Novartis International AG
Novartis Global Communications
CH-4002 Basel
Switzerland

http://www.novartis.com

MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Novartis' Cosentyx® is first biologic to show long-term efficacy in nail and palmoplantar psoriasis, which can impact up to 90% of psoriasis patients

- *Unique Cosentyx® (secukinumab) data reinforce treatment option for up to 90% of psoriasis patients who may develop nail or palmoplantar psoriasis[1–4]*
- *Cosentyx results represent the first data on biologic use for up to 2.5 years in these hard-to-treat types of psoriasis[1,2]*
- *Results add to body of evidence supporting the efficacy and safety of Cosentyx, including recently presented data showing response rates nearly 100% maintained from Year 1 to Year 5 in patients with moderate-to-severe plaque psoriasis [5–7]*

Basel, November 30, 2017 – Novartis, a global leader in Immunology & Dermatology, announced today first-of-its-kind long-term data showing that Cosentyx® (secukinumab) provided sustained improvements in nail and palmoplantar psoriasis out to 2.5 years[1,2]. These data are unique as it is the first time any biologic has demonstrated long-term efficacy and safety in nail and palmoplantar psoriasis. These new data from a clinical study were presented at the 8th International Congress of Psoriasis from Gene to Clinic in London, UK.

Up to 90% of psoriasis patients may develop nail psoriasis or palmoplantar psoriasis[3,4], which affects the palms of the hands and soles of the feet. Both nail and palmoplantar psoriasis heavily impact patients' quality of life leading to reduced mobility, functional impairment and physical discomfort[8–10].

Cosentyx addresses the cornerstone cytokine interleukin-17A (IL-17A) involved in the development and progression of psoriasis[11], and is the first and only fully human IL-17A inhibitor to show sustained skin clearance rates at 5 years in psoriasis[5]. By working to specifically target and inhibit IL-17A, Cosentyx can more effectively address the underlying cause of the disease[12–14]. To date, psoriasis treatments targeting other pathways have not shown long-term efficacy out to 2.5 years in these hard-to-treat forms[1-2].

"Patients with nail and palmoplantar psoriasis need effective treatment options to address the significant impact these conditions can have on their day-to-day lives," said Eric Hughes, Global Development Unit Head, Immunology & Dermatology. "As an IL-17A inhibitor, Cosentyx provides a highly targeted treatment option that can not only effectively treat the plaques caused by psoriasis, as evident by recently presented 5-year data, but also hard-to-treat forms and associated arthritic conditions."

In GESTURE, 59% and 53% palmoplantar psoriasis patients who received Cosentyx 300 mg and 150 mg respectively achieved clear or almost clear palms and soles at 2.5 years (as measured by Palmoplantar Investigator's Global Assessment (ppIGA) 0/1)[1]. In the TRANSFIGURE study, patients with nail psoriasis who were treated with Cosentyx 300 mg

and 150 mg showed a substantial NAPSI (Nail Psoriasis Severity Index) improvement from baseline of -73% and -63% respectively[2]. GESTURE, the largest and longest randomized controlled trial to date in palmoplantar psoriasis patients, and TRANSFIGURE, the first large, controlled trial to report long-term results in nail psoriasis, both demonstrated strong sustainability out to 2.5 years[1,2], with a favorable and consistent safety profile[1,2,5–7], including close to zero injection site reactions or associated pain[15,16].

The 8th International Congress of Psoriasis from Gene to Clinic is taking place in London from Thursday 30th November to Saturday 2nd December. For more information, visit: www.psoriasisg2c.com

About Cosentyx and IL-17A
Cosentyx, launched in 2015, is the first and only fully human IL-17A inhibitor approved to treat psoriasis, psoriatic arthritis (PsA) and ankylosing spondylitis (AS)[12]. Cosentyx is a targeted treatment that specifically inhibits the IL-17A cytokine which plays a significant role in the pathogenesis of plaque psoriasis, PsA and AS[13,14]. Cosentyx is also approved for the most hard-to-treat forms of plaque psoriasis – palmoplantar psoriasis (psoriasis of the palms of the hands and soles of the feet), nail psoriasis and scalp psoriasis[12].

Cosentyx delivers psoriasis patients long-lasting skin clearance, with proven sustainability, safety out to 5 years and convenient once-monthly dosing in a patient-friendly autoinjector[12].

