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Novartis Cosentyx® first to show efficacy in all key manifestations of psoriatic arthritis

- *First-of-its-kind data shows efficacy and safety of a biologic in the management of axial manifestations of psoriatic arthritis (PsA), which affect up to an estimated 35 million people worldwide*[1]
- *66.3% of patients treated with secukinumab 150 mg achieved rapid and significant improvements in the signs and symptoms of psoriatic arthritis with axial manifestations at Week 12*
- *Cosentyx bridges for the first time treatment of psoriasis, psoriatic arthritis and axial manifestations*
- *Results strengthen unique position of Cosentyx as a rapid, comprehensive treatment of spondyloarthritis and psoriatic disease, with over 200,000 patients treated worldwide*

Basel, June 12, 2019 — Novartis, a leader in rheumatology and immuno-dermatology, today announced new data from the MAXIMISE trial evaluating the efficacy and safety of Cosentyx (secukinumab) in the management of axial manifestations of psoriatic arthritis (PsA).

The ongoing 52-week Phase IIIb trial met both its primary and key secondary endpoint with 63.1% of Cosentyx 300 mg and 66.3% of Cosentyx 150 mg patients achieving ASAS20 at Week 12 (versus 31.3% for placebo) respectively. Rapid onset of relief was seen as early as week four, with the trial demonstrating a favorable safety profile consistent with previous clinical trials[2].

“Up to two thirds of patients with psoriatic arthritis experience inflammatory back pain, which can limit mobility,” said Dr. Laura Coates, NIHR Clinician Scientist and Senior Clinical Research Fellow at Nuffield Department of Orthopedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, UK. “This study provides clinicians with the evidence to help them choose a comprehensive treatment for psoriatic arthritis that addresses diverse patient phenotypes.”

PsA is a complex disease with multiple manifestations driving patient symptoms[3,4]. It is estimated to affect up to 50 million people worldwide[5-8] and is part of a family of long-term inflammatory diseases (spondyloarthritis) that target the joints. It is closely associated with psoriasis; up to 40% of patients with psoriasis have PsA[6].

“This is the first time we’ve seen the efficacy of a biologic in the axial manifestations of psoriatic arthritis at 12 weeks,” said Dr. Antonio Mera Varela, Head of Rheumatology, Hospital Clínico Universitario de Santiago de Compostela, Spain. “As a physician, it’s highly important that there is something that can help manage all aspects of my patients’ psoriatic arthritis,

including inflammation of the spine, joints, enthesitis, dactylitis and psoriasis of the skin and nails."

These data, which add to the existing evidence supporting Cosentyx as a treatment across multiple psoriatic disease manifestations, will be presented at the Annual European Congress of Rheumatology (EULAR) on 12–15 June in Madrid, Spain.

About MAXIMISE
MAXIMISE is a 52-week, double-blind, randomized, placebo-controlled Phase IIIb study to evaluate the efficacy and safety of Cosentyx in the management of axial manifestations of PsA. MAXIMISE enrolled 498 patients with PsA, clinician-diagnosed axial involvements, spinal pain rated as >40/100 on a visual analog scale (VAS) and BASDAI >4 despite trial of at least two non-steroid anti-inflammatory drugs. Patients were treated with subcutaneous Cosentyx 300 mg or 150 mg given weekly for 4 weeks and every 4 weeks thereafter. The primary endpoint was the proportion of patients achieving an ASAS20 response with Cosentyx 300 mg at Week 12. The key secondary endpoint was ASAS20 response with Cosentyx 150 mg at Week 12 after superiority of Cosentyx 300 mg was established. At Week 12, placebo patients were re-randomized to subcutaneous Cosentyx 300 mg or 150 mg[2].

ASAS20 is achieved when there is a measure of an improvement of at least 20% 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[9].

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 PsA, psoriasis (PsO), and ankylosing spondylitis (AS)[10].

Cosentyx is backed by robust clinical evidence, including dedicated studies in the persistent manifestations of psoriasis, namely nails, scalp, palms and soles, as well as PsA and AS[11-13]. Cosentyx has shown long-lasting efficacy and a favorable safety profile while addressing psoriatic disease, therefore offering a complete treatment[1311]. It has shown sustained safety and long-lasting efficacy in three 5-year Phase III extension studies in PsO, PsA and AS[12-14]. Today, more than 200,000 patients worldwide have been treated with Cosentyx since launch[15].

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About Novartis
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