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PRESS RELEASE

Novartis remibrutinib, a high-efficacy oral BTK inhibitor, significantly reduces relapse rates and shows favorable safety profile in Phase III RMS trials

Ad hoc announcement pursuant to Art. 53 LR

- *REMODEL-1/-2 trials met their primary endpoint, significantly reducing annualized relapse rate (ARR) vs teriflunomide in people living with relapsing multiple sclerosis (RMS)*[1]
- *Trials showed superiority of remibrutinib vs. teriflunomide on all key secondary endpoints within each trial, including reduction of MRI lesions*[1]
- *A clinically meaningful delay in disability progression was achieved, including a positive trend in 3mCDP and nominally significant 6mCDP in preplanned combined analysis of REMODEL-1/-2*[1]
- *Remibrutinib demonstrated a favorable safety profile with no liver safety signal, consistent with remibrutinib in chronic spontaneous urticaria (CSU)*[1]
- *Novartis to present late-breaking data at MSToronto2026 and plans to submit to health authorities globally*

Basel, September 1, 2026 – Novartis today announced positive topline results from its Phase III REMODEL-1/-2 trials of remibrutinib in relapsing multiple sclerosis.[1] Remibrutinib, a highly selective and potent oral Bruton's tyrosine kinase (BTK) inhibitor, demonstrated superiority versus teriflunomide in reducing annualized relapse rate (ARR) and inflammatory brain lesions with a favorable safety profile. The results of the REMODEL trials establish remibrutinib as a BTK inhibitor that achieved significant reductions in annualized relapse rate across two Phase III trials in adults with relapsing multiple sclerosis (RMS).[1]

Remibrutinib demonstrated clinically meaningful reductions versus teriflunomide in key secondary endpoints related to disability progression, with a positive trend in 3-month confirmed disability progression (3mCDP) and nominal significance in 6-month confirmed disability progression (6mCDP) in a preplanned combined analysis of REMODEL-1/-2.[1]

The safety profile in REMODEL-1/-2 was consistent with the broader development program of remibrutinib comprising more than 4,500 clinical trial participants in multiple indications.[1-4] Remibrutinib was well tolerated and continues to demonstrate no liver safety signal, including no cases meeting Hy's Law criteria.

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“Despite advances in treatment, an unmet need remains for oral therapies that can deliver robust relapse prevention, slow disability progression, while maintaining a favorable safety profile. The positive REMODEL results underscore the potential of remibrutinib as a high-efficacy oral therapy for people living with RMS with a differentiated benefit-risk profile,” said Shreeram Aradhye, President, Development, and Chief Medical Officer, Novartis. “Building on our long-standing commitment to advancing care in MS, these findings reinforce our continued ambition on driving innovation in this space and delivering therapies that address the evolving needs of people living with MS.”

Novartis will present the REMODEL-1 and REMODEL-2 data as a late-breaker at MSToronto2026 and intends to host an investor call following the congress presentation. Novartis plans to seek regulatory approval for remibrutinib in RMS globally.

About Multiple Sclerosis
Multiple sclerosis (MS) is a chronic inflammatory disease of the central nervous system characterized by myelin destruction and axonal damage in the brain, optic nerves and spinal cord.[5] MS, which affects nearly 3 million people worldwide, can be characterized into three main types: non-active secondary progressive (SPMS), primary progressive (PPMS), and relapsing MS (RMS).[6-7] RMS is the most common form and includes clinically isolated syndrome (CIS), relapsing-remitting (RRMS), and active SPMS.[7] The various forms of MS are distinguished by how the disease presents and progresses, including whether patients experience relapses, worsening disability over time, or a combination of both.[8]

