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Novartis' Cosentyx[®] sets new benchmark in psoriasis with robust 5-year sustained Phase III efficacy and safety data

- *Cosentyx[®] (secukinumab) is the first and only fully human IL-17A inhibitor to show sustained skin clearance rates at 5 years in phase III in psoriasis¹*
- *Landmark data show that PASI 90 and PASI 100 response rates were nearly 100% maintained with Cosentyx from Year 1 to Year 5 in patients with moderate-to-severe plaque psoriasis¹*
- *5-year data from a Phase III study reinforce Cosentyx long term skin clearance and safety¹*

Basel, September 13, 2017 – Novartis announced today, first of its kind Phase III data showing Cosentyx[®] (secukinumab) delivered high and long-lasting skin clearance in patients with moderate-to-severe plaque psoriasis at 5 years¹. These data were presented for the first time at the 26th European Academy of Dermatology and Venereology (EADV) Congress in Geneva, Switzerland.

By specifically targeting interleukin-17A (IL-17A), Cosentyx addresses the key cytokine involved in the development of psoriasis². IL-17A plays a significant role in the pathogenesis of plaque psoriasis, psoriatic arthritis (PsA) and ankylosing spondylitis (AS)³⁻⁵. Inhibiting IL-17A is important as up to 30% of patients with psoriasis may have PsA^{6,7}.

"These final data are meaningful for dermatologists as they show that the high efficacy and safety of secukinumab was sustained over the 5-year treatment period.", said Dr. Robert Bissonnette, Innovaderm Research, Montreal, Canada.

"The 5-year data reinforce Cosentyx as an important treatment option for those people living with psoriasis who aspire for skin clearance that can last," said Vas Narasimhan, Global Head, Drug Development and Chief Medical Officer, Novartis. "Cosentyx is the first and only IL-17A inhibitor approved for psoriasis, psoriatic arthritis and ankylosing spondylitis and has been prescribed to more than 100,000 patients since launch."

Clear skin is the aim of psoriasis treatment, and a Psoriasis Area and Severity Index (PASI) 75, 90 or 100 response is considered an important measure of treatment success⁸⁻¹¹. Over the extended treatment period from Year 1 (Week 52) to the end of Year 5 (Week 260), PASI 75/90/100 response rates remained consistent¹. PASI 75 and PASI 90 response rates were achieved by 89% and 69% of psoriasis patients, respectively, at Year 1 ('as observed' analysis) and this high rate was maintained to Year 5 (89% and 66%, respectively). In addition, 44% of psoriasis patients achieved completely clear skin (PASI 100) at Year 1 and this rate was maintained to Year 5 (41%). Cosentyx continued to have a favorable and consistent safety profile, and low immunogenicity^{1,3}.

To date, more than 100,000 patients worldwide have been prescribed Cosentyx in the post-marketing setting across all indications¹². In addition, 2017 marks 10 years since the first patient, first visit in a clinical trial with Cosentyx.

About Cosentyx and IL-17A

Cosentyx, launched in 2015, is the first and only fully-human IL-17A inhibitor approved to treat psoriasis, PsA and AS³. 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 AS³⁻⁵.

Cosentyx delivers long-lasting skin clearance, with proven sustainability, safety out to 5 years and convenient once-monthly dosing in a patient-friendly auto injector¹³. Cosentyx is also approved for the most difficult-to-treat types of plaque psoriasis – palmoplantar psoriasis (psoriasis of the hands and feet), scalp psoriasis, and nail psoriasis³.

Cosentyx is approved in 79 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 patients³. 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)¹⁴.

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 Japan¹².

About the 5-year Cosentyx extension study (A2304E1)¹

A2304E1 is a multicenter, double-blind and open-label, 5-year extension to the pivotal Phase III SCULPTURE study. The primary objective of this extension study was to assess the long-term safety and tolerability of Cosentyx in patients with moderate-to-severe plaque psoriasis. Efficacy measures included the proportion of patients achieving PASI 75, PASI 90 and PASI 100. This long-term extension study demonstrated the sustained efficacy and safety of Cosentyx. In 162 psoriasis patients at Year 1, PASI 75 and PASI 90 response rates were achieved by 89% and 69% of patients respectively. This high rate was maintained at Year 5 with 122 patients observed (89% and 66%, respectively). In SCULPTURE, PASI 75 responders at Week 12 were randomized to double-blind maintenance treatment of Cosentyx 300 mg or 150 mg, given either at a 4-week fixed-interval regimen or in a retreatment-as-needed regimen. Patients who completed 52 weeks of the SCULPTURE study were eligible to continue the same dose and regimen in the extension study (N=642).

About psoriasis

Psoriasis is a common, non-contagious, auto-immune disease that affects more than 125 million people worldwide¹⁵. 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.

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. Up to 30% of patients with psoriasis may develop PsA⁶. PsA is a condition in which the joints are also affected, causing debilitating symptoms including pain, stiffness and for some people, irreversible joint damage^{6,16}. Psoriasis is also associated with other serious health conditions, such as diabetes, heart disease and depression⁶.

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.

** Novartis co-promotes Xolair with Genentech in the US and shares a portion of the operating income, but does not book US sales.*

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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 119,000 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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References

1. 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..

2. Zeichner JA and Armstrong A. The role of IL-17 in the pathogenesis and treatment of psoriasis. *The Journal of Clinical and Aesthetic Dermatology*. 2016;9:S3–S6.
3. 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 September 2017.
4. Nestle FO et al. Mechanisms of disease psoriasis. *New England Journal of Medicine*. 2009;361:496-509
5. Girolomoni G et al. Psoriasis: rationale for targeting interleukin-17. *British Journal of Dermatology*. 2012;167:717-24.
6. National Psoriasis Foundation. Psoriatic disease: about psoriasis. Available at: www.psoriasis.org/about-psoriasis. Last accessed September 2017.
7. Mease PJ et al.. Prevalence of rheumatologist-diagnosed psoriatic arthritis in patients with psoriasis in European/North American dermatology clinics. *Journal of the American Academy of Dermatology*. 2013;69:729–35.
8. European Medicines Agency. Guideline on clinical investigation of medicinal products indicated for the treatment of psoriasis. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003329.pdf. Last accessed September 2017.
9. ACTAS Dermo-Sifiliográficas. Spanish Evidence-Based Guidelines on the Treatment of Psoriasis With Biologic Agents. Available at: <http://www.actasdermo.org/en/spanish-evidence-based-guidelines-on-treatment/articulo/S1578219013001789/>. Last accessed September 2017.
10. Canadian Dermatology Association. Canadian Guidelines for the Management of Plaque Psoriasis. Available at: <http://www.dermatology.ca/wp-content/uploads/2012/01/cdnpsoriasisguidelines.pdf>. Last accessed September 2017.
11. Langley RG et al. The 5-point Investigator's Global Assessment (IGA) Scale: a modified tool for evaluating plaque psoriasis severity in clinical trials. *Journal of Dermatology Treatment*. 2015;26:23–31.
12. Novartis. Data on file. September 2017.
13. Lacour JP et al. Secukinumab administration by autoinjector maintains reduction of plaque psoriasis severity over 52 weeks: results of the randomized controlled JUNCTURE trial. *Journal of the European Academy of Dermatology and Venereology*. 2017;31:847–56.
14. Cosentyx (secukinumab) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp, 2016.
15. 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 September 2017.
16. 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.

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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.vonheyhl@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