Novartis announces FDA approval for first IL-17A antagonist Cosentyx™ (secukinumab) for moderate-to-severe plaque psoriasis patients

Jan 21, 2015

- - Phase III data demonstrated Cosentyx resulted in clear or almost clear skin in the majority of patients with moderate-to-severe plaque psoriasis
- - Offering a new treatment option for patients, Cosentyx is the first approved human monoclonal antibody (mAb) that binds specifically to interleukin-17A (IL-17A)
- - Approval based on the efficacy and safety outcomes from 10 Phase II and III studies which included over 3,990 adult patients with moderate-to-severe plaque psoriasis
- - Affecting 7.5 million Americans, psoriasis can negatively impact daily life and is associated with increased risk for other chronic illnesses

EAST HANOVER, N.J., Jan. 21, 2015 /PRNewswire/ -- Novartis today announced the US Food and Drug Administration (FDA) has approved Cosentyx™ (secukinumab) 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). Cosentyx is the first approved psoriasis medication to selectively bind to IL-17A and inhibit its interaction with the IL-17 receptor. The approval is based on the efficacy and safety outcomes from 10 Phase II and III studies, including over 3,990 patients with moderate-to-severe plaque psoriasis, which demonstrated that Cosentyx resulted in clear or almost clear skin in the majority of patients and had an acceptable safety profile.

Experience the interactive multimedia release here: http://www.multivu.com/players/English/7400151-novartis-fda-approval-cosentyx/

"We have heard first-hand from patients and doctors about the negative impact of psoriasis and the need for innovative therapies. With the FDA approval of Cosentyx, a majority of people living with moderate-to-severe plaque psoriasis in the US now have available a new medication that can help them achieve clear or almost clear skin," said Christi Shaw, US Country Head, President of Novartis Corporation and Novartis Pharmaceuticals Corporation. "As the first approved treatment targeting the IL-17A pathway, which is believed to play a key role in the development of psoriasis, we are confident this novel treatment will make a difference for the psoriasis community."

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 and may negatively impact daily life. Nearly 35% of psoriasis patients suffer from moderate-to-severe plaque psoriasis.

"I have treated many patients with moderate-to-severe plaque psoriasis and have seen the significant physical impact the disease can have. Psoriasis plaques are scaly, itchy and painful all of which can have a significant impact on many aspects of a patient's life," said Andrew Blauvelt, MD, MBA, President of the Oregon Medical Research Center. "I'm excited to be able to offer my patients a new treatment option with Cosentyx, which showed significant skin clearance in large scale clinical trials."

The Phase III clinical program included four placebo-controlled studies which examined Cosentyx 300 mg and 150 mg in patients with moderate-to-severe plaque psoriasis. In these studies, Cosentyx met all primary and key secondary endpoints, including Psoriasis Area and Severity Index (PASI) 75 and 90 and Investigator's Global Assessment modified 2011 (IGA) 0/1 responses, showing significant skin clearance at Week 12. 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.

"Psoriasis has a profound emotional, social and psychological impact on many people," said Randy Beranek, president and CEO of the National Psoriasis Foundation. "The approval of Cosentyx for the physical signs and symptoms of the disease is significant for patients and their health care providers as it offers another treatment option for moderate-to-severe plaque psoriasis. What works to treat one person's psoriasis may not work for another, so we're excited that there is a new option on the market."

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.

About Cosentyx Clinical Trial Program

The approval of Cosentyx is based on the efficacy and safety outcomes from 10 Phase II and III studies which included over 3,990 patients with moderate-to-severe plaque psoriasis. This included the four pivotal Phase III trials:

- ERASURE: (Efficacy of Response And Safety of two fixed secUkinumab REgimens in psoriasis) was a randomized, double-blind, placebo-controlled, multicenter, parallel-group Phase III study involving 738 patients with moderate-to-severe plaque psoriasis.
- FIXTURE: (the Full year Investigative eXamination of secukinumab vs. eTanercept Using 2 dosing Regimens to determine Efficacy in psoriasis) was a randomized, double-blind, placebo and active controlled, multicenter, parallel-group Phase III study involving 1306 patients with moderate-to-severe plaque psoriasis.
- FEATURE: (First study of sEcukinumAb in prefilled syringes in subjecTs with chronic plaqUe-type psoriasis REsponse) was a randomized double-blind, placebo-controlled, multicenter, Phase III study involving 177 subjects with moderate-to-severe plaque psoriasis. In this study, prefilled syringes (PFS) were introduced into the Cosentyx clinical program.
- JUNCTURE: (Judging the efficacy of secUkinumab in patients with psoriasis using autoiNjector: a Clinical Trial evalUating treatment REsults) was a double-blind, placebo-controlled, multicenter, Phase III study involving 182 subjects with moderate-to-severe plaque psoriasis. In this study, the autoinjector/pen (AI) was introduced into the Cosentyx clinical program.

Please visit http://www.pharma.us.novartis.com/info/products/brands/Cosentyx.jsp for Cosentyx full Prescribing Information, as received from the US FDA on January 21, 2015.

About Cosentyx (secukinumab)

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

inhibitor 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).

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 "offering," "can," "believed," "confident," "will," "may," "offer," "offers," "excited," or similar terms, or by express or implied discussions regarding potential additional marketing authorizations 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.The foregoing release contains forward-looking statements that can be identified by words such as "to present," "to be presented," "will," "planned," "can," "may," "anticipated," or similar terms, or by express or implied discussions regarding potential marketing authorizations for AIN457, or regarding potential future revenues from AIN457. 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 AIN457 will be submitted in AS or PsA in any market, or approved for any indication, or at any particular time. Nor can there be any guarantee that AIN457 will be commercially successful in the future. In particular, management's expectations regarding AIN457 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, cost-saving generic pharmaceuticals, preventive vaccines, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. In 2013, the Group achieved net sales of USD 57.9 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 130,000 full-time-equivalent associates and sell products in more than 150 countries around the world. For more information, please visit http://www.novartis.com.

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To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/novartis-announces-fda-approval-for-first-il-17a-antagonist-cosentyx-secukinumab-for-moderate-to-severe-plaque-psoriasis-patients-300023737.html

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