New two year data for Novartis’ Cosentyx® show sustained response and no progression in spinal damage as shown by x-ray in up to 80% of patients with ankylosing spondylitis

- A sub-study showed up to 80% of ankylosing spondylitis (AS) patients treated with Cosentyx had no radiographic progression in the spine over two years.
- Cosentyx demonstrated a sustained response for signs and symptoms of AS in anti-TNF naïve patients with around 80%* achieving ASAS 20 at two years.
- Cosentyx is the first interleukin-17A inhibitor to demonstrate efficacy in Phase III studies in AS patients.

Basel, November 8, 2015 – Novartis announced today late-breaking two year results for Cosentyx® (secukinumab) showing up to 80% of patients with ankylosing spondylitis (AS) had no radiographic progression in the spine on x-ray assessment. This is the first time that data on structural spinal progression in AS have been presented for an interleukin-17A (IL-17A) inhibitor.

In addition, Cosentyx showed a sustained response in improvements of signs and symptoms, physical function and quality of life in AS patients over two years. These results from an extension phase of the MEASURE 1 pivotal study were revealed at the 2015 Annual Meeting of the American College of Rheumatology (ACR) in San Francisco, United States.

Cosentyx is the first IL-17A inhibitor and the first biologic treatment other than the current standard of care — anti-tumor necrosis factor medicines (anti-TNFs) — to demonstrate efficacy in Phase III AS studies. AS is a life-long and painful inflammatory disease that can cause irreversible joint and/or spinal damage for patients if not treated effectively.

“Many patients with ankylosing spondylitis will go on to experience stiffening of the spine. Cosentyx has shown the potential to reduce structural damage of the spine in ankylosing spondylitis patients across two years,” said Vasant Narasimhan, Global Head of Development, Novartis Pharmaceuticals. “Cosentyx is a real contender for becoming a new standard for treating ankylosing spondylitis patients.”

These results are important because up to 70% of patients with severe AS develop spinal fusion (where the bones grow together) over 10 to 15 years, which significantly reduces mobility. New treatment options are also urgently needed as many patients do not respond adequately to current medications such as non-steroidal anti-inflammatory drugs and anti-TNF therapies with up to 40% of patients not responding sufficiently to the latter.

* Observed data
Data from 125 patients presented for Cosentyx 150 mg showed that 74%† achieved an ASAS 20 response (Assessment of Spondyloarthritis International Society response criteria) at two years‡. The study enrolled patients who had either never taken, or who had previously been treated with, the current standard of care biologic, anti-TNF therapy². Quality of life and physical function scores were also maintained over two years. Cosentyx was well tolerated over the two year treatment period with a safety profile consistent with that observed in previous studies across multiple indications².

About the study
These results are from the MEASURE 1 study and represent the longest Cosentyx AS Phase III study presented to date. MEASURE 1 is a two year, multi-center, randomized, placebo-controlled Phase III study assessing the efficacy and safety of Cosentyx in patients with active AS. The study has now entered a three year extension period. 371 patients were enrolled and administered a Cosentyx intravenous loading dose of 10 mg/kg every two weeks for the first four weeks of treatment, followed by monthly subcutaneous maintenance dosing (75 mg and 150 mg)¹. 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. 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 24². In total, 103/124 and 97/125 patients randomized to Cosentyx 75 mg and 150 mg respectively completed 104 weeks. Observed analyses included in the extension phase at 104 weeks included only data available at a given time point. Patients with missing data at that time point were not included.

About ankylosing spondylitis
AS is part of a family of life-long inflammatory diseases that also includes psoriatic arthritis (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 risk⁸,⁹.

About Cosentyx and interleukin-17A
Cosentyx is a human monoclonal antibody that selectively neutralizes circulating IL-17A¹⁰. Cosentyx is the first IL-17A inhibitor with positive Phase III results for the treatment of AS and PsA³,⁴,¹¹,¹². Research suggests that IL-17A may play an important role in driving the body’s immune response in psoriasis, PsA and AS¹³.

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

¹ Imputed data
²ASAS 20 is improvement of ≥20% and ≥1 unit on a 10-unit scale in at least three of the four core ASAS domains, with no worsening of ≥20% and ≥1 unit in the fourth at 104 weeks.
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.

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

Novartis is on Twitter. Sign up to follow @Novartis at http://twitter.com/novartis

References

---

**Novartis Media Relations**

Central media line : +41 61 324 2200

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

Bhavin Vaid  
Novartis Global Pharma Communications  
+41 61 324 8175 (direct)  
+41 79 792 7510 (mobile)  
bhavin.vaid@novartis.com

e-mail: media.relations@novartis.com

For Novartis multimedia content, please visit [www.thenewsmarket.com/Novartis](http://www.thenewsmarket.com/Novartis)

For questions about the site or required registration, please contact: [journalisthelp@thenewsmarket.com](mailto:journalisthelp@thenewsmarket.com).

---

**Novartis Investor Relations**

Central phone:  
+41 61 324 7944
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

e-mail: investor.relations@novartis.com

North America:
Richard Pulik  
+1 212 830 2448
Sloan Pavsner  
+1 212 830 2417

e-mail: investor.relations@novartis.com