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New Novartis PREVENT data show Cosentyx® delivers early relief in axial spondyloarthritis

- *42.2% of patients with non-radiographic axial spondyloarthritis (nr-axSpA) treated with Cosentyx had improved ASAS40 scores through Week 16; improvements continued through Week 52*[1]
- *PREVENT is the largest ever study of a biologic in patients with nr-axSpA and underscores Novartis leadership in rheumatology*[1]
- *There are approximately 1.7 million patients with nr-axSpA in the EU and US*[2]
- *PREVENT adds to 5-year evidence in ankylosing spondylitis (AS) and is a step forward in providing patients with a treatment that addresses the complete axSpA disease spectrum*[3-5]

Basel, November 12, 2019 — Novartis, a leader in rheumatology and immuno-dermatology, announced today detailed results from the Phase III PREVENT trial, evaluating the efficacy and safety of Cosentyx® (secukinumab) in patients with non-radiographic axial spondyloarthritis (nr-axSpA)[1].

The ongoing trial met its primary endpoint of ASAS40 at Week 16, with 42.2% of nr-axSpA patients treated with Cosentyx 150 mg showing a significant and clinically meaningful reduction in disease activity versus placebo (42.2% vs 29.2%: $p<0.05$)[1]. Statistically significant improvements in secondary endpoints were also demonstrated, including pain, mobility and health-related quality of life[1]. The trial showed a sustained response and a safety profile consistent with previous clinical trials[1,3-8]. No new safety signals were detected[1].

“The PREVENT study showed clinically significant outcomes as early as week three, and these were maintained up to one year for patients treated with Cosentyx,” said Atul Deodhar, MD, professor of medicine and medical director of Rheumatology Clinics at Oregon Health & Science University, USA, and lead author for the trial. “Non-radiographic axial spondyloarthritis can have a debilitating symptom burden, and if approved, this would be a welcome addition to the limited treatment options currently available to treat this condition.”

“These data strengthen the evidence for Cosentyx as a treatment option that addresses the complete axSpA disease spectrum,” said Eric Hughes, Global Development Unit Head, Immunology, Hepatology & Dermatology, Novartis. “As the largest ever study of its kind in nr-axSpA, PREVENT is an example of how we’re working to reimagine medicine for improved patient outcomes.”

Novartis recently announced it has submitted to the EMA and plans to submit to the FDA for approval in nr-axSpA[9]. It would be the fourth indication for Cosentyx, which is backed by five-year sustained efficacy and safety data across AS, psoriasis and psoriatic arthritis[3-8].

PREVENT data are being presented as a late-breaking abstract at the 2019 American College of Rheumatology/Association of Rheumatology Professionals (ACR/ARP) Annual Meeting in Atlanta, Georgia, USA.

About axSpA
Axial spondyloarthritis (axSpA) is a spectrum of long-term inflammatory disease characterized by chronic inflammatory back pain[10]. 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[10]. Both parts of the disease spectrum have a similar symptom burden, including nocturnal pain, fatigue, morning stiffness and functional disability[11]. If left untreated, axSpA could impair activity, lead to lost work time and have a significant impact on quality of life[11].

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 a TNF inhibitor (not more than one) but had an inadequate response. Of the 555 patients enrolled in the study, 501 (90.3%) were biologic naïve. 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 in TNF-naive patients. Secondary endpoints include among others 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[12].

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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 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 109,000 people of more than 140 nationalities work at Novartis around the world. Find out more at www.novartis.com.

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