

MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG**Novartis new Cosentyx[®] data confirms robust efficacy and quality of life improvements in scalp psoriasis**

- *Majority of patients with scalp psoriasis on Cosentyx[®] (secukinumab) achieved clear skin (PSSI 90) at Weeks 12 and 24 and improved quality of life¹*
- *Scalp psoriasis affects 60 million people worldwide – a difficult-to-treat form of psoriasis with a substantial impact on quality of life¹⁻⁵*
- *Cosentyx data presented at AAD adds to robust evidence demonstrating sustained efficacy in plaque, nail, palmoplantar and scalp psoriasis as well as psoriatic arthritis⁶⁻¹²*

Basel, February 16, 2018 – Novartis has presented new Cosentyx[®] (secukinumab) data from the prospective Phase III SCALP study which showed significant improvement in skin clearance with Cosentyx in patients with scalp psoriasis. Due to the presence of hair, scalp psoriasis is particularly difficult to treat with common topical and phototherapy options¹³. These study results were presented at the 2018 American Academy of Dermatology (AAD) Annual Meeting in San Diego, California.

“Scalp psoriasis can be painful and in some cases, can lead to temporary hair loss and cause the involved area to crack and bleed,” said Kristian Reich, M.D., Ph.D., Georg-August-University Göttingen and Dermatologikum Hamburg, Germany. “The data presented at AAD is encouraging for both physicians and patients, who can have greater trust in Cosentyx as a complete treatment option for patients with plaque psoriasis who want to avoid scalp and other manifestations of psoriasis.”

Approximately 60 million people worldwide are impacted by scalp psoriasis^{4,5}, a form of the disease which can have a substantial impact on quality of life due its highly visible nature. Additional stress may be added as many psoriasis patients will not achieve an adequate response from standard treatments¹³.

“As a science driven company, we are committed to investigating the full potential of Cosentyx. It is our ambition to offer the best evidence to doctors, and to deliver the best treatment to patients,” said Eric Hughes, Global Development Unit Head, Immunology & Dermatology. “Cosentyx is backed by a large study program including more than 10,000 patients in over 60 studies since our first Cosentyx study initiation 10 years ago. We believe that study data on specific manifestations such as scalp help doctors reach the right decisions with their patients.”

Cosentyx is a fully human interleukin-17A (IL-17A) inhibitor which has demonstrated rapid and sustained long term efficacy in the treatment of moderate-to-severe psoriasis, psoriatic arthritis and ankylosing spondylitis, as well as a consistently favorable safety profile including injection site pain at rates similar to placebo⁶⁻¹². To date, Cosentyx has been prescribed to more than 140,000 patients worldwide across all indications since launch¹⁴.

About psoriasis

Psoriasis is a distressing and painful autoimmune disease that affects more than 125 million people worldwide⁴. It is a debilitating condition associated with a significant emotional and physical daily burden. In the long-term, psoriasis can also lead to other conditions, such as diabetes, heart disease, depression and psoriatic arthritis (PsA) – which up to 30% of patients with psoriasis may develop^{4,15}.

Plaque psoriasis is the most common form of the disease and appears as raised, red skin patches covered with a silvery white build-up of dead cells. Most patients with psoriasis will also develop difficult-to-treat forms of the disease which appear on the scalp, nails, palms of the hands or soles of the feet and are associated with further pain, decreased mobility and functional impairment^{2,16-18}.

About Cosentyx (secukinumab) and IL-17A

Cosentyx is the first and only fully human interleukin-17A (IL-17A) inhibitor approved to treat psoriasis, PsA and ankylosing spondylitis (AS)¹⁹. Cosentyx is a targeted treatment that specifically inhibits IL-17A, cornerstone cytokine involved in the pathogenesis of psoriasis, and the inflammation of the entheses in PsA and AS¹⁹⁻²².

Cosentyx delivers psoriasis patients long-lasting skin clearance, with proven sustainability and safety out to 5 years⁸. Cosentyx has been studied in dedicated trials for difficult-to-treat types of plaque psoriasis – palmoplantar psoriasis (psoriasis of the hands and feet), scalp psoriasis, and nail psoriasis¹⁹.

Cosentyx has a large clinical trials program in psoriasis, PsA and AS which includes over 60 studies and over 10,000 patients²³. To date, Cosentyx has been prescribed to more than 140,000 patients worldwide since launch¹⁴.

About the SCALP study¹

This study is a randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of Cosentyx in 102 patients with moderate-to-severe scalp psoriasis. Eligible patients were equally randomized to either subcutaneous Cosentyx 300 mg or placebo at Weeks 0, 1, 2, 3 and 4, then every four weeks for 12 weeks. At Week 12, patients in the placebo group who did not achieve at least a 90% improvement from baseline in the Psoriasis Scalp Severity Index (PSSI) score were re-randomized to Cosentyx 300 mg until study completion. The primary endpoint was the proportion of patients who achieved PSSI 90 response rate at Week 12.

In the SCALP study, PSSI 90 response rates were achieved by a significantly higher proportion of patients receiving Cosentyx vs. placebo at Week 12 (52.9% vs. 2.0%), with further improvements in those taking Cosentyx up to Week 24 (58.8%). The safety profile of Cosentyx was in line with the known safety profile for Cosentyx.

