Novartis presents positive Phase III results for Cosentyx® in children with active enthesitis-related arthritis (ERA) and juvenile psoriatic arthritis (JPsA) at ACR 2021

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- *Treatment with Cosentyx (secukinumab) resulted in a 72% reduced flare risk versus placebo, with improvement in disease activity over two years across both enthesitis-related arthritis (ERA) and juvenile psoriatic arthritis (JPsA)[1]. Safety in this pediatric population was consistent with the known safety profile of Cosentyx[1].*
- *Novartis has filed regulatory submissions for Cosentyx in ERA and JPsA [categories of juvenile idiopathic arthritis (JIA)] in the US and Europe with decisions anticipated in the coming months. The US Food and Drug Administration (FDA) granted a Priority Review for both indications.*
- *There are approximately 300,000 children in the US who are currently diagnosed with JIA[2,3]. The categories of JPsA and ERA are progressive, chronic, debilitating diseases and if approved, Cosentyx would be the first biologic for ERA patients in the US[4,5].*

East Hanover, November 8, 2021 — Novartis, a leader in rheumatology and immuno-dermatology, today announced new analyses from the two-year positive Phase III JUNIPERA study, which demonstrated the treatment response of Cosentyx® (secukinumab) in children and adolescents with enthesitis-related arthritis (ERA) and juvenile psoriatic arthritis (JPsA) – two categories of juvenile idiopathic arthritis (JIA). The safety profile was consistent with that of Cosentyx in adults with plaque psoriasis, psoriatic arthritis, non-radiographic axial spondyloarthritis and ankylosing spondylitis[1]. These data will be highlighted as an oral presentation at the American College of Rheumatology (ACR) Convergence all-virtual annual meeting, November 3-10, 2021[1]. Initial results from the Phase III JUNIPERA trial were previously presented at the European Alliance of Associations for Rheumatology (EULAR) 2021 European Congress of Rheumatology in June[6].

Two-year results from JUNIPERA demonstrated that patients treated with Cosentyx had a significantly longer time to flare, showing a 72% reduction in the risk of flare (P<.001) versus placebo, in children and adolescents ages two to 17 years old with active ERA (n=52; mean age: 13.7) and active JPsA (n=34; mean age: 12.2)[1]. At Week one, over 30% of patients showed improvement with Cosentyx (JIA American College of Rheumatology [ACR] 30) and nearly 90% achieved JIA ACR 30 by the end of the first treatment period (12 weeks)[1]. Additionally, by Week 12, nearly 35% of patients (N=86) achieved JIA ACR inactive disease status. Improvements in disease activity, as measured by the mean juvenile arthritis disease activity score (JADAS-27), were observed at Week one, reaching low disease activity from Week 12 through Week 104[1]. Safety in this pediatric population was consistent with the known safety profile of Cosentyx[1].

“If left untreated, ERA and JPsA can have a substantial negative impact on quality of life and may lead to deformities and long-term disability for children and adolescents who live with these conditions,” said Dr. Hermine Brunner, Cincinnati Children's Hospital Medical Center and lead investigator of the JUNIPERA study.

“It is promising that the JUNIPERA study shows that secukinumab demonstrated marked responses in patients with ERA and JPsA, a population that currently has limited treatment options available to help improve joint inflammation, dactylitis and enthesitis.”

Novartis has filed regulatory submissions for Cosentyx in ERA and JPsA in Europe and the US. Final decisions by the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) are anticipated in the coming months. By 2025 there will be an estimated 4,481-5,975 prevalent ERA and JPsA cases in children under 16 in the US[7]. If approved, Cosentyx would be the first biologic treatment for children living with ERA in the US.

In July 2020, Cosentyx received EU approval as a first-line systemic treatment for pediatric psoriasis and recently received approval in the US and China[8-10]. In Japan, Cosentyx has also been approved to treat psoriatic arthritis as well as psoriasis in pediatric patients aged 6 years or older, as well as generalized pustular psoriasis[11].

About the JUNIPERA Study

JUNIPERA is a two-year, three-part, double-blind, placebo-controlled, randomized-withdrawal, Phase III study that enrolled 86 children and adolescents aged 2 to 17 years with a confirmed diagnosis of JPsA or ERA according to the International League of Associations for Rheumatology classification criteria[1]. Patients were given open-label secukinumab 75 mg/150 mg (prefilled syringe at doses of 75 mg in patients <50 kg and 150 mg in patients ≥50 kg) up until Week 121. In this treatment period 1, patients achieving at least JIA ACR 30 response then progressed onto treatment period 2 where patients were allocated to one of two arms: secukinumab 75 mg/150 mg (depending on bodyweight) or placebo and responses observed up until Week 104[1]. The primary endpoint of the study was time to flare in the treatment period 2 (Week 12 to Week 104)[1]. Secondary endpoints in treatment period 1 (up to Week 12) included evaluation of JIA ACR 30/50/70/90/100 responses and each JIA ACR core component, change from baseline of the JADAS, and total enthesitis and dactylitis count[1].

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 of psoriatic arthritis (PsA), moderate to severe plaque psoriasis (PsO), ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)[12,13]. Cosentyx is a proven medicine and has been studied clinically for more than 14 years. The medicine is backed by robust evidence, including five years of clinical data in adults supporting long-term safety and efficacy across moderate to severe PsO, PsA and AS[14-20]. These data strengthen the position of Cosentyx as a treatment across AS and nr-axSpA, PsA and moderate to severe PsO, supported by more than 500,000 patients treated worldwide since launch in 2015[8,21,22].

INDICATIONS

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

- people 6 years of age and older 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)
- adults with active psoriatic arthritis
- adults with active ankylosing spondylitis

- adults 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, sometimes serious.

- 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; skin rash or hives (red, itchy bumps). **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 cap on the COSENTYX Sensoready® 150 mg/mL pen and the 150 mg/mL and 75 mg/0.5 mL prefilled syringes contain latex.

- have recently received or are scheduled to receive an immunization (vaccine). People who take COSENTYX **should not** receive live vaccines. Children should be brought up to date with all vaccines before starting COSENTYX.
- 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 healthcare provider decides that you or your 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 nearly 15,000 people in the United States. For more information, please visit https://www.novartis.us.

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List of links present in page

- https://www.novartis.com/us-en/us-en/news/media-releases/novartis-presents-positive-phase-iii-results-cosentyx-children-active-enthesitis-related-arthritis-era-and-juvenile-psoriatic-arthritis-jpsa-acr-2021
- http://www.fda.gov/medwatch
- https://www.novartis.com/us-en/us-en/sites/novartis_us/files/2022-03/cosentyx_0.pdf
- https://www.novartis.com/us-en/us-en/sites/novartis_us/files/2022-03/cosentyx_pmg_0.pdf
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