Novartis presents new data at WCD demonstrating significant efficacy of Cosentyx® in patients with psoriasis of the nails, palms and soles

- **Cosentyx** (secukinumab) met the primary endpoints of superiority compared to placebo in patients with difficult-to-treat psoriasis of the nails, palms and soles.¹,²

- One third of patients with moderate-to-severe palmoplantar psoriasis achieved clear or almost clear skin on their palms and soles after 16 Weeks of treatment with Cosentyx; severity of nail psoriasis decreased by almost a half.¹,²

- Cosentyx is first approved IL-17A inhibitor to show efficacy in patients with psoriasis in these locations; trial results considered most robust to date.

**Basel, 11 June, 2015** – Novartis announced today that Cosentyx® (secukinumab) met the primary endpoints in two new clinical studies, showing superior efficacy compared to placebo in patients with psoriasis of the palms, soles and nails, all difficult-to-treat locations of plaque psoriasis.¹,² Detailed findings were presented for the first time at the 23rd World Congress of Dermatology (WCD) in Vancouver, Canada.

In the GESTURE study in patients with moderate-to-severe palmoplantar psoriasis, Cosentyx (300 mg) was superior to placebo at Week 16 in achieving clear or almost clear palms and soles as assessed using the Palmoplantar Investigator’s Global Assessment (33.3% vs. 1.5%; P<0.0001).¹ Similarly, in the TRANSFIGURE study in patients with significant nail psoriasis, Cosentyx (300 mg) was superior to placebo at Week 16, as assessed by mean improvement (decrease) in the Nail Psoriasis Severity Index (NAPSI) compared to baseline (-45.3% vs -10.8%; P<0.0001).² The safety profile of Cosentyx in both studies was comparable to previously reported Phase III clinical trials.¹³

“These are the largest trials to prospectively compare an active therapy to placebo in patients with psoriasis affecting the palms, soles, and nails, an area where a high unmet need for an effective treatment still exists,” said Vasant Narasimhan, Global Head of Development, Novartis Pharmaceuticals. “These results add to the growing body of evidence that Cosentyx is setting a new standard of care for patients with even the most challenging types of psoriasis.”

Estimated to affect as many as 90% of all psoriasis patients at some point in their lifetime, psoriasis of the palms, soles and nails is extremely difficult to treat and often requires biologic treatment (a protein based medicine made from cells) to control.⁴⁻⁶ Patients with these locations of psoriasis endure significantly greater physical disabilities than those whose psoriasis is limited to other parts of the body.⁴,⁵ Patients may experience difficulty walking, more pronounced burning sensation and difficulty grasping and handling objects, skin soreness and difficulty participating in recreational activities, social and workplace interactions.⁴,⁵ Nail psoriasis is a significant predictor of psoriatic arthritis, an important comorbidity of psoriasis.⁷

Cosentyx is the first and only interleukin-17A (IL-17A) inhibitor approved for the treatment of moderate-to-severe plaque psoriasis. It was approved in January 2015 in the United States, Canada, Japan, Australia, Korea, China, Taiwan and Brazil and is currently under review in the European Union and other countries.
States and European Union, and is also approved in Australia, Canada, Chile, Japan, Singapore and Switzerland.

**About the GESTURE and TRANSFIGURE studies**

GESTURE has the largest sample size (N=205) and longest duration (132-week treatment period) of any biologic study in moderate-to-severe palmoplantar psoriasis and represents an important achievement in research in a patient population that has been underrepresented in psoriasis trials.1,8-10

TRANSFIGURE is the largest (N=198) and longest duration (132-week treatment period) randomized controlled study of a biologic in moderate-to-severe plaque psoriasis with significant nail psoriasis to report results to date.2,11

**About Cosentyx (seukinumab) and interleukin-17A (IL-17A)**

Cosentyx is a human monoclonal antibody that selectively neutralizes circulating interleukin-17A (IL-17A).12,13 Cosentyx works by inhibiting the action of IL-17A, a protein found in high concentrations in skin affected by the disease.12-14 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).3

In January 2015, Cosentyx (at a dose of 300 mg) became the first and only 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).

Secukinumab is also in Phase III development for psoriatic arthritis (PsA) and ankylosing spondylitis (AS). Global regulatory submissions for PsA and AS are planned for the first half of 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.15-17 Psoriasis affects up to 3% of the world’s population, or more than 125 million people.16

This common and distressing condition is not simply a cosmetic problem – even people with very mild symptoms are affected everyday.17 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.19 Of the patients surveyed, some were receiving no treatment (9.4-49.2%) or were undertreated (10.2-55.5%).18

**Disclaimer**

The foregoing release contains forward-looking statements that can be identified by words such as "to date," "growing," "planned," or similar terms, or by express or implied discussions regarding potential new indications or labeling 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 or approved for any additional indications or labeling in any market, 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 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 58.0 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 120,000 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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