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Novartis presents Cosentyx™ two-year efficacy and safety data showing sustainable effect in psoriasis patients

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- - New data at AAD shows 7 out of 10 psoriasis patients who were PASI 75 responders at 52 weeks achieved clear to almost clear skin (PASI 90) after two years of Cosentyx 300 mg treatment
- - After two full years of therapy with Cosentyx 300 mg, almost 9 out of 10 psoriasis patients sustained their PASI 75 response
- - Cosentyx is the first and only IL-17A antagonist approved in the US, the EU, Japan, Canada and Switzerland for adults with moderate-to-severe plaque psoriasis

EAST HANOVER, N.J., March 21, 2015 /PRNewswire/ -- Novartis today announced new two-year results demonstrating sustained efficacy with Cosentyx™ (secukinumab) with an acceptable safety profile for the treatment of psoriasis patients. The data comes from the extension study of the pivotal Phase III FIXTURE and ERASURE trials. Results were presented for the first time in a late-breaking session at the 73rd Annual Meeting of the American Academy of Dermatology (AAD) in San Francisco. Cosentyx is the first and only interleukin-17A (IL-17A) antagonist approved to treat adult moderate-to-severe plaque psoriasis patients.

"This two-year data is significant because it represents results from the longest continuous Phase III study to date evaluating an IL-17A antagonist in the treatment of psoriasis," said Andrew Blauvelt, MD, MBA, President of the Oregon Medical Research Center and lead study investigator. "The study not only strengthens our understanding of the efficacy and safety of Cosentyx, but reiterates that it is an important new longer-term treatment option for patients with moderate-to-severe plaque psoriasis."

In this extension of the FIXTURE and ERASURE studies, 995 patients who achieved Psoriasis Area Severity Index (PASI) 75 response after a year of therapy (Week 52) received either Cosentyx 300 mg, Cosentyx 150 mg or placebo for an additional year (Week 104). After two full years of therapy, 7 out of 10 (70.6%) patients treated with Cosentyx 300 mg had clear to almost clear skin (PASI 90); 4 out of 10 (43.9%) had clear skin (PASI 100) and almost 9 out of 10 (88.2%) patients maintained their PASI 75 response at Week 104.

For patients treated with Cosentyx 150 mg, 44.6% had clear or almost clear skin (PASI 90); 23.5% had clear skin (PASI 100) and 75.5% maintained their PASI 75 response at Week 104. PASI assesses treatment efficacy by measuring the reduction in redness, scaling and thickness of psoriatic plaques and the extent of involvement in each region of the body.

In the study, 94.8% of patients who initially received placebo (at the start of the extension) and were switched to receive Cosentyx 300 mg after relapse, were able to achieve PASI 75 and 70.3% achieved PASI 90 within 12 weeks of re-starting Cosentyx treatment.

"We are pleased to share new long-term data showing how the sustained efficacy and acceptable safety profile of Cosentyx helps psoriasis patients maintain clear or almost clear skin at the end of two years of treatment," said Vasant Narasimhan, Global Head of Development, Novartis Pharmaceuticals. "Psoriasis is a chronic condition causing itching, scaling and pain; patients need therapies that provide relief and clear skin

over a long period of time."

Cosentyx demonstrated an acceptable safety profile. The most common adverse events (AEs) for the 300 mg and 150 mg treatment arms were nasopharyngitis (24.1% and 17.0%, respectively), upper respiratory tract infection (5.3% and 5.0%), hypertension (4.3% and 5.2%), headache (5.6% and 2.9%) and arthralgia (4.0% and 4.2%). Infections and infestations were reported in 53.1% of patients receiving Cosentyx 300 mg and 41.6% of patients receiving 150 mg. There were 64 (6.0%) serious AEs (SAEs) in any Cosentyx dose and no deaths reported during the study.

