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Novartis to present first of its kind evidence for Cosentyx® on potential to maintain mobility in patients with AS and PsA

- *Long-term 4-year data in ankylosing spondylitis (AS) and 24-weeks data in psoriatic arthritis (PsA) to be presented at the 2017 ACR/ARHP Annual Meeting^{1,2}*
- *Structural disease progression is a major concern for AS and PsA patients as it may prompt mobility loss³ – new data to provide further evidence on the efficacy of Cosentyx to reduce structural disease progression*
- *Cosentyx is the first and only IL-17A inhibitor approved for AS and PsA as well as psoriasis, and has been used by more than 100,000 patients across indications worldwide⁴*

Basel, October 30, 2017 – New evidence on the efficacy of the innovative biologic Cosentyx® (secukinumab) demonstrating its potential to reduce structural disease progression in patients with specific rheumatological conditions will be presented at the 2017 ACR/ARHP Annual Meeting in San Diego, United States. The Cosentyx late breaking presentations will include new 4-year data from the MEASURE 1 study in patients with ankylosing spondylitis (AS), and 24-week data from the FUTURE 5 study in patients with psoriatic arthritis (PsA), two debilitating autoimmune diseases with a high risk of mobility loss.

“Maintaining mobility is our hope and vision for every patient with chronic inflammatory diseases such as AS and PsA.” said Vas Narasimhan, Global Head, Drug Development and Chief Medical Officer, Novartis. “Reducing radiographic progression would be a strong signal for patients who hope to stay mobile as this would result in a significant improvement of their quality of life.”

Cosentyx is a fully-human, targeted biologic approved for patients with AS, PsA, or psoriasis (PsO). Cosentyx is the first and only fully human monoclonal antibody that selectively neutralizes interleukin-17A (IL-17A), the key cytokine involved in the pathogenesis of AS, PsA and PsO⁵⁻⁷. Today, Cosentyx has been used by more than 100,000 patients worldwide⁴. Across all three indications, Cosentyx has demonstrated rapid and sustained efficacy as well as a consistently favorable safety profile^{1,2,8}, including close to zero injection site reactions or associated pain^{9,10}.

About Cosentyx and IL-17A

Cosentyx is the first and only IL-17A inhibitor approved to treat ankylosing spondylitis (AS) and psoriatic arthritis (PsA), two autoimmune diseases in rheumatology, as well as psoriasis⁵. Cosentyx is a fully-human, targeted biologic that specifically inhibits the IL-17A cytokine which plays a significant role in the pathogenesis of AS, PsA and plaque psoriasis⁵⁻⁷. IL-17A is a key cytokine involved in the inflammation of the entheses – the sites where tendons or ligaments connect to the bone¹¹⁻¹³.

Cosentyx is the first IL-17A inhibitor approved in more than 70 countries for the treatment of active AS and PsA, which includes the European Union countries and the US. Cosentyx is also approved for the treatment of PsA and pustular psoriasis in Japan⁴.

Cosentyx is also approved in more than 75 countries for the treatment of moderate-to-severe plaque psoriasis, which includes the European Union countries, Japan, Switzerland, Australia, the US and Canada. In Europe, Cosentyx is approved for the first-line 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)¹⁴.

Cosentyx has a proven safety profile with close to zero injection site reactions or injection site associated pain^{9,10}.

About ankylosing spondylitis (AS) and psoriatic arthritis (PsA)

Ankylosing spondylitis (AS) is part of a family of life-long inflammatory diseases, which also includes psoriatic arthritis (PsA). AS is characterized by inflammation of the sacroiliac joints and new bone formation caused by increased levels of IL-17A, with severe cases progressing to irreversible spinal fusion^{12,15}. AS can cause serious impairment of movement in the spine and physical function, which has an impact on quality of life. People in their teens and twenties, particularly males, are affected most often^{16,17}.

PsA is a debilitating autoimmune diseases with a high risk of mobility loss. 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 damage¹⁸. Up to 40% of people can suffer from joint destruction and permanent physical deformity¹⁹.

IL-17A plays a significant role in disease pathogenesis of AS, PsA and plaque psoriasis, which is significant as up to 30% of psoriasis patients will develop PsA during their lifetime¹⁸ and as many as 1 in 4 people with psoriasis may have undiagnosed PsA²⁰.

About the MEASURE 1 study

MEASURE 1 is a 2-year, multicenter, randomized, placebo-controlled Phase III study assessing the efficacy and safety of Cosentyx in patients with active AS. A total of 290 of 371 patients completed the trial, after which 274 patients were invited to enter a 3-year extension period^{1,21}. Primary endpoints assessed superiority of Cosentyx against placebo at Week 16 in the proportion of patients achieving at least a 20% improvement in the ASAS 20 response criteria^{1,22}. From Week 16, patients in the placebo arm of the study were re-randomized to Cosentyx 75 mg or 150 mg based on ASAS 20 response, with non-responders switched at Week 16, and responders at Week 24^{1,22}. In total, 83/87 and 95/100 patients who enrolled in the extension and randomized to Cosentyx 75 mg and 150 mg respectively completed 156 weeks¹.

About the FUTURE 5 study²

In the study, participants (n=996) with active PsA were randomized to receive Cosentyx at 300 mg with loading dose (LD), 150 mg with LD, 150 mg without LD, or placebo. All groups received Cosentyx or placebo at baseline (BL), weeks 1, 2, 3, and 4, and then every 4 weeks. At week 16, placebo non-responders (patients with <20% improvement from BL in tender or swollen joint counts) were switched to Cosentyx 300 mg or 150 mg; remaining placebo patients were switched at week 24. The primary endpoint was ACR20 at week 16 and the key secondary endpoint was radiographic structural progression, as measured by mTSS, assessed by two blinded readers, based on hand/wrist/foot X-rays obtained at BL, week 16 (non-responders), and week 24. With nearly 1,000 patients included in the Phase III study, FUTURE 5 is the largest randomized controlled trial (RCT) of a biologic conducted in PsA.

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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 119,000 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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