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PRESS RELEASE

New long-term Rhapsido® (remibrutinib) Phase III data show sustained efficacy through week 52 in chronic inducible urticaria (CIndU)

- *RemIND data show clinically meaningful responses through Week 52 across three most prevalent CIndU subtypes, including after switching from placebo at Week 24*[1]
- *Twice as many Rhapsido-treated patients achieved a treatment response by Week 1 in SD and ColdU vs placebo*
- *Rhapsido was well tolerated through Week 52, with an overall safety profile consistent with approved indications*[1]
- *Additional regulatory submissions for CIndU planned based on these data*

Basel, November 12, 2026 – Novartis today announced 52-week results from the Phase III RemIND program evaluating Rhapsido® (remibrutinib) in chronic inducible urticaria (CIndU). In the long-term analysis from the RemIND study, Rhapsido 25 mg twice daily showed early and sustained efficacy through Week 52 in patients across the three most prevalent CIndU subtypes: symptomatic dermographism (SD), cold urticaria (ColdU) and cholinergic urticaria (CholU).[1] The data will be presented as a late-breaking abstract at the American College of Allergy, Asthma & Immunology (ACAAI) Annual Scientific Meeting 2026.

"For people living with chronic inducible urticaria, everyday triggers like cold air, heat or even light scratching on the skin can lead to sudden, painful itching and swelling that can interfere with daily life," said Giselle Mosnaim, MD, MS, allergist and immunologist at Endeavor Health and lead RemIND investigator. "This research is an important step toward finding treatment options that can provide lasting relief and help patients better manage their condition."

RemIND is the largest Phase III clinical program conducted in CIndU.[1-5] Patients initially randomized to Rhapsido showed sustained efficacy through Week 52, with symptom improvements maintained throughout the treatment period.[1] After patients initially randomized to placebo switched to Rhapsido at Week 24, their response rates at Week 52 were similar to those observed in patients initially randomized to Rhapsido.[1]

Complete or partial response rates on subtype-specific provocation tests were 41.8% with Rhapsido versus 19.2% with placebo in SD and 67.4% versus 28.9% in ColdU at Week 1, and 65.2% versus 45.6% in CholU at Week 2. At Week 52, complete or partial response rates were 46.8%, 83.3% and 58.2% in patients initially randomized to Rhapsido and 47.7%, 88.9% and 69.8% in patients who switched from placebo to Rhapsido at Week 24 in the SD, ColdU and CholU cohorts, respectively.[1]

The 52-week RemIND results extend the safety evidence for Rhapsido in CIndU. Its safety profile through 52 weeks was consistent with previous studies and established experience in CSU.[1]

“The RemIND program has generated the most comprehensive Phase III evidence to date in chronic inducible urticaria,” said Angelika Jahreis, Global Head, Immunology Development, Novartis. “These long-term data further strengthen the clinical profile of Rhapsido and underscore our commitment to advancing innovative treatment options for patients living with chronic urticaria. They will help support ongoing efforts to bring Rhapsido to more patients worldwide.”

About Chronic Inducible Urticaria (CIndU)

CIndU affects an estimated 0.5 percent of the population, or 29 million people worldwide,[6,7] and differs from CSU, which has no specific triggers.[8] It significantly burdens daily life, with many patients trying multiple antihistamines without adequate relief.[9] The most prevalent subtype, symptomatic dermographism, causes itchy hives after skin friction or light scratching; hives appear within 5 minutes and usually last 30 minutes.[10] Cold urticaria causes wheals or angioedema within minutes of cold exposure, usually in exposed areas, while cholinergic urticaria causes small, punctate hives after active or passive body heating, including exercise, strong emotions or hot-water bathing.[10]

About Rhapsido® (remibrutinib)

Rhapsido® (remibrutinib) is a highly selective, oral Bruton’s tyrosine kinase (BTK) inhibitor that blocks the BTK pathway involved in immune-cell signaling and inflammation. Under the brand name Rhapsido, it is approved for chronic spontaneous urticaria (CSU) among other countries in the EU, US, CN and JP, and for symptomatic dermographism (SD), the most prevalent form of chronic inducible urticaria (CIndU), in the US.[2] Remibrutinib continues to be studied in other immune-mediated conditions, including hidradenitis suppurativa (HS), food allergy, chronic pruritus of unknown origin and papulopustular rosacea as well as multiple sclerosis (MS).

About the 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 Rhapsido in adults with CIndU inadequately controlled by H1-antihistamines. The RemIND trial enrolled 362 patients with CIndU whose symptoms remained inadequately controlled despite treatment with second-generation H1 antihistamines.[1,2] The primary endpoint of RemIND is the proportion of complete responders at Week 12 assessed through provocation tests specific to three CIndU subtypes. The secondary endpoints were change from baseline to the same endpoints at weeks 2 and 12; and the proportion of participants with complete response at weeks 2 and 24.[1,2] Data from RemIND supported the FDA approval of Rhapsido for the treatment of SD. The full data set will support additional regulatory submissions. [2]

About Novartis Immunology

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At Novartis, we're advancing bold science with the goal of bringing relief and a renewed sense of hope to people living with autoimmune and other immune-mediated 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 **www.novartis.com** and connect with us on **LinkedIn, Facebook, X/Twitter** and **Instagram.**

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