Giselle Mosnaim
gmosnaim@gmail.com

Remibrutinib Showed Sustained Efficacy and Favorable Safety Profile Through Week 52 in Chronic Inducible Urticaria

Ana Maria Giménez-Arnau,[1] Luis Felipe Ensina,[2] Silvia Mariel Ferrucci,[3] Lindsey Finklea,[4] Atsushi Fukunaga,[5] Koremasa Hayama,[6] Michihiro Hide,[7] Johannes S. Kern,[8] Moisés Labrador-Horrillo,[9] Philip H. Li,[10] **Giselle Mosnaim,**[11] John Reed,[12] Heike Rockmann,[13] Sarbjit Saini,[14] Petra Staubach,[15] Sebastian Volc,[16] Jinhua Xu,[17] Bin Yang,[18] Alis Burciu,[19] Li Chen,[20] Clarice Field,[21] Sibylle Haemmerle,[19] Karine Lheritier,[19] Christine-Elke Ortmann,[19] Miriam Porter,[19] Wei Wang,[22] Martin Metz[23]

[1]Department of Dermatology, Hospital del Mar and Research Institute, Universitat Pompeu Fabra, Barcelona, Spain
[2]CPAlpha Clinical Research Center, Barueri, Brazil
[3]Dermatology Unit, Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milan, Italy
[4]The University of Texas Health Science Center at San Antonio, San Antonio, TX, USA
[5]Osaka Medical and Pharmaceutical University, Takatsuki, Osaka, Japan
[6]Division of Cutaneous Science, Department of Dermatology, Nihon University School of Medicine, and Center for Allergy, Nihon University Itabashi Hospital, Tokyo, Japan
[7]Department of Dermatology, Hiroshima City Hiroshima Citizens Hospital, and Department of Dermatology, Hiroshima University, Hiroshima, Japan
[8]Department of Immunology, the School of Translational Medicine, Monash University and Department of Dermatology, Bayside Health – The Alfred, Melbourne, VIC, Australia
[9]Department of Allergy, Hospital Universitari Vall d'Hebron, Allergy Research Unit, Institut de Recerca Vall d'Hebron (VHIR), and Department of Medicine, Universitat Autònoma de Barcelona, Barcelona, Spain
[10]Division of Rheumatology and Clinical Immunology, Department of Medicine, Queen Mary Hospital, the University of Hong Kong, Pokfulam, Hong Kong
[11]Division of Allergy and Immunology, Department of Medicine, Endeavor Health, Evanston, IL, USA
[12]Department of Dermatology, Churchill Hospital, University of Oxford, Oxford, UK
[13]Department of Dermatology and Allergology, University Medical Centre Utrecht, Utrecht University, Utrecht, The Netherlands
[14]Johns Hopkins Asthma and Allergy Center, Baltimore, MD, USA
[15]Department of Dermatology, University Medical Center Mainz, Mainz, Germany
[16]University Dermatology Clinic, Tübingen University Hospital, Eberhard Karls University of Tübingen, Tübingen, Germany
[17]Department of Dermatology, Huashan Hospital, Fudan University and Shanghai Institute of Dermatology, Shanghai, China
[18]Dermatology Hospital, Southern Medical University, Guangzhou, China
[19]Novartis Pharma AG, Basel, Switzerland
[20]Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA
[21]Novartis Ireland Limited, Dublin, Ireland
[22]China Novartis Institutes for Biomedical Research Co., Ltd, Shanghai, China
[23]Institute of Allergology, Charité–University Medical Center Berlin, corporate member of Freie Universität Berlin and Humboldt Universität zu Berlin and Fraunhofer Institute for Translational Medicine and Pharmacology ITMP, Immunology and Allergology, Berlin, Germany

Disclosures and Acknowledgements

In relation to this presentation, the following real or perceived conflicts of interest were declared:

- **Giselle Mosnaim** receives current research grant support from ARS Pharma, AstraZeneca, Areteia, Blueprint, Celldex, Generate:Biomedicines, Genentech, GSK, Novartis, Sanofi, Regeneron, and Teva and receives consulting, advisory board, and/or speaking fees from Abbott, Amgen, AstraZeneca, Chiesi, Incyte, Genentech, GSK, Jasper, Eli Lilly, Novartis, Sanofi, Regeneron, and Teva.

The authors wish to thank all patients and physicians who participated in the study

Funding: This study was funded by Novartis Pharma AG, Basel, Switzerland.

This presentation was developed in accordance with Good Publication Practice (GPP3) guidelines. Authors had full control of the content and made the final decision on all aspects of this publication. Medical writing support was provided by Sofya S Perelman, PhD, and Michelle Chadwick, PhD, CMPP (Nucleus Global, an Inizio company) and was funded by Novartis Pharmaceuticals Corporation.

