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## **Novartis announces study data demonstrating Cosentyx<sup>®</sup> reduced signs and symptoms of psoriatic arthritis while inhibiting progression of joint structural damage**

- *Structural joint damage in psoriatic arthritis (PsA) patients taking Cosentyx<sup>®</sup> (secukinumab) was inhibited at 24 weeks versus placebo in all arms of the study<sup>1</sup>*
- *PsA can lead to reduced mobility and irreversible joint damage<sup>2</sup>*
- *FUTURE 5 is the largest randomized controlled trial of a biologic conducted to date in PsA, with nearly 1,000 patients studied<sup>1</sup>*

**Basel, November 7, 2017** – Novartis announced today results from the FUTURE 5 study showing Cosentyx<sup>®</sup> (secukinumab) reduced the signs and symptoms of psoriatic arthritis (PsA) while significantly inhibiting the progression of joint structural damage in PsA patients compared to placebo at 24 weeks<sup>1</sup>. The Phase III data were presented for the first time today as a late breaker during the 2017 American College of Rheumatology/Association of Rheumatology Health Professionals (ACR/ARHP) Annual Meeting in San Diego.

PsA is a painful, progressively debilitating inflammatory disease. Up to 40% of PsA patients can suffer from joint damage and permanent physical deformity<sup>3</sup>.

Study participants (n=996) were randomized to receive Cosentyx, 300 mg with loading dosage (LD), 150 mg with LD, 150 mg without LD, or placebo. At week 24, more participants treated with Cosentyx had no worsening of joint structural damage compared to placebo, as measured by the modified total van der Heijde Sharp score (mTSS)  $\leq 0.5$ ; 88% (300 mg), 80% (150 mg), 84% (150 mg without LD), and 74% (placebo).<sup>1</sup> mTSS is a detailed scoring method evaluating erosion in the joints<sup>4</sup>.

“People living with psoriatic arthritis deal with the daily impact of pain, tender joints, as well as the potential of reduced mobility, and irreversible joint damage,” said Philip Mease, MD, director of the Rheumatology Clinical Research Division of Swedish Medical Center and lead study investigator and clinical professor at the University of Washington School of Medicine in Seattle. “A treatment that reduces the signs and symptoms of psoriatic arthritis and addresses the disease on a structural level by slowing the progression of joint damage could offer a significant benefit for patients.”

Participants taking Cosentyx achieved significant improvements in the signs and symptoms of PsA compared to placebo, as measured by the ACR response criteria (ACR20) at 16 weeks, the study’s primary endpoint<sup>1</sup>. ACR is a standard tool used to assess improvement of PsA signs and symptoms such as tender and swollen joints, pain and physical functioning. The number of ACR20 responders at week 16 were 62% (300 mg,  $P < 0.0001$ ), 55% (150 mg,  $P < 0.0001$ ), 59% (150 mg without LD,  $P < 0.0001$ ), and 27.4% (placebo)<sup>1</sup>.

“With nearly 1,000 patients included in the study, FUTURE 5 is the largest randomized controlled trial of a biologic conducted to date in psoriatic arthritis,” said Vas Narasimhan,

Global Head, Drug Development and Chief Medical Officer, Novartis. ““The results are encouraging as they provide important information about the ability of Cosentyx to address key areas of concern for physicians when managing the symptoms and the underlying progression of joint structural damage of psoriatic arthritis.”

All hierarchical endpoints were significant for Cosentyx versus placebo at week 16 for all treatment arms, except for the 150 mg without LD in resolving enthesitis (tenderness or pain often occurring in the bottom of the foot, heel or elbow) and dactylitis (sausage-like swelling in the fingers or toes)<sup>1,5</sup>. Further, efficacy across all endpoints was greater in patients who had not been previously treated with anti-TNF therapies<sup>1</sup>. Participants taking the 300 mg and 150 mg dosages with LD had an earlier onset of response versus participants who receive 150 mg without LD<sup>1</sup>.

The safety profile was consistent with that observed in previous studies and similar across arms, with no new adverse events (AEs) identified<sup>6</sup>.

