Up to 80% of ankylosing spondylitis patients treated with Cosentyx® show no spinal x-ray progression as shown in Novartis new two-year observational data

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- - 104 Week sub-analysis data from the Cosentyx Phase III Measure 1 study in patients with ankylosing spondylitis (AS) presented at ACR 2015(1,2)
- - Two-year x-ray data from observational sub-analysis show no progression of joint damage in up to 80% of AS patients treated with Cosentyx(1)
- - Additional analysis shows patients receiving Cosentyx through Week 104 maintained ASAS20 (indicator of AS improvement) scores as seen at Week 16, when significant improvements versus placebo were observed(2)
- - Cosentyx is the first interleukin-17A (IL-17A) antagonist to report positive results in a Phase III study for AS patients dealing with this painful and often debilitating disease of the spine(3,4)

EAST HANOVER, N.J., Nov. 7, 2015 /PRNewswire/ -- Novartis announced two-year data for Cosentyx® (secukinumab) from an observational sub-analysis of a pivotal Phase III trial showing up to 80% of ankylosing spondylitis (AS) patients only treated with either Cosentyx 150 mg or 75 mg (combined n=168) had no radiographic progression in the spine on x-ray assessment.[1] This is the first study with two-year data on structural spinal progression in AS that has been conducted for patients treated with an interleukin-17A (IL-17A) antagonist. The results from this extension-phase of the MEASURE 1 trial will be presented as a late-breaker at the 2015 Annual Meeting of the American College of Rheumatology (ACR) in San Francisco.

"Patients with ankylosing spondylitis need new treatment options as not all current therapies work for all people," said Atul Deodhar, MD, professor of medicine and medical director of Rheumatology Clinics at Oregon Health & Science University, and an investigator in the secukinumab clinical trial program. "The two-year Cosentyx data further support its potential use as a treatment option for this patient population."

Data from a second MEASURE 1 sub-analysis also presented at ACR found patients receiving 150 mg or 75 mg of Cosentyx through Week 104 maintained a level of response on joint disease measures as seen at Week 16, when significant improvements versus placebo were observed.[2] These data were derived using a multiple imputation method.

Data presented from 125 patients treated with Cosentyx 150 mg across two years showed that from Week 16 (primary endpoint vs. placebo) 73.7% maintained at least a 20% improvement in AS symptoms as measured by the Assessment of Spondyloarthritis International Society response criteria (ASAS20)[*], a standard tool used to assess clinical improvement in AS. The MEASURE 1 trial enrolled patients who had either never taken, or who had previously been treated with, the current standard of care biologic, anti-tumor necrosis factor medicines (anti-TNF therapy).

These extension data add to the body of evidence for Cosentyx, the first IL-17A antagonist and the first biologic other than the current standard of care – anti-TNFs, to demonstrate efficacy in controlled Phase III AS studies.[3,4]

The most common adverse events (AEs) observed in patients treated with Cosentyx 150 mg at Week 104 were nasopharyngitis (common cold; 24.3%), diarrhea (13.8%), headache (12.2%) and pharyngitis (sore throat; 11.6%). 86.7% of Cosentyx patients experienced an AE and 12.2% experienced a serious adverse event (SAE).

About the MEASURE 1 study
The results presented at ACR 2015 include observed and imputed data from two separate sub-analyses from the MEASURE 1 trial and represent the longest Cosentyx AS Phase III study presented to date.

MEASURE 1 is a multi-center, randomized, placebo-controlled Phase III study assessing the efficacy and safety of Cosentyx in patients with active AS. Primary endpoints assessed Cosentyx against placebo at Week 16 in the proportion of patients

achieving at least a 20% improvement in the ASAS20 response criteria. In total, 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] From Week 16, patients in the placebo arm of the study were re-randomized to Cosentyx 150 mg or 75 mg based on ASAS20 response, with non-responders switched at Week 16, and responders at Week 24.[2] The study has now entered a three-year extension period.

In total, 103/124 and 97/125 patients randomized to Cosentyx 75 mg and 150 mg respectively completed 104 weeks.[1] 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.

