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PRESS RELEASE

Novartis provides update on Phase III GCAptAIN study of Cosentyx® in giant cell arteritis (GCA)

- *The GCAptAIN study did not meet its primary endpoint of sustained remission at Week 52 in adults with newly diagnosed or relapsing GCA*[1]
- *Safety in GCA patients was consistent with known safety profile of Cosentyx® (secukinumab)*[1]

Basel, July 03, 2025 – Novartis today announced top-line results from the Phase III GCAptAIN study evaluating Cosentyx® (secukinumab) in adults with newly diagnosed or relapsing giant cell arteritis (GCA).

In the study, Cosentyx was evaluated in combination with a 26-week steroid taper and compared to placebo plus a 52-week steroid taper. Cosentyx did not demonstrate a statistically significant improvement in sustained remission at Week 52 compared to placebo. While the secondary outcomes did not show statistical superiority, Cosentyx showed numerically better outcomes compared to placebo for cumulative steroid dose and steroid-related toxicity[1]. Safety in GCA was consistent with the known safety profile of Cosentyx[1], which is supported by robust evidence and 10 years of real-world data across its approved indications[2-7].

“While the Phase III results of GCAptAIN did not replicate the positive outcomes observed in the Phase II trial, we remain committed to continuing to drive scientific progress and deepening the understanding of immune-mediated diseases,” said Shreeram Aradhye, M.D., President, Development and Chief Medical Officer, Novartis. “We are grateful to the patients, investigators, and teams who made this study possible and will continue focusing on addressing areas of unmet medical need.”

Novartis will complete a full evaluation of the GCAptAIN data and share the results at a later date.

About GCAptAIN trial
The GCAptAIN trial (NCT04930094) is a global Phase III, multicenter, randomized, double-blind, placebo-controlled, parallel-group study conducted across 27 countries, evaluating the efficacy and safety of Cosentyx in patients with giant cell arteritis (GCA). Patients were randomized into three treatment arms: Cosentyx 300 mg, Cosentyx 150 mg, or placebo, all in combination with a glucocorticoid (GC) taper regimen. The primary endpoint of the trial is to assess whether secukinumab 300 mg s.c. plus a 26-week GC taper is superior to placebo plus a 52-week GC taper in achieving sustained remission at Week 52 and the first secondary endpoint is the cumulative GC dose through Week 52[8].

About Cosentyx (secukinumab)
Cosentyx is a fully human biologic that directly inhibits interleukin-17A, an important cytokine involved in the inflammation underlying multiple immune-mediated inflammatory diseases. It is approved for use in adults with psoriatic arthritis (PsA), moderate to severe plaque psoriasis (PsO), ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA), and hidradenitis suppurativa (HS)[9-11], as well as in pediatric patients with PsO, enthesitis-related arthritis (ERA), and juvenile psoriatic arthritis (JPsA)[12,13].Cosentyx is supported by robust evidence and 10 years of real-world data demonstrating its long-term safety and sustained efficacy[2-7]. Since its launch in 2015, it has been used to treat more than 1.8 million patients worldwide and is now approved in over 100 countries[2].

About giant cell arteritis (GCA)
Giant cell arteritis (GCA) is the most common form of systemic vasculitis, primarily affecting people over 50 years of age[14-16]. Because of its potential to cause irreversible vision loss and life-threatening aortic aneurysms, GCA is considered a medical emergency requiring prompt recognition and treatment[17-19]. Beyond its physical complications, GCA significantly impairs quality of life, contributing to fatigue, cognitive difficulties, and reduced independence[20-22].

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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 nearly 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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