Novartis new data reinforces superiority of Cosentyx® versus Stelara® in achieving skin clearance for psoriasis patients

- Results from CLARITY study show Cosentyx® (secukinumab) was significantly more effective than Stelara®* (ustekinumab) in delivering clear and almost clear skin at 12 weeks and at 16 weeks¹.

- Data support findings from the CLEAR study, which found Cosentyx was superior to Stelara®* in achieving sustained skin clearance (PASI 90) at 52 weeks².

- 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 study³.

Basel, January 16, 2018 – Novartis announced today results from the head-to-head CLARITY study demonstrating the superiority of Cosentyx® (secukinumab) compared to Stelara®* (ustekinumab) in delivering clear and almost clear skin in adults with moderate-to-severe plaque psoriasis at 12 weeks. The study results show 66.5% and 72.3% of patients treated with Cosentyx (p < 0.0001) achieved both co-primary endpoints PASI 90 and IGA mod 2011 0/1, respectively, compared to 47.9% and 55.4% patients, respectively, treated with Stelara®* (p < 0.0001)¹. At Week 12, patients receiving Cosentyx had significantly greater PASI 100 response rates (key secondary objective) compared to those taking Stelara®* (38.1% vs. 20.1%, respectively; p < 0.0001)¹. The study findings, which support previously presented data from the CLEAR study demonstrating the superiority of Cosentyx to Stelara®* in achieving sustained skin clearance (PASI 90 response rates) at 52 weeks², were presented as an abstract today at the Winter Clinical Dermatology Conference in Hawaii.

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 success⁴-⁷. All key secondary endpoints in the CLARITY study were met. At Week 4, PASI 75 response rates were significantly superior with Cosentyx compared to Stelara®* (40.2% vs. 16.3%; p < 0.0001). At Week 16, Cosentyx demonstrated significantly superior response rates compared to Stelara for PASI 75 (91.7% vs. 79.8%; p < 0.0001), PASI 90 (76.6% vs. 54.2%; p < 0.0001), PASI 100 (45.3% vs. 26.7%; p < 0.0001), and IGA mod 2011 0/1 (78.6% vs. 59.1%; p < 0.0001)¹.

“These data add to the robust body of evidence supporting the use of Cosentyx to treat moderate to severe plaque psoriasis,” said Mark Lebwohl, MD and Chairman of the Waldman Department of Dermatology at the Icahn School of Medicine at Mount Sinai Hospital in New York City. “With these findings, clinicians can have even greater confidence including Cosentyx in their treatment plans.”

Cosentyx continued to have a favorable and consistent safety profile¹. To date, Cosentyx has been used by more than 125,000 patients worldwide⁸.
About Cosentyx (secukinumab) and IL-17A
Cosentyx 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.

About the CLARITY study
CLARITY (NCT02826603) is a 52-week, multicenter, randomized, double-blind study to demonstrate the superiority of Cosentyx (secukinumab) 300 mg vs. Stelara® (ustekinumab) in moderate-to-severe plaque psoriasis patients. Co-primary endpoints were 90% or more improvement from Baseline Psoriasis Area and Severity Index (PASI 90) and Investigator’s Global Assessment (IGA) mod 2011 0/1 (clear or almost clear) response rates at Week 12. Key secondary objectives included demonstrating superiority of secukinumab vs. ustekinumab with respect to PASI 75 at Week 4; PASI 75 and 100 at Week 12; PASI 75, 90, 100 and IGA mod 2011 0/1 at Week 16. Missing values were handled by multiple imputation.

Patients were randomized 1:1 to receive subcutaneous secukinumab 300 mg (n = 550) at Baseline, Weeks 1, 2 and 3, then every 4 weeks from Week 4 to 48, or ustekinumab (n = 552) 45 mg or 90 mg subcutaneously (depending upon body weight at randomization), according to approved label.

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 build-up 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.

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.

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.
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® (everolimus) and Myfortic® (mycophenolic acid) 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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* Stelara® is a registered trademark of Janssen Biotech, Inc.
** In the US, Novartis Pharmaceuticals Corporation and Genentech, Inc. work together to develop and co-promote Xolair.

References
2. Blauvelt A et al. Secukinumab is superior to ustekinumab in clearing skin of subjects with moderate-to-severe plaque psoriasis up to 1 year: Results from the CLEAR study. J Am Acad Dermatol. 2017;76(1).

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