MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

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\(^\circledR\) (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 PsA10. 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 dosing10. The primary endpoint assessed superiority of Cosentyx against placebo in the proportion of patients achieving the ACR 20 response at Week 2410. 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 response10.

A total of 460 patients entered a three-year extension period following the initial two-year study1. Over 80% of patients who took part completed five years of Cosentyx treatment1. 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 respectively1. Efficacy improved proportionately with dose escalation of Cosentyx to 150mg or 300mg during the study1. The safety profile of Cosentyx was shown to be consistent with that previously seen in clinical trials across multiple indications4-6.

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 AS15. 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)16. 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 246,15.

A total of 290 of 371 patients completed the trial, after which 274 patients entered a three-year extension period2,6,15. Over 80% of patients who participated in the extension phase of the study completed five years of Cosentyx treatment2. 56% of patients on Cosentyx 75mg were escalated to Cosentyx 150 mg after Week 162. Improvements in ASAS 20 and ASAS 40 responses were sustained out to five years in all dosage cohorts2. In the dose escalation cohort, ASAS 20 responses improved from 74% for Cosentyx 75mg to 82% for Cosentyx 150 mg after 72 weeks2. The safety profile of Cosentyx was shown to be consistent with that previously seen in clinical trials across multiple indications4-6.

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 psoriasis10-13. IL-17A is produced by various cells from both the innate immune system (which can be triggered by mechanical stress) and the adaptive immune system17. To date, Cosentyx has been prescribed to more than 160,000 patients worldwide18 and is being evaluated in 100 studies, including a comprehensive head-to-head clinical trial program19-25.

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,” “plan,” “expect,” “anticipate,” “look forward,” “believe,” “committed,” “investigational,” “pipeline,” “launch,” or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for the investigational or approved products described in this press release, or regarding potential future revenues from such products. 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 the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations regarding such products 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, payer and general public pricing and reimbursement pressures; our ability 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.

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 1 billion people globally and we are finding innovative ways to expand access to our latest treatments. About 125,000 people of more than 140 nationalities work at Novartis around the world. Find out more at http://www.novartis.com

Novartis is on Twitter. Sign up to follow @Novartis at http://twitter.com/novartis
For Novartis multimedia content, please visit www.novartis.com/news/media-library
For questions about the site or required registration, please contact media.relations@novartis.com

References
5. Mease PJ et al. Secukinumab Provides Sustained Improvements in the Signs and Symptoms of Active Psoriatic Arthritis through 3 Years: Efficacy and Safety Results from a Phase 3 Trial. Presented at the American College of Rheumatology 2016. Presentation number 961.


---

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