Novartis Cosentyx receives FDA approval for new indication to treat active non-radiographic axial spondyloarthritis

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- FDA approval for Cosentyx is based on the Phase III PREVENT trial, demonstrating efficacy in active non-radiographic axial spondyloarthritis (nr-axSpA), which is part of the axial spondyloarthritis (axSpA) disease spectrum
- There are an estimated 2.7M people living with axial spondyloarthritis (axSpA) in the US; however, it remains significantly underdiagnosed(1,2)
- nr-axSpA approval is the fourth indication for Cosentyx, which is backed by five years of clinical data supporting long-term safety and efficacy across moderate to severe plaque psoriasis (PsO), psoriatic arthritis (PsA) and ankylosing spondylitis (AS)(3-8)

EAST HANOVER, N.J., June 16, 2020 /PRNewswire/ -- Novartis, a leader in rheumatology and immuno-dermatology, today announced that the US Food and Drug Administration (FDA) has approved Cosentyx® (secukinumab) for the treatment of active non-radiographic axial spondyloarthritis (nr-axSpA), confirming Cosentyx efficacy in addressing the axial spondyloarthritis (axSpA) disease spectrum[9].

"The results from the PREVENT trial show that there was a significant reduction in disease activity for patients treated with Cosentyx versus placebo," said Atul Deodhar, MD, professor of medicine and medical director of Rheumatology Clinics at Oregon Health & Science University, and an investigator in the PREVENT clinical trial. "This approval brings a new therapeutic option to people living with non-radiographic axial spondyloarthritis."

The approval of Cosentyx for nr-axSpA is based on efficacy and safety outcomes from the PREVENT Phase III study, which included 555 adults with active nr-axSpA who were biologic-treatment naïve or had an inadequate response / were intolerant to an anti-tumor necrosis factor-α therapy (anti-TNFs). Cosentyx met the primary endpoint achieving statistically significant improvements versus placebo in the signs and symptoms of nr-axSpA, as measured by at least a 40% improvement in the Assessment of Spondyloarthritis International Society (ASAS40) response criteria in biologic-naïve individuals at Week 52[10].

nr-axSpA patients treated with Cosentyx showed improvement in both load and without load arms compared to placebo-treated patients at Week 16 in health-related quality of life as measured by the Ankylosing Spondylitis Quality of Life (ASQoL) questionnaire (Least Squares mean change: Week 16: -3.5 and -3.6 vs -1.8, respectively). General health status and quality of life was assessed by the Short Form health survey (SF-36). At Week 16, patients treated with Cosentyx showed greater improvement from baseline in the SF-36 physical component summary (PCS) score and in the mental component summary (MCS) score[10]. The safety profile of Cosentyx in the PREVENT trial was shown to be consistent with previous clinical trials. No new safety signals were detected[3-8,10].

nr-axSpA is part of the axSpA spectrum, which is characterized by inflammatory arthritis of the spine associated with chronic inflammatory back pain[11]. The axSpA disease spectrum includes AS, in which joint

damage is visible on X-ray, and nr-axSpA, in which joint damage is generally not visible on X-ray[1,12]. The physical limitations of axSpA can affect activities of daily living as well as leisure activities causing limitations for patients[13,14].

"There is a need for additional treatment options. Having a new treatment option for the axSpA community is truly encouraging," said Cassie Shafer, Chief Executive Officer of the Spondylitis Association of America. "Helping reduce the burden on people living with non-radiographic axial spondyloarthritis by improving symptoms that affect their daily lives remains a critical focus for the SAA."

In April 2020, Novartis received European Medicines Agency approval of Cosentyx for the treatment of nr-axSpA[15].

About Cosentyx (secukinumab)

Cosentyx is the first and only fully-human biologic that directly inhibits interleukin-17A (IL-17A), an important cytokine involved in the inflammation and development of psoriatic arthritis (PsA), moderate to severe plaque psoriasis (PsO), ankylosing spondylitis (AS) and nr-axSpA[16,17]. Cosentyx has been studied clinically for more than 13 years. The medicine is backed by robust investigational evidence, including five years of clinical data supporting long-term safety and efficacy across moderate to severe plaque psoriasis (PsO), psoriatic arthritis (PsA) and ankylosing spondylitis (AS)[3-8]. These data strengthen the unique position of Cosentyx as a comprehensive treatment across axial spondyloarthritis, psoriatic arthritis and psoriatic disease, supported by more than 340,000 patients treated worldwide since launch[9,18, 19].

About PREVENT

PREVENT is a two-year randomized, double-blind, placebo-controlled Phase III study (with a two-year extension phase) to investigate the efficacy and safety of Cosentyx, in patients with active nr-axSpA. The study enrolled 555 male and female adult patients with active nr-axSpA (with onset before 45 years of age, spinal pain rated as ≥40/100 on a visual analog scale (VAS) and Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) ≥4) and who had been taking at least two different non-steroidal anti-inflammatory drugs (NSAIDs) at the highest dose up to 4 weeks prior to study start. Patients may have previously taken a TNF inhibitor (not more than one) but had had an inadequate response. Of the 555 patients enrolled in the study, 501 (90%) were biologic-naive. Patients were allocated to one of three treatment groups: Cosentyx 150 mg subcutaneously with loading dose (Induction: 150 mg Secukinumab subcutaneously weekly for 4 weeks, then maintenance with 150 mg Secukinumab monthly); Cosentyx 150 mg no loading dose (150 mg Secukinumab subcutaneously monthly), or placebo (induction of subcutaneously weekly for 4 weeks, followed by maintenance of once-monthly)[10].