Scan to obtain

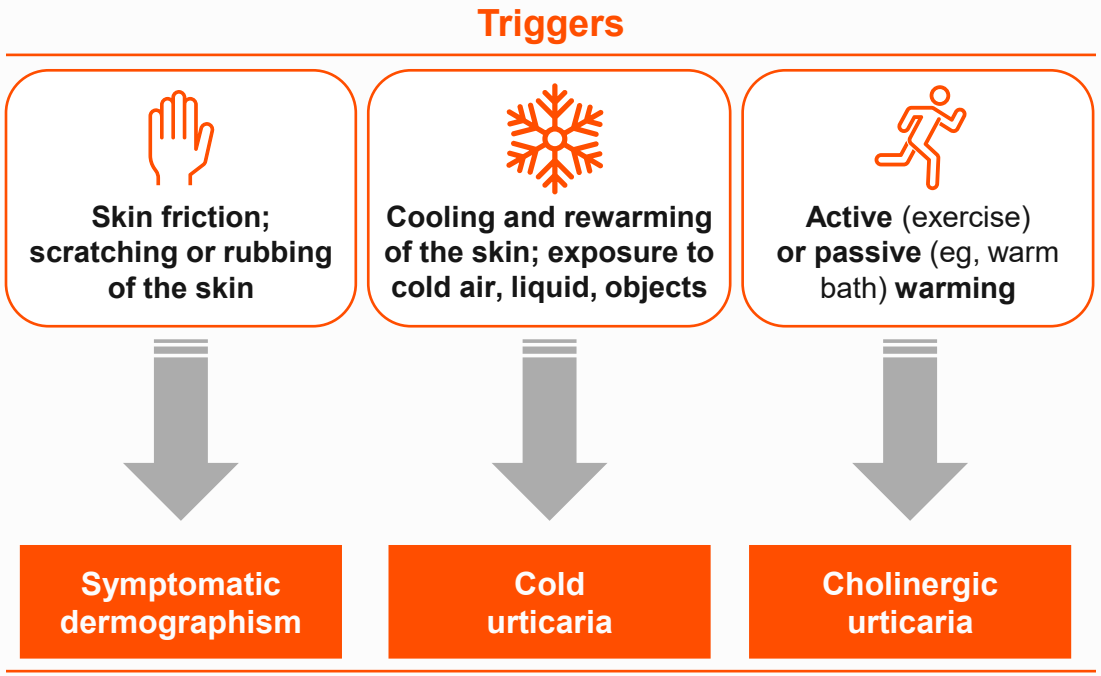
- **Presentation slides**

Copies of this presentation obtained through Quick Response (QR) code are for personal use only and may not be reproduced without permission of the authors.

Introduction: Chronic Inducible Urticaria

- **CIndU** is characterized by **itchy hives and/or angioedema** triggered by **common stimuli** and lasting >6 weeks, substantially **impacting quality of life**[1-7]
- **Avoiding triggers is recommended for disease management** and can reduce the occurrence of symptoms; however, it often **imposes severe restrictions** on daily activities, further contributing to the disease burden[1-4]
- **Over half of patients with CIndU remain symptomatic** despite treatment with guideline-recommended, standard-dose second-generation H_1-AHs[1,2,8-10]
- **Despite guideline-recommended treatment options, none are approved in CIndU**[1,2]

Most Prevalent CIndU Subtypes[3,11]



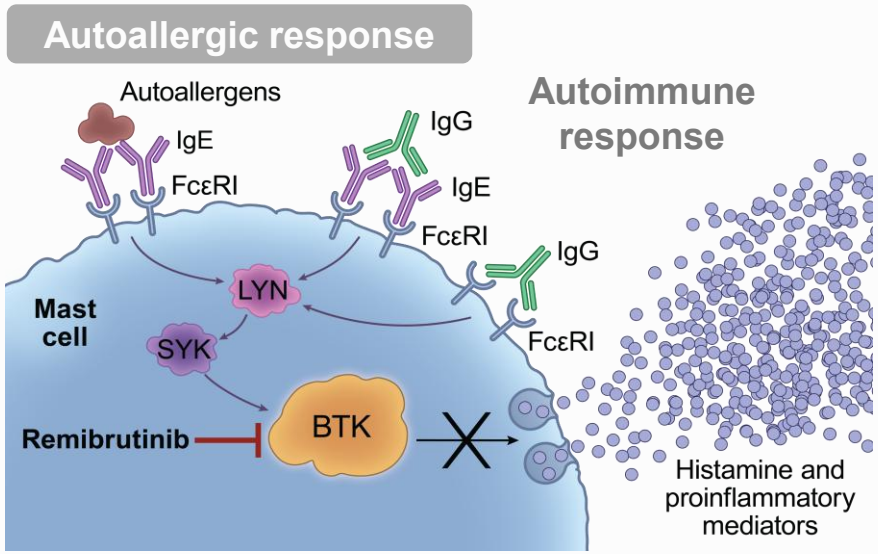
Mosnaim G, et al. Oral presented at: EAACI 2026; June 12-15, 2026; Istanbul, Türkiye. Abstract 100213. Adapted with permission by the author.[11]

AH, antihistamine; CIndU, chronic inducible urticaria; H_1, histamine 1.

1. Zuberbier T, et al. *Allergy.* 2026;81(8):2582-2632. 2. Muñoz M, et al. *Curr Allergy Asthma Rep.* 2024;24(8):457-469. 3. Kolkhir P, et al. *Nat Rev Dis Primers*. 2022;8(1):61. 4. Altrichter S, et al. *Front Allergy.* 2022;3:867227. 5. Fukunaga A, et al. *Am J Clin Dermatol.* 2023;24(1):41-54. 6. Schoepke N, et al. *J Eur Acad Dermatol Venereol.* 2015;29(4):708-712. 7. Winders T, et al. *Allergy.* 2025;80:S129. 8. Pereira ARF, et al. *Einstein (Sao Paulo).* 2020;18:eAO5175. 9. Kocatürk E, et al. *J Dermatol Sci.* 2017;87(1):60-69. 10. Ozdemir SO, et al. *Int Arch Allergy Immunol.* 2024;185(11):1055-1065. 11. Mosnaim G, et al. Oral presented at: EAACI 2026; June 12-15, 2026; Istanbul, Türkiye. Abstract 100213.

Introduction

Remibrutinib Mechanism of Action[1,2]



Saini S, et al. Oral presented at ACAAI Annual Scientific Meeting 2023. Abstract LB001. Adapted with permission by the author.[1]

- **Remibrutinib is an oral, highly selective BTK inhibitor with an early onset of action (observed as soon as week 1), sustained efficacy, and a favorable long-term safety profile in CSU[3-6]**
- In the US, EU, and other countries, **remibrutinib 25 mg twice daily is approved for adults with CSU who remain symptomatic despite H_1-AH treatment[4,7]**
- **In the phase 3 RemIND study, remibrutinib demonstrated superiority over placebo for complete symptom control at week 12 following provocation testing across CIndU subtypes (SD, ColdU, and CholU)[8]**
- **Remibrutinib has been recently approved in the US for adults with SD who remain symptomatic despite H_1-AH treatment, representing the first approved treatment for the most frequent CIndU subtype[4,7]**

Objective To report efficacy, safety, and tolerability of remibrutinib through **week 52** from the **phase 3 RemIND study**

