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Novartis receives approval in the EU for Cosentyx ® label update, includes long term superiority data versus Stelara ® in psoriasis

- *Label update includes 52 week data from CLEAR study demonstrating long-term superiority of Cosentyx® versus Stelara® in psoriasis[1,2]*
- *Update also includes use of Cosentyx in moderate-to-severe scalp psoriasis[1] – one of the most difficult-to-treat types of psoriasis[3]*
- *Cosentyx is the first interleukin-17A (IL-17A) inhibitor approved to treat psoriasis, psoriatic arthritis (PsA) and ankylosing spondylitis (AS)*

Basel, July 06, 2017 – Novartis announced today that the Committee for Medicinal Products for Human Use (CHMP) has approved a label update for Cosentyx® (secukinumab), the first interleukin-17A (IL-17A) approved to treat psoriasis. The label update includes 52 week data from the CLEAR study demonstrating the long-term superiority of Cosentyx versus Stelara® * (ustekinumab) in psoriasis[1,2]. The updated label also includes use of Cosentyx to treat moderate-to-severe scalp psoriasis[1] – one of the most difficult-to-treat forms of psoriasis[3], which affects approximately 60 million people worldwide[4,5]. The updated label is based on the proven efficacy and consistent safety profile of Cosentyx[1].

The addition of the CLEAR study data in the European product label reflects the benefit of Cosentyx for people living with this chronic and often distressing condition[3]. The 52 week data show that Cosentyx is superior to Stelara in delivering long-lasting clear or almost clear skin over one year of treatment in adults with moderate-to-severe psoriasis[2]. Cosentyx remained consistently superior to Stelara in achieving and sustaining a PASI 90 response (76% versus 61%) and significantly better in achieving a PASI 100 (clear skin) response (46% versus 36%) at Week 52[2].

The updated label for Cosentyx on scalp psoriasis, in a difficult-to-treat area of the body[3], addresses an important unmet need. Many patients with scalp psoriasis do not achieve an adequate response from currently available treatments[6]. Also, scalp psoriasis can be particularly challenging to treat as disease activity is often maintained through hair care, scratching, and shampooing of the scalp, adding to the fact that the application of topical treatments is challenging[3]. Approximately half of all 125 million patients with psoriasis worldwide suffer from scalp psoriasis[4,5].

“We are happy to see these two important label updates for our IL-17A-inhibitor, Cosentyx, the first IL-17A inhibitor approved to treat psoriasis. We are continually investigating new areas for Cosentyx to significantly enhance patients’ quality of life, such as scalp psoriasis,” said Vas Narasimhan, Global Head, Drug Development and Chief Medical Officer, Novartis. “Cosentyx is an innovative, groundbreaking treatment for people living with auto-inflammatory diseases, and we’re proud to continuously expand treatment possibilities for an even greater number of patients.”

Cosentyx is currently the only fully human IL-17A inhibitor to demonstrate efficacy and safety in a dedicated Phase III study of scalp psoriasis. The CHMP approval is based on results from

the 24 week study of moderate-to-severe scalp psoriasis where Cosentyx demonstrated superior efficacy compared to placebo[7]. Psoriasis Scalp Severity Index (PSSI) 90 responses were achieved by a significantly greater percentage of patients receiving Cosentyx 300 mg (53%) than placebo (2%) at Week 12 (P<0.001)[7].

The label update is applicable to all European Union and European Economic Area countries. Cosentyx is approved in more than 75 countries for the treatment of moderate-to-severe plaque psoriasis. Cosentyx is also approved in more than 70 countries for the treatment of active PsA and AS.

About psoriasis
Psoriasis is a common, non-contagious, auto-immune disease that affects more than 125 million people worldwide[4]. Plaque psoriasis is the most common form of the disease and appears as raised, red patches covered with a silvery white buildup of dead skin cells. Scalp psoriasis is a form of psoriasis that is reported to affect approximately half of all patients with psoriasis[5]. The disease has a significant impact on patients' quality of life, which is an aspect of the disease underestimated by most physicians[3].

Psoriasis is not simply a cosmetic problem, but a persistent, chronic (long-lasting), and sometimes distressing disease, which can affect even the smallest aspects of people's lives on a daily basis. Up to 30% of patients with psoriasis have, or will develop, PsA[8]. PsA is a condition in which the joints are also affected, causing debilitating symptoms including pain, stiffness and irreversible joint damage[8,9]. Psoriasis is also associated with other serious health conditions, such as diabetes, heart disease and depression[8].

About Cosentyx and IL-17A
Launched in January 2015, Cosentyx is a targeted treatment that specifically inhibits the IL-17A cytokine. Research suggests that IL-17A may play an important role in driving auto-inflammatory conditions in enthesis and ultimately the body's immune response in psoriasis, PsA and AS[10,11].

Cosentyx is approved in more than 75 countries for the treatment of moderate-to-severe plaque psoriasis, which includes the US, Canada, the European Union countries, Japan, Switzerland and Australia. In Europe, Cosentyx is approved for the first-line systemic treatment of moderate-to-severe plaque psoriasis in adult patients[1]. 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)[12].

Cosentyx is the first IL-17A inhibitor approved in more than 70 countries for the treatment of active PsA and AS, which includes the US and the European Union countries. Cosentyx is also approved for the treatment of PsA and pustular psoriasis in Japan[1].

About the CLEAR study[2]
CLEAR (Comparison to assess Long-term Efficacy, sAfety and toleRability of secukinumab versus ustekinumab) is a multi-center, double-blind, parallel-group study of Cosentyx (n=335 versus Stelara (n=336) to compare efficacy, safety, and tolerability in adults with moderate-to-severe plaque psoriasis. Patients were randomized to receive either Cosentyx (300 mg) by subcutaneous injection at Baseline, Weeks 1, 2 and 3, then every four weeks from Week 4, or Stelara (dosing per package label). Cosentyx achieved the primary objective of superior PASI 90 response at Week 16. The 52 week PASI 90 response is a secondary objective in this study. PASI 100 and PROs responses (including DLQI) at 52 weeks are exploratory endpoints.

About the SCALP study[7]
This study is a randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of Cosentyx in 102 patients with moderate-to-severe scalp psoriasis. Eligible

patients were equally randomized to either subcutaneous Cosentyx 300 mg or placebo at Weeks 0, 1, 2 and 3, then every four weeks for 12 weeks. At Week 12, patients in the placebo group who did not achieve at least a 90% improvement from baseline in the Psoriasis Scalp Severity Index (PSSI) score were re-randomized to Cosentyx 300 mg until study completion. The primary endpoint was the proportion of patients who achieved PSSI 90 response rate at Week 12.

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This press release contains forward-looking statements, including "forward-looking statements" within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as "potential," "can," "will," "plan," "expect," "anticipate," "look forward," "believe," "committed," "investigational," "pipeline," "launch," or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for the investigational or approved products described in this press release, or regarding potential future revenues from such products. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations 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 the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations regarding such products could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures; general economic and industry conditions, including the effects of the persistently weak economic and financial environment in many countries; safety, quality or 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, cost-saving generic and biosimilar pharmaceuticals and eye care. Novartis has leading positions globally in each of these areas. In 2016, the Group achieved net sales of USD 48.5 billion, while R&D throughout the Group amounted to approximately USD 9.0 billion. Novartis Group companies employ approximately 118,000 full-time-equivalent associates. Novartis products are sold in approximately 155 countries around the world. For more information, please visit http://www.novartis.com.

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* Stelara is a registered trademark of Janssen Biotech, Inc.

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