About Remibrutinib
Remibrutinib is a highly selective, oral Bruton’s tyrosine kinase (BTK) inhibitor that blocks the BTK pathway, reducing activation of B cells and innate immune cells to modulate immune regulatory networks and related neuroinflammation.[9-12] Discovered at Novartis, remibrutinib is being investigated in neuroscience indications, including the Phase III trials REMODEL in RMS, REMASTER in SPMS, as well as other immune-mediated conditions, such as hidradenitis suppurativa and food allergy.[13-14] Remibrutinib 25 mg was approved as Rhapsido® by the FDA in September 2025 and the EMA in April 2026 for the treatment of adults with chronic spontaneous urticaria (CSU).[15,16]

About the REMODEL Trials
REMODEL-1/-2 are identical multicenter, randomized, double-blind, active comparator-controlled Phase III studies evaluating the efficacy and safety of remibrutinib compared to teriflunomide for adult patients with relapsing multiple sclerosis (RMS).[17,18] Approximately 2,000 patients globally with evidence of recent disease activity and an Expanded Disability Status Scale (EDSS) of 0.0–5.5 were randomized 1:1 to receive remibrutinib 100 mg or teriflunomide. The studies consist of an initial double-blind Core Part with a flexible duration of up to a maximum of 30 months, followed by an open-label extension for up to 5 years. The primary endpoint is annualized relapse rate (ARR). Key secondary endpoints include 3- and 6-month confirmed disability progression, the number of new/enlarging T2 lesions per year, the number of Gd+ T1 lesions per scan, serum neurofilament light chain (sNfL) concentration, and the percentage of participants with no evidence of disease activity (NEDA-3).[17-19]

About Novartis Neuroscience
Neurological diseases are deeply personal, affecting people of any age, from newborns to seniors, often striking in the prime of life. In multiple sclerosis (MS), Novartis has helped shape the treatment landscape for decades through scientific innovation and leadership in advancing care for people living with MS. We remain focused on addressing unmet needs and pursuing new approaches that may improve outcomes for people across the MS journey. Building on this foundation, we're doubling down on our commitment to neurology, expanding our legacy of innovation in MS and spinal muscular atrophy (SMA) to work in neuroimmunology, neurodegeneration, and neuromuscular diseases. Our goal is to protect people’s health across their lifespan, developing more treatment options that lead to better outcomes.

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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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," "believe," "committed," "investigational," "launch," "building," "maintaining," "continued," "evolving," or similar expressions, or by express or implied discussions regarding: potential new products including remibrutinib; potential new indications for existing products; potential product launch of remibrutinib or potential future revenues from remibrutinib; results of ongoing clinical trials; or potential future, pending or announced transactions; or potential future sales or earnings from remibrutinib;. You should not place undue reliance on these statements. Such forward-looking statements are based on the current beliefs and expectations of management 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 remibrutinib 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 remibrutinib will be commercially successful in the future. In particular, our expectations could be affected by, among other things, uncertainties concerning: global healthcare cost containment, including ongoing government, payer and general public pricing and reimbursement pressures and requirements for increased pricing transparency; the success of our key products, commercial priorities and strategy; research and development of new products, including clinical trial results and additional analysis of existing clinical data; our ability to obtain or maintain proprietary intellectual property protection, including the ultimate extent of the impact on Novartis of the loss of patent protection and exclusivity on key products; our ability to realize the strategic benefits, operational efficiencies or opportunities expected from our external business opportunities; the development or adoption of new technologies, including artificial intelligence, and new business models; the implementation of our new IT projects and systems; potential significant breaches of information security or disruptions of our information technology systems; actual or potential legal proceedings, including regulatory actions or delays or government regulation related to the products and pipeline products described in this press release; safety, quality, data integrity, or manufacturing issues; major macroeconomic and geo- and socio-political developments, including the impact of any potential tariffs on our products or the impact of war in certain parts of the world; future global exchange rates; future demand for our products; and other risks and factors referred to in Novartis AG's most recently filed Form 20-F and in subsequent reports filed with, or furnished to, 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 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 **www.novartis.com** and connect with us on **LinkedIn**, **Facebook**, **X/Twitter** and **Instagram**.

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