Novartis receives FDA approval for Rhapsido® (remibrutinib), the only oral, targeted BTKi treatment for chronic spontaneous urticaria (CSU)

Ad hoc announcement pursuant to Art. 53 LR

- *Rhapsido helps to inhibit release of histamine and proinflammatory mediators by targeting BTK, offering unique approach to CSU treatment*[1]
- *Well-controlled disease observed as fast as two weeks, with demonstrated safety profile that requires no lab monitoring*[1]
- *1.7 million people in US live with CSU; more than half remain symptomatic despite increasing doses of antihistamines*[2,3]
- *Remibrutinib also in clinical development for chronic inducible urticaria, food allergy, and hidradenitis suppurativa, expanding Novartis Immunology portfolio*

Basel, September 30, 2025 – Novartis announced today that Rhapsido® (remibrutinib) received US Food and Drug Administration (FDA) approval as an oral treatment for adult patients with chronic spontaneous urticaria (CSU) who remain symptomatic despite H1 antihistamine treatment. Rhapsido is a pill taken twice daily and does not require injections or lab monitoring. It is the first FDA-approved Bruton's tyrosine kinase inhibitor (BTKi) for CSU. Rhapsido helps to inhibit the release of histamine and other proinflammatory mediators by targeting BTK, offering a unique approach to CSU treatment.[1]

"CSU is a serious disease that can cause debilitating symptoms and unpredictable flares. It's difficult to diagnose and manage," said Mark Lebwohl, MD, Dean for Clinical Therapeutics at the Icahn School of Medicine at Mount Sinai and member of the steering committee for the remibrutinib REMIX Phase III clinical trial program. "Remibrutinib represents a new way of treating CSU. By blocking the activity of BTK, remibrutinib stops a key pathway of the immune response in CSU. This is an exciting new option that has the potential to help a broad range of patients get fast relief."

CSU is a mast cell-driven condition thought to be caused by immune dysregulation. In people with CSU, the immune system can become activated through allergic (IgE) or autoimmune (IgG) pathways.[4] This causes certain immune cells—mast cells and basophils—to activate the BTK protein. While not fully understood, it is believed that once activated, BTK leads to the release of histamine and other proinflammatory mediators that may cause the red, swollen, and itchy hives commonly seen in CSU.[5,6]

CSU symptoms are unpredictable, recurring for six weeks or more without an identified cause.[7] Diagnosis can take up to 24 months.[8] Many CSU patients say their symptoms negatively

impact their sleep, work, and mental health.[9,10,11] Antihistamines are the first-line treatment, but over half of patients still have symptoms, even at higher doses.[2] Injectable treatments exist for those who don't respond to antihistamines, yet fewer than 20% of eligible patients receive them.[12]
“The approval of remibrutinib is an important development in CSU care. It quickly reduces symptoms, offering patients control of the hives and itching that they experience on a daily basis,” said Giselle Mosnaim, MD, MS, an Allergist and Immunologist from Endeavor Health, Clinical Associate Professor at the University of Chicago Pritzker School of Medicine and REMIX trial investigator. “This is significant because it expands beyond existing injectable treatments and gives patients an oral option that can easily be incorporated into their daily lives.”
“Many CSU patients feel misunderstood and settle for treatments that don’t fully meet their needs,” said Lynda Mitchell, CEO of Allergy & Asthma Network. “We support new treatment options that empower patients to choose what works best for them. This convenient new oral therapy offers a promising new way to manage CSU and potentially improve daily life for those living with this challenging condition.”

Clinical data supporting approval

The FDA approval of Rhapsido in CSU is based on results from the Phase III REMIX-1 (NCT05030311) and REMIX-2 (NCT05032157) clinical trials in patients who remained symptomatic on second-generation H1 antihistamines. Rhapsido demonstrated superiority in change from baseline versus placebo in itch (ISS7), hives (HSS7), and weekly urticaria activity (UAS7) at Week 12.[13] Significantly more patients treated with Rhapsido versus placebo achieved well-controlled disease (UAS7≤6) as early as Week 2 and at Week 12, and about one-third of patients achieved complete absence of itch and hives at Week 12.[13] Rhapsido has a demonstrated safety profile that requires no lab monitoring.[13] The most common adverse events (incidence ≥3%) were nasal congestion, sore throat, and runny nose (nasopharyngitis), bleeding, headache, nausea, and abdominal pain.[13]
Novartis has completed regulatory submissions for Rhapsido for the treatment of CSU across many countries, including in the European Union, Japan, and China, with priority review granted in China.

Transforming care in Immunology

“This approval of Rhapsido as the first and only BTK inhibitor in CSU is an important milestone in our journey to reshape care for overlooked immune-related conditions and offer more patients the potential to find fast relief,” said Victor Bultó, President, US, Novartis. “Building on our legacy in advancing the treatment of allergic, dermatologic, and rheumatologic conditions, we are deeply committed to further investing in innovative, patient-focused therapies across immunology.”
Discovered and developed by Novartis to target the BTK pathway as a driver of inflammation, remibrutinib is being investigated in ongoing clinical trials across a variety of immune-related conditions, including chronic inducible urticaria (CIndU), hidradenitis suppurativa (HS), and food allergy.

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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 nearly 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.

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