About the A2302E1 Extension Study (Cosentyx Extension Study to the FIXTURE and ERASURE studies)
A2302E1 is a multicenter, double-blind, randomized withdrawal extension study to the FIXTURE and ERASURE pivotal Phase III studies. The extension study was conducted to collect long term efficacy, safety and tolerability data on Cosentyx in patients who achieved a PASI 75 response to Cosentyx at Week 52 of the FIXTURE and ERASURE core studies in moderate-to-severe plaque psoriasis.

Patients who had been receiving Cosentyx 300 mg or 150 mg during the maintenance period of the core studies, and who exhibited a PASI 75 response at Week 52 of the core studies, were randomized to continue the same Cosentyx dose or receive placebo. Patients who exhibited partial response (PASI 50 to

During the extension study, patients randomized to placebo and who experienced relapse (defined as loss of >50% of the maximum PASI gain compared to baseline of the core study) at any study visit received Cosentyx 300 mg or 150 mg, respectively, once weekly for 4 weeks, followed by Cosentyx dosing every 4 weeks thereafter.

About the FIXTURE and ERASURE studies
FIXTURE (the Full year Investigative eXamination of secukinumab vs. eTanercept Using 2 dosing Regimens to determine Efficacy in psoriasis) and ERASURE (Efficacy of Response And Safety of two fixed secUkinumab REgimens in psoriasis) are part of the Cosentyx Phase II and Phase III studies which included over 3,990 adult patients with moderate-to-severe plaque psoriasis.

FIXTURE and ERASURE assessed the efficacy, safety and tolerability of induction period (at Week 12) and maintenance therapy (at Week 52) with subcutaneous Cosentyx 300 mg or 150 mg in patients with moderate-to-severe plaque psoriasis. Both studies were multicenter, randomized, double-blind, placebo-controlled (FIXTURE: also active controlled), parallel-group Phase III trials involving 1,306 patients and 738 patients with moderate-to-severe plaque psoriasis, respectively. Each study consisted of a 1-to-4-week screening period, a 12-week induction period, a 40-week maintenance period and an 8-week follow-up period. The co-primary endpoints in both studies, PASI 75 response and Investigator's Global Assessment (IGA mod 2011) 0/1 response at Week 12, were used to demonstrate superiority of Cosentyx vs. placebo ($p<0.001$ for all comparisons).

About Cosentyx (secukinumab) and interleukin-17A (IL-17A)
Cosentyx (secukinumab, previously known as AIN457) is a human monoclonal antibody (mAb) that selectively binds to interleukin-17A (IL-17A) and inhibits its interaction with the IL-17 receptor. It is the first IL-17A antagonist approved by the FDA for the treatment of 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).

About psoriasis
Affecting 7.5 million Americans, psoriasis is a chronic immune-mediated disease characterized by thick and extensive skin lesions (plaques), which can cause itching, scaling, and pain. Patients reported these symptoms can negatively impact their quality of life, both psychosocially and physically, which makes daily

functioning difficult. Additionally, patients with psoriasis are at increased risk for other chronic illnesses.

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 COSENTYX-treated subjects 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 COSENTYX-treated patients 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 COSENTYX-treated patients 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.

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 "can," "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. 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 for sale in any additional markets, or approved for any additional indications, 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 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 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.

About Novartis
Novartis Pharmaceuticals Corporation researches, develops, manufactures and markets innovative medicines aimed at improving patients' lives. We offer a broad range of medicines for cancer, cardiovascular disease, endocrine disease, inflammatory disease, infectious disease, neurological disease, organ transplantation, psychiatric disease, respiratory disease and skin conditions. The company's mission is to improve people's lives by pioneering novel healthcare solutions.

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 billion, while R&D throughout the Group amounted to approximately USD 9.9 billion (USD 9.6 billion excluding impairment and amortization charges). As of December 31, 2014 Novartis Group companies employed approximately 133,000 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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List of links present in page

1. https://qa1.novartis.us/us-en/us-en/news/media-releases/novartis-presents-cosentyxtm-two-year-efficacy-and-safety-data-showing-sustainable-effect-psoriasis-patients
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