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PRESS RELEASE

Novartis announces both ianalumab Phase III clinical trials met primary endpoint in patients with Sjögren's disease

Ad hoc announcement pursuant to Art. 53 LR

- *NEPTUNUS-1 and NEPTUNUS-2 are the first ever global phase III trials to demonstrate statistically significant reduction in disease activity for Sjögren's disease*[1]
- *Ianalumab has the potential to become the first and only targeted treatment approved for patients with Sjögren's disease*
- *Ianalumab was well tolerated and demonstrated a favorable safety profile in Sjögren's disease*[1,2]
- *Novartis plans to present its data at an upcoming medical congress and submit to health authorities globally*

Basel, August 11, 2025 – Novartis today announced positive top-line results from its Phase III trials evaluating ianalumab (VAY736) in adults with active Sjögren's disease. Both trials met the primary endpoint of demonstrating statistically significant improvements in disease activity[1]. These results support the potential for ianalumab, a drug with a dual mechanism of action, B-cell depletion and BAFF-R inhibition, to become the first targeted treatment for patients with Sjögren's disease, a chronic, disabling autoimmune disease[3,4,5].

"Sjögren's disease is a serious, progressive, systemic autoimmune disease, often unrecognized or misdiagnosed with a significant detrimental impact to quality of life, with very limited treatment options and an established unmet need. Both Phase III trials demonstrate that ianalumab improves disease activity in patients with Sjogren's disease." said Shreeram Aradhye, M.D., President of Development and Chief Medical Officer at Novartis. "These Phase III studies mark a significant milestone. We look forward to engaging with health authorities to discuss these findings in the near future."

The NEPTUNUS pivotal trials achieved the primary endpoint of improving disease activity measured by a reduction in EULAR Sjögren's syndrome disease activity index (ESSDAI), a multi-dimensional disease activity measurement compared to placebo[1]. Ianalumab was well tolerated and demonstrated a favorable safety profile in Sjögren's disease[1,2].

Novartis plans to present the NEPTUNUS-1 and NEPTUNUS-2 data at an upcoming medical meeting and submit ianalumab, which was granted Fast Track Designation by the US Food and Drug Administration (FDA), to health authorities globally[6].

About ianalumab
Ianalumab *(VAY736)* is a novel fully human monoclonal antibody being investigated for its potential to treat various B cell-driven autoimmune diseases, including Sjögren's disease, immune thrombocytopenia (ITP), systemic lupus erythematosus (SLE), lupus nephritis (LN), warm autoimmune hemolytic anemia (wAIHA) and diffuse cutaneous systemic sclerosis (dcSSc)[3,7-13]. Its mechanism of action targets B cells in two ways, namely combining B cell depletion via antibody-dependent cellular toxicity (ADCC) and interruption of BAFF- R mediated signals of B cell function and survival[3]. In clinical trials, ianalumab showed promising efficacy and a favorable safety profile in Sjögren's disease, systemic lupus erythematosus, and immune thrombocytopenia[2,14,15]. Ianalumab originates from an early collaboration with MorphoSys AG, a company which Novartis later acquired in 2024[16].

About NEPTUNUS-1 and NEPTUNUS-2
The 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[7,8]. These trials were designed to provide comprehensive data on ianalumab's potential as a targeted treatment for Sjögren's disease, in patients with active extraglandular disease.[3,7,8].

NEPTUNUS-1 is a randomized, double-blind, 2-arm multicenter phase III trial (N=275) to evaluate the clinical efficacy, safety, and tolerability of ianalumab 300 mg subcutaneous (s.c.) monthly compared with placebo for 52 weeks[7]. NEPTUNUS-2 is a randomized, double-blind, 3-arm multicenter phase III trial (N=504) to evaluate the clinical efficacy, safety, and tolerability of ianalumab 300 mg s.c. monthly or every 3 months compared with placebo for up to 52 weeks[8].

The primary endpoint was measured by improvements in systemic disease activity using ESSDAI (EULAR Sjögren's syndrome disease activity index)[7,8]. Patients currently enrolled in NEPTUNUS-1 and NEPTUNUS-2 have been given the opportunity to continue follow-up in these studies or enter a long-term extension trial[17].

About Sjögren's disease (previously called Sjögren's syndrome)
Sjögren's disease is a systemic, chronic autoimmune disorder that causes inflammation and tissue damage, impacting the entire body[4]. It primarily affects exocrine glands, leading to excessive dryness, with over 90 percent of patients experiencing dry eyes and dry mouth[4,18]. The disease is heterogenous, patients experience dryness, fatigue and widespread pain and 30-40 percent of patients will also show extraglandular organ involvement[5,19]. Extraglandular manifestation can be very diverse and can affect skin, musculoskeletal system, kidneys, lungs and other organs[19]. The risk of lymphoma is increased in patients with Sjögren's[5].

Sjögren's is one of the most prevalent rheumatic autoimmune diseases, affecting approximately 0.25 percent of the population with an estimated 50 percent undiagnosed [20-21]. Sjögren's is nine times more common in women than men[4]. B cell dysfunction plays a significant role in the disease by causing an autoimmune response that leads to inflammation and tissue damage[3,4]. There are no systemic treatments approved, with only limited symptomatic treatments available to provide temporary and partial symptomatic relief, highlighting the need for effective targeted therapies[3].

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," "investigational," "pipeline," "upcoming," "intends," or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for

ianalumab, or regarding potential future revenues from ianalumab. 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 ianalumab 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 ianalumab will be commercially successful in the future. In particular, our expectations regarding ianalumab 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.

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