Novartis presents new data showing that the majority of patients are able to maintain clear or almost clear skin with Cosentyx across 3 years

- Late-breaking data at EADV show that 8 out of 10 of psoriasis patients (83%) achieved 75% skin clearance (PASI 75) with Cosentyx™ after three years.

- 6 out of 10 patients (64%) had clear or almost clear skin (PASI 90 to PASI 100) with Cosentyx 300 mg at year three.

- Favorable safety profile seen with no new or unexpected safety signals.

Basel, October 10, 2015 – Novartis announced today new late-breaking data demonstrating that Cosentyx™ (secukinumab) provides high levels of skin clearance and sustained efficacy in patients with moderate-to-severe plaque psoriasis while maintaining a favorable safety profile across three years. The results of this study – the longest Phase III Cosentyx trial conducted to-date – were presented at the 24th Annual Congress of the European Academy of Dermatology and Venereology (EADV) in Copenhagen, Denmark. Cosentyx is the first fully human interleukin-17A (IL-17A) inhibitor approved to treat adult moderate-to-severe plaque psoriasis.

In this extension study, 320 patients received Cosentyx in a fixed dosing schedule for three years. 69% achieved clear or almost clear skin (PASI 90) at year one. This response was extremely well maintained after three years with 64% of patients continuing to have a PASI 90 response. In addition, 43% of patients maintained completely clear skin (PASI 100) at year three (from 44% at year one). 83% achieved the standard treatment goal of PASI 75 skin clearance at three years.

“Psoriasis patients want therapies that maintain high levels of skin clearance over the long-term given the impact of the disease on their physical and psychological wellbeing,” said Vasant Narasimhan, Global Head of Development, Novartis Pharmaceuticals. “In these new data from our longest Phase III trial to date with Cosentyx, we are pleased to show patients were able to maintain clear or almost clear skin for up to three years.”

The PASI score assesses the reduction from baseline in the redness, scaling and thickness of psoriatic plaques and to what extent it affects each area of the body. PASI 75 has historically been considered the goal for psoriasis treatment. However, with newer treatments with increased efficacy, there is now a focus on PASI 90 (clear or almost clear skin) and PASI 100 (clear skin) as the ultimate goal for treatment, as recommended by clinical guidelines and regulatory authorities.

In this study, Cosentyx had a favorable safety profile consistent with that observed in previous Phase III studies.

About the A2304E1 Extension Study (Cosentyx Extension Study to SCULPTURE and STATURE studies)
A2304E1 is a multicenter, double-blind and open-label, four-year extension to the pivotal Phase III SCULPTURE and STATURE studies. In SCULPTURE 642 patients who
completed 52 weeks of treatment continued into the extension. During the core study, PASI 75 responders at Week 12 were randomized to double-blind maintenance treatment of subcutaneous secukinumab 300 mg or 150 mg, administered either at a four-week fixed-interval (FI) regimen (320 patients) or in a retreatment-as-needed (RAN) regimen (322 patients). At entry into the extension, patients continued with the same blinded maintenance treatment regimen and dose that they had received in the SCULPTURE core study¹.

The primary objective of the extension study was to assess the long-term safety and tolerability of Cosentyx in patients with moderate-to-severe chronic plaque psoriasis. The secondary objective was to evaluate long-term efficacy of 300 mg and 150 mg Cosentyx administered in retreatment-as-needed versus fixed-interval regimens in patients who were PASI 75 responders at Week 12. Efficacy measures included proportion of patients achieving PASI 75, PASI 90 and PASI 100 as well as IGA mod 2011 0/1 responses¹.

About psoriasis
Psoriasis affects up to 3% of the world’s population, or more than 125 million people⁵. This common and distressing condition is not simply a cosmetic problem, even people with very mild symptoms are affected every day⁶. According to an analysis of surveys conducted on 5,600 patients by the National Psoriasis Foundation (NPF) between 2004 and 2011, 52% of patients with mild, moderate and severe psoriasis were dissatisfied with their disease management¹⁳. Of the patients surveyed, some were receiving no treatment (9.4-49.2%) or were undertreated¹³.

About Cosentyx (secukinumab) and interleukin-17A (IL-17A)
Cosentyx is a human monoclonal antibody that selectively neutralizes circulating interleukin-17A (IL-17A)¹⁴,¹⁵. IL-17A is found in high concentrations in skin affected by psoriasis and is a preferred target for investigational therapies¹⁴⁻¹⁹. Cosentyx works by inhibiting the action of IL-17A, a protein found in high concentrations in skin affected by the disease¹⁴⁻¹⁹.

In January 2015, Cosentyx (secukinumab) (at a recommended dose of 300 mg in the EU/US) became the first IL-17A inhibitor approved in Europe and the US. In Europe, Cosentyx is the only first-line biologic approved for the systemic treatment of moderate-to-severe plaque psoriasis in adult patients. In the US, Cosentyx is approved 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, Australia, Canada and a number of other countries for the treatment of moderate-to-severe plaque psoriasis and in Japan for the treatment of moderate-to-severe plaque psoriasis and psoriatic arthritis (PsA). More than 9,600 patients have been treated with Cosentyx in clinical trials across multiple indications, and over 9,000 patients have been treated in the post-marketing setting⁸⁻¹⁲,²⁰.

Disclaimer
The foregoing release contains forward-looking statements that can be identified by words such as “can,” “investigational,” 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 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 safety issues; unexpected manufacturing or quality 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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References

1. Bissonnette R., et al. Secukinumab maintains high levels of efficacy through 3 years of treatments: results from an extension to a phase 3 study (SCULPTURE). Presented as a late breaking abstract at the European Academy of Dermatology and Venereology 2015. October 10 2015


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