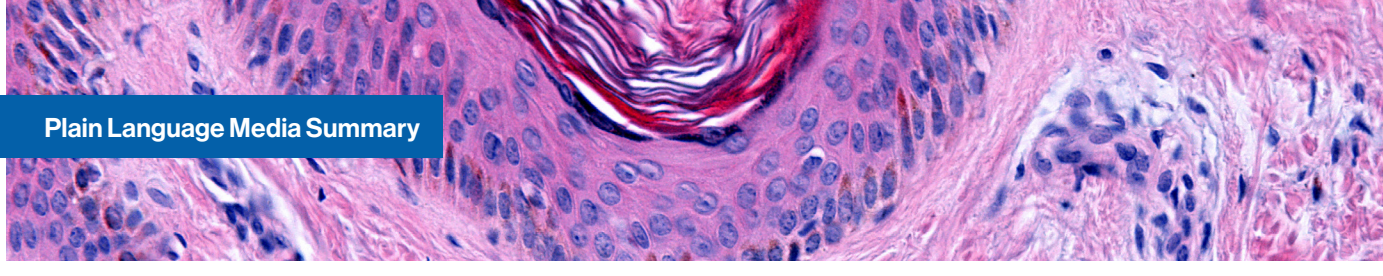


Plain Language Media Summary

New results show sustained long-term effect of Cosentyx® (secukinumab) in adults with hidradenitis suppurativa

Full article title: Secukinumab in Moderate to Severe Hidradenitis Suppurativa: Week 16 and 52 results from SUNSHINE and SUNRISE, two identical, double-blind, placebo-controlled, Phase 3 randomised trials

Abstract authors: Kimball AB, Jemec GBE, Alavi A, et al.

Date: February 2023

Please note that this summary contains information from data published in The Lancet and selected supporting references. This summary is not intended to provide medical advice.

Glossary key: *Words that are in* ***sky blue*** *are defined in the glossary at the end.*

What's new and why does it matter?

The Lancet has published 52-week data from the SUNSHINE and SUNRISE trials, evaluating the **biologic medicine** Cosentyx® (secukinumab) in hidradenitis suppurativa (HS). These results build on the positive primary analysis results seen at Week 16 shared at the European Academy of Dermatology and Venereology (EADV) Congress 2022.