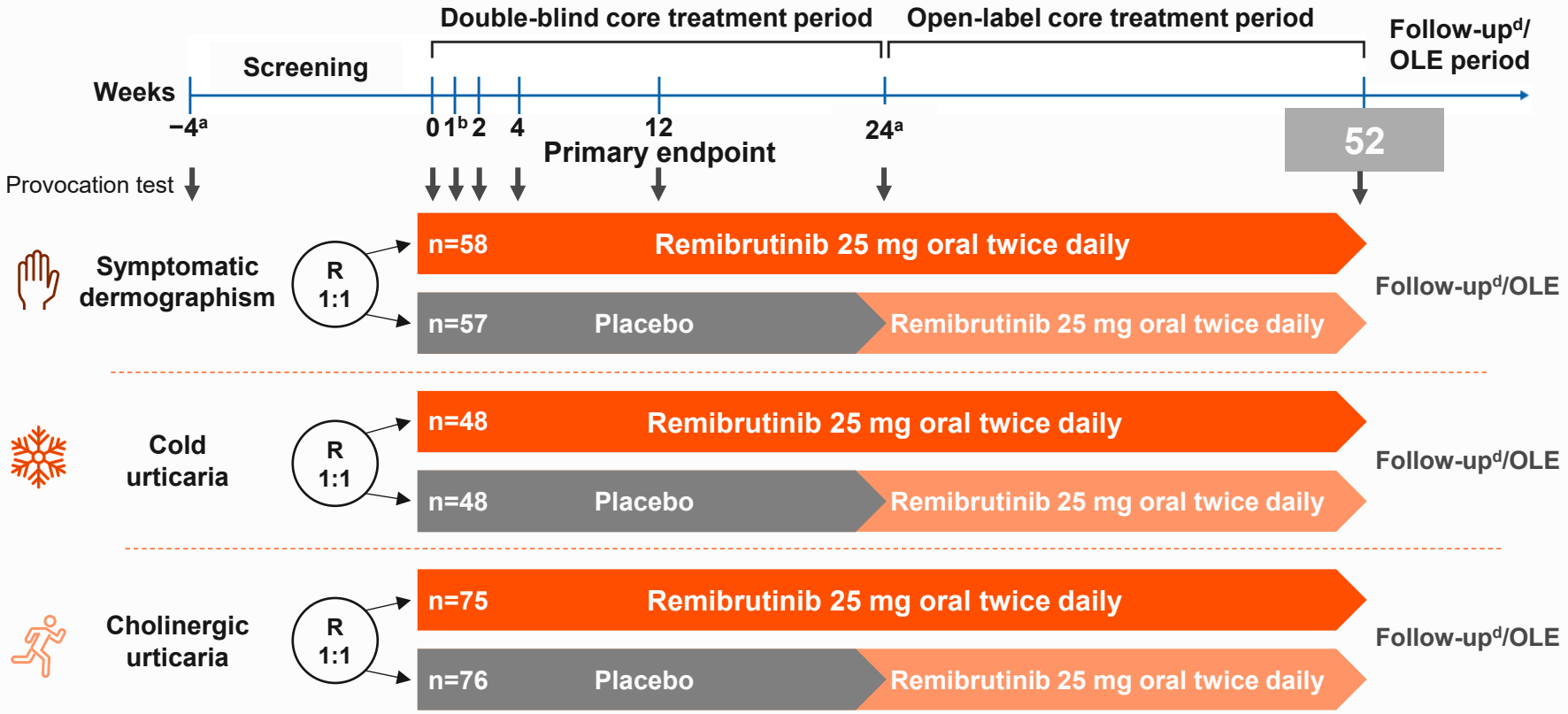
AH, antihistamine; BTK, Bruton's tyrosine kinase; CholU, cholinergic urticaria; CIndU, chronic inducible urticaria; ColdU, cold urticaria; CSU, chronic spontaneous urticaria; **Fc**εRI, high-affinity IgE receptor; H_1, histamine 1; Ig, immunoglobulin; LYN, LCK/YES novel tyrosine kinase; SD, symptomatic dermographism; SYK, spleen tyrosine kinase.

1. Saini S, et al. Oral presented at: ACAAI Annual Scientific Meeting 2023; November 9-13, 2023; Anaheim, CA. Abstract LB001. 2. Muñoz M, et al. *Curr Allergy Asthma Rep.* 2024;24(8):457-469. 3. Pulz R, et al. *Eur J Pharmacol.* 2025;1002:177747. 4. Rhapsido (remibrutinib). Prescribing information. Novartis Pharmaceuticals Corporation; 2026. 5. Metz M, et al. *N Engl J Med.* 2025;392:984-994. 6. Giménez-Arnau AM, et al. *J Allergy Clin Immunol.* 2026;157(1):143-154. 7. Novartis. News release. Accessed October 27, 2026. https://www.novartis.com/us-en/news/media-releases/novartis-rhapsido-remibrutinib-receives-fda-approval-first-treatment-symptomatic-dermographism-sd-expanding-its-use-beyond-chronic-spontaneous-urticaria-csu 8. Mosnaim G, et al. Oral presented at: EAACI 2026; June 12-15, 2026; Istanbul, Türkiye. Abstract 100213.

RemIND Study: Week 52 Analysis

Adults with a diagnosis of CIndU (for ≥4 months) who remain symptomatic with sgH_1-AHs

- Background sgH_1-AH use was required
- Rescue medication was used as needed[c]



Mosnaim G, et al. Oral presented at: EAACI 2026; June 12-15, 2026; Istanbul, Türkiye. Abstract 100213. Adapted with permission by the author.

- **RemIND** is a global, phase 3, randomized, double-blind, placebo-controlled basket study (a single study with 3 independent cohorts by CIndU subtype) of remibrutinib 25 mg twice daily vs placebo in adults with CIndU
- Efficacy was assessed for each subtype; safety data were from a pooled analysis across subtypes

AH, antihistamine; CIndU, chronic inducible urticaria; H_1, histamine 1; OLE, open-label extension; R, randomization; sg, second generation.
[a] Ice cube test for cold urticaria (diagnostic and threshold assessment). [b] Provocation test for symptomatic dermographism and cold urticaria only (diagnostic and threshold assessment). [c] sgH_1-AH as needed (different from the background H_1-AH, dose ≤4× the approved dose); oral corticosteroids (≤3 days) allowed after week 24. [d] Treatment-free safety follow-up for 28 days after last dose for patients not entering into the OLE period.
Mosnaim G, et al. Oral presented at: EAACI 2026; June 12-15, 2026; Istanbul, Türkiye. Abstract 100213.

