

PRESS RELEASE

Novartis Rhapsido® (remibrutinib) receives FDA approval as first treatment for symptomatic dermographism (SD), expanding its use beyond chronic spontaneous urticaria (CSU)

- *In Phase III RemIND trial, twice as many adults taking Rhapsido achieved complete hive resolution by Week 12 vs placebo, with responses seen by Week 2¹*
- *SD is most prevalent type of chronic inducible urticaria (CIndU)²; more than 50% of patients remain symptomatic despite taking H1 antihistamines³*
- *Rhapsido showed safety profile in SD consistent with CSU, with no routine lab monitoring required¹*
- *Approval builds on established role of Rhapsido in CSU and highlights potential of BTK inhibition across immune-mediated diseases*

Basel, October 7, 2026 – Novartis announced today that the U.S. Food and Drug Administration (FDA) approved Rhapsido® (remibrutinib), an oral, highly selective Bruton's tyrosine kinase inhibitor (BTKi), as the first treatment for adults with symptomatic dermographism (SD) inadequately controlled by H1 antihistamines. The approval represents an important advancement for people whose chronic hives and itch can be triggered by everyday skin friction, scratching, or rubbing.

Over 90% of adults with chronic hives experience chronic spontaneous urticaria (CSU) or SD. Rhapsido is the only prescription treatment with approved uses in both CSU and SD when antihistamines alone do not control symptoms.⁴

"SD is a chronic, debilitating condition with historically limited treatment options," said Giselle Mosnaim, MD, MS, an Allergist and Immunologist at Endeavor Health, Clinical Professor at the University of Chicago Pritzker School of Medicine, and lead RemIND trial investigator. "Remibrutinib offers, for the first time, an approach to treatment specifically for SD patients who remain inadequately controlled with H1 antihistamines alone, representing a meaningful step forward for this population."

The FDA approval is based on data from the SD cohort of the Phase III RemIND clinical trial in patients who remained symptomatic on second-generation H1 antihistamines. Rhapsido demonstrated higher rates of complete response from hives compared to placebo as measured by the Total Fric Score.¹ At Week 12, significantly more patients treated with Rhapsido versus placebo achieved complete response from hives (29.3% vs 14.0% with placebo; $p=0.0229$), with responses seen as early as Week 2.¹

In clinical trials up to Week 24, Rhapsido demonstrated a consistent safety profile in SD and CSU.¹ The most common adverse events (incidence $\geq 3\%$) were nasal congestion, sore throat, and runny nose (nasopharyngitis), bleeding, headache, nausea, and abdominal pain.¹

"As both a patient and an advocate, I know how important it is for SD to be recognized and understood," said Kristen Willard, Executive Director of We CU, a global community supporting people with chronic urticaria (CU) through awareness, advocacy, education, and research. "For the SD community, the approval of remibrutinib represents important progress. People living with this condition deserve treatment options developed specifically for this condition, and we are hopeful about what this milestone means for the community."



Expanding Rhapsido indications across chronic hives

With the FDA approval in SD, Rhapsido is now the only treatment indicated for the two most common forms of chronic hives: CSU and SD. Beyond SD, the RemIND study also evaluated remibrutinib in additional forms of CIndU, including cold urticaria (ColdU) and cholinergic urticaria (CholU). The company plans to submit the full RemIND dataset to health authorities globally, where appropriate.

“For people living with SD, seemingly routine contact with the skin can trigger hives and itch,” said Lindsey Finklea, MD, a Dermatologist and Adjunct Professor at the University of Texas at San Antonio and RemIND trial investigator. “Having the first FDA-approved medicine specifically for SD marks an important change in how clinicians can approach care and offers renewed hope for patients whose symptoms are not adequately controlled by H1 antihistamines.”

Remibrutinib continues to be studied in other immune-mediated conditions, including hidradenitis suppurativa (HS) and food allergy. In addition, Novartis recently announced positive topline results from its Phase III REMODEL-1/-2 trials in relapsing multiple sclerosis (RMS), showing that remibrutinib demonstrated a clinically meaningful reduction in annualized relapse rates and a clinically meaningful delay in disability progression vs teriflunomide with a favorable safety profile and no liver safety signals, consistent with CSU.⁵

“Today’s approval marks an important milestone for people living with SD and builds on the first FDA-approved indication for Rhapsido in CSU just over a year ago,” said Victor Bultó, President, US, Novartis. “With Rhapsido now approved for the two most common forms of chronic hives, more people may have the opportunity to find relief from persistent itch, regain confidence in their daily lives, and focus less on their symptoms and more on the moments that matter. We are proud to advance the science of BTK inhibition as we work to bring new treatment options to patients with unmet needs across immunology and beyond.”

About Rhapsido® (remibrutinib)

Rhapsido® (remibrutinib) is a highly selective, oral Bruton’s tyrosine kinase inhibitor (BTKi) that blocks the BTK pathway involved in the release of histamine, a key driver of hives (wheals) and swelling.¹ In the U.S., Rhapsido is an approved treatment for adults with chronic spontaneous urticaria (CSU) and symptomatic dermographism (SD) inadequately controlled by H1 antihistamines. Rhapsido is also approved in the EU, UK, and China for the treatment of adults with CSU inadequately controlled by H1 antihistamines. Remibrutinib continues to be studied in other immune-mediated conditions, including hidradenitis suppurativa (HS) and food allergy, as well as multiple sclerosis (MS).

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 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 <https://www.novartis.com> and connect with us on **LinkedIn, Facebook, X/Twitter** and **Instagram**.

References

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4. Data on file. Novartis Pharmaceuticals Corp. August 2026.
5. Data on file. Novartis to present late-breaking data at MSToronto2026. Novartis remibrutinib, a high-efficacy oral BTK inhibitor, significantly reduces relapse rates and shows favorable safety profile in Phase III RMS trials. <https://www.novartis.com/news/media-releases/novartis-remibrutinib-high-efficacy-oral-btk-inhibitor-significantly-reduces-relapse-rates-and-shows-favorable-safety-profile-phase-iii-rms-trials>. Accessed October 7, 2026.

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