FDA approves Novartis Cosentyx® as the first new biologic treatment option for hidradenitis suppurativa patients in nearly a decade

Oct 31, 2023

- FDA approval based on robust Phase III data in which Cosentyx® (secukinumab) showed rapid relief from symptoms of hidradenitis suppurativa (HS) as early as Week 2[1]
- As the only IL-17A inhibitor approved for HS, Cosentyx offers a meaningful new treatment option that demonstrated reductions in inflammatory nodules and abscesses, and flares[2]
- HS is a chronic, progressive and often painful disease that may affect 1 in 100 people worldwide[3,4]

EAST HANOVER, N.J., Oct. 31, 2023 -- Novartis, a global leader in immuno-dermatology and rheumatology, announced today that the US Food and Drug Administration (FDA) has approved Cosentyx® (secukinumab) to treat moderate to severe hidradenitis suppurativa (HS) in adults. Cosentyx is the only FDA-approved fully human biologic that directly inhibits interleukin-17A (IL-17A), a cytokine believed to be involved in the inflammation of HS.[2]

HS is a chronic, systemic and often painful skin disease that causes recurring boil-like lumps that may burst into open wounds and cause irreversible scarring, often in the most intimate parts of the body.[3] It may take people living with HS an average of up to 10 years to get a correct diagnosis, which can result in disease progression and significantly impact their quality of life.[5,6] Until now, there has been only one biologic approved to treat HS.[7]

"For many patients, the daily impact of HS and the search for symptom relief can last years – which can come with painful, irreversible physical and emotional scarring," said Alexa B. Kimball, MD, MPH, lead investigator of the SUNSHINE and SUNRISE trials, Professor of Dermatology at Harvard Medical School, President and CEO of Harvard Medical Faculty Physicians at Beth Israel Deaconess Medical Center, Boston. "This approval marks an important milestone for countless patients who have been faced with limited treatment possibilities and who now have a new option."

"HS is one of the most devastating and exhausting skin diseases. The pain of flares can be debilitating and limits my ability to work or participate in social activities. It can have a major impact on me physically and emotionally, including feelings of anxiety, stress and isolation," said Donna Atherton, EdD, Founder and Chief Mission Officer, International Association of Hidradenitis Suppurativa Network (IAHSN). "The approval of a new treatment option brings fresh hope to me and the HS community that we may find relief from the burden of the disease."

The FDA approval was based on analyses from the largest Phase III program in HS to date, SUNSHINE and SUNRISE, in which a higher proportion of patients given Cosentyx 300 mg either every two weeks or every four weeks achieved a Hidradenitis Suppurativa Clinical Response (HiSCR50) compared to placebo.[1]

Cosentyx for HS is approved as a 300 mg dose, administered every four weeks, with the option to increase to every two weeks if the patient has an inadequate response.[1]

In both the SUNSHINE and SUNRISE studies, which evaluated Cosentyx across 16-week (vs placebo) and 52-week treatment periods, the onset of action of Cosentyx occurred as early as Week 2.[1] Efficacy progressively increased to Week 16 and was observed up to Week 52.[2] The safety profile of Cosentyx observed in these HS trials was consistent with its known safety profile observed in the plaque psoriasis trials, affirming the differentiated safety profile of Cosentyx.[1]

"Cosentyx can offer effective, lasting relief from HS symptoms so that people with HS have a chance to live every day with confidence," said Victor Bultó, President, Novartis US. "With this sixth indication approval for Cosentyx – along with ongoing studies in numerous other conditions – we are reaffirming our commitment to reimagine medicine for those living with immunological diseases."

About the SUNSHINE and SUNRISE trials[2]
The SUNSHINE (NCT03713619) and SUNRISE (NCT03713632) trials comprise the largest Phase III program in hidradenitis suppurativa (HS), with a combined enrollment of more than 1,000 patients. SUNSHINE and SUNRISE are identical, global Phase III, multicenter, randomized, double-blind, placebo-controlled, parallel-group studies that evaluated the short- (16 weeks) and long-term (up to 52 weeks) efficacy, safety and tolerability of two dose regimens of Cosentyx in adults with moderate to severe HS. A Hidradenitis Suppurativa Clinical Response (HiSCR50), the primary endpoint in the two pivotal trials, is defined as at least a 50% decrease in abscess and inflammatory nodule (AN) count with no increase in the number of abscesses and/or draining tunnels. Secondary endpoints included a decrease in abscess and inflammatory nodules by at least 50% (AN50), the proportion of patients experiencing a flare, and the proportion of patients with a skin pain numeric rating scale 30 response up to 16 weeks of treatment.[2]

