

MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG**Novartis new data show Cosentyx[®] improved quality of life over 5 years in two thirds of patients with moderate to severe plaque psoriasis**

- *Two thirds of patients on Cosentyx[®] (secukinumab) reported no impact of skin disease on their quality of life over 5 years, SCULPTURE study shows¹*
- *Findings show absolute PASI $\leq 1/\leq 2/\leq 3$ responses were sustained in those treated with Cosentyx from Year 1 to Year 5¹*
- *Cosentyx is the first and only fully human interleukin-17A (IL-17A) inhibitor that showed sustained skin clearance rates at 5 years in patients from a psoriasis Phase III study²*

Basel, February 16, 2018 – Novartis announced today additional results from the SCULPTURE study showing that two thirds of moderate to severe plaque psoriasis patients treated with Cosentyx[®] (secukinumab) reported no impact of skin disease on their quality of life through 5 years, as described by the Dermatology Life Quality Index (DLQI) 0/1 response (72.7% at Year 1 and 65.5% at Year 5) – a questionnaire used to evaluate the impact of skin disease on a patient’s quality of life^{1,3}. These data were presented at the 2018 American Academy of Dermatology (AAD) Annual Meeting in San Diego, California.

Study findings also show absolute PASI $\leq 1/\leq 2/\leq 3$ scores at Year 1 (58.6%, 67.9% and 74.1%, respectively) were sustained to Year 5 (53.3%, 66.4% and 75.4%, respectively); as observed analysis¹. Absolute PASI scores can provide an indication of disease severity after treatment. Achievement of an absolute PASI score lower than 2 or 3 has been proposed as an indication of treatment success⁴.

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. “There is a link between achieving skin clearance and improved quality of life, and proper management of psoriasis should address both the physical symptoms of the disease and its impact on patients’ daily lives,” said Craig Leonardi, MD, Adjunct Professor of Dermatology at St. Louis University School of Medicine. “Results from the SCULPTURE study show treatment with Cosentyx can deliver both over the long-term. It’s encouraging to see such improvements in DLQI responses and absolute PASI scores below 3 through 5 years.”

“Patients with psoriasis are looking for a treatment that not only achieves clear skin, but also addresses the negative impact psoriasis has on their lives,” said Shreeram Aradhya, Chief Medical Officer and Global Head, Medical Affairs, Novartis Pharmaceuticals. “We are excited by this new evidence, showing two thirds of psoriasis patients reporting no impact on their quality of life at 5 years when treated with Cosentyx, and the possibilities this offers patients.”

The most common adverse events included nasopharyngitis, upper respiratory tract infection and headache, consistent with those reported in the core study and previous Phase III studies¹.

Cosentyx is the first and only fully human IL-17A inhibitor approved to treat ankylosing spondylitis (AS), psoriatic arthritis (PsA) and moderate to severe plaque psoriasis⁵. To date, Cosentyx has been prescribed to more than 140,000 patients worldwide since launch⁶.

About psoriasis

Psoriasis is a distressing and painful autoimmune disease that affects more than 125 million people worldwide⁷. 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 – which up to 30% of patients with psoriasis may develop⁸.

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 impairment⁹⁻¹².

About Cosentyx (secukinumab) and IL-17A

Cosentyx is the first and only fully human IL-17A inhibitor approved to treat psoriasis, PsA and ankylosing spondylitis (AS)⁵. 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 AS^{5,13-15}.

Cosentyx delivers psoriasis patients long-lasting skin clearance, with proven sustainability and safety out to 5 years². Cosentyx is also approved for the most difficult-to-treat forms of plaque psoriasis – palmoplantar psoriasis (psoriasis of the palms of the hands and soles of the feet), nail psoriasis and scalp psoriasis⁵.

Cosentyx has a large clinical trials program in psoriasis, PsA and AS which includes over 60 studies and over 10,000 patients¹⁶. To date, Cosentyx has been prescribed to more than 140,000 patients worldwide since launch⁶.

About the Cosentyx 5-year extension study (NCT01406938)^{1,2}

NCT01406938 is a multicenter, double-blind and open-label, 5-year extension to the core 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, examining both treatment and quality of life outcomes.

Efficacy measures included proportion of patients achieving PASI 75, PASI 90 and PASI 100, and quality of life improvement as measured by Dermatology Life Quality Index (DLQI). This long-term extension study demonstrated the sustained efficacy and safety of Cosentyx. The current as observed analysis describes, PASI 75/90/100 at Year 1 (88.9%, 68.5% and 43.8%, respectively) and Year 5 (88.5%, 66.4% and 41%); absolute PASI $\leq 1/\leq 2/\leq 3$ responses at Year 1 (58.6%, 67.9% and 74.1%, respectively) and Year 5 (53.3%, 66.4% and 75.4%, respectively), DLQI 0/1 at Year 1 (72.7%) and Year 5 (65.5%), and long-term safety and tolerability.

In the core Phase III SCULPTURE study, 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). Patients subsequently entered the extension phase and continued the same double-blinded treatment regimen to Year 3, and thereafter un-blinded to the end of the study at Year 5 (n=126 at Week 260). No topical treatments were allowed in

SCULPTURE, and only in the extension study when applied to the scalp, face, and/or genitoanal area for a maximum of 14 days. 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.

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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 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>.

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