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Novartis Cosentyx® data at AAD VMX shows improvement in skin symptoms and quality of life was maintained up to one year in children with moderate to severe plaque psoriasis

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- *At least 75% of children six years and older achieved PASI 90 at Week 52 when treated with Cosentyx in two pivotal studies*[1,2]
- *Majority of children experienced improved health-related quality of life at Week 52, as measured by CDLQI 0/1 responses, when treated with Cosentyx in both studies*[1,2]
- *In children with severe plaque psoriasis, numerically greater clinical improvement was observed with Cosentyx compared to Enbrel® at Week 52*[1]
- *Supplemental Biologics License Application for Cosentyx in this pediatric patient population currently under FDA review with a decision anticipated in Q2 2021*

East Hanover, April 23, 2021 — Novartis announced today results from two pivotal Phase III international studies showing Cosentyx® (secukinumab) improved skin symptoms and quality of life for up to 52 weeks in children and adolescents aged 6 to <18 years old with either severe or moderate to severe plaque psoriasis.[1,2] Results were presented at the 2021 American Academy of Dermatology Virtual Meeting Experience (AAD VMX). Plaque psoriasis is a chronic, inflammatory disease which may impact up to 350 000 children worldwide, with onset most common during adolescence.[3,4]

“These one-year pivotal data are encouraging as they show the majority of pediatric Cosentyx patients maintained improvement in their psoriasis skin symptoms as well as in their health-related quality of life,” said John Browning, MD, FAAD, FAAP, MBA, clinical trial investigator, Adjunct Associate Professor of Pediatrics and Dermatology at University of Texas, San Antonio. “Living with moderate to severe plaque psoriasis can have a significant impact on children’s physical and emotional well-being, and these findings support the potential for Cosentyx to become an additional treatment option for this patient population."

The first study was a multicenter, randomized, double-blind, study that included 162 children with severe plaque psoriasis. At Week 52, reduced psoriasis severity was observed with low dose (LD) (75-50 mg) and high dose (HD) (75-300 mg) Cosentyx, compared to Enbrel® (etanercept): Psoriasis Area Severity Index (PASI) 75 response (87.5% LD, 87.5% HD vs 68.3% Enbrel®), PASI 90 (75% LD, 80% HD vs 51.2% Enbrel®), and PASI 100 (40% LD, 47.5% HD vs 22% Enbrel®). Investigator’s Global Assessment modified 2011 [IGA mod 2011] 0/1 response at Week 52 was 72.5% (LD) and 75% (HD) vs 56.1% for Enbrel®. A higher proportion of patients treated with Cosentyx reported improvement in health-related quality of life as measured by a Children’s Dermatology Life Quality Index (CDLQI) score of 0 or 1 compared to Enbrel® at Week 52 (60.6% LD, 66.7% HD vs. Enbrel® 44.4%). As reported previously, the study achieved its primary objectives of showing superiority of Cosentyx vs. placebo in PASI 75 and IGA 0/1 responses at Week 12.[1]

The second study was a multicenter, randomized, open-label study that included 84 children with moderate to severe plaque psoriasis. At Week 52, the proportion of Cosentyx treated patients who achieved PASI

75/90/100 responses were 88.1%/76.2%/52.4% (LD) and 90.5%/83.3%/69% (HD). IGA mod 2011 0/1 response at Week 52 was 85.7% (LD) and 83.3% (HD). Additionally, approximately 70% of evaluable patients achieved a CDLQI score of 0 or 1 at Week 52 (70.7% LD; 70.3% HD). As reported previously, the study achieved its primary objectives of showing superiority of Cosentyx vs. historical placebo in PASI 75 and IGA 0/1 responses at Week 12.[2]

The safety profile reported in both studies was consistent with the safety profile reported in adult plaque psoriasis patients and no new safety signals were observed.[1,2]

Cosentyx has not been approved by the U.S. Food and Drug Administration for use in pediatric patients.

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
- 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

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

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2. Magnolo N, Kingo K, Laquer V, et al. Secukinumab treatment demonstrated high efficacy and safety in pediatric patients with moderate-to-severe plaque psoriasis: 52 Week results from a randomized trial. Presented as a poster presentation at the American Academy of Dermatology Virtual Meeting Experience; April 23 - 25, 2021.
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