Hidradenitis suppurativa (HS): What is it and why does this matter? (2022) September 2022

**What is hidradenitis suppurativa (HS)?**

HS is a painful, chronic condition, with a significant impact on quality of life, and current treatment regimens fail to address underlying disease control, thereby only providing temporary and moderate relief.

**Why does this matter?**

The main outcome measure assessed in SUNSHINE and SUNRISE was clinical response, defined as a 5-point reduction.

**What are the SUNSHINE and SUNRISE trials?**

Two Phase 3 clinical trials sponsored by Novartis evaluated the clinical efficacy and safety of Cosentyx, an interleukin-17A (IL-17A) inhibitor, in the treatment of adult patients with moderate-to-severe HS, with the potential to improve health-related quality of life.

**Study design**

SUNSHINE and SUNRISE are randomized, double-blind, placebo-controlled, multicenter trials assessing the safety and efficacy of two Cosentyx studies. The SUNSHINE study evaluated Cosentyx 300 mg every 2 weeks, while the SUNRISE study assessed Cosentyx 300 mg every 4 weeks. Both studies were sponsored by Novartis and the writing of this plain language media summary.

**What are the key results?**

- **Primary endpoint**
  - A statistically significant increase in the number of abscesses and/or draining tunnels in patients treated with Cosentyx 300 mg every 2 weeks compared with placebo. This improvement was noticeable as early as 2 weeks into treatment.

- **Secondary endpoints**
  - Significantly more patients achieved a HiSCR (HS Clinical Response) with Cosentyx 300 mg every 2 weeks and every 4 weeks compared with placebo.
  - More patients reported an improvement in nodules, occurrence of flares, and HS-related pain when treated with Cosentyx 300 mg every 2 weeks and every 4 weeks compared with placebo.

- **Tolerability**
  - 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.

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

- Placebo: 33.7%
- Cosentyx 300 mg every 2 weeks: 20.1%
- Cosentyx 300 mg every 4 weeks: 28.9%

**What is Cosentyx® (secukinumab)?**

Cosentyx is a human monoclonal antibody developed by Novartis to selectively target IL-17A, a naturally occurring cytokine that is involved in normal inflammatory and immune responses. It was approved for the treatment of moderate-to-severe plaque psoriasis in 2015.

**Safety**

SUNSHINE and SUNRISE pooled: a “dummy” injection containing no active ingredient. To check if any effects were due to Cosentyx, the results were compared with those given a placebo. This was assessed by the Patient’s Global Assessment of Skin Pain and selected supporting references. The results of this study may not reflect those of other studies.

**Funding**

This summary is not intended to provide medical advice. Please note that this summary only contains information from the full EADV 2022 scientific abstract analysis from the SUNSHINE and SUNRISE Phase 3 trials and selected supporting references. The results of this study may not reflect those of other studies.

**Warning**

This is not a prescription. Cosentyx is indicated for the treatment of plaque psoriasis, psoriatic arthritis, and ankylosing spondylitis. The summary of product characteristics and patient information leaflet contains important information on the use and possible side effects of Cosentyx.

**Further reading**

- National Institute of Health (NIH) Genetic and Rare Diseases Information Center (GARD). https://rarediseases.info.nih.gov/