Novartis Cosentyx® shows early synovitis reduction in patients with psoriatic arthritis in first-of-its-kind study

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- Significant reduction of synovitis (joint lining inflammation) was demonstrated with Cosentyx® at Week 12 vs. placebo, with improvements as early as Week 11
- ULTIMATE is the first ever Phase IIIb imaging study primarily looking at the time course of response to Cosentyx® in biologic-naïve patients with active psoriatic arthritis (PsA) using Power Doppler ultrasonography (PDUS)1
- PDUS is a sensitive technology, allowing detection and monitoring of early changes in synovitis and enthesitis1 with earlier insights into treatment efficacy
- More than 400,000 patients have been treated with Cosentyx® across moderate-to-severe psoriasis, PsA, ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA) worldwide since launch2

EAST HANOVER, N.J., Nov. 5, 2020 /PRNewswire/ -- Novartis, a leader in rheumatology and immuno-dermatology, today announced 12-week results from the first-of-its-kind Phase IIIb ULTIMATE randomized controlled trial, which demonstrated the significant treatment response of Cosentyx® (secukinumab) on synovitis (joint lining inflammation) in psoriatic arthritis (PsA) versus placebo. Synovitis was assessed using an advanced and sensitive imaging technique called Power Doppler ultrasonography (PDUS). These data are being presented at the American College of Rheumatology (ACR) All-Virtual Annual Meeting, November 5-9, 2020.

"Psoriatic arthritis can have a significant impact on a patient's joints. Joint lining inflammation, also known as synovitis, if left untreated, can cause pain to worsen, joint damage and may decrease physical function," said Dr. Maria A. D'Agostino, Professor of Rheumatology at the Catholic University of Rome. "These data are highly encouraging, showing Cosentyx® can significantly reduce synovitis at Week 12 versus placebo with results seen as early as Week 1, and that ultrasound is a sensitive and objective tool to monitor joint inflammation in PsA patients."

The use of a standardized ultrasound synovitis score (GLOESS) as the primary endpoint showed objectively the significant benefit of Cosentyx® versus placebo on synovitis at Week 12 with an early improvement observed from Week one. Treatment with Cosentyx® also significantly improved key secondary endpoints versus placebo, including ACR20 (68% vs 34%, respectively), ACR50 (46% vs 9%, respectively) and enthesitis (mean change from baseline in Spondyloarthritis Research Consortium of Canada enthesitis index score [SPARCC] of -2.4 vs -1.7 respectively)[1]. The safety profile of Cosentyx® through 12 weeks was consistent with previous studies[1].

Novartis anticipates disclosing full 24-week data from the ongoing ULTIMATE trial at the European League Against Rheumatism (EULAR) annual meeting in 2021 and final analysis at ACR 2021.

"As a strong believer in the diagnostic and treatment monitoring benefits of ultrasound, this first large randomized double-blind placebo-controlled clinical trial in PsA with an ultrasonographic primary endpoint is incredibly exciting. The ability to use a sensitive imaging technique to assess synovitis and enthesitis in PsA represents a breakthrough in how we conceptualize treatment goals," said Dr. Catherine Bakewell of Intermountain Medical Group in Salt Lake City, UT and an investigator in the ULTIMATE study. "In addition to other measures, PDUS helps to provide earlier insight into treatment response and that patients are more effectively treated across multiple domains of this heterogeneous psoriatic disease spectrum."

PsA is a complex disease with multiple manifestations driving patient symptoms[3,4]. In PsA, synovitis may lead to joint damage and if left untreated, the joint damage can be irreversible[5,6]. In addition to reducing synovitis, Cosentyx® has been proven to provide long-lasting inhibition of radiographic progression in PsA, limiting joint damage and helping to improve outcomes for patients with this debilitating condition[7,8].

About Psoriatic Arthritis (PsA)

PsA is estimated to affect up to 50 million people worldwide[9,10]. It is part of a family of life-long inflammatory diseases (spondyloarthritis) that target the joints and is closely associated with psoriasis[10]. Up to 40% of patients with psoriasis may develop PsA[10]. Symptoms of PsA include joint pain and stiffness, skin and nail psoriasis, swollen toes and fingers, persistent painful swelling of the tendons and irreversible joint damage[10].

About ULTIMATE

ULTIMATE is the first ongoing 52-week double-blind, placebo-controlled Phase IIIb study using ultrasound to assess time-course of response of Cosentyx® on synovitis in psoriatic arthritis. The study enrolled 166 adult biologic-naïve patients with active Psoriatic arthritis. Patients were randomized (1:1) to receive either secukinumab (300-mg or 150-mg according to severity of skin disease) or placebo weekly for a month with treatment starting at Week 4, followed by a once-a-month dose for the next 11 months.

The primary endpoint is the difference in mean change from baseline to Week 12 between secukinumab and placebo in Global Omeract-European League Against Rheumatism Ultrasound Synovitis Score (GLOESS). GLOESS is a standardized composite score that has shown to be sensitive to change and able to detect and score synovitis[11]. Secondary endpoints include ACR20, ACR50 and change in Spondyloarthritis Research Consortium of Canada (SPARCC) enthesitis index from baseline to Week 12 compared with placebo.

ACR20 and ACR50 are composite measures defined as both improvement of 20% or 50% in the number of tender and number of swollen joints, and a 20% or 50% improvement in three of the following five criteria: patient global assessment, physician global assessment, Health Assessment Questionnaire, visual analog pain scale and erythrocyte sedimentation rate or C-reactive protein[12]. The SPARCC enthesitis index is a validated clinical tool for evaluation of enthesitis[13,14].

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[15,16]. 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)[17-22,23]. These data strengthen the unique position of Cosentyx® as a comprehensive treatment across axial spondyloarthritis, psoriatic arthritis and psoriatic disease, supported by more than 400,000 patients treated worldwide since launch[2,23,24].

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

Located in East Hanover, NJ Novartis Pharmaceuticals Corporation – an affiliate of 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 employs about 15,000 people in the United States. For more information, please visit https://www.novartis.us.

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