Assessments and Endpoints

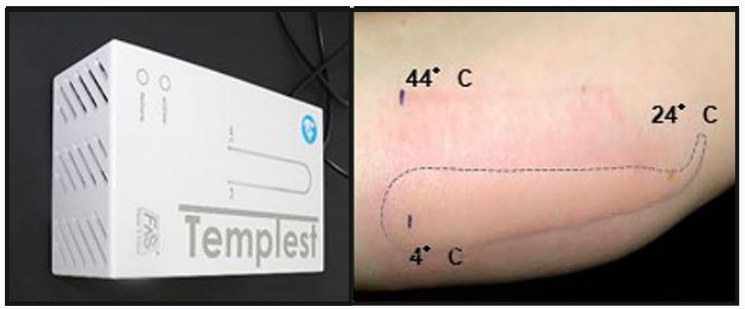
Symptomatic dermographism

FricTest®



Cold urticaria

TempTest®



Cholinergic urticaria

Pulse-controlled ergometry test



Adapted from Muñoz M, et al. *Curr Allergy Asthma Rep.* 2024;24(8):457-469. Licensed under Creative Commons Attribution 4.0 International License (https://creativecommons.org/licenses/by/4.0/).

Primary endpoints:

- **Proportion of patients with complete response** to FricTest (TFS=0), TempTest (CTT<4°C [39.2°F]), or pulse-controlled ergometry test (itch NRS score=0)[a] **at week 12[b]**

Exploratory and post hoc analyses:

- **Proportion of patients with complete response over time through week 52**
  - In patients who did not achieve complete response: **proportion of patients with partial response** (reductions from baseline of ≥2 in TFS, ≥4°C [7.2°F] in CTT, and ≥2 in itch NRS) **over time through week 52**

CIndU, chronic inducible urticaria; CTT, Critical Temperature Threshold; NRS, Numeric Rating Scale; TFS, Total Fric Score.
[a] Itch NRS (11-point scale) was assessed 10 minutes after the provocation test. [b] Provocation test and complete response definition are CIndU subtype specific. Each cohort is analyzed independently.

Patient Demographics and Baseline Characteristics[a]

	Symptomatic dermographism		Cold urticaria		Cholinergic urticaria	
	Remibrutinib 25 mg twice daily (n=58)	Placebo (n=57)	Remibrutinib 25 mg twice daily (n=48)	Placebo (n=48)	Remibrutinib 25 mg twice daily (n=75)	Placebo (n=76)
Age, mean (SD)**, years**	**40.0** (12.04)	**38.5** (12.47)	**43.6** (14.98)	**43.9** (13.14)	**32.7** (12.16)	**33.7** (13.56)
Female, %	**69.0**	**73.7**	**81.3**	**83.3**	**30.7**	**39.5**
UCT7, mean (SD)	**6.55** (4.25)	**6.58** (3.52)	**7.38** (3.48)	**7.65** (3.88)	**6.18** (3.28)	**6.49** (3.47)
DLQI score, mean (SD)	**10.11** (7.53)	**10.00** (6.03)	**9.40** (7.04)	**8.37** (5.84)	**12.31** (6.74)	**12.39** (7.18)
Prior use of sgAHs, %						
Licensed dose	**55.2**	**57.9**	**54.2**	**75.0**	**52.0**	**44.7**
Updosed	**44.8**	**42.1**	**43.8**	**25.0**	**48.0**	**55.3**
No prior	**0**	**0**	**2.1**	**0**	**0**	**0**
Duration of CIndU, mean (SD)**, years**	**6.76** (8.13)	**4.88** (6.29)	**11.36** (13.00)	**13.61** (11.22)	**5.54** (5.45)	**6.91** (7.34)

Mosnaim G, et al. Oral presented at: EAACI 2026; June 12-15, 2026; Istanbul, Türkiye. Abstract 100213. Adapted with permission by the author.

- Patient demographics and baseline characteristics were generally balanced across remibrutinib and placebo arms

AH, antihistamine; CIndU, chronic inducible urticaria; DLQI, Dermatology Life Quality Index; sg, second generation; UCT7, weekly Urticaria Control Test.
[a] Randomized set.
Mosnaim G, et al. Oral presented at: EAACI 2026; June 12-15, 2026; Istanbul, Türkiye. Abstract 100213.

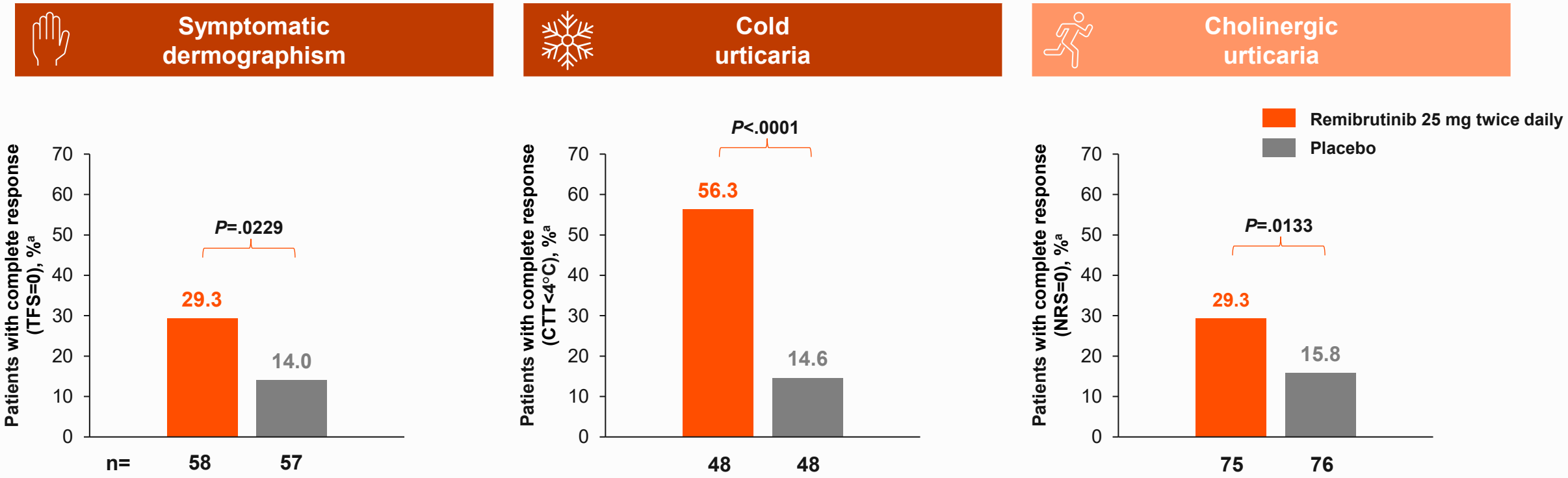
Patient Disposition During the Entire Core Treatment Period[a]