The primary endpoints are the proportion of patients achieving an ASAS40 response with Cosentyx 150 mg at Weeks 16 and 52. Secondary endpoints include change in BASDAI over time and change in the Ankylosing Spondylitis Disease Activity Score with CRP (ASDAS-CRP)[10].

ASAS40 is achieved when there is a measure of an improvement of at least 40% and an improvement of at least 20 units on a 0–100 scale in at least three of the following domains: Patient global assessment, Pain assessment, Function (Bath Ankylosing Spondylitis Functional Index (BASFI)), and Inflammation (morning stiffness severity and duration) and no worsening in the remaining domains[20]. BASDAI assesses a patient's disease activity on six measures: fatigue, spinal pain, joint pain/swelling, enthesitis, morning stiffness duration and morning stiffness severity[20].

COSENTYX® (secukinumab) is a prescription medicine used to treat adults:

- with moderate to severe plaque psoriasis that involves large areas or many areas of the body, and who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet or UV light, alone or with systemic therapy)
- with active psoriatic arthritis
- with active ankylosing spondylitis
- with active non-radiographic axial spondyloarthritis and objective signs of inflammation

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.

1. Your doctor should check you for tuberculosis (TB) before starting treatment with COSENTYX.
2. 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.
3. 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 full Prescribing Information, including Medication Guide.

About Novartis
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References

1. Strand V and Singh JA. Evaluation and Management of the Patient With Suspected Inflammatory Spine Disease. Mayo ClinProc 2017;92:555–564.
2. Spondylitis.org. Overview of Ankylosing Spondylitis Ankylosing. Available from: https://www.spondylitis.org/Ankylosing-Spondylitis. Last accessed: January 2020.
3. Data on file. CAIN457F2310 (MEASURE 2): 5 Year Report. Novartis Pharmaceuticals Corp; September 15, 2015.
4. Data on file. Data Analysis Report: Study CAIN457A2302E1. Novartis Pharmaceuticals Corp; November 30, 2015.
5. Data on file. CAIN457F2310 and CAIN457F2305 Summary of 5-Year Clinical Safety in (Ankylosing Spondylitis). Novartis Pharmaceuticals Corp; May 2019.
6. Data on file. CAIN457F2312 (FUTURE 2): 5 Year- Interim Report. Novartis Pharmaceuticals Corp; May 2019.
7. Data on file. CAIN457F2312 Data Analysis Report. Novartis Pharmaceuticals Corp; November 2008.
8. Data on file. CAIN457F2310 (MEASURE 1 and 2): Pooled Safety Data. Novartis Pharmaceuticals Corp; July 23, 2018.
9. Cosentyx [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; 2020
10.Data on File. CAIN457H2315 [PREVENT]. CSR Week 52 analysis. Novartis Pharmaceuticals Corp. November 12, 2019.
11. Strand V, et al. Patient Burden of Axial Spondyloarthritis. J Clin Rheumatol. 2017 Oct; 23(7): 383–391.
12. Rudwaleit M, et al. The development of Assessment of SpondyloArthritis international Society classification criteria for axial spondyloarthritis (part II): validation and final selection. Ann Rheum Dis 2009;68:777–783.

13. Doward LC, Spoorenberg A, Cook SA, et al. Development of the ASQoL: a quality of life instrument specific to ankylosing spondylitis. Ann Rheum Dis. 2003;62:20-26.
14. Moncur C. Ankylosing spondylitis measures. Arthritis Rheum (Arthritis Care Res). 2003;49:S197-S209.
15. Novartis. Novartis Cosentyx gains fourth indication in EU with first-in-class approval in axial spondyloarthritis spectrum. Available from: https://www.novartis.com/news/media-releases/novartis-cosentyx-gains-fou.... Last accessed: May 2020.
16. Novartis Europharm Limited. Cosentyx (secukinumab): Summary of Product Characteristics. Available from: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medici.... Last accessed: August 2019.
17. Girolomoni G, et al. Psoriasis: rationale for targeting interleukin-17. Br J Dermatol 2012;167:717–724.
18. Data on file. COSENTYX Access. Novartis Pharmaceuticals Corp; May 2020.
19. Data on file. AIN457A2102 Clinical Study Report. Novartis Pharmaceuticals Corp; December 2008.
20. Landewe R, et al. Clinical Tools to Assess and Monitor Spondyloarthritis. Curr Rheumatol Rep. 2015;17(7):47.

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- https://www.novartis.com/us-en/us-en/news/media-releases/novartis-cosentyx-receives-fda-approval-new-indication-treat-active-non-radiographic-axial-spondyloarthritis
- https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program
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- https://spondylitis.org/about-spondylitis/types-of-spondylitis/ankylosing-spondylitis/
- https://www.novartis.com/news/media-releases/novartis-cosentyx-gains-fourth-indication-eu-first-class-approval-axial-spondyloarthritis-spectrum
- https://www.ema.europa.eu/en/medicines/human/EPAR/cosentyx