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Head-to-head psoriasis study demonstrates superiority of Novartis Cosentyx™ to Stelara® in clearing skin

- Cosentyx showed superiority to Stelara®, meeting the primary endpoint of achieving PASI 90, which represents clear or almost clear skin at Week 16 and secondary endpoint of achieving PASI 75 at Week 4 for psoriasis patients¹.

- CLEAR is the second head-to-head study for Cosentyx following the Phase III FIXTURE study that showed Cosentyx was superior to Enbrel® (etanercept)².

- CHMP recommended Cosentyx as first-line systemic therapy for the treatment of moderate-to-severe plaque psoriasis in adult patients in Europe.

- 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 treatment².

Basel, December 12, 2014 – Novartis announced today that the Phase IIIb CLEAR study for Cosentyx™ (secukinumab, formerly known as AIN457) demonstrated superiority to Stelara®* (ustekinumab) and met its primary endpoint of achieving PASI 90, which represents clear or almost clear skin at Week 16 for psoriasis patients¹. The study also met the secondary endpoint of achieving PASI 75 at Week 4¹. Safety results were consistent with previously reported Phase III clinical trials for Cosentyx.

The CLEAR study is the second head-to-head study for Cosentyx versus established psoriasis biologic treatments. It follows on from the Phase III FIXTURE study, which showed that Cosentyx was superior to Enbrel®** (etanercept), a current standard-of-care, in clearing psoriasis skin with a comparable safety profile².

Achieving clear skin is the ultimate aim of psoriasis treatment for patients. Data from the Cosentyx clinical trial program has also shown a significant positive relationship between achieving clear to almost clear skin and psoriasis patients’ health-related quality of life³. Additionally, 50% of psoriasis patients are not content with current therapies, including biologic treatments⁴⁻⁷.

“We are delighted that our IL-17A inhibitor Cosentyx showed superiority over Stelara, a widely-used biologic for moderate-to-severe psoriasis patients and a newer treatment alternative to TNF inhibitors,” said Vasant Narasimhan, Global Head of Development, Novartis Pharmaceuticals. “Patients need more effective treatment options for psoriasis and these impressive results add to the robust body of evidence that patients dramatically benefit and can achieve clear skin with Cosentyx.”

The study involved 679 moderate-to-severe plaque psoriasis patients and will be submitted for presentation at an international medical congress in 2015.

Topline results follow a positive CHMP opinion for Cosentyx as a first-line systemic treatment for patients with moderate-to-severe psoriasis. Currently, all biologic treatments for psoriasis, including anti-tumor necrosis factor therapies (anti-TNFs) and ustekinumab are recommended for second-line systemic therapy in Europe⁸⁻¹⁰. In
addition, the FDA Advisory Committee voted unanimously for the approval of Cosentyx in the US.

Cosentyx works by inhibiting the action of IL-17A, a protein that is found in high concentrations in skin affected by psoriasis\textsuperscript{11-16}.

Psoriasis is a chronic immune-mediated disease associated with significant impairment of physical and psychological quality of life\textsuperscript{4,17,18}. Psoriasis affects up to 3\% of the world’s population, or more than 125 million people\textsuperscript{19}.

**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 the second head-to-head Phase III study initiated with Cosentyx, and compared the efficacy, long-term safety and tolerability of Cosentyx versus ustekinumab, in patients with moderate-to-severe plaque psoriasis\textsuperscript{1}. Twenty-four countries across North America, Europe, Asia and Australia\textsuperscript{1} participated in the study, with enrollment reaching 679 patients in record time.

The primary endpoint measured at Week 16 is at least a 90\% reduction in the severity of psoriasis symptoms (redness, thickness and scaling) and the extent of skin affected by the disease, known as Psoriasis Area and Severity Index (PASI) 90\textsuperscript{1}. 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\textsuperscript{20}. Additionally the secondary endpoint measured at Week 4 is at least a 75\% reduction in the severity of psoriasis symptoms (PASI 75).

The CLEAR study follows the pivotal Phase III head-to-head FIXTURE study, which showed Cosentyx was superior to Enbrel in clearing skin\textsuperscript{2}. Enbrel is a current standard-of-care anti-TNF-alpha medication approved to treat moderate-to-severe plaque psoriasis\textsuperscript{8}, and 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 IL-17A\textsuperscript{11,12}. IL-17A is found in high concentrations in skin affected by psoriasis and is a preferred target for investigational therapies\textsuperscript{11-16}.

Phase IIIb studies in psoriasis in addition to the CLEAR study are also ongoing, including studies 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 for Cosentyx in these diseases are planned for 2015.

**About Psoriasis**

Psoriasis is a chronic autoimmune 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\textsuperscript{4,17,18}. Psoriasis affects up to 3\% of the world’s population, or more than 125 million people\textsuperscript{19}.

This common and distressing condition is not simply a cosmetic problem – even people with very mild symptoms are affected everyday\textsuperscript{3}. 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\textsuperscript{4-7}.

**Disclaimer**

The foregoing release contains forward-looking statements that can be identified by words such as “recommended,” “will,” “positive CHMP opinion,” “recommendation,”
"ongoing," 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 market, or approved for any indication, 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
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*Stelara® is a registered trademark of Janssen Biotech, Inc.
**Enbrel® is a registered trademark of Amgen Inc.

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