#### **About the FUTURE 5 study (NCT02404350)<sup>1</sup>**

In the study, participants (n=996) with active PsA were randomized to receive Cosentyx at 300 mg with 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 ACR 20 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 to date in PsA.

#### **About PsA**

Closely associated with psoriasis, PsA is part of a spectrum of long-term diseases impacting joints, known as spondyloarthritis (SpA)<sup>7</sup>. 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<sup>2</sup>. Up to 40% of people can suffer from joint destruction and permanent physical deformity<sup>3</sup>.

PsA is closely associated with psoriasis. Up to 30% of psoriasis patients will develop PsA at some point during their lifetime<sup>2</sup> and as many as 1 in 4 people with psoriasis may have undiagnosed PsA<sup>8</sup>.

#### **About Cosentyx (secukinumab) and interleukin-17A (IL-17A)**

Cosentyx, launched in 2015, is the first and only fully human IL-17A inhibitor approved to treat PsA, AS, and psoriasis<sup>9</sup>. Cosentyx is a targeted treatment that specifically inhibits the IL-17A cytokine, which plays a significant role in the pathogenesis of PsA, AS and plaque psoriasis<sup>9,10,11</sup>.

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 Japan<sup>12</sup>.

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<sup>9</sup>. 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)<sup>13</sup>.

To date, more than 100,000 patients worldwide have been prescribed Cosentyx in the post-marketing setting across all indications<sup>14</sup>. In addition, 2017 marks 10 years since the first patient, first visit in a clinical trial with Cosentyx<sup>14</sup>.

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### **References**

1. P. Mease, et al. Subcutaneous Secukinumab Inhibits Radiographic Progression in Psoriatic Arthritis: Primary Results from a Large Randomized, Controlled, Double-Blind Phase 3 Study. Presented as a late-breaker at the 2017 ACR/ARHP Annual Meeting. November 7, 2017.

2. Mease PJ, Armstrong AW. Managing patients with psoriatic disease: the diagnosis and pharmacologic treatment of psoriatic arthritis in patients with psoriasis. *Drugs*. 2014; 74:423-441.
3. Anwar AH, Diamond H. Psoriatic arthritis: practice essentials, background, pathophysiology and etiology. Medscape reference website. Available at: <http://emedicine.medscape.com/article/2196539-overview#a6>. Last accessed October 2017.
4. D van der Heijde. Psoriatic arthritis imaging: a review of scoring methods. *BMJ*. 2005; 64(Suppl II):ii61–ii64. doi: 10.1136.
5. National Psoriasis Foundation. Media Kit. <https://www.psoriasis.org/sites/default/files/for-media/MediaKit.pdf>. Accessed May 2017.
6. Novartis Data on File. FUTURE 5 First Interpretable Results: Week 24 Interim Analysis. August 2017.
7. Armstrong A et al. Treatment Trends, and Treatment Dissatisfaction Among Patients With Psoriasis and Psoriatic Arthritis in the United States: Findings From the National Psoriasis Foundation Surveys, 2003-2011. *JAMA Dermatol*. 2013; 149(10):1180-1185.
8. National Psoriasis Foundation. Could You Have Psoriatic Arthritis? Know the Signs. Available at <https://www.psoriasis.org/psoriatic-arthritis/know-the-signs>. Last accessed October 2017.
9. Cosentyx Summary of Product Characteristics. Novartis Europharm Limited. Available at: [http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003729/human\\_med\\_001832.jsp&mid=WC0b01ac058001d124](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003729/human_med_001832.jsp&mid=WC0b01ac058001d124). Last accessed October 2017.
10. Nestle FO et al. Mechanisms of disease psoriasis. *New England Journal of Medicine*. 2009;361:496-509
11. Girolomoni G et al. Psoriasis: rationale for targeting interleukin-17. *British Journal of Dermatology*. 2012;167:717-24.
12. Pharmaceuticals and Medical Devices Agency. Review Report. [www.pmda.go.jp. http://www.pmda.go.jp/files/000216877.pdf](http://www.pmda.go.jp/files/000216877.pdf). Last accessed October 2017.
13. Cosentyx (secukinumab) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp, 2016.
14. Novartis Data on file. Number of Patients Prescribed Cosentyx. May 2017.

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