% (n)	Symptomatic dermographism		Cold urticaria		Cholinergic urticaria	
	Remibrutinib 25 mg twice daily (n=58)	Placebo-remibrutinib 25 mg twice daily (n=57)	Remibrutinib 25 mg twice daily (n=48)	Placebo-remibrutinib 25 mg twice daily (n=48)	Remibrutinib 25 mg twice daily (n=75)	Placebo-remibrutinib 25 mg twice daily (n=76)
Completed core treatment period	**84.5** (49)	**75.4** (43)	**83.3** (40)	**77.1** (37)	**80.0** (60)	**73.7** (56)
Discontinued core treatment period	**15.5** (9)	**24.6** (14)	**16.7** (8)	**22.9** (11)	**20.0** (15)	**26.3** (20)
Primary reason for discontinuation of core treatment period[b]						
Patient decision	**8.6** (5)	**14.0** (8)	**10.4** (5)	**16.7** (8)	**13.3** (10)	**18.4** (14)
Adverse event	**5.2** (3)	**1.8** (1)	**2.1** (1)	**2.1** (1)	**5.3** (4)	**7.9** (6)
Loss to follow-up	**0**	**1.8** (1)	**4.2** (2)	**4.2** (2)	**0**	**0**
Pregnancy	**0**	**3.5** (2)	**0**	**0**	**1.3** (1)	**0**
Physician decision	**0**	**3.5** (2)	**0**	**0**	**0**	**0**
Protocol deviation	**1.7** (1)	**0**	**0**	**0**	**0**	**0**

- Rates of treatment discontinuation during the entire core treatment period through week 52 were low

[a] Randomized set. “Placebo-remibrutinib 25 mg twice daily” includes patients initially randomized to placebo. [b] The primary reason for discontinuation as given by the investigator on the treatment disposition electronic Case Report Form is summarized.

A Statistically Significantly Higher Proportion of Patients Achieved Complete Response With Remibrutinib vs Placebo at Week 12[a]



Mosnaim G, et al. Oral presented at: EAACI 2026; June 12-15, 2026; Istanbul, Türkiye. Abstract 100213. Adapted with permission by the author.

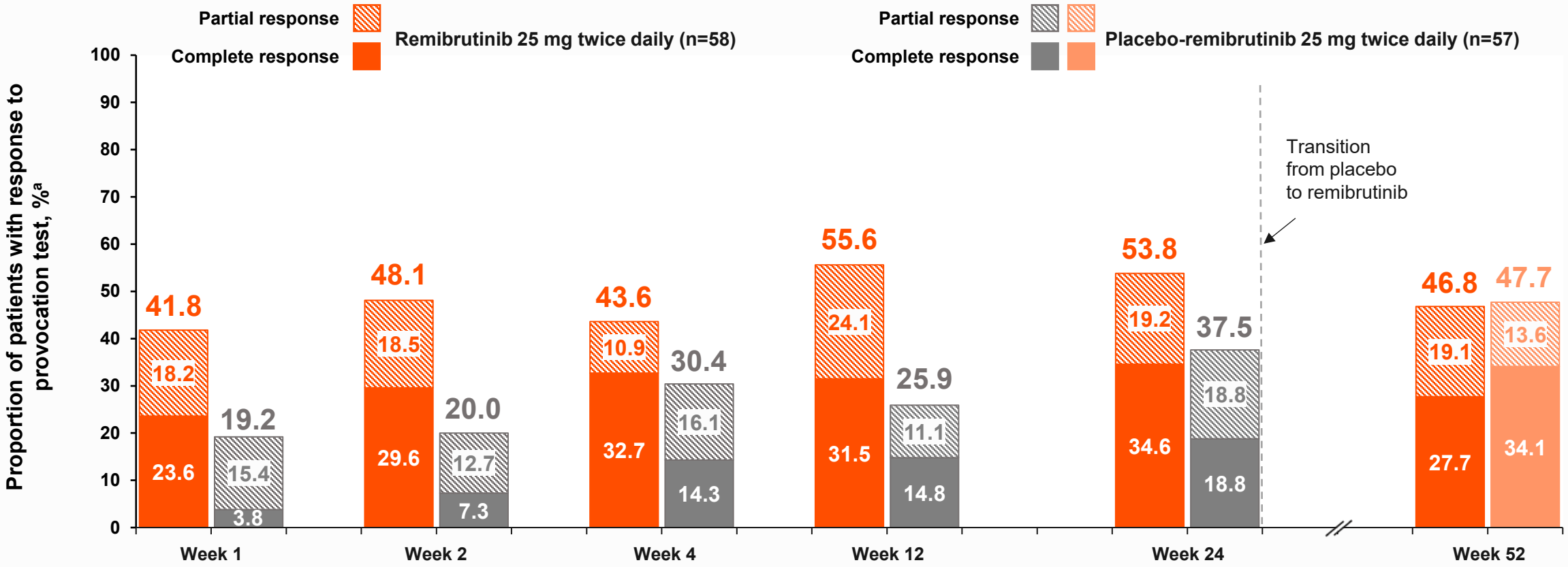
- **In the primary analysis, remibrutinib demonstrated superiority vs placebo** for the proportion of patients achieving complete response **at week 12 in all 3 CIndU subtypes evaluated** *(primary endpoint)*

CIndU, chronic inducible urticaria; CTT, Critical Temperature Threshold; NRS, Numeric Rating Scale; TFS, Total Fric Score.

