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MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Novartis receives two landmark European approvals for Cosentyx to treat patients with ankylosing spondylitis and psoriatic arthritis

- *Cosentyx is the first and only IL-17A inhibitor from a new class of medicines shown to treat two of the most common inflammatory joint conditions in Europe*[1]
- *Cosentyx shows rapid and sustained clinical benefits in ankylosing spondylitis (AS) and psoriatic arthritis (PsA) with no progression of spinal damage in approximately 80% of AS patients and joint damage in 84% of PsA patients as measured by x-ray over two years*[2-5]
- *Urgent unmet need for new medicines exists as a significant number of patients do not respond well to current treatments*[6]

Basel, November 23, 2015 – Novartis announced today that the European Commission (EC) has approved Cosentyx® (secukinumab) for the treatment of people living with ankylosing spondylitis (AS) and psoriatic arthritis (PsA). For AS, this is the first new treatment advance in 16 years since the development of the current standard of care, anti-tumor necrosis factor (anti-TNF) therapy[7].

Cosentyx is the first in a new class of medicines called interleukin-17A (IL-17A) inhibitors to be made available in Europe for AS and PsA. These approvals follow on from the earlier EC approval of Cosentyx for the first-line treatment of patients with moderate-to-severe plaque psoriasis.

AS and PsA are common inflammatory joint conditions affecting approximately five million people in Europe, yet they remain significantly under-diagnosed and under-treated[1,8-12]. If not treated effectively, they can lead to irreversible damage to the spine and joints, causing life-long pain and disability[13]. New treatments are urgently needed for both conditions as many patients do not respond well to existing treatments, with up to 40% not responding sufficiently to anti-TNFs[6].

“The strong treatment benefits seen in our studies suggest that Cosentyx may give patients the chance to stop the disease from progressing, preventing living with pain and disability,” said David Epstein, Division Head, Novartis Pharmaceuticals. “These approvals mean that people living with ankylosing spondylitis and psoriatic arthritis across Europe can now start to benefit from this next generation biologic that has the potential to become a new standard of care for these common but under-treated inflammatory conditions.”

Recent studies have shown that Cosentyx provided a significant reduction in the signs and symptoms of AS or PsA as early as Week 1-3, which were sustained over two years[2,3]. Up to 80% of AS patients treated with Cosentyx showed no progression in spinal damage as measured by x-ray over two years[4]. In PsA, 84% of patients showed no progression of joint damage on x-ray over two years[5].

More than 9,600 patients have been treated with Cosentyx in clinical trials across multiple indications, and over 12,500 patients have been treated in the post-marketing setting[14].

The safety profile of Cosentyx was shown to be consistent with that seen in clinical trials across multiple indications[2-5,14].

Cosentyx is now licensed to treat active AS in adults who have responded inadequately to conventional therapy, such as non-steroidal anti-inflammatory drugs, and for the treatment of active PsA in adult patients alone or in combination with methotrexate when the response to previous disease modifying anti-rheumatic drug therapy has been inadequate.

About the European Commission approval
The European Commission marketing authorizations for Cosentyx are applicable to all European Union and European Economic Area countries.

For patients with AS and PsA, the approved dose is Cosentyx 150 mg by subcutaneous injection (under the skin) with initial dosing at Weeks 0, 1, 2 and 3, followed by monthly maintenance dosing starting at Week 4. For patients with PsA who also have moderate-to-severe plaque psoriasis, or who are anti-TNF inadequate responders, the recommended dose is Cosentyx 300 mg.

Pivotal Phase III studies in the Cosentyx clinical trial program, that provided key data for the submission, were MEASURE 1 and MEASURE 2 in AS, and FUTURE 1 and FUTURE 2 in PsA[2,3,15,16]. These are ongoing multi-center, randomized, placebo-controlled studies that have been designed to evaluate the efficacy and safety of Cosentyx in AS and PsA.

About ankylosing spondylitis (AS)
AS is a painful, progressively debilitating condition caused by inflammation of the spine. Up to 70% of patients with severe AS develop spinal fusion (where new bone growth immobilizes the spine) over 10 to 15 years, which significantly reduces mobility and quality of life[17]. AS occurs in approximately 1.78 million people in Europe[8,9] and typically affects young men and women aged 25 or older[18].

About psoriatic arthritis (PsA)
PsA is an inflammatory condition of the joints and is often associated with a scaly skin condition called psoriasis. It occurs in approximately 3.1 million people in Europe[8,10]. As many as 30% of people with psoriasis have PsA and up 25% of people with psoriasis may have undiagnosed PsA[19,20].

About Cosentyx and interleukin-17A (IL-17A)
Cosentyx is a human monoclonal antibody that selectively neutralizes circulating IL-17A[21]. Cosentyx is the first IL-17A inhibitor with positive Phase III results for the treatment of PsA and AS. Research suggests that IL-17A may play an important role in driving the body's immune response in psoriasis, PsA and AS[22].

In total, 50 countries have approved Cosentyx for the treatment of moderate-to-severe plaque psoriasis which includes the European Union countries, Switzerland, Australia, the US and Canada. 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 Japan, Cosentyx is approved for the treatment of moderate-to-severe plaque psoriasis and also for the treatment of PsA. In Ecuador, Cosentyx is approved for the treatment of PsA and AS.

Disclaimer
The foregoing release contains forward-looking statements that can be identified by words such as "can," "suggest," "may," "potential," "ongoing," "suggests," 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.

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