

Novartis' Cosentyx shows sustained improvements in signs and symptoms for both AS and PsA in up to 80% of patients at 3 years

- *Cosentyx[®] is the first and only IL-17A inhibitor to show sustained improvements in signs and symptoms of ankylosing spondylitis (AS) and psoriatic arthritis (PsA)^{1,2}*
- *Additional data show rapid and sustained pain relief with Cosentyx as early as Week 3 which is sustained out to 2 years in PsA patients³*
- *Patient recruitment underway for the new EXCEED head-to-head clinical trial to show superiority of Cosentyx versus Humira[®]* in PsA⁴*

Basel, June 15, 2017 – Novartis announced today data showing Cosentyx[®] (secukinumab) shows sustained improvements in the signs and symptoms for active ankylosing spondylitis (AS) at 3 years¹, consistent with previous findings in active psoriatic arthritis (PsA) at 3 years². New data also show Cosentyx provides rapid and sustained pain relief in patients with active PsA out to 2 years³. These findings were presented at the Annual European Congress of Rheumatology (EULAR 2017), in Madrid, Spain.

Cosentyx is the only fully human interleukin-17A (IL-17A) inhibitor to demonstrate 3-year efficacy and safety in Phase III studies of both AS and PsA^{1,2,5}, which are life-long debilitating inflammatory diseases. Cosentyx is also used to treat moderate-to-severe psoriasis, which is significant as up to 8 in 10 patients with PsA also have psoriasis⁶.

“These data reconfirm that Cosentyx provides patients with long-lasting relief from the symptoms of ankylosing spondylitis and psoriatic arthritis, as well as now demonstrating rapid pain relief from psoriatic arthritis”, said Vas Narasimhan, Global Head of Drug Development and Chief Medical Officer, Novartis. “We are pleased that Cosentyx continues to provide sustained benefits for patients with psoriasis, psoriatic arthritis, and ankylosing spondylitis.”

In the MEASURE 1 extension study, 80% of AS patients consistently achieved an ASAS 20 response (Assessment of Spondyloarthritis International Society response criteria) at 3 years^{1†}. This was consistent with previous findings from the FUTURE 1 study in active PsA where Cosentyx demonstrated sustained improvements in the signs and symptoms of disease in approximately 80% of patients at 3 years as measured by ACR 20 response (American College of Rheumatology response criteria)^{2†}.

A 2-year post-hoc analysis of the FUTURE 2 study evaluated Cosentyx in PsA, where almost every patient (99%) reported moderate-to-extreme pain or discomfort before initiating treatment³. By Week 3, half of those (50%) treated with Cosentyx reported clinically meaningful improvements in pain of over 20%, as measured by Visual Analogue Scale (VAS)³. At Week 4, the proportion of patients reporting no pain or discomfort was greater for Cosentyx (15%) than for placebo (5%) and this increased through to Week 104 (28%)³. Cosentyx continues to have a favorable safety profile, which was consistent with that shown in Phase III studies^{1,7-10}.

Cosentyx is the only IL-17A inhibitor approved in psoriasis, PsA and AS with more than 80,000 patients treated in the post-marketing setting worldwide across all indications¹¹.

About Cosentyx and interleukin-17A (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 autoinflammatory conditions in enthesitis and ultimately the body's immune response in psoriasis, AS and PsA^{12,13}.

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 Japan¹¹.

Cosentyx is 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 patients⁵. 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.

About the MEASURE 1 study

MEASURE 1 is a 2-year, multi-center, 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 patients were invited to enter a 3-year extension period¹. Of these, 274 entered the extension trial, with 260 completing 156 weeks¹. At the start of the 2-year study, 371 patients were enrolled and administered a Cosentyx intravenous loading dose of 10 mg/kg every 2 weeks for the first 4 weeks of treatment, followed by monthly subcutaneous maintenance dosing (75 mg and 150 mg)^{8,15}. 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^{8,15}. 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^{8,15}. In total, 83/87 and 95/100 patients randomized to Cosentyx 75 mg and 150 mg respectively completed 156 weeks¹.

About the FUTURE 1 and FUTURE 2 studies

FUTURE 1 is a randomized, double-blind, placebo-controlled Phase III study of Cosentyx in patients with active PsA. A total of 476 of 606 patients completed the trial to demonstrate the 24 week efficacy and assess the long-term safety, tolerability and efficacy up to 2 years of a 10 mg/kg intravenous loading dose followed by subcutaneous doses of Cosentyx 75 mg, 150 mg^{2,10}. Of these 476 patients, 457 entered the FUTURE 1 extension study, with 435 completing 156 weeks².

FUTURE 2 is a randomized, double-blind, placebo-controlled Phase III study, in 397 patients with active PsA, to demonstrate the efficacy of subcutaneous Cosentyx 75 mg, 150 mg, 300 mg in prefilled syringes at 24 weeks and to assess the long-term efficacy, safety and tolerability for up to 5 years^{9,16}.

Both studies included patients who were anti-TNF therapy naïve or inadequate responders; randomization was stratified so that approximately 70% and 65% were required to be anti-TNF therapy naïve in FUTURE 1 and FUTURE 2, respectively. In both trials, the primary endpoint was the percentage of patients achieving an ACR 20 response at Week 24. FUTURE 2 and the extension of FUTURE 1 are currently ongoing to investigate the longer-term efficacy of Cosentyx^{9,10}.

About ankylosing spondylitis and psoriatic arthritis

AS is part of a family of life-long inflammatory diseases, which also includes PsA. It generally results in 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. Family members of those with AS are at higher risk^{17,18}.

PsA is also closely associated with psoriasis. Approximately 30% of patients with psoriasis have PsA and as many as 1 in 4 people with psoriasis may have undiagnosed PsA^{19,20}. 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 damage⁶. Up to 40% of people can suffer from joint destruction and permanent physical deformity²¹.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by words such as “underway,” “suggests,” “may,” “long-term,” “ongoing,” “to investigate,” “longer-term” 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 clinical trial results and additional analysis of existing clinical data; 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 and reimbursement pressures; 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.

* *Humira is a registered trademark of AbbVie Inc.*

† *In AS 80% of patients achieved ASAS 20 response; this includes both the anti-TNF naïve and anti-TNF inadequate response arms of the study.*

‡ *In PsA 77% of patients achieved ACR 20 response; this includes both the anti-TNF naïve and anti-TNF inadequate response arms of the study.*

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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Novartis Media Relations

Central media line: +41 61 324 2200
E-mail: media.relations@novartis.com

Eric Althoff
Novartis Global Media Relations
+41 61 324 7999 (direct)
+41 79 593 4202 (mobile)
eric.althoff@novartis.com

Friedrich von Heyl
Novartis Global Pharma Communications
+41 61 324 8984 (direct)
+41 79 749 0286 (cell)
friedrich.vonheyhl@novartis.com

Novartis Investor Relations

Central investor relations line: +41 61 324 7944
E-mail: investor.relations@novartis.com

Central
Samir Shah +41 61 324 7944
Pierre-Michel Bringer +41 61 324 1065
Thomas Hungerbuehler +41 61 324 8425
Isabella Zinck +41 61 324 7188

North America
Richard Pulik +1 212 830 2448
Cory Twining +1 212 830 2417