Cosentyx is approved in 80 countries for the treatment of moderate-to-severe plaque psoriasis, which includes the European Union countries, Japan, Switzerland, Australia, the US and Canada. In Europe, Cosentyx is approved for the first-line systemic treatment of moderate-to-severe plaque psoriasis in adult patients[12]**.** In the US, Cosentyx is approved as a treatment for moderate-to-severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy (light therapy)[17].

In addition, Cosentyx is the first IL-17A inhibitor approved in more than 70 countries for the treatment of active AS and PsA, which includes the European Union countries and the US. Cosentyx is also approved for the treatment of PsA and pustular psoriasis in Japan[18].

To date, more than 125,000 patients worldwide have been prescribed Cosentyx in the post-marketing setting across all indications[19].

About the GESTURE study[1]
GESTURE is the largest and longest duration randomized, placebo-controlled trial to date to investigate the safety and efficacy of Cosentyx 150 mg and 300 mg subcutaneous with moderate-to-severe palmoplantar psoriasis. The effect of Cosentyx treatment on palm and sole skin clearance was determined using the Palmoplantar Investigator's Global Assessment (ppIGA) and Palmoplantar Psoriasis Area and Severity Index (ppPASI). Positive impact on quality of life was assessed via the Dermatology Life Quality Index (DLQI) and palmoplantar Quality of Life Instrument (ppQLI) scores.

The results from 205 patients who participated in the study showed that 59% and 53% of patients who received Cosentyx 300 mg and 150 mg respectively achieved clear or almost clear palms and soles at 2.5 years, as measured by ppIGA. Consistent benefits were seen in changes in ppPASI score, an important measure of treatment success, and quality of life enhancements derived from marked improvements in pain and function of palms and soles. The safety profile of Cosentyx was shown to be consistent with that seen in clinical trials across multiple indications[1,2,5–7].

About the TRANSFIGURE study[2]
TRANSFIGURE is the first large, double-blind, randomized, placebo-controlled Phase IIIb study to investigate the long-term safety and efficacy of a biologic in moderate-to-severe nail

psoriasis. TRANSFIGURE investigated the superiority of two dosing regimens of Cosentyx (150 mg and 300 mg subcutaneous) versus placebo, with clinical effect assessed at 2.5 years using the Nail Psoriasis Severity Index (NAPSI) and Psoriasis Area and Severity Index (PASI). Impact on quality of life was measured using the Nail Assessment in Psoriasis and Psoriatic Arthritis (NAPPA) and EuroQOL 5-Dimension Health Status Questionnaire (EQ-5D).

The results from the 198 patients who participated in the study showed a substantial NAPSI improvement from baseline of -73% and -63% in patients who received Cosentyx 300 mg and 150 mg respectively, which was sustained out to 2.5 years. Similarly, sustained improvements in the scores from NAPPA and the EQ-5D highlighted the quality of life benefits received from treatment, with patients reporting decreased pain and discomfort. The safety profile of Cosentyx was shown to be consistent with that seen in clinical trials across multiple indications[1,2,5–7].

About psoriasis
Psoriasis is a common, non-contagious, autoimmune disease that affects more than 125 million people worldwide[20]. Plaque psoriasis is the most common form of the disease and appears as raised, red patches covered with a silvery white buildup of dead skin cells. Palmoplantar psoriasis, which appears on the palms of the hands and soles of the feet, occurs in up to 40% of plaque psoriasis patients and is frequently resistant to treatment[4,10].

During their lifetime, approximately 90% of psoriasis patients will develop scaling on their nails[3]. Often hard-to-treat, nail psoriasis is associated with decreased finger mobility, functional impairment, pain and reduced quality of life[3]. Furthermore, nail psoriasis is an important predictor of PsA which affects up to 30% of patients with psoriasis[21]. PsA is a condition in which the joints are also affected, causing debilitating symptoms including pain, stiffness and for some people, irreversible joint damage[21,22].

Psoriasis is not simply a cosmetic problem, but a persistent, chronic (long-lasting), and sometimes distressing disease, which can affect even the smallest aspects of people's lives on a daily basis. Psoriasis is also associated with other serious health conditions, such as diabetes, heart disease and depression[21].

