO Pharma, Novartis, Nuvo Pharmaceuticals, Sanofi, Stallergenes, Merck, Schering Plough, Regeneron and ALK; is a medical advisor and/or has received payment for lectures from Merck, Novartis, CSL Behring, Pfizer, Anaphylaxis Canada, the Allergy Asthma and Immunology Society of Ontario and the Canadian Hereditary Angioedema Network. **Sibylle Haemmerle** is an employee of Novartis Pharma AG, Basel, Switzerland. **Noriko Seko** is an employee of Novartis Pharma KK, Tokyo, Japan. **Pengpeng Wang** is an employee of Novartis (China) Biomedical Research, Shanghai, China. **Clarice Field** is an employee of Novartis Ireland, Dublin, Ireland. **Michael Palumbo** serves as a speaker for AstraZeneca, CSL Behring, Grifols, Regeneron, Sanofi-Genzyme and Amgen.

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