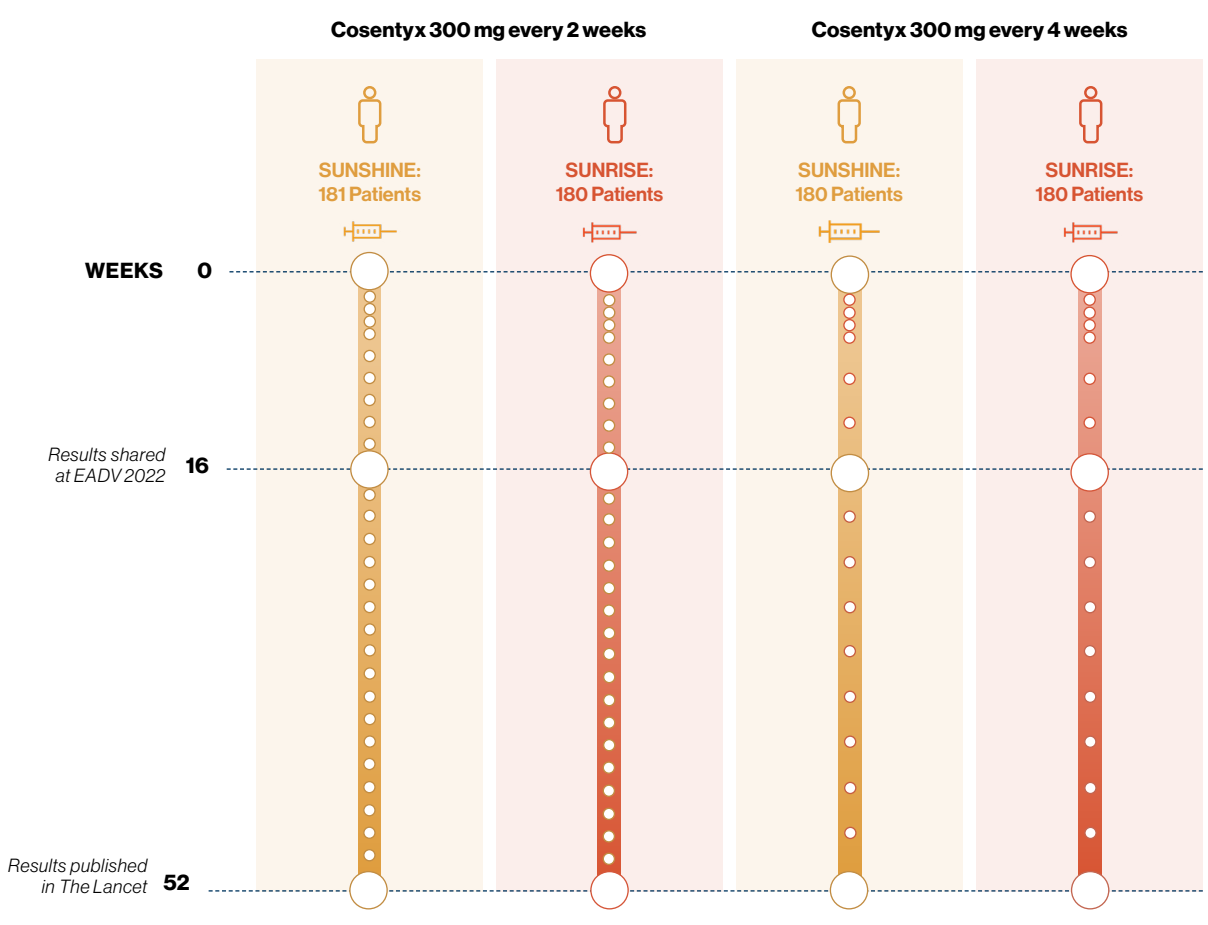
The data show that Cosentyx treatment response rates continued to improve beyond the primary endpoint analysis at Week 16 to more than 55% at Week 52, as evaluated by the HS Clinical Response (HiSCR) measure.

There remains an extremely high unmet need among patients and treating physicians for more treatment options that bring long-term symptom reduction for people living with HS.

There is currently only one approved biologic treatment and around 50% of patients treated can lose response[1]

What are the SUNSHINE and SUNRISE clinical trials?

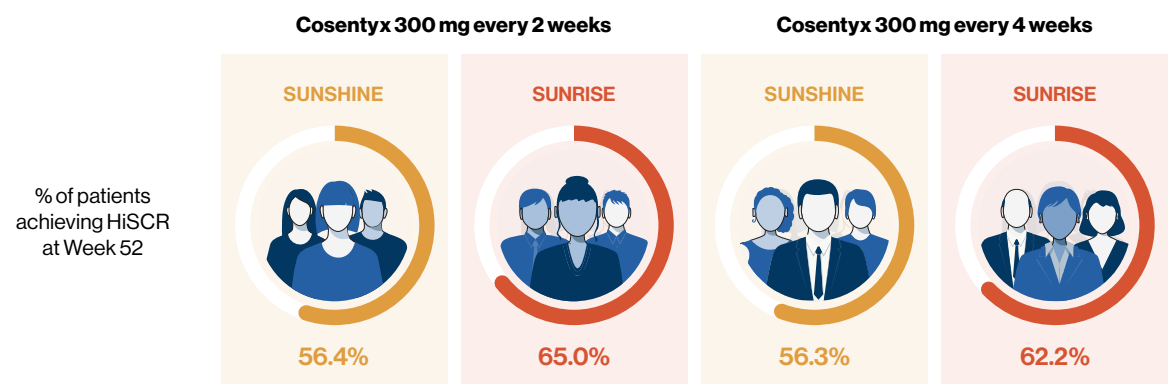
SUNSHINE and SUNRISE are two identical Phase III multicenter, randomized clinical trials assessing the safety and efficacy of Cosentyx dosed every 2 or 4 weeks in adult patients with moderate-to-severe HS, compared with **placebo.**



