Novartis International AG
Novartis Global Communications
CH-4002 Basel
Switzerland
http://www.novartis.com

MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Novartis Cosentyx™ is the first IL-17 inhibitor to receive EU approval for first-line treatment of moderate-to-severe psoriasis patients

- *Cosentyx is the only biologic that can be used as first-line systemic therapy in the treatment of psoriasis and as an alternative to treatments that have significant side effects[1]; all other biologics are recommended for second-line therapy[2-4]*
- *Cosentyx showed superiority to Stelara® in the Phase IIIb CLEAR study[5]*
- *In Phase III studies, 70% or more Cosentyx 300 mg patients achieved clear skin (PASI 100) or almost clear skin (PASI 90) during the first 16 weeks of treatment[6]*
- *Achieving clear skin is the ultimate treatment goal for patients with psoriasis; 50% of psoriasis patients are not content with current therapies[7-10]*

Basel, 19 January 2015 – Novartis announced today that the European Commission (EC) has approved Cosentyx™ (secukinumab, formerly known as AIN457) as a first-line systemic* treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy.

Cosentyx (at a dose of 300 mg) is the first and only interleukin-17A (IL-17A) inhibitor to be approved in Europe and this approval marks a significant milestone in the treatment of psoriasis, providing a new and important first-line biologic treatment option for patients. Currently, all biologic treatments for psoriasis, including anti-tumor necrosis factor therapies (anti-TNFs) and Stelara®** (ustekinumab) are recommended for second-line systemic therapy in Europe[2-4].

“With this groundbreaking news from the European Commission, clear skin may now be a reality for patients living with psoriasis,” said David Epstein, Division Head, Novartis Pharmaceuticals. “Nearly half of psoriasis patients are not content with current therapies, including biologic treatments, showing a significant unmet need for patients. Cosentyx, with a first-line systemic indication for treatment of psoriasis will provide patients a better chance of achieving clear or almost clear skin.”

The key treatment goal for psoriasis patients is achieving clear skin. In clinical studies, 70% or more Cosentyx 300 mg patients achieved clear skin (PASI 100) or almost clear skin (PASI 90), during the first 16 weeks of treatment and importantly, this was maintained with continued treatment in the majority of patients up to Week 52[6]. Data from the Cosentyx clinical trial program also showed a significant positive relationship between achieving clear to almost clear skin and psoriasis patients’ health-related quality of life[11].

The EU approval follows the recent results of the Phase IIIb CLEAR study, which showed that Cosentyx was superior to Stelara®** in clearing skin of patients living with moderate-to-severe plaque psoriasis. The CLEAR study was the second head-to-head study for Cosentyx. Cosentyx also showed superiority to Enbrel®*** (etanercept) in clearing skin in the FIXTURE study[6]. In the Phase III clinical program the overall safety profile of

Cosentyx was favorable, with minimal differences seen between etanercept and ustekinumab in head-to-head comparison[5,6].

In addition to the EU, Cosentyx has been approved in Australia 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).

The US Food and Drug Administration (FDA) decision in moderate-to-severe plaque psoriasis is anticipated early in 2015 following the unanimous recommendation of approval in October 2014 from the Dermatologic and Ophthalmic Drugs Advisory Committee (DODAC) to the US FDA.

About Cosentyx (secukinumab) and interleukin-17A (IL-17A)
Cosentyx is a human monoclonal antibody that selectively neutralizes IL-17A[12,13]. IL-17A is found in high concentrations in skin affected by psoriasis and is a preferred target for investigational therapies[12-17]. Cosentyx works by inhibiting the action of interleukin-17A (IL-17A), a protein found in high concentrations in skin affected by the disease[12-17]. In the Phase III program, Cosentyx demonstrated a favorable safety profile, with similar incidence and severity of adverse events between secukinumab treatment arms (300 mg and 150 mg)[5,18-20].

Phase IIIb studies in psoriasis are ongoing in palmo-plantar psoriasis, nail psoriasis and palmo-plantar pustulosis.

Cosentyx is also in Phase III development for psoriatic arthritis (PsA) and ankylosing spondylitis (AS); 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 life[7,21,22]. Psoriasis affects up to 3% of the world's population, or more than 125 million people[23]. In Europe, the estimate is about 0.8%, which means that plaque psoriasis affects about 3.7 million Europeans, with about 2.4 million considered to have moderate-to-severe disease[24].

This common and distressing condition is not simply a cosmetic problem – even people with very mild symptoms are affected everyday[7]. Furthermore, there is an urgent need for new psoriasis treatments, as up to 50% of patients are not content with current therapies, including biologic treatments[7-10].

Disclaimer
The foregoing release contains forward-looking statements that can be identified by words such as "can," "recommended," "groundbreaking," "may," "will," "goal," "anticipated," "recommendation," "investigational," "ongoing," "planned," or similar terms, or by express or implied discussions regarding potential 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 indication, or at any particular time. Nor can there be any guarantee that Cosentyx will receive regulatory approval or 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, cost-saving generic pharmaceuticals, preventive vaccines and over-the-counter products. Novartis is the only global company with leading positions in these areas. In 2013, the Group achieved net sales of USD 57.9 billion, while R&D throughout the Group amounted to approximately USD 9.9 billion (USD 9.6 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 130,000 full-time-equivalent associates and sell products in more than 150 countries around the world. For more information, please visit http://www.novartis.com.

