Novartis 5-year data in psoriatic arthritis and ankylosing spondylitis reinforces Cosentyx® leadership in spondyloarthritis

- Data from the MEASURE 1 and FUTURE 1 studies show rapid and long-lasting sustained improvement in the signs and symptoms of ankylosing spondylitis (AS) and psoriatic arthritis (PsA)\(^1,2\)
- In rheumatology, Cosentyx is now the most prescribed biologic therapy in the US for PsA patients starting or switching biologic agents\(^3\)
- New data follow five-year data in psoriasis, reinforcing unique position of Cosentyx as a long-lasting comprehensive treatment across multiple indications\(^4\)

Basel, October 16, 2018 – Novartis, a leader in immuno-dermatology and rheumatology, announced today it will be presenting five-year data from the ongoing extensions of the phase III FUTURE 1 and MEASURE 1 studies for Cosentyx® (secukinumab) in patients with psoriatic arthritis (PsA)\(^1\) and ankylosing spondylitis (AS)\(^2\) respectively. These new data will be presented at the 2018 American College of Rheumatology/Association of Rheumatology Health Professionals (ACR/ARHP) Annual Meeting in Chicago, United States.

“AS and PsA have a significant impact on the quality of patients’ lives, and they require a comprehensive treatment which targets all of the manifestations of their disease,” said Professor Georg A. Schett, Professor and Chair, Department of Medicine, Rheumatology and Immunology at University of Erlangen-Nuremberg. “The presentation of long-term data in PsA and AS supports the central role of Cosentyx in the long-term sustained management of these complex and multi-faceted conditions.”

New long-term data from FUTURE 1 and MEASURE 1 confirm that Cosentyx provides sustained improvements in the signs and symptoms of PsA and AS out to five years\(^1,2\). In FUTURE 1, 83% and 94% of PsA patients achieved total resolution of enthesitis and dactylitis, respectively\(^1\). Over 80% of patients who entered the extension phases of both studies completed five years\(^1,2\), with a safety profile consistent with previous reports\(^4,6\). These data add to findings from the SCULPTURE study, in which two thirds of patients on Cosentyx reported no impact of skin disease on their quality of life over five years\(^4\).

PsA and AS are both debilitating, chronic and progressive conditions, which can significantly impact mobility and consequently patients’ quality of life\(^7,9\). As a result, patients and physicians are increasingly looking for treatments that show long-lasting efficacy with a favorable safety profile\(^2,4,10\). Cosentyx delivers long–lasting, comprehensive treatment through targeted inhibition of IL-17A, a cornerstone cytokine involved in the development of spondyloarthritis and psoriatic diseases\(^11-14\).

“Five-year data is often seen as a benchmark for proving long-term efficacy and safety,” said Eric Hughes, Global Development Unit Head, Immunology, Hepatology and Dermatology. “By adding five-year data in PsA and AS to the already reported five-year data in psoriasis, we are...
reinforcing the robust profile of Cosentyx and reimagining the standard of care for patients who search for a complete treatment for spondyloarthritis and psoriatic disease."

**About FUTURE 1**

FUTURE 1 is a two-year, multi-center, randomized, placebo-controlled Phase III pivotal study to evaluate the efficacy of Cosentyx in patients with active PsA. FUTURE 1 enrolled 606 patients with active PsA and assessed Cosentyx with intravenous loading (10 mg/kg) and subcutaneous (75 mg and 150 mg) maintenance dosing. The primary endpoint assessed superiority of Cosentyx against placebo in the proportion of patients achieving the ACR 20 response at Week 24. From Week 16, patients in the placebo arm of the study were re-randomized to receive Cosentyx 75 mg or 150 mg at either Week 16 or Week 24, based on clinical response.

A total of 460 patients entered a three-year extension period following the initial two-year study. Over 80% of patients who took part completed five years of Cosentyx treatment. Cosentyx provided sustained improvements in the signs and symptoms of PsA out to five years, including total resolution of enthesitis and dactylitis in 83% and 94% of patients respectively. Efficacy improved proportionately with dose escalation of Cosentyx to 150mg or 300mg during the study. The safety profile of Cosentyx was shown to be consistent with that previously seen in clinical trials across multiple indications.

**About MEASURE 1**

MEASURE 1 is a two-year, multi-center, randomized, placebo-controlled Phase III study assessing the efficacy and safety of Cosentyx in patients with active AS. Primary endpoints assessed superiority of Cosentyx against placebo at Week 16 in patients who achieved at least a 20% improvement in the ASAS 20 response (Assessment of Spondyloarthritis International Society response criteria). From Week 16, patients in the placebo arm of the study were re-randomized to Cosentyx 75 mg or 150 mg based on ASAS 20 response, with non-responders switched at Week 16, and responders at Week 24.

A total of 290 of 371 patients completed the trial, after which 274 patients entered a three-year extension period. Over 80% of patients who participated in the extension phase of the study completed five years of Cosentyx treatment. 56% of patients on Cosentyx 75mg were escalated to Cosentyx 150 mg after Week 16. Improvements in ASAS 20 and ASAS 40 responses were sustained out to five years in all dosage cohorts. In the dose escalation cohort, ASAS 20 responses improved from 74% for Cosentyx 75mg to 82% for Cosentyx 150 mg after 72 weeks. The safety profile of Cosentyx was shown to be consistent with that previously seen in clinical trials across multiple indications.

**About Cosentyx (secukinumab)**

Cosentyx is the first and only fully-human treatment that specifically inhibits IL-17A, a cornerstone cytokine involved in the inflammation and development of AS, PsA and psoriasis. IL-17A is produced by various cells from both the innate immune system (which can be triggered by mechanical stress) and the adaptive immune system. To date, Cosentyx has been prescribed to more than 160,000 patients worldwide and is being evaluated in 100 studies, including a comprehensive head-to-head clinical trial program.

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Novartis Media Relations
Central media line: +41 61 324 2200
E-mail: media.relations@novartis.com

Eric Althoff
Novartis Global Media Relations
+41 61 324 7999 (direct)
+41 79 593 4202 (mobile)
eric.althoff@novartis.com

Friedrich von Heyl
Novartis Global Pharma Communications
+41 61 324 8984 (direct)
+41 79 749 0286 (mobile)
friedrich.vonheyl@novartis.com

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

Central
Samir Shah +41 61 324 7944
Pierre-Michel Bringer +41 61 324 1065
Thomas Hungerbuehler +41 61 324 8425
Isabella Zinck +41 61 324 7188

North America
Richard Pulik +1 212 830 2448
Cory Twining +1 212 830 2417