[a] Full analysis set. Primary endpoint. Statistical model used logistic regression adjusting for treatment group, geographic region, and baseline score. All intercurrent events are handled by treatment policy with multiple imputation. One-sided *P*-values are shown.

Mosnaim G, et al. Oral presented at: EAACI 2026; June 12-15, 2026; Istanbul, Türkiye. Abstract 100213.

Higher Rates of Complete or Partial Response Were Achieved in Patients With Symptomatic Dermographism Treated With Remibrutinib vs Placebo[a]

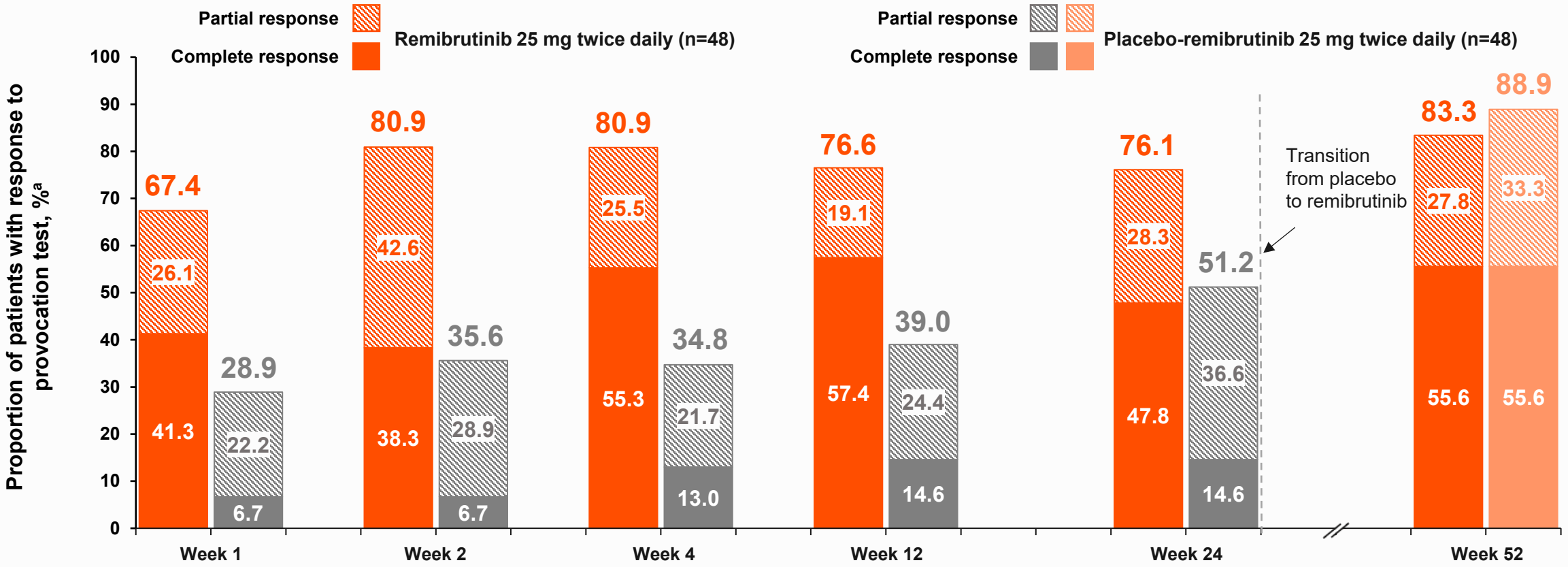


- **Numerically higher rates of complete or partial response** were achieved in patients with **symptomatic dermographism** treated with remibrutinib vs placebo **as early as week 1**[b]
- **At week 52, similar response rates were reported in patients who transitioned from placebo to remibrutinib**

TFS, Total Fric Score.

[a] Full analysis set; observed data. Only patients with a value at both baseline and post baseline were evaluable for the derivation of the response status. Complete response: TFS=0; partial response: reduction from baseline of ≥2 in TFS in patients who did not achieve complete response. [b] The earliest time point assessed.

Higher Rates of Complete or Partial Response Were Achieved in Patients With Cold Urticaria Treated With Remibrutinib vs Placebo[a]