Novartis is on Twitter. Sign up to follow @Novartis at http://twitter.com/novartis.

*Systemic: treatments or medication absorbed into the blood stream, allowing them to be carried where they are needed to work
**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. Mohanan S, Ramassamy S, Chandrashekar L et al. A retrospective analysis of combination methotrexate–cyclosporine therapy in moderate–severe psoriasis. *Journal of Dermatological Treatment*, 2014; 25: 50–53.
2. European Medicines agency website, "Enbrel Summary of Product Characteristics" http://www.ema.europa.eu/docs/en_GB/document_library/EPAR__Product_Information/human/000262/WC500027361.pdf. Accessed November 2014.
3. European Medicines agency website, "Humira Summary of Product Characteristics" http://www.ema.europa.eu/docs/en_GB/document_library/EPAR__Product_Information/human/000481/WC500050870.pdf. Accessed November 2014.
4. European Medicines agency website, "Stelara Summary of Product Characteristics" http://www.ema.europa.eu/docs/en_GB/document_library/EPAR__Product_Information/human/000958/WC500058513.pdf. Accessed November 2014.
5. Novartis, Data on file.
6. 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.
7. 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 Investig Dermatol Symp*. 2004;9(2):136-9.Nestle FO, Kaplan DH, Barker J. Psoriasis. *N Engl J Med*. 2009; 361(5):496-509.
8. Christophers E, Griffiths CEM, Gaitanis G, et al. The unmet treatment need for moderate to severe psoriasis: results of a survey and chart review. *J Eur Acad Dermatol Venereol*. 2006;20:921-925.
9. Krueger JG, Koo J, Lebwohl M, et al. The impact of psoriasis on quality of life: Results for a 1998 National Psoriasis Foundation patient membership survey. *Arch Derm*. 2001;137:280-284.
10. Sterry W, Barker J, Boehncke WH, et al. Biological therapies in the systemic management of psoriasis: International Consensus Conference. *Br J Dermatol*. 2004;151 Suppl 69:3-17.
11. McLeod LD, Mallya UG, Fox T, Strober BE. Psoriasis Patients With PASI 90 Response Achieve Greater Health-Related Quality-of-Life Improvements Than Those With PASI 75 Response. European Association of Dermatology and Venereology, Amsterdam, Netherlands, 2014. Poster 1681.
12. Gaffen SL. Structure and signaling in the IL-17 receptor family. *Nat Rev Immunol*. 2009;9(8):556-67.
13. Ivanov S, Linden A. Interleukin-17 as a drug target in human disease. *Trends Pharmacol Sci*. 2009;30(2):95-103.
14. Kopf M, Bachmann MF, Marsland BJ. Averting inflammation by targeting the cytokine environment. *Nat Rev Drug Discov*. 2010; 9(9):703-18.
15. Onishi RM, Gaffen SL. Interleukin-17 and its target genes: mechanisms of interleukin-17 function in disease. *Immunology*. 2010;129(3):311-21.
16. 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.
17. 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.
18. 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; [published online ahead of print August 16, 2014].

19. 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; [published online ahead of print September 22, 2014].
20. Novartis data on file. 2013: Clinical study reports for CAIN457A2302 [ERASURE] ; CAIN457A2303 [FIXTURE] ; CAIN457A2304 [SCULPTURE] ; CAIN457A2307 [JUNCTURE] ; CAIN457A2308 [FEATURE].
21. 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.
22. Farley E et al. Psoriasis: comorbidities and associations. *G Ital Dermatol Venereol*. 2011 Feb;146(1):9-15.
23. International Federation of Psoriasis Associations (IFPA) World Psoriasis Day website. "About Psoriasis." http://www.worldpsoriasisday.com/web/page.aspx?refid=114. Accessed February 2014.
24. European Federation of Pharmaceutical Industries and Associations (EFPIA) website. "Psoriais." http://www.efpia.eu/diseases/134/59/Psoriasis. Accessed September 2014.

# # #

Novartis Media Relations

Central media line : +41 61 324 2200

Eric Althoff
Novartis Global Media Relations
+41 61 324 7999 (direct)
+41 79 593 4202 (mobile)
eric.althoff@novartis.com

Katrina Lucking
Novartis Global Pharma Communications
+41 61 324 12 18 (direct)
+41 79 171 8267 (mobile)
katrina.lucking@novartis.com

e-mail: media.relations@novartis.com

For Novartis multimedia content, please visit www.thenewsmarket.com/Novartis
For questions about the site or required registration, please contact:
journalisthelp@thenewsmarket.com.

Novartis Investor Relations

Central phone:	+41 61 324 7944		
Samir Shah	+41 61 324 7944	**North America:**	
Pierre-Michel Bringer	+41 61 324 1065	Richard Pulik	+1 212 830 2448
Thomas Hungerbuehler	+41 61 324 8425	Susan Donofrio	+1 862 778 9257
Isabella Zinck	+41 61 324 7188		

e-mail: investor.relations@novartis.com

e-mail: investor.relations@novartis.com