

Effect of Cosentyx® (secukinumab) in adults with hidradenitis suppurativa after 16 weeks

Full abstract title: Secukinumab in moderate to severe hidradenitis suppurativa: Primary endpoint analysis from the SUNSHINE and SUNRISE Phase 3 trials

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Please note that this summary only contains information from the full EADV 2022 scientific abstract and selected supporting references. The results of this study may not reflect those of other studies. This summary is not intended to provide medical advice.

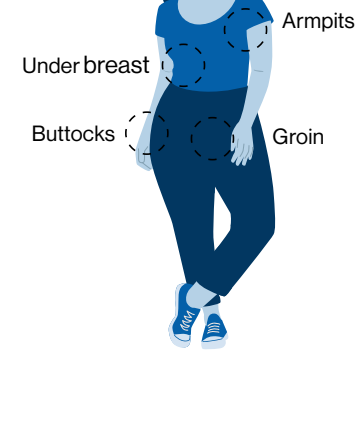
What is hidradenitis suppurativa (HS)?

HS is a chronic, inflammatory skin condition that is characterized by recurrent boil-like lumps under the skin that become inflamed and painful, breaking open to cause swelling, odor and wounds^{1,2}. These lumps can recur and spread under the skin, causing tunnels connecting the lumps and painful scarring on the surface of the skin³.

Once considered a rare condition, it is now thought to affect as many as 1 in 100 people worldwide¹.

People living with HS can experience social withdrawal, unemployment and depression, leading to a profoundly negative effect on quality of life⁴. The chronic, debilitating nature of HS makes it one of the most distressing dermatological conditions with a considerable psychological burden on sufferers⁵.

Commonly affected areas include (but are not limited to):



What are the SUNSHINE and SUNRISE trials?

SUNSHINE and SUNRISE are the names of two parallel, Phase III, multicenter, randomized studies assessing the safety and efficacy of two Cosentyx dose regimens vs placebo for 16 weeks in adult patients with moderate-to-severe HS and evaluating the long-term maintenance over 52 weeks^{6,7}.

What is Cosentyx® (secukinumab)?

Cosentyx is a type of medication called a biologic. It helps reduce inflammation by blocking one of the proteins that activates the cells of the immune system, called interleukin-17A (IL-17A). It is being investigated as a potential treatment option for HS⁸.

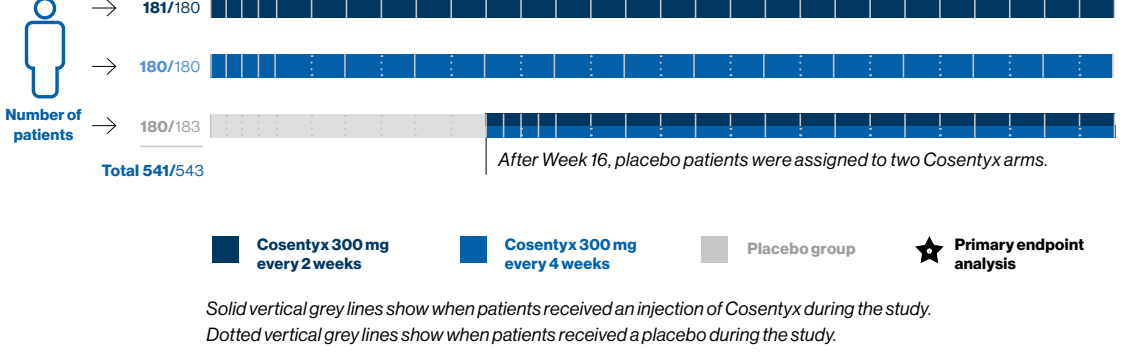
These two studies looked at how many patients achieved improvement in symptoms after being treated with Cosentyx at 16 weeks to 52 weeks^{6,7}.

Clinical effect was measured using a scoring system known as the HS Clinical Response (HiSCR) that assesses the reduction in skin symptoms including nodules and abscesses^{6,7}. Other outcomes, such as occurrence of nodules, occurrence of flares and HS-related pain, were also assessed^{6,7}.

