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PRESS RELEASE

Novartis Rhapsido® receives European Commission approval as first oral targeted treatment for chronic spontaneous urticaria

- *Significant improvements as early as Week 1, favorable safety profile and no liver safety concerns in REMIX 1 & 2 studies of highly selective, oral BTKi*[1]
- *Rhapsido recommended in 2026 International Urticaria Guideline for all patients who remain symptomatic after H1-antihistamine treatment*[2]
- *CSU affects nearly 4 million people in Europe; more than 50% continue to experience debilitating symptoms after conventional antihistamine therapy*[3-5]

Basel, April 27, 2026 – Novartis announced today that the European Commission (EC) approved Rhapsido® (remibrutinib) for chronic spontaneous urticaria (CSU) in adult patients with inadequate response to H1-antihistamine treatment. Rhapsido is the first oral targeted treatment approved for CSU, offering a unique approach to CSU treatment in a pill taken twice daily without any lab monitoring required[1].

“CSU is a serious disease that causes debilitating symptoms, like itch and swelling, with unpredictable flares that greatly impact patients' emotional wellbeing, sleep, and productivity,” says Prof. Dr med. Martin Metz, Deputy Director, Institute of Allergology, Charité Universitätsmedizin Berlin, Germany. “The approval of Rhapsido marks a major step forward, offering fast relief by blocking a key immune pathway, which may help a broad range of patients experience significant control of their disease.”

Rhapsido received a positive opinion in February 2026 from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) and is included in the 2026 International Guideline for the Definition, Classification, Diagnosis and Management of Urticaria[2].

“Today’s approval represents an important advance for CSU patients, offering new hope for faster relief and better day to day disease control. Rhapsido is being developed for multiple immune-mediated conditions in addition to CSU— such as chronic inducible urticaria, food allergy, hidradenitis suppurativa—highlighting the broad potential of a targeted oral BTK pathway approach,” said Patrick Horber, M.D., President, International, Novartis.

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[6-8]. By reducing histamine release, Remibrutinib helps relieve the symptoms of chronic spontaneous urticaria (CSU)[9,10]. Remibrutinib is approved in the US,China and several other countries for the treatment of adult patients with CSU who have an inadequate response to H1-antihistamines. 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[11-15].

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, hives, and weekly urticaria activity 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[15,16].

About chronic spontaneous urticaria (CSU)
CSU is a chronic skin condition affecting approximately 40 million people worldwide[5,18], impacting nearly twice as many women than men[8] and occurring most frequently between the ages of 20-40 years. It is characterized by the sudden appearance of itchy hives (wheals) and/or deep tissue swelling (angioedema), which can appear on the face, throat, hands, and feet[8,19] and occur without exposure to any allergen or external trigger[5,8,17]. Symptoms last for 6 weeks or longer and cause significant physical and emotional distress. The majority of CSU patients suffer from sleep deprivation, and high rates of mental disorders, such as anxiety or depression, as well as decreased work productivity[8].

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 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**

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