Novartis International AG
Novartis Global Communications
CH-4002 Basel
Switzerland

https://www.novartis.com
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MEDIA & INVESTOR RELEASE

Novartis Cosentyx® receives FDA approval for new indication to treat active non-radiographic axial spondyloarthritis

- *FDA approval for Cosentyx® is based on the Phase III PREVENT trial, demonstrating efficacy in active non-radiographic axial spondyloarthritis (nr-axSpA), which is part of the axial spondyloarthritis (axSpA) disease spectrum*
- *There are an estimated 2.7M people living with axial spondyloarthritis (axSpA) in the US; however, it remains significantly underdiagnosed*[1,2]
- *nr-axSpA approval is the fourth indication for Cosentyx, which is backed by five years of clinical data supporting long-term safety and efficacy across moderate to severe plaque psoriasis (PsO), psoriatic arthritis (PsA) and ankylosing spondylitis (AS)*[3-8]

Basel, June 17, 2020 — Novartis, a leader in rheumatology and immuno-dermatology, today announced that the US Food and Drug Administration (FDA) has approved Cosentyx® (secukinumab) for the treatment of active non-radiographic axial spondyloarthritis (nr-axSpA), confirming Cosentyx efficacy in addressing the axial spondyloarthritis (axSpA) disease spectrum[9].

“The results from the PREVENT trial show that there was a significant reduction in disease activity for patients treated with Cosentyx versus placebo,” said Atul Deodhar, MD, professor of medicine and medical director of Rheumatology Clinics at Oregon Health & Science University, and an investigator in the PREVENT clinical trial. “This approval brings a new therapeutic option to people living with non-radiographic axial spondyloarthritis.”

The approval of Cosentyx for nr-axSpA is based on efficacy and safety outcomes from the PREVENT Phase III study, which included 555 adults with active nr-axSpA that were biologic treatment naïve or had an inadequate response / were intolerant to an anti-tumor necrosis factor-α therapy (anti-TNFs). Cosentyx met the primary endpoints achieving statistically significant improvements versus placebo in the signs and symptoms of nr-axSpA, as measured by at least a 40% improvement in the Assessment of Spondyloarthritis International Society (ASAS40) response criteria in biologic-naïve individuals at week 52[10].

nr-axSpA patients treated with Cosentyx showed improvement in both load and without load arms compared to placebo-treated patients at Week 16 in health-related quality of life as measured by the Ankylosing Spondylitis Quality of Life (ASQoL) questionnaire (Least Squares mean change: Week 16: -3.5 and -3.6 -vs -1.8, respectively). General health status and quality of life was assessed by the Short Form health survey (SF-36). At Week 16, patients treated with Cosentyx showed greater improvement from baseline in the SF-36 physical

component summary (PCS) score and in the mental component summary (MCS) score[10]. The safety profile of Cosentyx in the PREVENT trial was shown to be consistent with previous clinical trials. No new safety signals were detected[3-8,10].

nr-axSpA is part of the axSpA spectrum, which is characterized by inflammatory arthritis of the spine associated with chronic inflammatory back pain[11]. The axSpA disease spectrum also includes AS, in which joint damage is visible on x-ray, and nr-axSpA, in which joint damage is generally not visible on x-ray[1,12]. The physical limitations of axSpA can affect activities of daily living as well as leisure activities causing limitations for patients[13,14].

“There is a need for additional treatment options. Having a new treatment option for the axSpA community is truly encouraging," said Cassie Shafer, Chief Executive Officer of the Spondylitis Association of America. “Helping reduce the burden on people living with non-radiographic axial spondyloarthritis by improving symptoms that affect their daily lives remains a critical focus for the SAA.”

In April 2020, Novartis received European Medicines Agency approval of Cosentyx for the treatment of nr-axSpA[15].

About Cosentyx (secukinumab)
Cosentyx is the first and only fully-human biologic that directly inhibits interleukin-17A (IL-17A), an important cytokine involved in the inflammation and development of psoriatic arthritis (PsA), moderate to severe plaque psoriasis (PsO), ankylosing spondylitis (AS) and nr-axSpA[16,17]. Cosentyx has been studied clinically for more than 13 years. The medicine is backed by robust investigational evidence, including five years of clinical data supporting long-term safety and efficacy across moderate to severe plaque psoriasis (PsO), psoriatic arthritis (PsA) and ankylosing spondylitis (AS)[3-8]. These data strengthen the unique position of Cosentyx as a comprehensive treatment across axial spondyloarthritis, psoriatic arthritis and psoriatic disease, supported by more than 340,000 patients treated worldwide since launch[18-20].

About PREVENT
PREVENT is a 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 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)[10].

The primary endpoints are the proportion of biologic-naïve 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)[10].

ASAS40 is achieved when there is a measure of an improvement of at least 40% and an improvement of at least 20 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) and no worsening in the remaining domains[21]. BASDAI assesses a patient’s disease activity on six

measures: fatigue, spinal pain, joint pain/swelling, enthesitis, morning stiffness duration and morning stiffness severity[21].

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,” “may,” “could,” “remains,” “expectations,” “encouraging,” investigational,” “launch,” “brings,” or similar terms, or by express or implied discussions regarding potential or actual marketing approvals, 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 sale or for any additional indications or labeling in any additional markets, 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, economic and business conditions, including the effects of and efforts to mitigate pandemic diseases such as COVID-19; 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

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Novartis Media Relations
E-mail: media.relations@novartis.com

Antonio Ligi
Novartis Global External Communications
+41 61 324 1374 (direct)
antonio.ligi@novartis.com

Louise Clark
Novartis Pharma Communications
+41 61 324 2970 (direct)
louise.clark@novartis.com

Eric Althoff
Novartis US External Communications
+1 646 438 4335
eric.althoff@novartis.com

Novartis Investor Relations
Central investor relations line: +41 61 324 7944
E-mail: investor.relations@novartis.com

Central		North America	
Samir Shah	+41 61 324 7944	Sloan Simpson	+1 862 778 5052
Thomas Hungerbuehler	+41 61 324 8425	Cory Twining	+1 862 778 3258
Isabella Zinck	+41 61 324 7188		