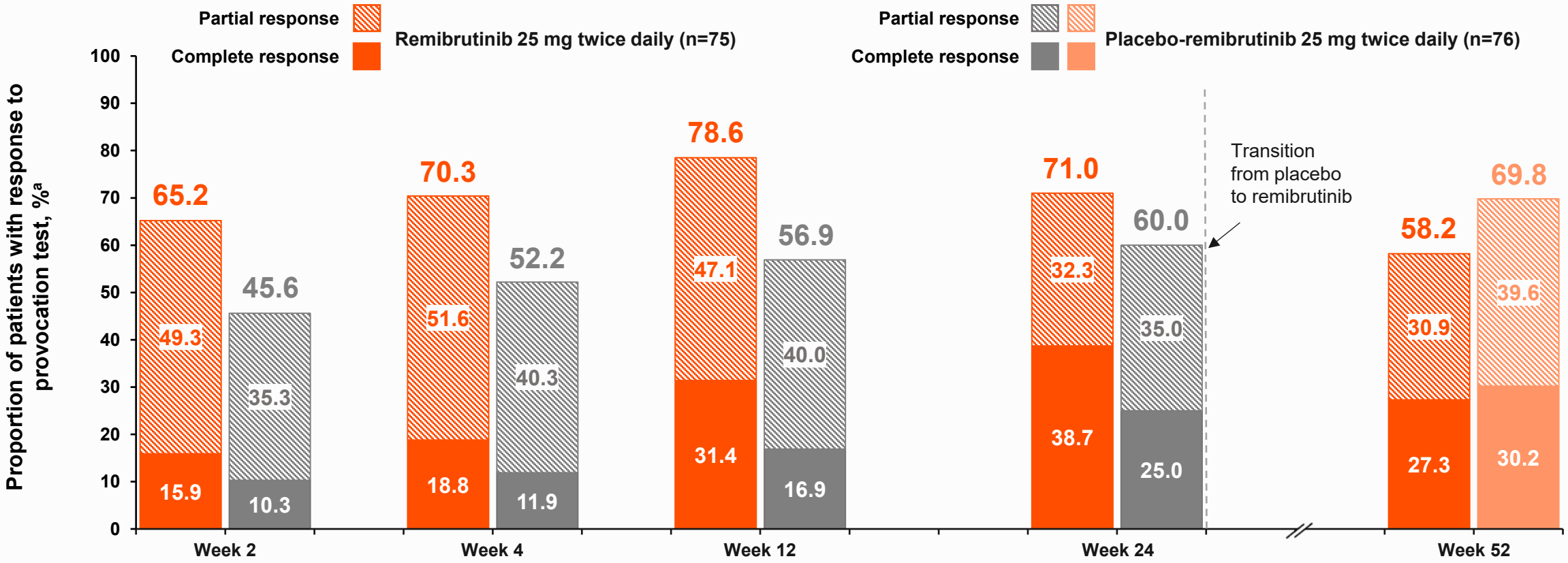


- **Numerically higher rates of complete or partial response** were achieved in patients with **cold urticaria** treated with remibrutinib vs placebo **as early as week 1**[b]
- **At week 52, similar response rates were reported in patients who transitioned from placebo to remibrutinib**

CTT, Critical Temperature Threshold.

[a] Full analysis set; observed data. Only patients with a value at both baseline and post baseline were evaluable for the derivation of the response status. Complete response: CTT<4°C (39.2°F); partial response: reduction from baseline of ≥4°C (7.2°F) in CTT in patients who did not achieve complete response. [b] The earliest time point assessed.

Higher Rates of Complete or Partial Response Were Achieved in Patients With Cholinergic Urticaria Treated With Remibrutinib vs Placebo[a]



- **Numerically higher rates of complete or partial response** were achieved in patients with **cholinergic urticaria** treated with remibrutinib vs placebo **as early as week 2**[b]
- **At week 52, similar response rates were reported in patients who transitioned from placebo to remibrutinib**

NRS, Numeric Rating Scale.

[a] Full analysis set; observed data. Only patients with a value at both baseline and post-baseline were evaluable for the derivation of the response status. Complete response: itch NRS=0; partial response: reduction from baseline of ≥2 in itch NRS patients who did not achieve complete response. [b] The earliest time point assessed.

Through Week 52, AEs With Remibrutinib Were Primarily Mild or Moderate in Severity; AEs Leading to Discontinuations Were Infrequent (Pooled Analysis)[a,b]

	24-week double-blind core period		52-week entire core period	28-week open-label core period
	Remibrutinib 25 mg twice daily (n=181)	Placebo (n=181)	Remibrutinib 25 mg twice daily (n=181)	Placebo transitioned to remibrutinib 25 mg twice daily[c] (n=152)
Exposure, median, weeks	**24.00**	**24.00**	**52.00**	**28.00**
Any AEs, % (n) [EAIR, per 100 PY]	**64.6** (117) [284.3]	**63.0** (114) [289.0]	**75.1** (136) [208.3]	**46.1** (70) [127.0]
Mild	**40.3** (73) [130.2]	**39.2** (71) [132.3]	**40.9** (74) [66.6]	**31.6** (48) [75.3]
Moderate	**23.8** (43) [62.4]	**22.1** (40) [60.3]	**30.9** (56) [41.7]	**12.5** (19) [25.3]
Severe	**0.6** (1) [1.2]	**1.7** (3) [3.9]	**3.3** (6) [3.6]	**2.0** (3) [3.7]
SAEs, % (n) [EAIR, per 100 PY]	**0**	**2.8** (5) [6.5]	**3.3** (6) [3.6]	**1.3** (2) [2.5]
AEs leading to treatment discontinuation, % (n) [EAIR, per 100 PY]	**4.4** (8) [10.0]	**2.8** (5) [6.5]	**4.4** (8) [4.8]	**2.0** (3) [3.7]
SAEs leading to treatment discontinuation, % (n)	**0**	**0.6** (1)	**0**	**0.7** (1)

- Overall, AE profiles were **generally consistent** across **CIndU subtypes**
- **No deaths** were reported

AE, adverse event; CholU, cholinergic urticaria; ColdU, cold urticaria; EAIR, exposure-adjusted incidence rate (the number of patients with the event per 100 PY of exposure, where the exposure time at risk is event-specific [terminated by incident events]); PY, patient-years; SAE, serious adverse event; SD, symptomatic dermographism.
[a] Safety set, pooled analysis across all 3 cohorts (SD, ColdU, and CholU). [b] A patient with multiple occurrences of an AE under one treatment is counted only once in this AE category for that treatment. [c] Includes only data collected after the transition to remibrutinib 25 mg twice daily.

EAIRs of the Most Common AEs (≥5% in Any Treatment Group, Pooled Analysis) Did Not Increase With Long-Term Treatment Through Week 52[a,b]

	24-week double-blind core period		52-week entire core period	28-week open-label core period
	Remibrutinib 25 mg twice daily (n=181)	Placebo (n=181)	Remibrutinib 25 mg twice daily (n=181)	Placebo transitioned to remibrutinib 25 mg twice daily[c] (n=152)
Exposure, median, weeks	**24.00**	**24.00**	**52.00**	**28.00**
Any AEs, % (n) [EAIR, per 100 PY]	**64.6** (117) [284.3]	**63.0** (114) [289.0]	**75.1** (136) [208.3]	**46.1** (70) [127.0]
Nasopharyngitis	**12.2** (22) [29.6]	**7.7** (14) [19.2]	**17.1** (31) [21.1]	**3.9** (6) [7.6]
Headache	**8.3** (15) [20.0]	**6.1** (11) [14.9]	**8.8** (16) [10.4]	**3.3** (5) [6.3]
Petechiae	**7.2** (13) [17.0]	**0.6** (1) [1.3]	**7.7** (14) [8.9]	**3.3** (5) [6.3]
Upper respiratory tract infection	**5.5** (10) [12.9]	**6.1** (11) [14.6]	**8.8** (16) [10.1]	**3.9** (6) [7.6]

- The **overall remibrutinib safety profile** was **consistent** with that reported in patients with **CSU**[1,2]

AE, adverse event; CholU, cholinergic urticaria; ColdU, cold urticaria; CSU, chronic spontaneous urticaria; EAIR, exposure-adjusted incidence rate (the number of patients with the event per 100 PY of exposure, where the exposure time at risk is event-specific [terminated by incident events]); PY, patient-years; SD, symptomatic dermographism.

