

Novartis positive 52-week PREVENT data confirm Cosentyx® efficacy in addressing entire axSpA spectrum

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- - Phase III PREVENT study met 52-week primary endpoint of ASAS40, showing a sustained response in patients with non-radiographic axial spondyloarthritis (nr-axSpA)(1)
- - Novartis plans FDA submission for nr-axSpA, having submitted to EMA previously(1). This would be the fourth indication for Cosentyx(2),(3)
- - PREVENT underlines Cosentyx leadership and is a step forward in providing patients with a treatment that addresses the complete axSpA disease spectrum
- - There are approximately 1.7 million patients with nr-axSpA in the US and EU(4)

EAST HANOVER, N.J., Oct. 2, 2019 /PRNewswire/ -- Novartis, a leader in rheumatology and immuno-dermatology, today announced additional positive data from the PREVENT trial, evaluating the efficacy and safety of Cosentyx® (secukinumab) in patients with non-radiographic axial spondyloarthritis (nr-axSpA). The ongoing Phase III trial met its primary endpoint of ASAS40 at Week 52, showing a significant and clinically meaningful reduction in disease activity for patients treated with Cosentyx versus placebo. The trial demonstrated a sustained response and a safety profile consistent with previous clinical trials. No new safety signals were detected^{1,5-10}.

Positive 16-week PREVENT data were announced mid-September and submitted to EMA for approval in nr-axSpA¹¹. These data add to the five-years of clinical data supporting the long-term efficacy and safety of Cosentyx across ankylosing spondylitis, psoriatic arthritis and psoriasis⁵⁻¹⁰.

"Non-radiographic axial spondyloarthritis is a chronic debilitating disease, which left untreated can have a significant impact on patients' quality of life," said Atul Deodhar, MD, professor of medicine and medical director of Rheumatology Clinics at Oregon Health & Science University, and an investigator in the secukinumab clinical trial program. "These positive results indicate a potential new treatment option to help patients experience relief from the signs and symptoms of their disease."

"These data are encouraging for people living with nr-axSpA, where there are only limited treatment options available," said John Tsai, M.D., Head of Global Drug Development and Chief Medical Officer for Novartis. "It's a great example of how we're working to reimagine medicine to help patients realize early relief from this disease."

Detailed data is planned to be presented at a future scientific congress.

About axSpA

Axial spondyloarthritis (axSpA) is a spectrum of long-term inflammatory disease characterized by chronic inflammatory back pain¹². The axSpA disease spectrum includes ankylosing spondylitis (AS), in which joint damage is generally visible on x-ray, and non-radiographic axial spondyloarthritis (nr-axSpA), in which joint damage is not visible on x-ray^{12,13}. Both parts of the disease spectrum have a similar symptom burden, including nocturnal pain, fatigue, morning stiffness and functional disability¹⁴. If left untreated, axSpA could impair activity, lead to lost work time and have a significant impact on quality of life¹⁴.

About PREVENT

PREVENT is an ongoing 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 $\geq 40/100$ 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)¹.

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)¹.

ASAS40 is achieved when there is a measure of an improvement of at least 40% and an improvement of at least 10 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 domains¹⁵. BASDAI assesses a patient's disease activity on six measures: fatigue, spinal pain, joint pain/swelling, enthesitis, morning stiffness duration and morning stiffness severity¹⁵.

INDICATIONS

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

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 full [Prescribing Information](#), including [Medication Guide](#).

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 "plans," "submitted," "would," "step forward," "ongoing," "supporting," "potential," "encouraging," "planned," "could," "to investigate," "expectations," 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 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 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, our expectations regarding Cosentyx 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 and requirements for increased pricing transparency; 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

Novartis is reimagining medicine to improve and extend people's lives. As a leading global medicines company, we use innovative science and digital technologies to create transformative treatments in areas of great medical need. In our quest to find new medicines, we consistently rank among the world's top companies investing in research and development. Novartis products reach more than 750 million people globally and we are finding innovative ways to expand access to our latest treatments. About 108,000 people of more than 140 nationalities work at Novartis around the world. Find out more at www.novartis.com.

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