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PRESS RELEASE

Novartis receives positive CHMP opinion for remibrutinib in chronic spontaneous urticaria (CSU)

- *Remibrutinib, a highly selective oral BTKi, has potential to be first targeted therapy approved for CSU in Europe*
- *Improvements with remibrutinib observed as early as Week 1 in REMIX 1 & 2, with favorable safety profile including no liver safety concerns through Week 52*[1]
- *CSU affects nearly 4 million people in Europe, with over 50% of patients remaining symptomatic despite H1-antihistamines*[2-4]

Basel, February 27, 2026 – Novartis announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending marketing authorization for remibrutinib. The opinion supports its use as an oral treatment for chronic spontaneous urticaria (CSU) in adult patients with inadequate response to H1-antihistamine treatment.

“The introduction of remibrutinib represents a major advancement, providing clinicians with an oral Bruton’s tyrosine kinase inhibitor (BTKi) treatment, with improvements in symptoms observed as early as Week 1,” said Prof. Dr. med. Martin Metz, Deputy Director, Institute of Allergology, Charité Universitätsmedizin Berlin. “CSU continues to impose a substantial unmet medical need, as many patients struggle to achieve adequate disease control with currently available therapies.”

The positive CHMP opinion is supported by results from the pivotal REMIX-1 and REMIX-2 Phase III trials. Remibrutinib showed improvements in itch and hives as early as Week 1, with benefits sustained through Week 52[1]. Improvements in quality of life and sleep were also observed early in treatment [1]. Remibrutinib was well tolerated and demonstrated a favorable safety profile, including no liver safety concerns across both studies through Week 52[1].

“People living with CSU often endure years of frustration, and difficulty being taken seriously. For many, the unpredictable itch flare-ups can make it hard to sleep, focus on daily responsibilities, or even perform their jobs at times,” said Tonya Winders, President and CEO, Global Allergy & Airways Patient Platform (GAAPP). “The arrival of a new oral treatment option brings us one step closer to ensuring that every person has the opportunity to live fully again.”

“Today’s positive CHMP opinion is an important step towards addressing the significant unmet needs of adults living with CSU in Europe,” said Patrick Horber, M.D., President, International, Novartis. “We will continue to collaborate with regulatory authorities globally to make this important medicine, discovered and developed by Novartis, available to patients who need it most.”

Following the CHMP recommendation for approval, the European Commission (EC) is expected to issue a final decision within approximately two months.

About remibrutinib
Remibrutinib is a highly selective, oral BTK inhibitor that blocks the BTK pathway involved in the release of histamine, a key driver of itchy hives (wheals) and swelling[5-7]. By reducing histamine release, remibrutinib helps relieve the symptoms of chronic spontaneous urticaria (CSU)[8,9]. In the US and China, remibrutinib is approved for the treatment of adult patients with CSU who have an inadequate response to H1-antihistamines, under the brand name Rhapsido®. Remibrutinib has shown positive topline results in chronic inducible urticaria (CIndU) across the three most prevalent subtypes in the pivotal Phase III RemIND trial. It is also 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[10-14].

About REMIX-1 and REMIX-2
REMIX-1 (NCT05030311) and REMIX-2 (NCT05032157) are two identically designed, global, multicenter, randomized, double-blind, parallel-group, placebo-controlled Phase III trials, consisting of 925 patients who remained symptomatic on second-generation H1-antihistamines. Remibrutinib demonstrated superiority in change from baseline versus placebo in itch (ISS7), hives (HSS7), and weekly urticaria activity (UAS7) at Week 12. Remibrutinib has a demonstrated safety profile that requires no lab monitoring. The most common adverse events (incidence ≥3%) were nasal congestion, sore throat, and runny nose (nasopharyngitis), bleeding, headache, nausea, and abdominal pain[14,15].

About chronic spontaneous urticaria (CSU)
CSU is the medical term for chronic hives that last for 6 weeks or longer, where the underlying cause is internal rather than exposure to any allergen or external trigger[4,7,16]. CSU affects approximately 40 million people worldwide[4,17]. It is characterized by the sudden appearance of itchy hives (wheals) and/or deep tissue swelling (angioedema), which can occur on the face, throat, hands, and feet[7,18]. CSU affects all ages but occurs most frequently between the ages of 20-40 years, with women affected nearly twice as often as men[7]. CSU causes significant emotional distress, with the majority of patients suffering from sleep deprivation, and high rates of mental disorders, such as anxiety or depression, as well as decreased work productivity[7].

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.

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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

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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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