Novartis International AG
Novartis Global Communications
CH-4002 Basel
Switzerland

http://www.novartis.com

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Novartis positive 52-week PREVENT data confirm Cosentyx® efficacy in addressing entire axSpA spectrum

- *Phase III PREVENT study met 52-week primary endpoint of ASAS40, showing a sustained response in patients with non-radiographic axial spondyloarthritis (nr-axSpA)*[1]
- *Novartis plans FDA submission for nr-axSpA, having submitted to EMA previously*[1]*. This would be the fourth indication for Cosentyx*[2,3]
- *PREVENT underlines Cosentyx leadership and is a step forward in providing patients with a treatment that addresses the complete axSpA disease spectrum*
- *There are approximately 1.7 million patients with nr-axSpA in the US and EU*[4]

Basel, October 02, 2019 – Novartis, a leader in rheumatology and immuno-dermatology, today announced additional positive data from the PREVENT trial, evaluating the efficacy and safety of Cosentyx® (secukinumab) in patients with non-radiographic axial spondyloarthritis (nr-axSpA). The ongoing Phase III trial met its primary endpoint of ASAS40 at Week 52, showing a significant and clinically meaningful reduction in disease activity for patients treated with Cosentyx versus placebo. The trial demonstrated a sustained response and a safety profile consistent with previous clinical trials. No new safety signals were detected[1,5-10].

Positive 16-week PREVENT data were announced mid-September and submitted to EMA for approval in nr-axSpA[11]. These data add to the five-years of clinical data supporting the long-term efficacy and safety of Cosentyx across ankylosing spondylitis, psoriatic arthritis and psoriasis[5-10].

“Non-radiographic axial spondyloarthritis is a chronic debilitating disease, which left untreated can have a significant impact on patients' quality of life,” said Atul Deodhar, MD, professor of medicine and medical director of Rheumatology Clinics at Oregon Health & Science University, and an investigator in the secukinumab clinical trial program. “These positive results indicate a potential new treatment option to help patients experience relief from the signs and symptoms of their disease.”

“These data are encouraging for people living with nr-axSpA, where there are only limited treatment options available,” said John Tsai, M.D., Head of Global Drug Development and Chief Medical Officer for Novartis. “It’s a great example of how we’re working to reimagine medicine to help patients realize early relief from this disease.”

Detailed data is planned to be presented at a future scientific congress.

About axSpA
Axial spondyloarthritis (axSpA) is a spectrum of long-term inflammatory disease characterized by chronic inflammatory back pain[12]. The axSpA disease spectrum includes ankylosing

spondylitis (AS), in which joint damage is generally visible on x-ray, and non-radiographic axial spondyloarthritis (nr-axSpA), in which joint damage is not visible on x-ray[12,13]. Both parts of the disease spectrum have a similar symptom burden, including nocturnal pain, fatigue, morning stiffness and functional disability[14]. If left untreated, axSpA could impair activity, lead to lost work time and have a significant impact on quality of life[14].

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) and no worsening in the remaining domains[15]. BASDAI assesses a patient's disease activity on six measures: fatigue, spinal pain, joint pain/swelling, enthesitis, morning stiffness duration and morning stiffness severity[15].

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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.

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# # #

Novartis Global External Communications
E-mail: media.relations@novartis.com

Antonio Ligi Friedrich von Heyl

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

Novartis Pharma Communications
+41 61 324 8984 (direct)
+41 79 749 0286 (mobile)
friedrich.vonheyl@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
Pierre-Michel Bringer	+41 61 324 1065	Cory Twining	+1 212 778 3258
Thomas Hungerbuehler	+41 61 324 8425		
Isabella Zinck	+41 61 324 7188		