Novartis receives FDA approval for inclusion of new evidence that Cosentyx® inhibits progression of joint structural damage in psoriatic arthritis

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- - New prescribing information to include data demonstrating Cosentyx® (secukinumab) slows progression of joint structural damage associated with psoriatic arthritis (PsA) at Week 24(1)
- - PsA can lead to reduced mobility and irreversible joint damage if left untreated(2,3)
- - PsA affects an estimated 2 million people in the US and is characterized by joint pain and stiffness(3)

EAST HANOVER, N.J., June 19, 2018 /PRNewswire/ -- Novartis announced today that the US Food and Drug Administration (FDA) approved the inclusion of new evidence that Cosentyx® (secukinumab) significantly slows the progression of joint structural damage at Week 24 versus placebo in those with active psoriatic arthritis (PsA).[1] The data will be added to the drug's prescribing information and is effective in the US immediately. Cosentyx is the first and only interleukin-17A (IL-17A) antagonist approved to treat active PsA, active ankylosing spondylitis, and moderate to severe plaque psoriasis in adults.[1]

PsA can lead to reduced mobility and irreversible joint damage if left untreated.[2,3] The update to the prescribing information is based on data from FUTURE 5, the largest Phase III study for a biologic done in PsA to date (996 patients).

"While daily psoriatic arthritis symptoms can seriously affect a patient, the progressive nature of this disease should not be ignored. The joint damage that often results from having the disease over time can potentially be permanent," said Marcia Kayath, Head US Clinical Development and Medical Affairs, Novartis. "Now physicians and their patients with psoriatic arthritis can be confident that Cosentyx not only offers significant symptom relief, but also helps slow the progression of the disease."

PsA affects an estimated 2 million people in the US and is characterized by joint pain and stiffness.[3] PsA can lead to irreversible joint damage and disability caused by years of inflammation.[3,2]

More than 74,000 patients in the US have been prescribed Cosentyx in the post-marketing setting across all indications since launch.[4]

About Cosentyx (secukinumab) and interleukin-17A (IL-17A)
Cosentyx is a fully human monoclonal antibody (mAB) that selectively binds to the interleukin-17A (IL-17A) cytokine and inhibits its interaction with the IL-17 receptor.[1]

Cosentyx is approved in more than 75 countries, which includes the European Union countries and the US, across all indications – psoriatic arthritis (PsA), psoriasis and ankylosing spondylitis (AS). Cosentyx is approved for the treatment of PsA in 77 countries, including the US, Canada, the European Union countries and Australia.

About the FUTURE 5 data (NCT02404350)[5]

In the study, participants (n=996) with active psoriatic arthritis (PsA) were randomized to receive Cosentyx 300 mg with loading dose (LD), 150 mg with LD, 150 mg without LD, or placebo. All groups received Cosentyx or placebo at baseline (BL), Weeks 1, 2, 3, and 4, and then every 4 weeks. At Week 16, placebo non-responders (patients with <20% improvement from BL in tender or swollen joint counts) were switched to Cosentyx 300 mg or 150 mg; remaining placebo patients were switched at Week 24. The primary endpoint was ACR20 at Week 16 and the key secondary endpoint was radiographic structural progression, as measured by mTSS, assessed by two blinded readers, based on hand/wrist/foot X-rays obtained at BL, Week 16 (non-responders), and Week 24.

About psoriatic arthritis (PsA)
Closely associated with psoriasis, psoriatic arthritis (PsA) is part of a spectrum of long-term diseases impacting joints, known as spondyloarthritis.[3,6] Up to 2 million people are currently diagnosed with PsA in the US and approximately one in four of people with psoriasis may have undiagnosed PsA.[3] Symptoms of PsA include joint pain and stiffness, skin and nail psoriasis, swollen toes and fingers, and persistent painful tendonitis.[3]

INDICATIONS

Cosentyx is a human interleukin-17A antagonist indicated for the treatment of:

- moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy
- adults with active psoriatic arthritis (PsA)
- adults with active ankylosing spondylitis (AS)

IMPORTANT SAFETY INFORMATION

Do not use Cosentyx if you have had a severe allergic reaction to secukinumab or any of the other ingredients in Cosentyx. See the Medication Guide for a complete list of ingredients.

