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New Novartis data shows Cosentyx™ is significantly superior to Stelara® and clears skin (PASI 90) in nearly 80% of psoriasis patients

- *CLEAR study at AAD showed over 21% more psoriasis patients achieved clear to almost clear skin (PASI 90) with Cosentyx™ compared to Stelara® at Week 16¹*
- *Cosentyx showed greater improvements to Stelara across all study endpoints up to Week 16, including PASI 100 and onset of action¹*
- *PASI 90 and PASI 100 are both considered important measures of treatment success for psoriasis patients, demonstrating clear to almost clear skin^{2,3}*
- *Cosentyx, the first and only IL-17A inhibitor approved for psoriasis, has now shown superiority to both Stelara and Enbrel®, widely used biologic treatments^{1,4}*

Basel, March 20, 2015 – Novartis announced today results from the CLEAR study demonstrating that Cosentyx™ (secukinumab) is significantly superior to Stelara®* (ustekinumab), a widely used biologic, in achieving clear or almost clear skin for psoriasis patients¹. The detailed findings were presented in a late-breaking research session at the 73rd Annual Meeting of the American Academy of Dermatology (AAD) in San Francisco, USA. Cosentyx (at a dose of 300 mg) is the first and only interleukin-17A (IL-17A) inhibitor approved to treat adult patients with moderate-to-severe plaque psoriasis.

In this Phase IIIb study, Cosentyx met the primary endpoint of showing superiority to Stelara as assessed by the Psoriasis Area Severity Index (PASI) 90 response, known as clear to almost clear skin², at Week 16 (79.0% vs. 57.6%, $P < 0.0001$)¹. PASI 90 is considered an important measure of treatment success by the European Medicines Agency² and an optimal treatment goal for patients³. In addition, completely clear skin (PASI 100) at Week 16 was achieved by significantly more patients treated with Cosentyx than those receiving Stelara (44.3% vs. 28.4%, $P < 0.0001$)¹.

“The robust results from the CLEAR study further demonstrate how Cosentyx is changing the way psoriasis is treated and helping patients achieve clear skin,” said Vasant Narasimhan, Global Head of Development, Novartis Pharmaceuticals. “With Cosentyx now approved in many countries around the world, we are committed to helping psoriasis patients significantly improve their overall quality of life.”

In addition, Cosentyx demonstrated rapid onset of action and greater efficacy at all time points in the study up to Week 16, with 50% of Cosentyx patients achieving PASI 75 as early as Week 4 compared to Stelara (50.0% vs. 20.6%, $P < 0.0001$)¹. The safety profile of Cosentyx was comparable to Stelara and consistent with previously reported Phase III clinical trials for Cosentyx^{1,4-6}.

About the CLEAR study

CLEAR (Comparison to assess Long-term Efficacy, sAfeTy and toleRability of secukinumab vs. ustekinumab), a 52-week, multicenter, randomized, double-blind study, is a head-to-head Phase IIIb study initiated with Cosentyx, and compares the efficacy,

long-term safety and tolerability of Cosentyx (secukinumab) versus Stelara (ustekinumab), in patients with moderate-to-severe plaque psoriasis¹. Twenty-four countries across North America, Europe, Asia and Australia participated in the study, with enrollment reaching 679 patients in record time¹.

The primary endpoint measured at Week 16 is PASI 90¹. PASI 90 is considered a more robust measure of the extent of skin clearance compared to the standard efficacy measures used in most psoriasis clinical studies, such as PASI 75. Additionally the secondary endpoint measured at Week 4 is PASI 75¹. PASI 100 at Week 16 was one of the exploratory endpoints¹. Week 52 data will follow in due course.

The CLEAR study follows the pivotal Phase III FIXTURE study, which showed Cosentyx was superior to Enbrel^{®**} (etanercept) in clearing skin⁴. Results from the FIXTURE study were first announced in October 2013.

About Cosentyx (secukinumab) and interleukin-17A (IL-17A)

Cosentyx is a human monoclonal antibody that selectively neutralizes interleukin-17A (IL-17A)^{7,8}. IL-17A is found in high concentrations in skin affected by psoriasis and is a preferred target for investigational therapies⁷⁻¹². Cosentyx works by inhibiting the action of IL-17A, a protein found in high concentrations in skin affected by the disease⁷⁻¹². In the Phase III program, Cosentyx demonstrated a favorable safety profile, with similar incidence and severity of adverse events between Cosentyx treatment arms (300 mg and 150 mg)^{1,4-6}.

In January 2015, Cosentyx (at a dose of 300 mg) became the first and only interleukin-17A (IL-17A) inhibitor approved in Europe as a first-line systemic treatment of moderate-to-severe plaque psoriasis in adult patients, and in the US as a treatment for moderate-to-severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy (light therapy). In addition to the EU and the US, Cosentyx has been approved in Switzerland, Chile, Australia, Canada and Singapore for the treatment of moderate-to-severe plaque psoriasis and in Japan for the treatment of moderate-to-severe plaque psoriasis and active psoriatic arthritis (PsA).

Cosentyx is also in Phase III development for PsA and ankylosing spondylitis (AS); global regulatory applications are planned for 2015.

About Psoriasis

Psoriasis is a chronic immune-mediated disease characterized by thick and extensive skin lesions, called plaques, known to cause itching, scaling and pain; it is associated with significant impairment of physical and psychological quality of life¹³⁻¹⁵. Psoriasis affects up to 3% of the world's population, or more than 125 million people¹⁶.

