New Novartis data show more Cosentyx™-treated psoriasis patients achieved clear or almost clear skin (PASI 90) compared to Stelara®

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- - Phase IIIb CLEAR study at AAD showed over 21% more psoriasis patients achieved clear to almost clear skin (PASI 90) with Cosentyx™ (secukinumab) compared to Stelara® (ustekinumab) at Week 16
- - In assessing superiority, a higher percentage of Cosentyx patients achieved PASI 90 at Week 16 and PASI 75 at Week 4, compared to Stelara patients
- - Exploratory analysis showed a higher percentage of Cosentyx patients achieved completely clear skin (PASI 100) compared to Stelara patients at Week 16
- - Cosentyx is the first and only FDA-approved psoriasis treatment that binds specifically to IL-17A, which is involved in inflammatory and immune response, and inhibits interaction with the IL-17A receptor

EAST HANOVER, N.J., March 20, 2015 /PRNewswire/ -- Novartis today announced results from the CLEAR study demonstrating Cosentyx™ (secukinumab) improved skin clearance at Week 16 in significantly more moderate-to-severe plaque psoriasis patients compared to Stelara®* (ustekinumab), a widely used biologic. The detailed findings were presented in a late-breaking research 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 patients with moderate-to-severe plaque psoriasis.

"As a clinician I have seen first-hand the impact that moderate-to-severe plaque psoriasis can have on patients' lives and the frustration some feel when they are unable to achieve clear or near clear skin," said Andrew Blauvelt, MD, MBA, President of the Oregon Medical Research Center and lead study investigator. "The CLEAR data are an important step forward for clinicians and patients as they demonstrate Cosentyx compares favorably to Stelara, a widely used biologic."

In this Phase IIIb study, Cosentyx met the primary endpoint of superiority to Stelara as assessed by the Psoriasis Area Severity Index (PASI) 90 response, known as clear to almost clear skin, at Week 16 (79.0% vs. 57.6%, P<0.0001). The secondary endpoint found 50% of Cosentyx patients achieved PASI 75 at Week 4 compared to 20.6% of Stelara patients (P<0.0001).

PASI measures the redness, scaling and thickness of psoriatic plaques, and the extent of involvement in each region of the body. Treatment efficacy is assessed by the reduction of the score from baseline (i.e., a 75% reduction is known as PASI 75 and a 90% reduction is known as PASI 90). PASI 90 is a higher standard of skin clearance compared to PASI 75.

In an exploratory analysis, completely clear skin (PASI 100) at Week 16 was achieved by significantly more patients treated with Cosentyx than those receiving Stelara (44.3% vs. 28.4%).

"Helping psoriasis sufferers achieve clear skin remains the goal for both patients and their physicians, yet many patients still do not achieve this," said Christi Shaw, US Country Head, President of Novartis Corporation and Novartis Pharmaceuticals Corporation. "The findings from the CLEAR study demonstrate that Cosentyx helps a majority of patients relieve the thick, red, scaling and extensive plaques that are common in those

living with psoriasis. The data reinforce the importance of Cosentyx as a beneficial new treatment option, offering hope to psoriasis patients so they can take control of this often isolating disease."

The safety profile of Cosentyx was comparable to Stelara and consistent with previously reported Phase III clinical trials for Cosentyx. In the study, the most common adverse events (AEs) in the Cosentyx-treatment arm were headache (7.8%), nasopharyngitis (6.9%), diarrhea and fatigue (4.2% each), and arthralgia (3.9%). The most common AEs in the Stelara-treatment arm were nasopharyngitis (10.1%), headache (8.0%), arthralgia (4.2%), diarrhea (3.6%), and fatigue (2.7%). Infections and infestations were comparable between the Cosentyx and Stelara treatment groups (29.3% and 25.3%, respectively). Non-fatal serious adverse events in both treatment groups were the same (3%). No deaths have been reported, to date.

About the CLEAR study
CLEAR (Comparison to assess Long-term Efficacy, sAfety and toleRability of secukinumab vs. ustekinumab), a 52-week, multicenter, randomized, double-blind study, is a head-to-head Phase IIIb study initiated with Cosentyx, and compares the efficacy, long-term safety and tolerability of Cosentyx (secukinumab) versus Stelara (ustekinumab), in patients with moderate-to-severe plaque psoriasis. Twenty-four countries across North America, Europe, Asia and Australia participated in the single study, with enrollment reaching 679 patients in record time.

The primary endpoint measured at Week 16 is PASI 90. PASI 90 is considered a more robust measure of the extent of skin clearance compared to the standard efficacy measures used in most psoriasis clinical studies, such as PASI 75. Additionally the secondary endpoint measured at Week 4 is PASI 75. PASI 100 at Week 16 was one of the exploratory endpoints. Week 52 data will follow in due course.

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 duringand 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 "step forward," "goal," "hope," "can," "will," 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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*Stelara® is a registered trademark of Janssen Biotech, Inc.

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List of links present in page

1. https://qa1.novartis.us/news/media-releases/new-novartis-data-show-more-cosentyxtm-treated-psoriasis-patients-achieved-clear-or-almost-clear-skin-pasi-90-compared-stelara
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