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MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Novartis presents new two year data for Cosentyx® showing no progression in joint damage in 84% of psoriatic arthritis patients

- *New x-ray assessment data, from a sub-study, showed no progression of joint structural damage in the majority of patients with psoriatic arthritis over two years*[1]
- *Psoriatic arthritis patients on Cosentyx maintained treatment response in joint and skin disease, physical function and quality of life over two years*[1]
- *Cosentyx is the first interleukin-17A inhibitor to demonstrate efficacy in Phase III studies of patients with psoriatic arthritis*[2,3]

Basel, November 8, 2015 – Novartis announced today new results for Cosentyx® (secukinumab) showing no further progression in joint damage in 84% of patients with psoriatic arthritis (PsA). In addition, Cosentyx maintained a treatment response in joint and skin disease, physical function and quality of life in patients over two years of treatment[1]. These results from the extension phase of the FUTURE 1 study were presented at the 2015 Annual Meeting of the American College of Rheumatology (ACR) in San Francisco, United States.

Cosentyx is the first of a new class of medicines called interleukin-17A (IL-17A) inhibitors to demonstrate efficacy in Phase III studies in PsA – a life-long inflammatory disease that affects the skin and joints. If not treated effectively, it can lead to irreversible joint damage and disability caused by years of inflammation[2-4].

“Psoriatic arthritis patients need therapies that can prevent the progression of this debilitating disease. In this two-year study, Cosentyx showed no further progression in joint damage in over 80% of PsA patients while maintaining improvements in joint and skin disease, physical function, and quality of life,” said Vasant Narasimhan, Global Head of Development, Novartis Pharmaceuticals. “These results show the potential for Cosentyx to create an important new option for the treatment of psoriatic arthritis”.

New medicines with an alternative way of working are needed as many patients do not achieve an adequate response from current treatments, such as disease-modifying anti-rheumatic drugs, non-steroidal anti-inflammatories or anti-tumor necrosis factor (anti-TNF) therapies. Many patients do not respond to or tolerate these therapies, with approximately 45% of PsA patients dissatisfied with their treatments[5-7].

These results from the FUTURE 1 study represent the longest Cosentyx Phase III study in PsA to date. Responses in joint and skin disease, physical function, and quality of life at Week 24, were maintained over two years. After two years of treatment, 67%* of patients (n=202) treated with Cosentyx 150 mg achieved the standard treatment goal of an ACR 20 response (American College of Rheumatology response criteria)[1]. In addition, 84% of patients showed no further progression in joint damage as shown by x-ray

* Imputed data

assessment[†]. Cosentyx was well tolerated with a safety profile consistent with that observed in previous studies[1].

About the FUTURE 1 study
FUTURE 1 is a two year, multi-center, randomized, placebo-controlled Phase III pivotal study to evaluate the efficacy of Cosentyx in patients with active PsA. FUTURE 1 enrolled 606 patients with active PsA and assessed Cosentyx with intravenous loading (10 mg/kg) and subcutaneous (75 mg and 150 mg) maintenance dosing[1]. The primary endpoint assessed superiority of Cosentyx against placebo in the proportion of patients achieving the ACR 20 response at Week 24. From Week 16, patients in the placebo arm of the study were re-randomized to receive Cosentyx 150 mg or 75 mg at either Week 16 or Week 24, based on clinical response[1-2].

About psoriatic arthritis
PsA is part of a family of life-long inflammatory diseases that also includes ankylosing spondylitis (AS). It is also closely associated with psoriasis. Approximately 30% of patients with psoriasis have PsA[8] and as many as one in four people with psoriasis may have undiagnosed PsA[9]. Symptoms of PsA include joint pain and stiffness, skin and nail psoriasis, swollen toes and fingers, persistent painful swelling of the tendons, and irreversible joint damage[4]. Up to 40% of people can suffer from joint destruction and permanent physical deformity[10].

About Cosentyx and interleukin-17A
Cosentyx is a human monoclonal antibody that selectively neutralizes circulating IL-17A[11]. Cosentyx is the first IL-17A inhibitor with positive Phase III results for the treatment of PsA and AS[2,3,12,13]. Research suggests that IL-17A may play an important role in driving the body's immune response in psoriasis, PsA and AS[14].

In October 2015, Cosentyx was recommended for approval in Europe by the Committee for Medicinal Products for Human Use (CHMP) for the treatment of AS and PsA patients. For patients with AS and PsA, the recommended dose is Cosentyx 150 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2 and 3, followed by monthly maintenance dosing starting at Week 4. For PsA patients with concomitant moderate-to-severe plaque psoriasis, or who are anti-TNF inadequate responders, the recommended dose is Cosentyx 300 mg. Cosentyx is an investigational treatment in the US for AS and PsA.

In total, 49 countries have approved Cosentyx for the treatment of moderate-to-severe plaque psoriasis which includes the European Union and European Economic Area countries. In January 2015, Cosentyx (at a recommended dose of 300 mg in the US and EU) became the first IL-17A inhibitor approved in the EU and US for the treatment of moderate-to-severe plaque psoriasis. 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, Cosentyx has been approved in Switzerland, Australia, Canada and a number of other countries for the treatment of moderate-to-severe plaque psoriasis. In Japan, Cosentyx is approved for the treatment of moderate-to-severe plaque psoriasis and also for the treatment of 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 setting[15].

Disclaimer
The foregoing release contains forward-looking statements that can be identified by words such as "can," "could," "may," "suggests," "recommended," or similar terms, or by express or implied discussions regarding potential new indications or labeling for Cosentyx, or regarding potential

[†] Defined as a change from baseline in mTSS of ≤0.5 (n=202)

future revenues from Cosentyx, or regarding the long-term impact of a patient's use of 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. Neither can there be any guarantee regarding the long-term impact of a patient's use of Cosentyx. 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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