[a] Safety set, pooled analysis across all 3 cohorts (SD, ColdU, and CholU). [b] A patient with multiple occurrences of an AE under one treatment is counted only once in this AE category for that treatment. [c] Includes only data collected after the transition to remibrutinib 25 mg twice daily.

1. Metz M, et al. *N Engl J Med.* 2025;392:984-994. 2. Giménez-Arnau AM, et al. *J Allergy Clin Immunol.* 2026;157(1):143-154. 3. Giménez-Arnau AM, *J Allergy Clin Immunol Pract*. 2026;14(8):1901-1913.

Select Safety Topics (Pooled Analysis)[a]

	24-week double-blind core period		52-week entire core period	28-week open-label core period
	Remibrutinib 25 mg twice daily (n=181)	Placebo (n=181)	Remibrutinib 25 mg twice daily (n=181)	Placebo transitioned to remibrutinib 25 mg twice daily[b] (n=152)
Exposure, median, weeks	**24.00**	**24.00**	**52.00**	**28.00**
Infection AEs, % (n) [EAIR, per 100 PY][c]	**34.8** (63) [100.7]	**34.3** (62) [103.4]	**49.7** (90) [81.3]	**20.4** (31) [43.6]
Bleeding AEs, % (n) [EAIR, per 100 PY][c]	**14.9** (27) [37.3]	**3.3** (6) [7.9]	**17.1** (31) [21.4]	**7.9** (12) [15.8]
Cytopenia AEs, % (n) [EAIR, per 100 PY][c]	**3.3** (6) [7.7]	**2.2** (4) [5.3]	**5.5** (10) [6.2]	**2.0** (3) [3.7]
Newly occurring liver enzyme abnormalities, % (m/M)[d]				
ALT or AST >3 × ULN	**1.1** (2/179)	**1.1** (2/176)	**1.7** (3/179)	**0** (0/150)
ALT or AST >8 × ULN	**0.6** (1/179)	**0.6** (1/177)	**0.6** (1/179)	**0** (0/151)
ALT or AST >10 × ULN	**0** (0/179)	**0** (0/177)	**0** (0/179)	**0** (0/151)
ALT or AST >3 × ULN & TBL >2 × ULN and ALP <2 × ULN (potential Hy's law)	**0** (0/179)	**0** (0/177)	**0** (0/179)	**0** (0/151)

- **Petechiae AEs** were primarily **mild** in severity and occurred within **the first 3 months** of treatment, which was **consistent with the pattern previously reported in CSU[1]; none** led to study treatment **interruption**
  - **Only 1 bleeding AE led to study treatment discontinuation** (mild petechiae of antecubital fossa in the patient with CholU treated with remibrutinib)
- **Newly occurring liver transaminase elevations** were **infrequent, transient,** and **balanced** between remibrutinib and placebo during the double-blind treatment period; **no cases** of **potential Hy's law** were reported

AE, adverse event; ALP, alkaline phosphatase; ALT, alanine aminotransferase; AST, aspartate aminotransferase; CholU, cholinergic urticaria; ColdU, cold urticaria; EAIR, exposure-adjusted incidence rate (the number of patients with the event per 100 PY of exposure, where the exposure time at risk is event-specific [terminated by incident events]); M, number of patients at risk (having a baseline measurement not meeting the criterion or missing, and ≥1 postbaseline measurement for the laboratory test(s) under consideration); m, number of patients who had a new abnormality; PY, patient-years; SD, symptomatic dermographism; TBL, total bilirubin; ULN, upper limit of normal.

[a] Safety set, pooled analysis across all 3 cohorts (SD, ColdU, and CholU). [b] Includes only data collected after the transition to remibrutinib 25 mg twice daily. [c] A patient with multiple AEs within AE category is counted only once in corresponding category. [d] Newly occurring: patient not meeting criterion at baseline and meeting criterion post baseline.

1. Giménez-Arnau AM, et al. *J Allergy Clin Immunol.* 2026;157(1):143-154.

Conclusions

- In the long-term analysis from the RemIND study, **remibrutinib** 25 mg twice daily **showed early[a] and sustained efficacy** (through to week 52) in patients across the 3 most prevalent CIndU subtypes: symptomatic dermographism, cold urticaria, and cholinergic urticaria[1]
- **Remibrutinib was well tolerated through week 52**, with a safety profile consistent with that reported in patients with CSU[2-4]
  - Most AEs were mild or moderate; serious AEs and discontinuations due to AEs were infrequent
  - Exposure-adjusted incidence rates of the most common AEs did not increase with long-term treatment through to week 52
- **Overall, remibrutinib showed early[a] and sustained efficacy with a favorable long-term safety profile up to week 52 in patients with the 3 most prevalent CIndU subtypes who remained symptomatic despite treatment with sgH_1-AHs[1]**

AE, adverse event; AH, antihistamine; CIndU, chronic inducible urticaria; CSU, chronic spontaneous urticaria; H_1, histamine 1; sg, second generation.
[a] As early as week 1 for symptomatic dermographism and cold urticaria and week 2 for cholinergic urticaria, the earliest time point measured for respective subtype cohorts.
1. Kolkhir P, et al. *Nat Rev Dis Primers*. 2022;8(1):61. 2. Metz M, et al. *N Engl J Med.* 2025;392:984-994. 3. Giménez-Arnau AM, et al. *J Allergy Clin Immunol.* 2026;157(1):143-154.
4. Giménez-Arnau AM, *J Allergy Clin Immunol Pract*. 2026;14(8):1901-1913.