About Novartis Immunology & Dermatology
Novartis is a global leader in Immunology & Dermatology. We are transforming the lives of people living with immunologic diseases, focusing on specialty dermatology, rheumatology, auto-inflammatory, transplant and specialty liver diseases where high unmet medical needs exist. Our leading brand Cosentyx® (secukinumab) is an innovative biologic approved in more than 70 markets for the treatment of moderate-to-severe psoriasis (PsO), ankylosing spondylitis (AS) and psoriatic arthritis (PsA). Other key brands include Xolair® (omalizumab)* in chronic spontaneous urticaria (CSU), Zortress®/Certican® and Myfortic® in transplant and Ilaris® (canakinumab), approved to treat several rare diseases including some Periodic Fever Syndromes. Our I&D pipeline includes multiple compounds in liver disease.

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; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures; general economic and industry conditions, including the effects of the persistently weak economic and financial environment in many countries; safety, quality or manufacturing issues, 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 2016, the Group achieved net sales of USD 48.5 billion, while R&D throughout the Group amounted to approximately USD 9.0 billion. Novartis Group companies employ approximately 121,000 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

**In the US, Novartis Pharmaceuticals Corporation and Genentech, Inc. work together to develop and co-promote Xolair.*

References

1. 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.
2. Reich K et al. Secukinumab Shows High and Sustained Efficacy in Nail Psoriasis: 2.5-Year Results From the TRANSFIGURE Study. Abstract presented at the 2017 Psoriasis Gene to Clinic Congress, London, United Kingdom. 30th November 2017.
3. Baran R. The burden of nail psoriasis: an introduction. Dermatol. 2010:221 Suppl 1:1-5.
4. Kumar B et al. Palmoplantar lesions in psoriasis: a study of 3065 patients. Acta Dermatol Venereol. 2002;82:192-5.
5. Bissonnette R et al. Secukinumab demonstrates high sustained efficacy and a favorable safety profile through 5 years of treatment in moderate to severe psoriasis. Presented as eposter P2223 at 26th EADV Congress 2017. 13th September 2017.
6. 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.
7. Braun J et al. Effect of secukinumab on clinical and radiographic outcomes in ankylosing spondylitis: 2-year results from the randomised phase III MEASURE 1 study. Ann Rheum Dis. 2016;doi: 10.1136/annrheumdis-2016-209730.
8. van der Velden HM et al. The impact of fingernail psoriasis on patients' health-related and disease-specific quality of life. Dermatol. 2014;229(2):76-82.
9. Pettey AA et al. Patients with palmoplantar psoriasis have more physical disability and discomfort than patients with other forms of psoriasis: implications for clinical practice. J Am Acad Dermatol. 2003;49(2):271-5.

10. 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.
11. Zeichner JA and Armstrong A. The role of IL-17 in the pathogenesis and treatment of psoriasis. J Clin Aesthet Dermatol. 2016;9:S3–S6.
12. 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 November 2017.
13. Nestle FO et al. Mechanisms of disease psoriasis. N Eng J Med. 2009;361:496-509.
14. Girolomoni G et al. Psoriasis: rationale for targeting interleukin-17. Br J Dermatol. 2012;167:717-24.
15. 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.
16. Bissonnette R et al. Secukinumab Sustains Good Efficacy and Favourable Safety in Moderate to Severe Psoriasis up to 3 Years of Treatment: Results from A Double-Blind Extension Study. British Journal of Dermatol. 2017 Jun 5. doi: 10.1111/bjd.15706
17. Cosentyx (secukinumab) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp, 2016.
18. Pharmaceuticals and Medical Devices Agency. Review Report. Available at: http://www.pmda.go.jp/files/000216877.pdf. Last accessed November 2017.
19. Novartis, data on file.
20. 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 November 2017.
21. National Psoriasis Foundation. Psoriatic disease: about psoriasis. Available at: www.psoriasis.org/about-psoriasis. Last accessed November 2017.
22. Mease PJ and Armstrong AW. Managing patients with psoriatic disease: the diagnosis and pharmacologic treatment of psoriatic arthritis in patients with psoriasis. Drugs. 2014; 74:423–41.

# # #

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		North America	
Samir Shah	+41 61 324 7944	Richard Pulik	+1 212 830 2448
Pierre-Michel Bringer	+41 61 324 1065	Cory Twining	+1 212 830 2417
Thomas Hungerbuehler	+41 61 324 8425		
Isabella Zinck	+41 61 324 7188		