Novartis presents new data at WCD that shows significant efficacy of Cosentyx® in patients with psoriasis of the palms, soles of feet and nails

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- - Cosentyx (secukinumab) met the primary endpoints of superiority compared to placebo in patients with difficult-to-treat psoriasis of the palms and soles of feet (palmoplantar) and nails
- - One third of patients with moderate to severe palmoplantar psoriasis achieved clear or almost clear skin on their palms and soles after 16 weeks of treatment with Cosentyx; severity of nail psoriasis decreased by up to 45.3%
- - Cosentyx is the only IL-17A antagonist, FDA approved for moderate to severe plaque psoriasis, to also show superior efficacy compared to placebo in these difficult-to-treat psoriasis patients

EAST HANOVER, N.J., June 11, 2015 /PRNewswire/ -- Novartis announced today that Cosentyx® (secukinumab) met the primary endpoints in two new clinical studies, showing superior efficacy compared to placebo in patients with psoriasis of the palms, soles of feet and nails, all of these difficult-to-treat locations of plaque psoriasis. It is the only IL-17A antagonist, FDA approved for moderate to severe plaque psoriasis, to also demonstrate these results to date. Detailed findings were presented for the first time at the 23rd World Congress of Dermatology (WCD) in Vancouver, Canada.

"Moderate to severe plaque psoriasis can be a difficult disease for patients to live with, and palmoplantar psoriasis can be even more so because it is quite challenging to treat," notes Alice Gottlieb, MD, PhD, Chair of the Department of Dermatology and Dermatologist-in-Chief at Tufts Medical Center and Harvey B. Ansell Professor of Dermatology at Tufts University School of Medicine.

In the GESTURE study in patients with moderate to severe palmoplantar psoriasis, Cosentyx (300 mg and 150 mg) was superior to placebo at Week 16 in achieving clear or almost clear palms and soles as assessed using the Palmoplantar Investigator's Global Assessment (ppIGA) (33.3% Cosentyx 300 mg [P<0.0001], 22.1% Cosentyx 150 mg [P<0.001], 1.5% placebo). Similarly, in the TRANSFIGURE study in patients with significant nail psoriasis (fingernail NAil Psoriasis Severity Index (NAPSI) ≥16 and number of fingernails involved ≥4), Cosentyx (300 mg and 150 mg) was superior to placebo at Week 16, as assessed by mean improvement (decrease) in the NAPSI compared to baseline (-45.3% Cosentyx 300 mg [P<0.0001], -37.9% Cosentyx 150 mg [P<0.0001], -10.8% placebo).

"These are the largest prospective, double-blind, randomized, placebo controlled studies to report robust results in the difficult-to-treat psoriasis of palms, soles and nails, which has previously been investigated less extensively, and where there is still high unmet need for effective treatments," said Vasant Narasimhan, Global Head of Development, Novartis Pharmaceuticals. "These results add to the growing body of evidence that Cosentyx is effective for patients; including those with the most challenging types of psoriasis."

The most common adverse events (AEs) in the GESTURE trial for the 300 mg and 150 mg Cosentyx treatment arms versus placebo were nasopharyngitis (2.9%, 7.4% and 5.9%), upper respiratory tract infection (4.3%, 5.9% and 4.4%), and headache (10.1%, 5.9% and 8.8%), respectively. Serious adverse event (SAE)

rates were 2.9% (300 mg), 5.9% (150 mg), and 2.9% (placebo). The most common AEs in the TRANSFIGURE study for the 300 mg and 150 mg Cosentyx treatment arms versus placebo were nasopharyngitis (16.9%, 20.9% and 12.3%), headache (6.2%, 6.0% and 6.2%) and upper respiratory tract infections (1.5%, 7.5% and 1.5%), respectively. SAE rates were 1.5% (300 mg), 3.0% (150 mg) and 3.1% (placebo).

Patients with psoriasis of the palms, soles of feet and nails endure significantly greater physical disabilities than those whose psoriasis is limited to other parts of the body. Patients may experience difficulty walking, more pronounced burning sensation and difficulty grasping and handling objects, skin soreness and difficulty participating in recreational activities, social and workplace interactions.

Cosentyx is the first and only interleukin-17A (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 the GESTURE and TRANSFIGURE studies
GESTURE is a double-blind, randomized, placebo-controlled, parallel-group Phase IIIb study of patients with moderate to severe non-pustular palmoplantar psoriasis. The primary objective was to evaluate Cosentyx 300 mg and/or 150 mg for superiority versus placebo as assessed by ppIGA 0 or 1 (0=clear, 1=almost clear/minimal) response at Week 16. Subjects (N=205) were randomized 1:1:1 to receive either Cosentyx 300 mg, Cosentyx 150 mg or placebo subcutaneously for 76 weeks. At Week 16 subjects in the placebo group who did not achieve a ppIGA 0 or 1 were re-randomized 1:1 to receive either 300 mg or 150 mg Cosentyx. GESTURE has the largest sample size and longest duration (ongoing 132-week treatment period) of any biologic study in moderate to severe palmoplantar psoriasis and represents an important achievement in research in a patient population that has been underrepresented in psoriasis trials.

TRANSFIGURE is a double-blind, randomized, placebo-controlled, parallel-group Phase IIIb study of patients with chronic moderate to severe plaque psoriasis including significant nail involvement. The primary objective was to evaluate Cosentyx 300 mg and/or 150 mg for superiority versus placebo as measured by fingernail NAil Psoriasis Severity Index (NAPSI) at Week 16. Subjects (N=198) were randomized 1:1:1 to receive either Cosentyx 300 mg, Cosentyx 150 mg or placebo subcutaneously up to Week 76. At Week 16, all subjects receiving placebo were re-randomized 1:1 to either 300 mg or 150 mg Cosentyx.

About Cosentyx (secukinumab) and interleukin-17A (IL-17A)
Cosentyx (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 only 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). The recommended dose of Cosentyx is 300 mg by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 followed by 300 mg every 4 weeks. For some patients, a dose of 150 mg may be acceptable.

About Psoriasis
Affecting as many as 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. 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 "growing," "may," or similar terms, or by express or implied discussions regarding potential new indications or labeling for Cosentyx (secukinumab), 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 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). 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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Julie Masow

Novartis Media Relations

+1 212-830-2465 (direct)

+1 862-579-8456 (mobile)

julie.masow@novartis.com

Michelle Bauman

Novartis Pharmaceuticals Corporation

+1 862-778-6519 (direct)

+1 973-714-8043 (mobile)

michelle.bauman@novartis.com

e-mail: us.mediarelations@novartis.com

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