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PRESS RELEASE

Novartis RemIND data at EAACI show Rhapsido® potential as first targeted therapy for chronic inducible urticaria (CIndU)

- *Rhapsido demonstrated statistically significant and clinically meaningful symptom control in twice as many patients vs placebo[1], with favorable safety profile and no observed liver safety concerns[2]*

- *With global CIndU prevalence of 29 million[3,4]; greater than 50% of patients experience significant disease burden despite treatment with H1-antihistamines; no approved targeted therapies exist[5,6]*

- *Rhapsido is under FDA review for CIndU symptomatic dermographism subtype; additional submissions to health authorities globally to continue in 2026*

Basel, June 12, 2026 – Novartis today presented data from the Phase III RemIND trial at the European Academy of Allergy and Clinical Immunology (EAACI) Congress showing that Rhapsido® (remibrutinib) met its primary endpoints across the three most common chronic inducible urticaria (CIndU) subtypes, becoming the first-ever treatment to demonstrate efficacy in a global CIndU clinical trial[7]. In the RemIND trial, higher rates of complete responses were observed at week 12, with responses seen as early as week 2 in two subtypes. These results demonstrate that Rhapsido may provide sustained relief for patients whose disease remains inadequately controlled after treatment with second-generation H1-antihistamines[7].

“Chronic inducible urticaria (CIndU) is a form of chronic hives in which everyday triggers—such as pressure, heat, cold, or sunlight—can lead to itchy wheals, and there are currently no approved targeted treatment options,” said Prof. Dr. med. Martin Metz, Deputy Director, Institute of Allergology, Charité–Universitätsmedizin Berlin, Germany. “The RemIND results across the three most common CIndU subtypes highlight the potential of Rhapsido as an important new treatment option for patients with significant unmet need.”

The three most prevalent CIndU subtypes are symptomatic dermographism (SD), cold urticaria, and cholinergic urticaria, with SD being the most common[8]. Novartis has submitted a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) seeking approval of Rhapsido for the treatment of SD subtype and will continue additional filings to health authorities globally throughout 2026. Rhapsido is approved for use in the U.S., European Union, China and several other countries for the treatment of chronic spontaneous urticaria (CSU), in adult patients with inadequate response to H1-antihistamines.

“Rhapsido significantly improves symptom control for patients living with the three most common subtypes of chronic inducible urticaria, and it has the potential to become the first approved targeted therapy. This is a major step forward for CIndU patients who have limited options,” said Angelika Jahreis, Global Head, Immunology Development, Novartis. “The CIndU data presented today are consistent with Rhapsido’s proven efficacy and favorable safety profile in chronic spontaneous urticaria and demonstrate Novartis’ commitment to developing truly meaningful innovation for patients with complex immune-mediated diseases.”

Primary endpoint results at Week 12 in the RemIND trial[1]

CIndU subtypes	Patients achieving complete response* at week 12	
	Rhapsido oral 25 mg twice/day	**Placebo**
Symptomatic Dermographism	29.3%	14.0%
Cold Urticaria	56.3%	14.6%
Cholinergic Urticaria	29.3%	15.8%

**Proportion of participants with complete response to FricTest® (TFS=0), TempTest® (CTT<4°C), or pulse-controlled ergometry test at week 12 (itch NRS score=0).*

About Rhapsido®
Rhapsido (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[9-11]. By reducing histamine release, Rhapsido helps relieve the symptoms of CIndU[2,12]. In the U.S., European Union, China, South Korea and several other countries, Rhapsido is approved for the treatment of adult patients with CSU who have an inadequate response to H1-antihistamines. 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[13-16].

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[17]. The primary endpoint of RemIND is the proportion of complete responders at Week 12 assessed through provocation tests specific to three CIndU subtypes[17]. 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.

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[3,4]. CIndU differs from chronic spontaneous urticaria (CSU), which has no specific triggers[19]. CIndU places a significant burden on daily life, with many patients cycling through antihistamines without adequate relief[20]. With no approved targeted therapies available today, there remains a clear and longstanding gap in effective treatment options for these patients[20,21].

The most prevalent CIndU subtype, 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[18]. 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[18]. 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[18].

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.

Product Information
For full prescribing information, including approved indications and important safety information about marketed products, please visit https://www.novartis.com/about/products.

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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 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**.

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