

# Novartis receives FDA approval for Cosentyx® label update to include moderate to severe scalp psoriasis

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- - US label updated to include Cosentyx® (secukinumab) data in moderate to severe scalp psoriasis - one of the difficult-to-treat types of psoriasis(1,2)
- - Approximately half of all 125 million patients with psoriasis may suffer from scalp psoriasis, which can have an impact on patients' quality of life(2-4)
- - This follows a similar European label update in June 2017(5)

EAST HANOVER, N.J., Feb. 8, 2018 /PRNewswire/ -- Novartis announced today that the US Food and Drug Administration (FDA) has approved a label update for Cosentyx® (secukinumab), the first interleukin-17A (IL-17A) antagonist approved to treat moderate to severe plaque psoriasis.<sup>1</sup> The updated label includes Cosentyx data in moderate to severe scalp psoriasis – one of the difficult-to-treat forms of the disease, which affects approximately half of all psoriasis patients.<sup>1-3</sup> The label update is effective in the US immediately, and is based on the proven efficacy and consistent safety profile of Cosentyx from a dedicated Phase III scalp psoriasis trial.<sup>6</sup>

The updated label for Cosentyx in scalp psoriasis addresses an important unmet need. Scalp psoriasis can be challenging to treat with topical agents or phototherapy due to the presence of hair and other factors.<sup>2</sup> Approximately half of all 125 million patients with psoriasis may suffer from scalp psoriasis.<sup>2,4</sup>

"This is an important label update for Cosentyx, the first IL-17A inhibitor approved for moderate to severe plaque psoriasis. It confirms the additional value Cosentyx offers to patients who seek a treatment effective in various areas of the body," said Eric Hughes, Global Development Unit Head, Immunology & Dermatology. "We're proud to expand treatment possibilities of Cosentyx for an even greater number of patients."

Cosentyx is currently the only fully human IL-17A antagonist to demonstrate efficacy and safety in a dedicated Phase IIIb study of scalp psoriasis.<sup>6</sup> The label update is based on 12-week primary endpoint results from the US study of moderate to severe scalp psoriasis patients where Cosentyx (300 mg) demonstrated superior efficacy compared to placebo.<sup>1,6</sup>

Cosentyx, in a separate study, has demonstrated sustained long-term efficacy, as well as a safety profile consistent with that seen in pivotal trials.<sup>7</sup> To date, more than 125,000 patients worldwide have been prescribed Cosentyx in the post-marketing setting across all indications since launch.<sup>8</sup>

About Cosentyx (secukinumab) and IL-17A

Cosentyx, launched in 2015, is the first and only fully-human interleukin-17A (IL-17A) antagonist approved to treat moderate to severe plaque psoriasis, psoriatic arthritis (PsA) and ankylosing spondylitis (AS).<sup>1</sup> By specifically targeting IL-17A, Cosentyx addresses an important cytokine involved in the development of psoriasis.<sup>1,9</sup> IL-17A plays a significant role in the pathogenesis of plaque psoriasis, PsA and AS.<sup>1,9-11</sup>

Inhibiting IL-17A is important as up to 30% of patients with psoriasis may have PsA.<sup>12</sup>

In psoriasis, Cosentyx delivers long-lasting skin clearance with a sustained response and favorable safety profile out to 5 years, as demonstrated in a clinical study, along with convenient dosing in a patient-friendly auto injector.<sup>7,13</sup> Cosentyx has been studied in dedicated trials for the most difficult-to-treat types of plaque psoriasis – palmoplantar psoriasis (psoriasis of the hands and feet), scalp psoriasis, and nail psoriasis.<sup>6,14,15</sup>

Cosentyx is approved in more than 75 countries for the treatment of moderate to severe plaque psoriasis, which includes the European Union countries, Japan, Switzerland, Australia, the US and Canada. In Europe, Cosentyx is approved for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy.<sup>5</sup> In the US, Cosentyx is approved as a treatment for moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy (light therapy).<sup>1</sup>

In addition, Cosentyx is the first IL-17A antagonist approved in more than 65 countries for the treatment of active AS and PsA, which includes the European Union countries and the US. Cosentyx is also approved for the treatment of PsA and pustular psoriasis in Japan.<sup>16</sup>

About the SCALP study<sup>1,6</sup>

This study is a randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of Cosentyx in 102 patients with moderate to severe scalp psoriasis. Eligible patients were equally randomized to either subcutaneous Cosentyx 300 mg or placebo at Weeks 0, 1, 2 and 3, then every four weeks for 12 weeks. At Week 12, patients in the placebo group who did not achieve at least a 90% improvement from baseline in the Psoriasis Scalp Severity Index (PSSI) score were switched to Cosentyx 300 mg at weeks 12, 13, 14, 15, 16 and 20 (study completion - 24 weeks). The primary endpoint was the proportion of patients who achieved PSSI 90 response at Week 12. The key secondary objective was Investigator's Global Assessment modified 2011 (IGA) 0 (clear) or 1 (almost clear) response (for the scalp only) at week 12. The proportion of patients achieving an IGA scalp only score of 0 or 1 (clear or almost clear) were 56.9% and 5.9% for Cosentyx and the placebo groups, respectively.

About psoriasis

Psoriasis is a common, non-contagious, auto-immune disease that affects more than 125 million people worldwide.<sup>4</sup> Plaque psoriasis is the most common form of the disease and appears as raised, red patches covered with a silvery white build-up of dead skin cells.<sup>17</sup>

Psoriasis is not simply a cosmetic problem, but a persistent, chronic (long-lasting), and sometimes distressing disease, which can affect even the smallest aspects of people's lives on a daily basis.<sup>17</sup> Up to 30% of patients with psoriasis may have PsA.<sup>12</sup> PsA is a condition in which the joints are also affected, causing debilitating symptoms including pain, stiffness and for some people, irreversible joint damage.<sup>18</sup> Psoriasis is also associated with other serious health conditions, such as diabetes, heart disease and depression.<sup>17</sup>

## INDICATIONS

Cosentyx is a human interleukin-17A antagonist indicated for the treatment of:

- moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy
- adults with active psoriatic arthritis (PsA)
- adults with active ankylosing spondylitis (AS)

## 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](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

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

#### Disclaimer

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