To check if any effects were due to Cosentyx, the results were compared with those given a placebo – a “dummy” injection containing no active ingredient^{6,7}.

Study design

SUNSHINE and SUNRISE are parallel trials of the same design with two Cosentyx dose regimens in people living with moderate-to-severe HS^{6,7}.



What did these studies find?

Primary endpoint

Efficacy (measured using HiSCR)

In people treated with Cosentyx 300 mg every 2 weeks, significantly more people achieved a HiSCR at Week 16, compared with placebo, in both studies. In people treated with Cosentyx 300 mg every 4 weeks, a significant difference vs placebo was only seen in one of the studies at Week 16.

HiSCR response is defined as at least a 50% decrease in abscess and inflammatory nodule count with no increase in the number of abscesses and/or draining tunnels⁹.

SUNSHINE



SUNRISE



*Denotes statistical significance

Secondary endpoints

Abscess and inflammatory nodule count

Abscess and inflammatory nodule count was significantly reduced in both trials following treatment with Cosentyx vs placebo at Week 16 for Cosentyx 300 mg given every 2 weeks. In those receiving Cosentyx 300 mg every 4 weeks, abscess and nodule count was significantly reduced in one of the groups at Week 16.

SUNSHINE



SUNRISE



*Denotes statistical significance

Occurrence of flares

Cosentyx met statistical significance compared with placebo for treating HS flares at Week 16 in SUNSHINE for Cosentyx 300 mg given every two weeks, and in SUNRISE for Cosentyx 300 mg given every four weeks. A flare was defined as at least a 25% increase in abscesses and inflammatory nodule count with a minimum increase of 2 nodules compared with baseline^{6,7}.

Proportion of patients who experienced at least one flare over 16 weeks:

SUNSHINE



SUNRISE



*Denotes statistical significance

HS-related skin pain

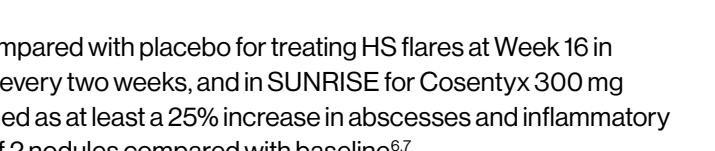
When pooling data from both studies, more patients had a significant reduction in HS-related pain when treated with Cosentyx 300 mg every 2 weeks vs placebo at Week 16. No significant difference was seen with Cosentyx 300 mg every 4 weeks. This was assessed by the Patient's Global Assessment of Skin Pain Numeric Rating Scale (NRS30). NRS30, a measurement of pain control, is described as at least a 30% reduction in the numerical rating scale for pain (ranging from 0 to 10), compared with the time before initiating treatment. Only patients with a baseline NRS of greater than or equal to 3 were included in this analysis^{6,7}.

SUNSHINE and SUNRISE pooled:

Cosentyx 300 mg every 2 weeks

Cosentyx 300 mg every 4 weeks

Placebo



*Denotes statistical significance

Patient-reported quality of life

More patients treated with Cosentyx 300 mg every 2 weeks and every 4 weeks reported an improvement in health-related quality of life, as measured by the Dermatology Life Quality Index (DLQI), compared with placebo. This improvement was noticeable as early as 2 weeks into treatment and sustained over 16 weeks of treatment. DLQI response rates – the % of patients who achieved a DLQI response, defined as a 5-point reduction – are shown below:

SUNSHINE



SUNRISE



Statistical analyses were not completed for exploratory endpoints

Safety

No new safety signals were observed compared with the established safety profile of Cosentyx, as known from clinical and post-marketing experience across approved indications.

Why does this matter?

These studies showed that, compared with placebo, more patients living with HS experienced improved symptoms when treated with Cosentyx after 16 weeks of treatment^{6,7}.