This common and distressing condition is not simply a cosmetic problem – even people with very mild symptoms are affected everyday¹³. According to an analysis of surveys conducted of 5,600 patients by the National Psoriasis Foundation (NPF) between 2003 and 2011, 52% of patients with mild, moderate and severe psoriasis were dissatisfied with their disease management¹⁷. Of the patients surveyed, some were receiving no treatment (9.4-49.2%) or were undertreated (10.2-55.5%)¹⁷.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by words such as “committed,” “will,” “investigational,” “planned,” or similar terms, or by express or implied discussions regarding potential additional marketing authorizations for Cosentyx, or regarding potential future revenues from Cosentyx. You should not place undue reliance on these statements. Such forward-looking statements are based on the current beliefs and expectations of management 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 Cosentyx will be submitted for sale in any additional markets, or approved for any additional indications, or at any particular time. Nor can there be any guarantee that Cosentyx will be commercially successful in the future. In particular, management's expectations regarding Cosentyx could be affected by, among other things, the uncertainties inherent in research and development, including unexpected clinical trial results and additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain proprietary intellectual property protection; general economic and industry conditions; global trends toward health care cost containment, including ongoing pricing pressures; unexpected 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, eye care and cost-saving generic pharmaceuticals. Novartis is the only global company with leading positions in these areas. In 2014, the Group achieved net sales of USD 58 billion, while R&D throughout the Group amounted to approximately USD 9.9 billion (USD 9.6 billion excluding impairment and amortization charges). As of December 31, 2014 Novartis Group companies employed approximately 133,000 full-time-equivalent associates. Novartis products are available in more than 180 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.

**Enbrel[®] is a registered trademark of Amgen Inc. Enbrel used in the FIXTURE study was European sourced.

References

1. Thaci D, Blauvelt A, Reich K, et al. Secukinumab is superior to ustekinumab in clearing skin of subjects with moderate to severe plaque psoriasis: 16 week results from the CLEAR study. American Academy of Dermatology 73rd Annual Meeting. San Francisco, California. 20th March.
2. European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) Guidelines on clinical investigation of medicinal products indicated for the treatment of psoriasis. 2004. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003329.pdf Accessed February 9, 2015.
3. Mrowietz, U. Implementing treatment goals for successful long-term management of psoriasis. *Journal of the European Academy of Dermatology and Venereology*, 26: 12–20. doi: 10.1111/j.1468-3083.2011.04411.x
4. Langley RG, Elewski BE, Lebwohl M, et al. Secukinumab in plaque psoriasis: results of two phase three trials. *N Engl J Med*. 2014. Jul 9;371(4):326-38.
5. Blauvelt A, Prinz J, Gottlieb AB, et al. Secukinumab Administration by Pre-filled Syringe: Efficacy, Safety, and Usability Results from a Randomized Controlled Trial in Psoriasis (FEATURE). *Br J Dermatol*. 2014. Dec 11; 172(2): 484–493. doi: 10.1111/bjd.13348
6. Paul C, Lacour JP, Tedremets L, et al. Efficacy, safety, and usability of secukinumab administration by autoinjector/pen in psoriasis: a randomized, controlled trial (JUNCTURE). *J Eur Acad Dermatol Venereol*. 2014. Sep 22; doi: 10.1111/jdv.12751
7. Gaffen SL. Structure and signaling in the IL-17 receptor family. *Nat Rev Immunol*. 2009;9(8):556-67.
8. Ivanov S, Linden A. Interleukin-17 as a drug target in human disease. *Trends Pharmacol Sci*. 2009;30(2):95-103.
9. Kopf M, Bachmann MF, Marsland BJ. Averting inflammation by targeting the cytokine environment. *Nat Rev Drug Discov*. 2010; 9(9):703-18.
10. Onishi RM, Gaffen SL. Interleukin-17 and its target genes: mechanisms of interleukin-17 function in disease. *Immunology*. 2010;129(3):311-21.
11. Krueger J, Fretzin S, Suárez-Fariñas M, et al. IL-17A is essential for cell activation and inflammatory gene circuits in subjects with psoriasis. *J Allergy Clin Immunol*. 2012;130(1):145-154.
12. Johansen C, Usher PA, Kjellerup RB, et al. Characterization of the interleukin-17 isoforms and receptors in lesional psoriatic skin. *Brit J Dermatol*. 2009;160(2):319-24.
13. Stern RS, Nijsten T, Feldman S, et al. Psoriasis Is Common, Carries a Substantial Burden Even When Not Extensive, and Is Associated with Widespread Treatment Dissatisfaction. *J Invest Dermatol Symp*. 2004;9(2):136-9. Nestle FO, Kaplan DH, Barker J. Psoriasis. *N Engl J Med*. 2009; 361(5):496-509.

14. Rapp SR, Feldman SR, Exum ML, Fleischer AB, Jr., Reboussin DM. Psoriasis causes as much disability as other major medical diseases. *J Am Acad Dermatol*. 1999; 41(3 Pt 1):401-7.
15. Farley E et al. Psoriasis: comorbidities and associations. *G Ital Dermatol Venereol*. 2011 Feb;146(1):9-15.
16. International Federation of Psoriasis Associations (IFPA) World Psoriasis Day website. "About Psoriasis." <http://www.worldpsoriasisday.com/web/page.aspx?refid=114>. Accessed February 2014.
17. Armstrong AW, Robertson AD, Wu J, Schupp C, Lebwohl MG. Undertreatment, treatment trends, and treatment dissatisfaction among patients with psoriasis and psoriatic arthritis in the United States: findings from the National Psoriasis Foundation surveys, 2003–2011. *JAMA Dermatol*. 2013;149(10):1180-1185.

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