Novartis receives two new FDA approvals for Cosentyx® (secukinumab) to treat patients with ankylosing spondylitis and psoriatic arthritis

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- - Cosentyx is the first and only interleukin-17A (IL-17A) antagonist approved for adult patients with active ankylosing spondylitis (AS) and psoriatic arthritis (PsA)
- - Approvals for both indications based on efficacy and safety outcomes shown across four Phase III studies, including over 1,500 patients with either AS or PsA(1)
- - In studies, Cosentyx met the primary endpoints showing statistically significant improvements versus placebo in the signs and symptoms of AS and PsA

EAST HANOVER, N.J., Jan. 15, 2016 /PRNewswire/ -- Novartis announced today that the US Food and Drug Administration (FDA) has approved Cosentyx® (secukinumab) for two new indications - the treatment of adult patients with active ankylosing spondylitis (AS) and active psoriatic arthritis (PsA). AS and PsA are both life-long, painful and debilitating inflammatory diseases that affect the joints and/or spine. If not treated effectively, both conditions can lead to irreversible joint and/or spinal bone damage caused by years of inflammation.[2,3,4]

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With these new approvals, Cosentyx is now the first and only interleukin-17A (IL-17A) antagonist approved for AS, as well as moderate to severe plaque psoriasis and PsA, which impacts as many as 30% of patients with psoriasis.[5] Cosentyx was approved for adult patients with moderate to severe plaque psoriasis in January 2015 and more than 13,000 patients with this disease in the US have already been treated with Cosentyx.

"We were inspired by patients to pursue new indications for AS and PsA, because these diseases can result in significant pain and impede the simplest of tasks in a person's daily life," said Christi Shaw, US Country Head, President at Novartis Corporation and Novartis Pharmaceuticals Corporation. "The approval of additional indications for Cosentyx represents an important milestone for AS and PsA patients, their caregivers, and their doctors."

The approvals are based on the efficacy and safety outcomes from two AS and two PsA placebo-controlled Phase III studies which included more than 1,500 adult patients with either AS or PsA. In the studies, Cosentyx met the primary endpoints achieving statistically significant improvements versus placebo in the signs and symptoms of AS and PsA, as measured by at least a 20% improvement in the Assessment of Spondyloarthritis International Society criteria (ASAS20) at Week 16 and a 20% reduction in the American College of Rheumatology (ACR20) response criteria at Week 24, respectively.[1] ASAS20 and ACR20 are standard tools used to assess clinical improvement in AS and PsA. The safety profile is consistent across the three approved indications.[1]

"Working directly with patients who have AS and PsA, I have seen firsthand the devastating impact the diseases can have," said Philip Mease, MD, director of rheumatology research at Swedish Medical Center,

clinical professor at the University of Washington School of Medicine in Seattle and an investigator in the Cosentyx clinical trial program. "I welcome the addition of Cosentyx as a new treatment option for my patients with AS and PsA."

About ankylosing spondylitis (AS)

- Ankylosing spondylitis (AS) is a painful and often progressively debilitating disease, 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]
- In the United States, the prevalence of AS is estimated to be between 0.2% and 0.5%, with nearly half a million people affected.[8,9]
- Males are affected most often and family members of those with AS are at higher risk.[10]
- Approximately 20-40% of patients do not respond well to standard of care biologic medicines, and there are few therapeutic options available to those patients.[11]

About psoriatic arthritis (PsA)

- Between 0.3% and 1% of the general population may be affected by psoriatic arthritis (PsA) and up to 15% of people with psoriasis may have undiagnosed PsA.[12,13]
- Symptoms of PsA include joint pain and stiffness, skin and nail psoriasis, swollen toes and fingers and persistent painful ethesitis (inflammation of the sites where tendons or ligaments insert into the bone).[3]
- PsA can lead to irreversible joint damage and disability caused by years of inflammation.[3]
- Up to 40% of people can suffer from joint destruction and permanent physical deformity.[14]
- New medicines are needed as many patients do not respond to, or tolerate current therapies and approximately 45% of PsA patients are dissatisfied with treatments.[15]

About Cosentyx AS and PsA clinical trial programs
Pivotal Phase III studies in the Cosentyx clinical trial program that provided key data for the submission were MEASURE 1 and MEASURE 2 involving 590 patients with AS, and FUTURE 1 and FUTURE 2 including 1,003 patients with PsA. Data from these pivotal trials were published in The New England Journal of Medicine and The Lancet. These are multi-center, randomized, placebo-controlled studies designed to evaluate the efficacy and safety of Cosentyx in AS and PsA.[16,17,18] Additional follow-up of patients from these trials is still ongoing.

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 15, 2016.

About Cosentyx (secukinumab)
Cosentyx is a human monoclonal antibody (mAb) that selectively binds to IL-17A and inhibits its interaction with the IL-17 receptor.[19] It is the first and only IL-17A antagonist to be approved by the FDA for active AS and active PsA. Cosentyx was approved by the FDA in January 2015 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).

In total, over 50 countries have approved Cosentyx for the treatment of moderate to severe plaque psoriasis which includes the European Union countries, Japan, Switzerland, Australia, the US and Canada. In November 2015, the European Commission (EC) approved Cosentyx for the treatment of people living with AS and PsA. Additionally, Cosentyx is approved for the treatment of AS and PsA in Ecuador, and for the treatment of PsA in Japan.

INDICATIONS

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

COSENTYX is indicated for the treatment of adult patients with active psoriatic arthritis.

COSENTYX is indicated for the treatment of adult patients with active ankylosing spondylitis.

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 in patients with moderate to severe plaque psoriasis, 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. A similar increase in risk of infection was seen in placebo-controlled trials in patients with psoriatic arthritis and ankylosing spondylitis. 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.

Inflammatory Bowel Disease

Caution should be used when prescribing COSENTYX to patients with inflammatory bowel disease. Exacerbations, in some cases serious, occurred in patients treated with COSENTYX during clinical trials in plaque psoriasis, psoriatic arthritis, and ankylosing spondylitis. In addition, new onset inflammatory bowel disease cases occurred in clinical trials with COSENTYX. In an exploratory study in 59 patients with active Crohn's disease, there were trends toward greater disease activity and increased adverse events in the secukinumab group as compared to the placebo group. Patients who are treated with COSENTYX should be monitored for signs and symptoms of inflammatory bowel disease.

Hypersensitivity Reactions

Anaphylaxis and cases of urticaria occurred in patients treated with COSENTYX in 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 "inspired," "can," "will," "may," "ongoing," 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 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 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
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 58.0 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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