Secondary endpoints assessed signs and symptoms, physical function and quality of life measures at Week 16 including: ASAS40 response, change from baseline in high-sensitivity C-reactive protein (hsCRP), ASAS5/6 improvement; changes from baseline in total BASDAI score, Medical Outcomes Study Short Form-36 Health Survey physical component summary score (SF-36 PCS), Ankylosing Spondylitis Quality of Life score (ASQoL), ASAS partial remission, and overall safety and tolerability.[2]

About ankylosing spondylitis
Ankylosing spondylitis (AS) is a common type of spondyloarthritis (SpA), a spectrum of long-term diseases of joints (inflammatory disease).[5] AS is painful and often progressively debilitating, caused by spine inflammation that can result in irreversible damage.[6] Up to 70% of patients who go on to develop severe AS will form spinal fusions (where the bones grow together) over 10 to 15 years, which significantly reduces mobility.[7] People in their teens and twenties, particularly males, are affected most often. Family members of those with AS are at higher risk.[6,8] Approximately 20-40% of patients do not respond well to standard of care biologic medicines, and there are few therapeutic options available to those people.[9]

About Cosentyx and interleukin-17A (IL-17A)
Cosentyx is not indicated for AS.

Cosentyx is a human monoclonal antibody (mAb) that selectively binds to IL-17A and inhibits its interaction with the IL-17 receptor.[10] Cosentyx is the first IL-17A antagonist to report positive results in AS Phase III trials.[3,4] Research suggests that IL-17A may play an important role in driving the body's immune response in certain inflammatory arthritic diseases, including AS.[11]

In January 2015, Cosentyx became the first and only IL-17A antagonist approved by the FDA as a treatment for moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy (a drug that is absorbed into the bloodstream and distributed to all parts of the body) or phototherapy (light therapy).

[*]ASAS20 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.

INDICATION

COSENTYX® (secukinumab) is indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

COSENTYX is contraindicated in patients with a previous serious hypersensitivity reaction to secukinumab or to any of the excipients.

WARNINGS AND PRECAUTIONS

Infections
COSENTYX may increase the risk of infections. In clinical trials, a higher rate of infections was observed in subjects treated with COSENTYX compared to placebo-treated subjects. In placebo-controlled clinical trials, higher rates of common infections such as nasopharyngitis (11.4% versus 8.6%), upper respiratory tract infection (2.5% versus 0.7%), and

mucocutaneous infections with candida (1.2% versus 0.3%) were observed with COSENTYX compared with placebo. The incidence of some types of infections appeared to be dose-dependent in clinical studies.

Exercise caution when considering the use of COSENTYX in patients with a chronic infection or a history of recurrent infection.

Instruct patients to seek medical advice if signs or symptoms suggestive of an infection occur. If a patient develops a serious infection, the patient should be closely monitored and COSENTYX should be discontinued until the infection resolves.

Pre-treatment Evaluation for Tuberculosis
Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with COSENTYX. Do not administer COSENTYX to patients with active TB infection. Initiate treatment of latent TB prior to administering COSENTYX. Consider anti-TB therapy prior to initiation of COSENTYX in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Patients receiving COSENTYX should be monitored closely for signs and symptoms of active TB during and after treatment.

Exacerbations of Crohn's Disease
Exercise caution when prescribing COSENTYX to patients with active Crohn's disease, as exacerbations of Crohn's disease, in some cases serious, were observed in patients treated with COSENTYX during clinical trials. Patients who are treated with COSENTYX and have active Crohn's disease should be monitored closely.

Hypersensitivity Reactions
Anaphylaxis and cases of urticaria occurred in patients treated with COSENTYX in the clinical trials. If an anaphylactic or other serious allergic reaction occurs, administration of COSENTYX should be discontinued immediately and appropriate therapy initiated.

The removable cap of the COSENTYX Sensoready® pen and the COSENTYX prefilled syringe contains natural rubber latex which may cause an allergic reaction in latex-sensitive individuals. The safe use of the COSENTYX Sensoready pen or prefilled syringe in latex-sensitive individuals has not been studied.

Vaccinations
Prior to initiating therapy with COSENTYX, consider completion of all age appropriate immunizations according to current immunization guidelines. Patients treated with COSENTYX should not receive live vaccines.

Non-live vaccinations received during a course of COSENTYX may not elicit an immune response sufficient to prevent disease.

MOST COMMON ADVERSE REACTIONS

Most common adverse reactions (>1%) are nasopharyngitis, diarrhea, and upper respiratory tract infection.

Please see accompanying full Prescribing Information, including Medication Guide.

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

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Located in East Hanover, New Jersey, Novartis Pharmaceuticals Corporation is an affiliate of Novartis AG, which 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.

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Novartis Media Relations

Eric Althoff	Anna Frable
Novartis Global Media Relations	Novartis Pharmaceuticals Corporation
+41 61 324 7999 (direct)	+1 862 778 5388 (direct)
+41 79 593 4202 (mobile)	+1 732 673 5262 (mobile)
eric.althoff@novartis.com	anna.frable@novartis.com

e-mail: us.mediarelations@novartis.com

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