About Novartis Immunology & Dermatology

Novartis is a global leader in Immunology & Dermatology. We are dedicated to transforming the lives of people living with immunologic diseases, focusing on immunodermatology, rheumatology and specialty liver diseases. Our Immunology & Dermatology pipeline includes multiple compounds in liver disease and other immunological areas where high unmet medical needs exist.

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, payor 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 provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic and biosimilar pharmaceuticals and eye care. Novartis has leading positions globally in each of these areas. In 2017, the Group achieved net sales of USD 49.1 billion, while R&D throughout the Group amounted to approximately USD 9.0 billion. Novartis Group companies employ approximately 122,000 full-time-equivalent associates. Novartis products are sold in approximately 155 countries around the world. For more information, please visit <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

1. Reich K et al. Secukinumab Shows Sustained Efficacy in Difficult-to-Treat Palmoplantar, Nail, and Scalp Psoriasis: Long-term Results From 3 Phase III Placebo-Controlled Randomized Trials. Eposter presented at 2018 American Academy of Dermatology (AAD) Annual Meeting; February 16–20, 2018, San Diego, California. Poster #6813.
2. Zampieron A et al. Quality of life in patients with scalp psoriasis. *G Ital Dermatol Venereol*. 2015 Jun;150(3):309-16
3. American academy of dermatology. Scalp Psoriasis. Available at: <https://www.aad.org/public/diseases/hair-and-scalp-problems/scalp-psoriasis#symptoms>. Last accessed January 2018.
4. International Federation of Psoriasis Associations (IFPA) World Psoriasis Day website. "About Psoriasis." Available at: <http://www.worldpsoriasisday.com/web/page.aspx?refid=114>. Last accessed January 2018.
5. Farber EM, Nall L. Natural history and treatment of scalp psoriasis. *Cutis*. 1992;49:396-400.
6. Gottlieb AB et al. Secukinumab Shows High and Sustained Efficacy in Subjects with Moderate to Severe Palmoplantar Psoriasis: 2.5-Year Results From the GESTURE Study. Abstract presented at the 2017 Psoriasis Gene to Clinic Congress, London, United Kingdom. 30th November 2017.
7. Braun J et al. Secukinumab demonstrates low radiographic progression and sustained efficacy through 4 years in patients with active ankylosing spondylitis. Late breaking abstract presented at the 2017 ACR/ARHP Annual Meeting, San Diego, USA. 7th November 2017.
8. Bissonnette, R., Luger, T., Thaçi, D., Toth, D., Lacombe, A., Xia, S., Mazur, R., Patekar, M., Charef, P., Milutinovic, M., Leonardi, C. and Mrowietz, U. Secukinumab Demonstrates High Sustained Efficacy and a Favorable Safety Profile in Patients with Moderate to Severe Psoriasis through 5 Years of Treatment

- (SCULPTURE Extension Study). *J Eur Acad Dermatol Venereol*. Accepted Author Manuscript. doi:10.1111/jdv.14878
9. 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. *Ann Rheum Dis*. 2017;76:952–953.
 10. Baeten D et al. Secukinumab, interleukin-17A inhibition in ankylosing spondylitis. *N Engl J Med*. 2015; 373:2534–48.
 11. McInnes IB et al. Secukinumab, a human anti-interleukin-17A monoclonal antibody, in patients with psoriatic arthritis (FUTURE 2): a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet*. 2015; 386(9999):1137–1146.
 12. Reich K et al. Secukinumab, a fully human anti-interleukin-17A monoclonal antibody, exhibits minimal immunogenicity in patients with moderate-to-severe plaque psoriasis. *Br. J. Dermatol*. 2017;176:752–58.
 13. Crowley JJ. Nail, Scalp, and Palmoplantar Psoriasis. *Biologic and Systemic Agents in Dermatology*. 2018; 160-174.
 14. Novartis Data on File. Number of Patients Prescribed Cosentyx. Novartis Pharmaceuticals Corp; Nov. 2017.
 15. National Psoriasis Foundation. Psoriatic disease: about psoriasis. Available at: www.psoriasis.org/about-psoriasis. Last accessed January 2018.
 16. Baran R. The burden of nail psoriasis: an introduction. *Dermatol*. 2010;221 Suppl 1:1-5.
 17. Kumar B et al. Palmoplantar lesions in psoriasis: a study of 3065 patients. *Acta Dermatol Venereol*. 2002;82:192-5.
 18. Chung J et al. Palmoplantar psoriasis is associated with greater impairment of health-related quality of life compared with moderate to severe plaque psoriasis. *J Am Acad Dermatol*. 2014;71(4):623-32.
 19. EU Cosentyx Summary of Product Characteristics. Novartis Europharm Limited. Available at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003729/human_med_001832.jsp&mid=WC0b01ac058001d124. Last accessed January 2018.
 20. Smith JA et al. Review: The Interleukin 23/Interleukin 17 Axis in Spondyloarthritis Pathogenesis: Th17 and Beyond. *Arthritis Rheumatol*. 2014;66:231–41.
 21. Nestle FO et al. Mechanisms of disease psoriasis. *N Eng J Med*. 2009;361:496–509.
 22. Girolomoni G et al. Psoriasis: rationale for targeting interleukin-17. *Br J Dermatol*. 2012;167:717–24.
 23. Novartis, data on file.

###

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.vonheyhl@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