Novartis International AG
CH-4002 Basel
Switzerland

https://www.novartis.com
https://x.com/NovartisNews

PRESS RELEASE

Novartis remibrutinib first therapy to achieve Phase III primary endpoint in chronic inducible urticaria (CIndU)

- *Statistically significant and clinically meaningful results seen in RemIND trial with complete responses achieved in 3 CIndU types*[1]
- *Remibrutinib, a highly selective oral BTK inhibitor, was well-tolerated and demonstrated a favorable safety profile, including no liver safety concerns*[1]
- *Oral remibrutinib has potential to be first targeted therapy approved for CIndU, which affects estimated 29 million adults worldwide*[2,3]

Basel, February 18, 2026 – Novartis today announced positive topline results from its pivotal Phase III RemIND trial of oral remibrutinib in chronic inducible urticaria (CIndU)[1]. The primary endpoint was met for the three most prevalent types of CIndU: symptomatic dermographism, cold urticaria and cholinergic urticaria, achieving significantly higher complete response rates versus placebo at Week 12[1]. These data represent an important advance in the treatment of CIndU, demonstrating the potential of remibrutinib to be the first targeted therapy for CIndU and address a major unmet need.

“The positive RemIND trial results across three different types of CIndU underscore the potential of oral remibrutinib to achieve complete symptom relief for people living with CIndU and build on its recent FDA approval in chronic spontaneous urticaria (CSU),” said Angelika Jahreis, Global Head, Immunology Development, Novartis. “Today’s findings reinforce that remibrutinib could be the first targeted therapy to improve spontaneous and inducible forms of chronic urticaria, helping address a major gap in care for people living with these conditions.”

Novartis has submitted a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) seeking approval of remibrutinib for the treatment of symptomatic dermographism, the most prevalent type of CIndU. In the coming months, the full data set will be submitted to health authorities globally, and the RemIND trial findings will be presented in upcoming medical congresses.

About remibrutinib
Remibrutinib is a highly selective, oral BTK inhibitor that blocks the BTK pathway involved in the release of histamine, a key driver of hives (wheals) and swelling[4-6]. By reducing histamine release, remibrutinib helps relieve the symptoms of CIndU[1,7]. In the US and China, remibrutinib is approved for the treatment of adult patients with CSU who have an inadequate response to H1-antihistamines, under the brand name Rhapsido®. Remibrutinib is being investigated in other immune-mediated conditions, such as hidradenitis suppurativa (HS) and food allergy, in addition to other indications in the company’s Neuroscience portfolio[8-11].

About RemIND trial
The RemIND trial (NCT05976243) is a global Phase III, multicenter, randomized, double-blind, placebo-controlled, parallel-group study evaluating the efficacy, safety, and tolerability of remibrutinib in adults with CIndU inadequately controlled by H1-antihistamines[12]. The primary endpoint of RemIND is the proportion of complete responders at Week 12 assessed through provocation tests specific to three CIndU subtypes[12].

About Chronic Inducible Urticaria (CIndU)
CIndU is a chronic skin condition affecting an estimated 0.5 percent of the population or 29 million people worldwide[2,3]. It is a form of chronic urticaria characterized by hives and/or swelling, with identifiable external triggers, like pressure, sunlight, friction, heat, cold or water[13]. CIndU differs from chronic spontaneous urticaria (CSU), which has no specific triggers[14]. CIndU places a significant burden on daily life, with many patients cycling through antihistamines without adequate relief[15]. With no approved targeted therapies available today, there remains a clear and longstanding gap in effective treatment options for these patients[15,16].

The most prevalent CIndU subtypes are symptomatic dermographism, cold urticaria, and cholinergic urticaria[17]. Symptomatic dermographism manifests with itchy hives caused by shear force on skin, such as friction or light scratching, which appear in less than 5 minutes after contact and usually last 30 minutes[13]. Cold urticaria occurs after skin exposure to cold, leading to wheals or angioedema that develop within minutes after exposure and are usually limited to exposed areas[13]. Cholinergic urticaria manifests with characteristic small, punctate hives triggered by active or passive heating of the body, including exercise, strong emotions, or bathing in hot water [13].

About Novartis Immunology
At Novartis, we're advancing bold science with the goal of bringing relief and a renewed sense of hope to people living with autoimmune diseases. Building on our legacy of first-in-class innovation across rheumatology, dermatology and allergy, and a diverse industry-leading pipeline, we're committed to shaping what's next in Immunology.

