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PRESS RELEASE

Novartis ianalumab receives FDA Breakthrough Therapy designation for Sjögren's disease

- *Designation based on clinical evidence supporting potential of ianalumab in Sjögren's disease, including phase III trials[1]*
- *Distinction expedites development and review of treatments for serious conditions that may demonstrate improvement over standard of care*
- *Novartis plans to submit to health authorities globally starting in early 2026*
- *Ianalumab has potential to become first targeted treatment for this autoimmune disease with significant unmet need*

Basel, January 16, 2026 – Novartis today announced that the US Food and Drug Administration (FDA) has granted Breakthrough Therapy designation to ianalumab for Sjögren's disease, the second most prevalent rheumatic autoimmune disease[2]. Ianalumab is a fully human monoclonal antibody with a novel dual mechanism of action that depletes B-cells and inhibits their activation and survival via BAFF-R blockade[3]. Novartis plans to submit ianalumab for regulatory approval globally starting in early 2026. If approved, ianalumab would become the first targeted treatment for patients with Sjögren's disease.

"This Breakthrough Therapy designation recognizes the potential for ianalumab to substantially improve the standard of care for people with Sjögren's disease, who currently don't have effective treatment options for this debilitating disease," said Angelika Jahreis, Global Head, Development, Immunology, Novartis. "We look forward to working with the agency through the regulatory review process with the hope of making ianalumab available to appropriate patients as quickly as possible."

Building on the Fast Track designation that ianalumab was awarded in 2016, the FDA Breakthrough Therapy designation aims to expedite the development and review of therapies intended to treat serious conditions and address significant unmet needs[4]. Awarding of the Breakthrough Therapy designation is supported by positive data from multiple studies, including replicate phase III trials.

Sjögren's disease is a serious, progressive, autoimmune condition that affects multiple organs causing a wide spectrum of symptoms such as dryness, fatigue, pain, and an increased risk of lymphoma, which can carry a significant burden and impact on quality of life[5,6]. Its heterogenous nature often causes it to go unrecognized or misdiagnosed[7]. Sjögren's affects approximately 0.25% of the population, and it is estimated that 50% of people with Sjögren's are undiagnosed[8,9]. There are no approved targeted treatments available for Sjögren's disease.

About NEPTUNUS-1 and NEPTUNUS-2
The ianalumab Phase III clinical trials, NEPTUNUS-1 and NEPTUNUS-2, are global, multicenter, pivotal studies evaluating the efficacy and safety of ianalumab in patients with Sjögren's disease[10,11]. In both trials, ianalumab delivered a clinically meaningful benefit, showing improvement in disease activity and reductions in patient burden[1]. Ianalumab demonstrated a favorable safety profile with an overall incidence of adverse events and serious adverse events comparable to placebo in both studies[1].

Disclaimer
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 nearly 300 million people worldwide.

Novartis in 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. From small molecules to biologics and CAR-T cell therapy, our pioneering science is focused on where we can have the greatest impact on patient outcomes. And by elevating the patient voice and building on a common purpose across the healthcare ecosystem, we are not just addressing the needs of people with autoimmune diseases – we're reimagining medicine, together.

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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