Cosentyx is a medicine that affects your immune system. Cosentyx may increase your risk of having serious side effects such as:

Infections

Cosentyx may lower the ability of your immune system to fight infections and may increase your risk of infections.

- Your doctor should check you for tuberculosis (TB) before starting treatment with Cosentyx.
- If your doctor feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with Cosentyx and during treatment with Cosentyx.
- Your doctor should watch you closely for signs and symptoms of TB during treatment with Cosentyx. Do not take Cosentyx if you have an active TB infection.

Before starting Cosentyx, tell your doctor if you:

- are being treated for an infection
- have an infection that does not go away or that keeps coming back
- have TB or have been in close contact with someone with TB
- think you have an infection or have symptoms of an infection such as:

- fevers, sweats, or chills
- muscle aches
- cough
- shortness of breath
- blood in your phlegm
- weight loss
- warm, red, or painful skin or sores on your body
- diarrhea or stomach pain
- burning when you urinate or urinate more often than normal

After starting Cosentyx, call your doctor right away if you have any signs of infection listed above. Do not use Cosentyx if you have any signs of infection unless you are instructed to by your doctor.

Inflammatory Bowel Disease

New cases of inflammatory bowel disease or "flare-ups" can happen with Cosentyx, and can sometimes be serious. If you have inflammatory bowel disease (ulcerative colitis or Crohn's disease), tell your doctor if you have worsening disease symptoms during treatment with Cosentyx or develop new symptoms of stomach pain or diarrhea.

Serious Allergic Reactions

Serious allergic reactions can occur. Get emergency medical help right away if you get any of the following symptoms: feeling faint; swelling of your face, eyelids, lips, mouth, tongue, or throat; trouble breathing or throat tightness; chest tightness; or skin rash. If you have a severe allergic reaction, do not give another injection of Cosentyx.

Before starting Cosentyx, tell your doctor if you:

- have any of the conditions or symptoms listed above for infections
- have inflammatory bowel disease (Crohn's disease or ulcerative colitis)
- are allergic to latex. The needle caps contain latex.
- have recently received or are scheduled to receive an immunization (vaccine). People who take Cosentyx should not receive live vaccines.
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if Cosentyx can harm your unborn baby. You and your doctor should decide if you will use Cosentyx.
- are breastfeeding or plan to breastfeed. It is not known if Cosentyx passes into your breast milk.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of your medicines to show your doctor and pharmacist when you get a new medicine.

How should I use Cosentyx?

See the detailed Instructions for Use that comes with your Cosentyx for information on how to prepare and inject a dose of Cosentyx, and how to properly throw away (dispose of) used Cosentyx Sensoready® pens and prefilled syringes.

- Use Cosentyx exactly as prescribed by your doctor.
- If your doctor decides that you or a caregiver may give your injections of Cosentyx at home, you should receive training on the right way to prepare and inject Cosentyx. Do not try to inject Cosentyx yourself, until you or your caregiver has been shown how to inject Cosentyx by your doctor or nurse.

The most common side effects of Cosentyx include: cold symptoms, diarrhea, and upper respiratory infections. These are not all of the possible side effects of Cosentyx. Call your doctor for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see accompanying full Prescribing Information, including Medication Guide.

Disclaimer

This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as "potential," "can," "will," "plan," "expect," "anticipate," "look forward," "believe," "committed," "investigational," "pipeline," "launch," or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for the investigational or approved products described in this press release, or regarding potential future revenues from such products. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations 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 the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations regarding such products could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; general political and economic conditions; safety, quality or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, 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

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