Results from the US Food and Drug Administration (FDA)-requested analyses at Week 16 showed that a significantly higher proportion of patients achieved HiSCR50 when treated with Cosentyx 300 mg dosed every two weeks (after standard weekly loading doses), compared with placebo in both the SUNSHINE and SUNRISE trials (44.5% vs 29.4% [*P<0.05] and 38.3% vs 26.1% [*P<0.05], respectively).[1] A greater proportion of patients randomized to Cosentyx 300 mg dosed every four weeks (after standard weekly loading doses) achieved HiSCR50 compared with placebo in both SUNSHINE (41.3% vs 29.4%) and SUNRISE (42.5% vs 26.1% [*P<0.05]) trials.[1]

An exploratory analysis assessed the long-term effects of Cosentyx for each of the primary and secondary endpoints for up to 52 weeks. HiSCR values observed at Week 16 following either dose regimen of Cosentyx were improved over time to Week 52 (SUNSHINE: SECQ2W [56.4%]; SECQ4W [56.3%]; SUNRISE: SECQ2W [65.0%]; SECQ4W [62.2%]), with rapid improvements seen in patients who switched from placebo at Week 16.[8]

*Statistically significant versus placebo based on the pre-defined hierarchy (from the pre-specified primary statistical analysis) with overall alpha = 0.05 (two-sided).

About Cosentyx® (secukinumab)
Cosentyx is the first and only fully human biologic that specifically targets and blocks interleukin-17A (IL-17A), an important cytokine involved in the inflammation of psoriatic arthritis (PsA), moderate to severe plaque psoriasis, ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA).[9,10] Cosentyx is a proven medicine and has been studied clinically for more than 14 years. The medicine is backed by robust evidence, including 8 years of real-world data in adults and 5 years of long-term safety and efficacy across

moderate to severe plaque psoriasis, PsA and AS.[11-17] These data strengthen the position of Cosentyx as a treatment across AS, nr-axSpA, PsA, moderate to severe plaque psoriasis (adult and pediatric) and two subtypes of juvenile idiopathic arthritis (JIA), enthesitis-related arthritis and juvenile psoriatic arthritis.[1] More than 1 million patients have been treated with Cosentyx worldwide since its launch in 2015.[18] Cosentyx is approved in more than 100 countries, most recently gaining approval for JIA and HS in the US and Europe.[19,20]

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

- people 6 years of age and older with moderate to severe plaque psoriasis (PsO) 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)
- people 2 years of age and older with active psoriatic arthritis (PsA)
- adults with active ankylosing spondylitis (AS)
- adults with active non-radiographic axial spondyloarthritis (nr-axSpA) and objective signs of inflammation
- people 4 years of age and older with active enthesitis-related arthritis (ERA)
- adults with moderate to severe hidradenitis suppurativa (HS)

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.

What is the most important information I should know about COSENTYX?
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. Some people have died from these 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 use 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.

What are the possible side effects of COSENTYX?

COSENTYX may cause serious side effects, including:

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.

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.

Severe skin reactions that look like eczema can happen during treatment with COSENTYX from days to months after your first dose and can sometimes lead to hospitalization. Your doctor may temporarily stop treatment with COSENTYX if you develop severe skin reactions. Tell your doctor if you have any of the following signs or symptoms: redness or rash; itching; small bumps or patches; your skin is dry or feels like leather; blisters on the hands or feet that ooze or become crusty or skin peeling.

The most common side effects of COSENTYX include: cold symptoms, diarrhea, and upper respiratory tract infections.

These are not all of the possible side effects of COSENTYX. Call your doctor for medical advice about side effects.

Before using 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® pen, and 150 mg/mL and 75 mg/0.5 mL prefilled syringes contains 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 and all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Keep a list of your medicines to show your healthcare provider and pharmacist when you get a new medicine.
- 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.

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 click here for Cosentyx full Prescribing Information.

Disclaimer
This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as "potential," "can," "will," "plan," "may," "could," "would," "expect," "anticipate," "look forward," "believe,"

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About Novartis

Novartis is a focused innovative medicines company. Every day, we work to reimagine medicine to improve and extend people's lives so that patients, healthcare professionals and societies are empowered in the face of serious disease. Our medicines reach more than 250 million people worldwide.

Reimagine medicine with us: Visit us at https://www.novartis.com and connect with us on LinkedIn, Facebook, X/Twitter and Instagram.

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