Novartis Cosentyx receives FDA approval for treatment of children and adolescents with moderate to severe plaque psoriasis

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- Approval for moderate to severe pediatric patients six years and older is based on pivotal trial data showing Cosentyx demonstrated superior improvements of skin symptoms compared to placebo(1)
- The safety profile of Cosentyx in pediatric patients with plaque psoriasis was demonstrated in two Phase III trials(1)
- Plaque psoriasis is a chronic, inflammatory disease that may impact up to 350,000 children worldwide, with onset most common during adolescence(2,3)

EAST HANOVER, N.J., June 1, 2021 - Novartis, a leader in immuno-dermatology and rheumatology, today announced the U.S. Food and Drug Administration (FDA) has approved Cosentyx® (secukinumab) for the treatment of moderate to severe plaque psoriasis in pediatric patients six years and older who are candidates for systemic therapy or phototherapy[1]. This is the first approval for Cosentyx in a pediatric population in the US. The Cosentyx clinical profile is supported by five years of adult data showing long-lasting efficacy and a consistent safety profile across moderate to severe plaque psoriasis, psoriatic arthritis and ankylosing spondylitis[4-10].

"Treating moderate to severe plaque psoriasis in children can be complicated, as we need to balance the ability of a treatment to provide symptom relief while considering the safety profile as the top priority," said John Browning, MD, FAAD, FAAP, MBA, clinical trial investigator, Adjunct Associate Professor of Pediatrics and Dermatology at the University of Texas Health, San Antonio. "In the pediatric pivotal study, the majority of patients treated with Cosentyx were able to achieve clear or almost clear skin with a safety profile consistent with previous clinical trials in adults. Due to the systemic nature of the disease, Cosentyx is a welcome addition as a treatment option for families dealing with this challenging condition."

Psoriasis is a common chronic, inflammatory condition which affects approximately 8 million Americans and 1% of children and adolescents in the US[2,11]. Onset is most common during adolescence, with one-third of psoriasis cases beginning in the pediatric years[2,12]. Psoriasis can have a negative impact on the quality of life of children, especially during their formative years[13].

The approved pediatric dosing for Cosentyx is 75 mg or 150 mg depending on the child's weight at the time of dosing and is administered by subcutaneous injection every four weeks after an initial loading regimen[1]. After initial counseling and proper training in injection technique, Cosentyx can be administered by an adult caregiver outside of a healthcare provider's office via a single-dose prefilled syringe or Sensoready® pen.

"Today's FDA approval represents an important milestone for Cosentyx demonstrating our commitment to help meet the needs of pediatric plaque psoriasis patients and their families," said Victor Bulto, President, Novartis Pharmaceuticals Corporation. "With more than 400,000 patients treated in over 100 countries worldwide, this expanded indication builds on the established safety and efficacy profile of Cosentyx."

This Cosentyx approval is based on two Phase III studies evaluating the use of Cosentyx in children aged 6 to <18 years with plaque psoriasis. The safety profile reported in these trials was consistent with the safety profile reported in adult plaque psoriasis trials. No new safety signals were observed.

The first study, which evaluated efficacy and safety, was a 52-week (236 weeks total), randomized, double-blind, placebo- and active-controlled study which included 162 children six years of age and older with severe plaque psoriasis. The data showed Cosentyx reduced psoriasis severity at Week 12 compared with placebo as demonstrated by the following efficacy results by baseline weight strata for the approved doses (75mg for <50kg and 150mg for ≥50kg): Psoriasis Area Severity Index (PASI) 75 response (55% 75 mg vs 10% placebo (N=22 and N=20, respectively), 86% 150 mg vs 19% placebo (N=21 and N=21, respectively), 70% total Cosentyx vs 15% total placebo (N=43 and N=41, respectively) and Investigator's Global Assessment modified 2011 (IGA) "clear" or "almost clear" skin response (32% 75 mg vs 5% placebo, 81% 150 mg vs 5% placebo, 56% total Cosentyx vs 5% total placebo), co-primary endpoints of the study[1].

The second Phase III study was a randomized open-label, 208-week trial of 84 subjects six years of age and older with moderate to severe plaque psoriasis[1].

"Living with psoriasis is challenging, and can be highly stressful for children and adolescents," said Randy Beranek, President and CEO, National Psoriasis Foundation. "Having expanded treatment options for this patient population is a step in the right direction to help reduce the burden of plaque psoriasis."

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 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 Psoriasis

Psoriasis is a chronic, inflammatory disease that affects more than 125 million people worldwide[2,11]. One-third of psoriasis cases begin in childhood and, of these, the onset is most common during adolescence[2,12]. Psoriasis may impact up to 350,000 children worldwide and approximately 1% of children and adolescents in the US[2,3]. The incidence of pediatric psoriasis has more than doubled between 1970 and 1999 in the US[12].

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, ankylosing spondylitis (AS) and nr-axSpA[14,15]. Cosentyx 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 plaque psoriasis, PsA and AS[4-10]. These data strengthen the position of Cosentyx as a comprehensive treatment across axial spondyloarthritis, psoriatic arthritis and moderate to severe plaque psoriasis, supported by more than 400,000 patients treated worldwide since launch in 2015[1,16,17].

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 16,000 people in the United States. For more information, please visit https://www.novartis.us.

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