**Solid white dots in the above graphic show when patients received a dose of Cosentyx during the study.*

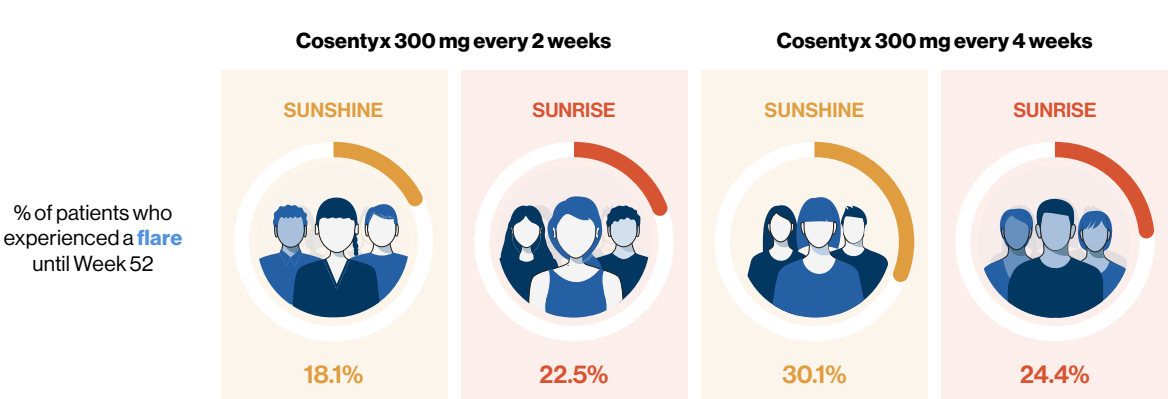
HS clinical response (HiSCR)

Defined as at least a 50% decrease in **abscess** and **inflammatory nodule** count (AN) with no increase in the number of **abscesses** and/or in the number of **draining tunnels**[2,3].



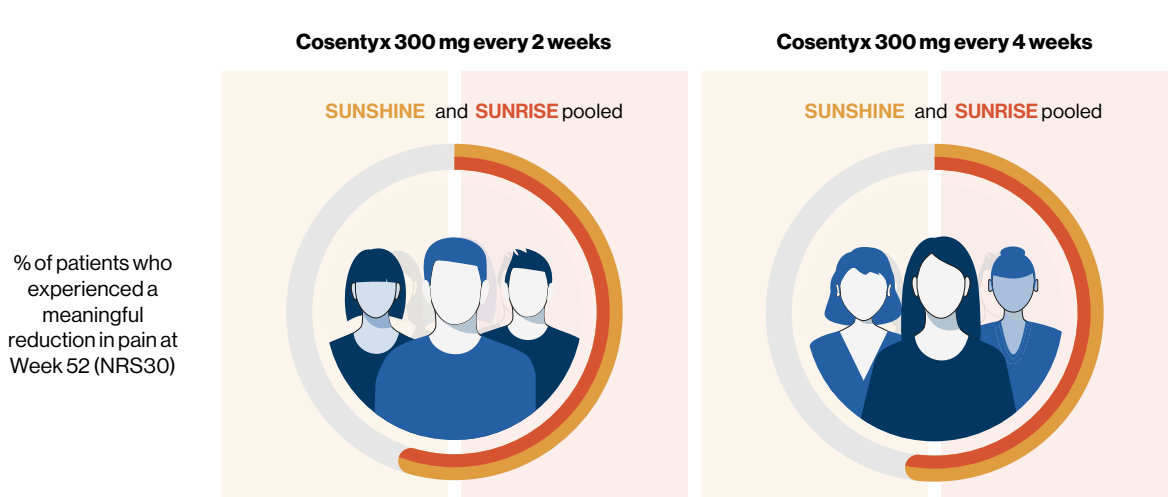
Occurrence of HS flares

Defined as at least 25% increase in AN count with a minimum increase of two AN compared to baseline.



