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\(^5\)–\(^10\).

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, less direct, 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. 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, with a favorable and consistent safety profile, including close to zero injection site reactions or associated pain.

The 8th International Congress of Psoriasis from Gen 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). 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. 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.

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.

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. 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).

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.

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

**About the GESTURE study**

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.

**About the TRANSFIGURE study**

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. 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. Often hard-to-treat, nail psoriasis is associated with decreased finger mobility, functional impairment, pain and reduced quality of life. Furthermore, nail psoriasis is an important predictor of PsA which affects up to 30% of patients with psoriasis. 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.

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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.

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

References

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.

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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 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