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MEDIA & INVESTOR RELEASE

Novartis PREVENT data show Cosentyx® helps patients realize early and lasting relief in axial spondyloarthritis

- *Phase III PREVENT data show Cosentyx® 150 mg provided significant and sustained improvement in signs and symptoms of non-radiographic axial spondyloarthritis (nr-axSpA) up to Week 52[1]*
- *nr-axSpA is the fourth EU indication for Cosentyx, providing patients in Europe with a first-in-class treatment that addresses the axial spondyloarthritis (axSpA) disease spectrum*
- *There are approximately 1.7 million patients with nr-axSpA in the top five EU countries and US[2]*
- *PREVENT is the largest ever study of a biologic in patients with nr-axSpA; data reinforce Cosentyx leadership in rheumatology and immuno-dermatology*

Basel, June 4, 2020 — Novartis, a leader in rheumatology and immuno-dermatology, today announced the full 52-week results from the Phase III PREVENT trial, which reinforce the substantial and sustained benefits of Cosentyx® (secukinumab) across the axial spondyloarthritis (axSpA) spectrum.

The study found patients treated with Cosentyx 150 mg showed significant and sustained improvements in signs and symptoms of non-radiographic axial spondyloarthritis (nr-axSpA) at 52 weeks. nr-axSpA is a painful and debilitating condition affecting 1.7 million people in the top five EU countries and the US[2]. However, because nr-axSpA is underdiagnosed, with an average delay in diagnosis of more than seven years, that number may be higher[3].

“Axial spondyloarthritis can have a serious impact on a patient’s quality of life and ability to carry out everyday tasks. PREVENT demonstrated the efficacy and safety of secukinumab in non-radiographic axial spondyloarthritis, showing early and sustained relief from the signs and symptoms of this often painful disease,” said Jürgen Braun, MD, Professor of Rheumatology at Ruhr-University Bochum, Germany, and an investigator in the secukinumab clinical trial program.

The PREVENT trial met its primary endpoint of 40% improvement in the Assessment of Spondyloarthritis International Society (ASAS40) in biologic treatment-naïve patients at Week 16 and Week 52 versus placebo (41.5% vs 29.2%: P<0.05 and 35.4% vs 19.9%: P<0.05), respectively when a loading dose was used. Secondary endpoints indicating improvements in pain, mobility and health-related quality of life were also met in the trial up to Week 52. The trial demonstrated a safety profile consistent with previous clinical trials with no new safety

signals reported[1]. The PREVENT data are being presented at the Annual European Congress of Rheumatology (EULAR) e-congress 2020.

“With these new data and the recent first-in-class European approval of Cosentyx in non-radiographic axial spondyloarthritis, we are continuing to build on our heritage in the axial spondyloarthritis disease spectrum,” said Eric Hughes, Global Development Unit Head, Immunology, Hepatology & Dermatology at Novartis. “This fourth indication for Cosentyx further demonstrates our commitment to reimagine care for more patients.”

Cosentyx is the first fully-human interleukin (IL)-17A inhibitor indicated for patients in Europe with nr-axSpA and 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).

In April 2020, Novartis received approval of Cosentyx from the European Commission for the treatment of nr-axSpA[4]. Novartis has also submitted Cosentyx for review by the US Food and Drug Administration (FDA) and the Japan Pharmaceuticals and Medical Devices Agency (PMDA) for the treatment of adults with nr-axSpA.

About axSpA
AxSpA is a spectrum of long-term inflammatory disease characterized by chronic inflammatory back pain[5]. The axSpA spectrum includes AS, in which joint damage is generally visible on X-ray, and nr-axSpA, in which joint damage is not visible on X-ray[5,6]. Both parts of the disease spectrum have a comparable symptom burden, including nocturnal waking caused by pain, spinal pain, morning stiffness, fatigue and functional disability[7]. If left untreated, axSpA impairs activity, leads to lost work time and has a significant impact on quality of life, including family relationships[7].

About Cosentyx
Cosentyx is the first and only fully-human biologic that directly inhibits IL-17A, a cornerstone cytokine involved in the inflammation and development of PsO, PsA and AS[8-11].

Cosentyx is backed by robust clinical evidence, including five-year data across three indications of PsO, PsA and AS, as well as data from real world evidence[12-14]. These data strengthen the unique position of Cosentyx as a rapid and long-lasting comprehensive treatment across axSpA, PsA and psoriatic disease, with more than 300,000 patients treated worldwide with Cosentyx since launch[15].

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).

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].

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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 nearly 800 million people globally and we are finding innovative ways to expand access to our latest treatments. About 109,000 people of more than 145 nationalities work at Novartis around the world. Find out more at https://www.novartis.com.

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15. Novartis data on file.

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