

FDA Expands Remibrutinib Approval to Symptomatic Dermographism

The FDA has expanded the indication of the Bruton's tyrosine kinase (BTK) inhibitor remibrutinib (Rhapsido) to treat symptomatic dermographism, the most common form of chronic inducible urticaria.

The approval expands remibrutinib's use beyond chronic spontaneous urticaria (CSU), providing a new targeted treatment option for patients with symptomatic dermographism.

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.”

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