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Novartis Cosentyx® positive 16-week PREVENT results advance potential new indication for patients with axial spondyloarthritis

- *Phase III PREVENT study met 16-week primary endpoint of ASAS40 in patients with active non-radiographic axial spondyloarthritis (nr-axSpA). All secondary endpoints were also met*[1]

- *Novartis has submitted to EMA for approval in nr-axSpA, which would be the fourth indication for Cosentyx*[2]*. 52-week data from the PREVENT study, to support FDA submission, are expected later in the year*

- *There are approximately 1.7 million patients with nr-axSpA in the EU and US*[3]*. nr-axSpA forms part of the axial spondyloarthritis (axSpA) spectrum and is characterized by chronic inflammatory back pain and symptoms such as nocturnal pain, morning stiffness and impaired quality of life*[4,5]

- *The PREVENT study underlines Cosentyx leadership and is a step forward in providing patients with a treatment that addresses the complete axSpA disease spectrum*

Basel, September 17, 2019 – Novartis, a leader reimagining rheumatology and immuno-dermatology, today announced positive new data from the PREVENT trial evaluating the efficacy and safety of Cosentyx® (secukinumab) in patients with nr-axSpA (non-radiographic axial spondyloarthritis). The ongoing Phase III trial met its primary endpoint of ASAS40 at Week 16, showing a significant and clinically meaningful reduction in disease activity for patients treated with Cosentyx versus placebo. The trial demonstrated a favorable safety profile consistent with previous clinical trials[1,6,7,8].

“These study results for Cosentyx build on our long-standing experience in ankylosing spondylitis and are a step toward a new treatment option that could allow patients to realize relief much earlier in axial spondyloarthritis,” said John Tsai, M.D., Head of Global Drug Development and Chief Medical Officer for Novartis. “If approved, this would be the fourth indication for Cosentyx.”

Detailed data is planned to be presented at a future scientific congress. These data add to the existing evidence supporting Cosentyx as a rapid and long-lasting comprehensive treatment, backed by evidence from over 100 studies, across axial spondyloarthritis, psoriatic arthritis and psoriatic disease, with over 250,000 patients treated worldwide[9,10].

About axSpA
Axial spondyloarthritis (axSpA) is a spectrum of long-term inflammatory disease characterized by chronic inflammatory back pain[4]. The axSpA disease spectrum includes ankylosing spondylitis (AS), in which joint damage is visible on x-ray, and non-radiographic axial spondyloarthritis (nr-axSpA), in which joint damage is not visible on x-ray[4]. Both parts of the disease spectrum have a similar symptom burden, including nocturnal pain, fatigue, morning

stiffness and functional disability[5]. If left untreated, axSpA could impair activity, lead to lost work time and have a significant impact on quality of life[5].

About PREVENT
PREVENT is an ongoing two-year randomized, double-blind, placebo-controlled Phase III study (with a two-year extension phase) to investigate the efficacy and safety of Cosentyx, in patients with active nr-axSpA. The study enrolled 555 male and female adult patients with active nr-axSpA (with onset before 45 years of age, spinal pain rated as ≥40/100 on a visual analog scale (VAS) and Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) ≥4) and who had been taking at least two different non-steroidal anti-inflammatory drugs (NSAIDs) at the highest dose up to 4 weeks prior to study start. Patients may have previously taken an TNF inhibitor (not more than one) but had had an inadequate response. Of the 555 patients enrolled in the study, 501 (90%) were biologic naive. Patients were allocated to one of three treatment groups: Cosentyx 150 mg subcutaneously with loading dose (Induction: 150 mg Secukinumab subcutaneously weekly for 4 weeks, then maintenance with 150 mg Secukinumab monthly); Cosentyx 150 mg no loading dose (150 mg Secukinumab subcutaneously monthly), or placebo (induction of subcutaneously weekly for 4 weeks, followed by maintenance of once-monthly)[1].

The primary endpoints are the proportion of patients achieving an ASAS40 response with Cosentyx 150 mg at weeks 16 and 52. Secondary endpoints include change in BASDAI over time and change in the Ankylosing Spondylitis Disease Activity Score with CRP (ASDAS-CRP)[1].

ASAS40 is achieved when there is a measure of an improvement of at least 40% and an improvement of at least 10 units on a 0–100 scale in at least three of the following domains: Patient global assessment, Pain assessment, Function (Bath Ankylosing Spondylitis Functional Index (BASFI)), and Inflammation (morning stiffness severity and duration). BASDAI assesses a patient's disease activity on six measures: fatigue, spinal pain, joint pain/swelling, enthesitis, morning stiffness duration and morning stiffness severity[11].

About Cosentyx (secukinumab)
Cosentyx is the first and only fully-human biologic that directly inhibits interleukin-17A (IL-17A), a cornerstone cytokine involved in the inflammation and development of psoriatic arthritis (PsA), psoriasis (PsO), and ankylosing spondylitis (AS)[2,12].

Cosentyx is backed by robust clinical evidence, including 5-year data across three indications of psoriasis, PsA and AS as well as data from real world evidence [6,7.8,13-22]. These data strengthen the unique position of Cosentyx as a rapid and long-lasting comprehensive treatment across axial spondyloarthritis, psoriatic arthritis and psoriatic disease, with more than 250,000 patients treated worldwide with Cosentyx since launch[10].

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 "advance," "potential," "submitted," "would," "to support," "expected," "later in the year," "ongoing," "builds on," "step toward," "could," "planned," "supporting," "launch," or similar terms, or by express or implied discussions regarding potential new indications or labeling for Cosentyx, or regarding potential future revenues from Cosentyx. 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 Cosentyx will be submitted or approved for any

additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that Cosentyx will be commercially successful in the future. In particular, our expectations regarding Cosentyx 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 and economic conditions; safety, quality 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 reimagining medicine to improve and extend people's lives. As a leading global medicines company, we use innovative science and digital technologies to create transformative treatments in areas of great medical need. In our quest to find new medicines, we consistently rank among the world's top companies investing in research and development. Novartis products reach more than 750 million people globally and we are finding innovative ways to expand access to our latest treatments. About 108,000 people of more than 140 nationalities work at Novartis around the world. Find out more at www.novartis.com.

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