HS is a painful, chronic condition, with a significant impact on quality of life, and current treatment regimens are limited. Treatments are often either inadequate, cannot be taken over a long period of time or do not address underlying disease control, thereby only providing temporary and moderate relief^{10,12}.

These results provide support that Cosentyx could be an effective treatment option with a good safety profile for people with moderate-to-severe HS, with the potential to improve health-related quality of life¹⁰.

In addition to the ongoing SUNSHINE and SUNRISE trials, Novartis is exploring other potential biologic and oral treatment options for HS with different mechanisms of actions (i.e., how the medicine works) to further address the needs of people living with HS beyond Cosentyx¹³.

Glossary

Biologic medicine:

A treatment made using living organisms, rather than being chemically synthesized.

Hidradenitis suppurativa (HS):

[hi-drad-uh-NIE-tis sup-yoo-ruh-TIE-vuh]:

A chronic inflammatory skin condition that features recurrent and progressive boil-like lumps, nodules or abscesses under the skin^{1,2}.

Hidradenitis Suppurativa Clinical Response (HiSCR):

At least a 50% decrease in abscess and inflammatory nodule count with no increase in the number of abscesses and/or in the number of draining tunnels⁹.

Inflammation:

The body's response to an irritant or pathogen, which involves a variety of cells that release different substances to help the body fight the external agent causing inflammation (i.e., trigger factor).

Interleukin-17A:

A naturally occurring cytokine that is involved in normal inflammatory and immune responses¹⁴.

Placebo:

A “dummy” treatment; a substance with no active component and no therapeutic effect.

Significant(ly):

“Significance” is the measure of success of a study; the difference between the trial groups is unlikely to have occurred by chance. This difference is, therefore, likely to be related to the treatment given to the patients, and it is robust if it meets the “statistical significance”.

Who sponsored these studies?

Novartis Pharma AG, Basel, Switzerland sponsored both of these studies and the writing of this plain language media summary.

Further information

More on the SUNRISE and SUNSHINE studies can be found here:

<https://clinicaltrials.gov/ct2/show/NCT03713632>

<https://clinicaltrials.gov/ct2/show/NCT03713619>

References

- MedLine Plus. <https://medlineplus.gov/genetics/condition/hidradenitis-suppurativa/>. [Last accessed: September 2022].
- National Institute of Health (NIH) Genetic and Rare Diseases Information Center (GARD). https://rarediseases.info.nih.gov/diseases/6659/hidradenitis-suppurativa/ref_15130 [Last accessed: September 2022].
- Mayo Clinic. <https://www.mayoclinic.org/diseases-conditions/hidradenitis-suppurativa/symptoms-causes/svc-20352306> [Last accessed: September 2022].
- Sabat R, et al. *Nat Rev Dis Primers*. 2020;6:18.
- Mac Mahon J, et al. *Patient Relat Outcome Meas*. 2020;11:21-26.
- ClinicalTrials.gov. NCT03713619. <https://clinicaltrials.gov/ct2/show/NCT03713619>. [Last accessed: September 2022].
- ClinicalTrials.gov. NCT03713632. <https://clinicaltrials.gov/ct2/show/NCT03713632>. [Last accessed: September 2022].
- Novartis Europharm Limited. Cosentyx® (secukinumab): Summary of Product Characteristics. Available from: https://www.ema.europa.eu/en/documents/product-information/cosentyx-epar-product-information_en.pdf [Last accessed: September 2022].
- Kimball AB, et al. *J Eur Acad Dermatol Venereol*. 2016;30:989-994.
- Kimball AB, et al. LB-3549. Presented at the 31st European Academy of Dermatology and Venereology (EADV) Congress 2022.
- Gill L, et al. *F1000Prime Rep*. 2014;6:112.
- Vinhal C and Thomsen SF. *J Clin Aesthet Dermatol*. 2018;11:17-23.
- ClinicalTrials.gov. NCT03827798. <https://clinicaltrials.gov/ct2/show/NCT03827798> [Last accessed: September 2022].
- Fletcher JM, et al. *Clin Exp Immunol*. 2020;201:121-134.