Disclaimer
This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as "potential," "can," "will," "plan," "may," "could," "would," "expect," "anticipate," "look forward," "believe," "committed," "investigational," "pipeline," "launch," or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for the investigational or approved products described in this press release, or regarding potential future revenues from such products. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations regarding such products could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures and requirements for increased pricing transparency; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; general political, economic and business conditions, including the effects of and efforts to mitigate pandemic diseases; safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, and other risks and factors referred to in

Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Novartis
Novartis is an innovative medicines company. Every day, we work to reimagine medicine to improve and extend people's lives so that patients, healthcare professionals and societies are empowered in the face of serious disease. Our medicines reach more than 300 million people worldwide.

Reimagine medicine with us: Visit us at **https://www.novartis.com** and connect with us on **LinkedIn**, **Facebook**, **X/Twitter** and **Instagram**.

References

1. Data on files
2. Maurer M, et al. How to approach Chronic Inducible Urticaria, *The Journal of Allergy and Clinical Immunology*, 2018, Volume 6, Issue 4, Pages 1119-1130
3. World Population Prospects, Department of Economic and Social Affairs Population Division, United Nations. Available from: https://population.un.org/wpp/downloads?folder=Standard%20Projections&group=Population [Last accessed: February 2026]
4. Maurer M, Berger W, Giménez-Arnau A, et al. Remibrutinib, a novel BTK inhibitor, demonstrates promising efficacy and safety in chronic spontaneous urticaria. *J Allergy Clin Immunol 2022*; 150: 1498-1506.
5. Angst D, Gessier F, Janser P, et al. Discovery of LOU064 (remibrutinib), a potent and highly selective covalent inhibitor of Bruton's Tyrosine Kinase. *J Med Chem 2020*; 63: 5102-5118.
6. Powell RJ, Leech SC, Till S, et al. BSACI guideline for the management of chronic urticaria and angioedema. *Clin Exp Allergy* 2015; 45: 547-565.
7. Patient. Antihistamines. Last updated 12 October 2022. Available from: https://patient.info/allergies-blood-immune/allergies/antihistamines [Last accessed: February 2026].
8. ClinicalTrials.gov. NCT03827798. Study of efficacy and safety of investigational treatments in patients with moderate to severe hidradenitis suppurativa. Available from: https://clinicaltrials.gov/ct2/show/NCT03827798. [Last accessed: February 2026]
9. ClinicalTrials.gov. NCT05432388. Study of efficacy, safety and tolerability of remibrutinib in adult participants with an allergy to peanuts. Available from: https://clinicaltrials.gov/study/NCT05432388 [Last accessed: February 2026].
10. ClinicalTrials.gov. NCT05147220. Efficacy and safety of remibrutinib compared to teriflunomide in participants with relapsing multiple sclerosis (RMS) (REMODEL-1). Available from: https://clinicaltrials.gov/study/NCT05147220 [Last accessed: February 2026].
11. ClinicalTrials.gov. NCT05156281. Efficacy and safety of remibrutinib compared to teriflunomide in participants with relapsing multiple sclerosis (RMS) (REMODEL-2). Available from: https://clinicaltrials.gov/study/NCT05156281 [Last accessed: February 2026].
12. ClinicalTrials.gov. NCT05976243. A Study to Investigate Efficacy, Safety, and Tolerability of Remibrutinib Compared With Placebo in Adults With CINDU Inadequately Controlled by H1-antihistamines. Available from: https://clinicaltrials.gov/study/NCT05976243 [Last accessed: February 2026].
13. Pozderac I, et al. Chronic inducible urticaria: classification and prominent features of physical and non-physical types. Acta Dermatovenerol *Alp Pannonica Adriat*. 2020;29(3):141–8
14. Zuberbier et al. The international EAACI/GA^{2}LEN/EuroGuiDerm/APAAACI guideline for the definition, classification, diagnosis and management of urticaria. *Allergy.*2022;77(3):734–66
15. M Kern B, et al. Physician estimation of the prevalence and clinical impact of chronic urticaria: results of the global, multicenter UCARE CU-PAPER study, *Frontiers in allergy*, 2026, volume 6:1732893
16. Munoz M, et al. New insights into chronic inducible urticaria. *Current Allergy and Asthma Reports*, 2024 volume 24, 457-469
17. Kolkhir P, et al. Urticaria. *Nat Rev Dis Primers*. 2022;8(61)

# # #

Novartis Media Relations
E-mail: media.relations@novartis.com

Novartis Investor Relations
Central investor relations line: +41 61 324 7944
E-mail: investor.relations@novartis.com