Novartis to present new late-breaking Cosentyx™ data at AAD 2015 showing significant patient benefit in achieving clear skin

- Detailed results from the CLEAR study will be revealed showing Cosentyx superiority to Stelara® in clearing skin (PASI 90 and PASI 100)
- New data from the long-term Phase III program to be presented demonstrating Cosentyx efficacy and safety over two years in psoriasis patients
- Cosentyx is the first and only IL-17A inhibitor approved in Europe, the US, Japan Canada and Switzerland for moderate-to-severe plaque psoriasis

Basel, 13 March 2015 – Novartis announced today that new results for Cosentyx™ (secukinumab) in moderate-to-severe plaque psoriasis, including detailed findings from the head-to-head CLEAR study and long-term data from the Phase III program, will be presented as late breaking research at the 73rd Annual Meeting of American Academy of Dermatology (AAD), from 20 – 24 March in San Francisco, California, USA. In total, 25 posters from the Novartis Dermatology portfolio will be highlighted at this leading congress.

New data from the CLEAR study will include results that demonstrate Cosentyx is superior to Stelara® (ustekinumab) in clearing skin (PASI 90 and PASI 100) at Week 16. CLEAR is the first Phase III psoriasis study designed with a PASI 90 objective, which is considered an important measure of treatment success by the European Medicines Agency and an optimal treatment goal for patients.

In addition, new long-term results for Cosentyx up to two years from the Phase III program will be highlighted for the first time at the congress. The data comes from an extension of the pivotal FIXTURE and ERASURE studies. In the FIXTURE study, Cosentyx cleared the skin of 72% psoriasis patients compared to 31% for Enbrel (etanercept) at Week 16.

“We are excited to present new late-breaking research at AAD, following the back-to-back regulatory approvals received earlier this year,” said Vasant Narasimhan, Global Head of Development, Novartis Pharmaceuticals. “Our commitment is to keep demonstrating more evidence on the ability of Cosentyx to clear psoriasis skin, to inform physicians and give hope to people living with this life-long disease who need treatments that provide long-term relief.”

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 psoriasis patients who are candidates for systemic therapy (a drug that is absorbed into the bloodstream and distributed to all parts of the body) or phototherapy (light therapy). In addition to the EU and the US, Cosentyx has been approved in Switzerland, Chile, Australia and Canada 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).
Novartis dermatology highlights at AAD 2015

Cosentyx presentations
A total of 18 Cosentyx abstracts will be presented for the first time at AAD 2015, including:

- **Late-breaking oral presentations:**
  - Secukinumab is superior to ustekinumab in clearing skin of subjects with moderate to severe plaque psoriasis: 16-week results from the CLEAR study (Friday 20 March, 10:00 PST / 18:00 CET)
  - Secukinumab treatment maintains efficacy in moderate-to-severe plaque psoriasis through second year of treatment: a randomized extension of the ERASURE and FIXTURE studies (Friday 20 March, 11:00 PST / 19:00 CET)

- **Highlights of electronic posters available throughout the congress:**
  - Secukinumab demonstrates sustained efficacy in moderate-to-severe plaque psoriasis across disease severity subgroups
  - Secukinumab shows efficacy in subjects regardless of previous exposure to biologic therapy: a pooled subanalysis from four Phase 3 clinical trials in psoriasis
  - Pooled analysis of phase 3 ERASURE and FIXTURE trials: Secukinumab 300 mg shows superior efficacy in moderate to severe plaque psoriasis vs. placebo in ERASURE vs. etanercept 50 mg and placebo in FIXTURE across subjects’ body weight groups
  - Secukinumab long-term self-administration by prefilled syringe or auto-injector/pen is highly acceptable to subjects with moderate-to-severe plaque psoriasis
  - Secukinumab, a novel anti–IL-17A antibody, exhibits low immunogenicity in clinical trials and human in vitro Assays

Other Cosentyx Phase III analyses at AAD 2015 include the efficacy and safety of Cosentyx in Asian patients and North American patients, efficacy on the head and neck, scalp psoriasis and a Phase III safety analysis.

**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 compared the efficacy, long-term safety and tolerability of Cosentyx (secukinumab) versus Stelara (ustekinumab), in patients with moderate-to-severe plaque psoriasis.

Twenty-four countries across North America, Europe, Asia and Australia participated in the study, with enrolment reaching 679 patients in record time.

The primary endpoint measured at Week 16 is PASI 90. 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. Additionally, the secondary endpoint measured at Week 4 is PASI 75. PASI 100 at Week 16 is an exploratory endpoint.

The CLEAR study follows the pivotal Phase III FIXTURE study, which showed Cosentyx was superior to Enbrel** in clearing skin. 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). IL-17A is found in high concentrations in skin affected by psoriasis and is a
Cosentyx works by inhibiting the action of IL-17A, a protein found in high concentrations in skin affected by the disease. 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).

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); 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 life. Psoriasis affects up to 3% of the world’s population, or more than 125 million people.

This common and distressing condition is not simply a cosmetic problem – even people with very mild symptoms are affected everyday. 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 management. Of the patients surveyed, some were receiving no treatment (9.4-49.2%) or were undertreated (10.2-55.5%).

**Disclaimer**

The foregoing release contains forward-looking statements that can be identified by words such as “to present,” “will,” “to be presented,” “excited,” “commitment,” “investigational,” “ongoing,” “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](http://www.novartis.com).

*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


# # #

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

e-mail: media.relations@novartis.com

Bhavin Vaid
Novartis Global Pharma Communications
+41 61 324 8175 (direct)
bhavin.vaid@novartis.com

Novartis Media Relations

Bhavin Vaid
Novartis Global Pharma Communications
+41 61 324 8175 (direct)
bhavin.vaid@novartis.com

Novartis Media Relations

Bhavin Vaid
Novartis Global Pharma Communications
+41 61 324 8175 (direct)
bhavin.vaid@novartis.com

Novartis Media Relations

Bhavin Vaid
Novartis Global Pharma Communications
+41 61 324 8175 (direct)
bhavin.vaid@novartis.com

Novartis Media Relations

Bhavin Vaid
Novartis Global Pharma Communications
+41 61 324 8175 (direct)
bhavin.vaid@novartis.com

Novartis Media Relations

Bhavin Vaid
Novartis Global Pharma Communications
+41 61 324 8175 (direct)
bhavin.vaid@novartis.com

Novartis Media Relations

Bhavin Vaid
Novartis Global Pharma Communications
+41 61 324 8175 (direct)
bhavin.vaid@novartis.com

Novartis Media Relations

Bhavin Vaid
Novartis Global Pharma Communications
+41 61 324 8175 (direct)
bhavin.vaid@novartis.com

Novartis Media Relations

Bhavin Vaid
Novartis Global Pharma Communications
+41 61 324 8175 (direct)
bhavin.vaid@novartis.com

Novartis Media Relations

Bhavin Vaid
Novartis Global Pharma Communications
+41 61 324 8175 (direct)
bhavin.vaid@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
Pierre-Michel Bringer  +41 61 324 1065  
Thomas Hungerbuehler  +41 61 324 8425
Isabella Zinck  +41 61 324 7188

**North America:**
Richard Pulik  +1 212 830 2448
Susan Donofrio  +1 862 778 9257

e-mail: investor.relations@novartis.com  e-mail: investor.relations@novartis.com