Pain

Assessed by the Patient's Global Assessment of Skin Pain Numeric Rating Scale (NRS), a measurement of pain control. NRS30 is defined as at least a 30% reduction in pain compared to baseline.



From Week 0 to Week 16, 363 patients were treated with **placebo** to be compared against those given Cosentyx. At Week 16, patients taking **placebo** were switched to Cosentyx treatment. These patients also experienced rapid improvements across all observed areas, sustained up to Week 52.

Safety

No new safety signals were observed compared to the well-established safety profile of Cosentyx, as known from extensive clinical experience across approved indications.

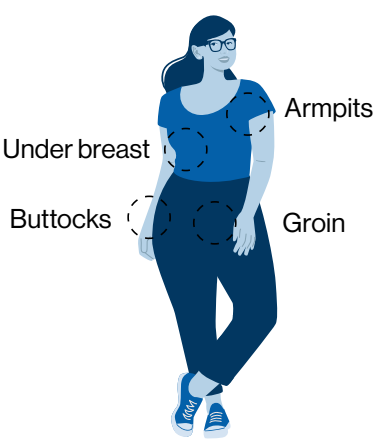
What is hidradenitis suppurativa (HS)?

[hi-dra-duh-NIE-tis sup-per-ruh-TI-vuh]

HS is a painful and recurrent inflammatory skin disease[4], which causes boil-like **abscesses** that can burst, creating open wounds. These **abscesses** often occur in the most intimate parts of the body, resulting in irreversible scarring[4,5].

HS impacts a patient's quality of life more than any other skin disease, and people living with HS often experience comorbidities such as obesity, diabetes, arthritis and depression[5,6]. It can take 10 years to get a diagnosis[7], even though HS affects approximately one in 100 people globally[4].

Commonly affected areas include (but are not limited to)[4]:



Glossary

Abscesses:
In HS, abscesses are inflammatory nodules that have progressed and are filled with pus and fluid.

Biologic medicine:
A treatment made using living organisms, rather than being chemically made.

Clinical trial terminology:

- **Primary endpoint:** The main results measured to see if a given treatment works.
- **Secondary endpoint:** Additional measures that may support assessment of whether a treatment works; they can be related to the primary endpoint measures.

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).

Inflammatory nodule:
A painful, boil-like lump that often appears first when HS begins to develop.

HS flares/flare-ups:
A period when a patient's HS has noticeably increased; flare-ups can come and go in cycles *(flares are a secondary endpoint for these trials, defined as at least a 25% increase in abscesses and inflammatory nodules count with a minimum increase of two nodules compared to flare-free time*).

HS draining tunnels:
Over time these can form under the skin between inflammatory nodules and abscesses, where fluid can leak between them.

Placebo:
A 'dummy' treatment; a substance with no medicinal component.

1. Kimball A B, et al. *N Engl J Med.* 2016;375:422-34.
2. ClinicalTrials.gov. NCT03713632. Available at: https://clinicaltrials.gov/ct2/show/NCT03713632 [Last accessed: January 2023].
3. ClinicalTrials.gov. NCT03713619. Available at: https://clinicaltrials.gov/ct2/show/NCT03713619 [Last accessed: January 2023].
4. MedLine Plus. Hidradenitis suppurativa. Available at: https://medlineplus.gov/genetics/condition/hidradenitis-suppurativa [Last accessed: January 2023].
5. Sabat R, et al. *Nat Rev Dis Primers.* 2020;6:18.
6. Mac Mahon J, et al. *Patient Relat Outcome Meas.* 2020;11:21-26.
7. Kokolakis G, et al. *Dermatology.* 2020;236:421-430.

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