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Effects of secukinumab on HiSCR 75, HiSCR 90 and HiSCR 100 endpoints in patients with moderate to severe hidradenitis suppurativa: A post hoc analysis of the SUNSHINE and SUNRISE phase 3 trials

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Introduction & Objectives:

Hidradenitis suppurativa (HS) is a chronic inflammatory skin condition characterised by deep and painful nodules, abscesses and tunnels.¹ Secukinumab (SEC), a fully human, monoclonal antibody that selectively inhibits interleukin-17A, has previously demonstrated sustained efficacy with a favourable safety profile in patients with moderate to severe HS.² The HS clinical response (HiSCR), defined as a $\geq 50\%$ decrease in abscess and inflammatory nodule [AN] count with no increase in the number of abscesses and/or draining tunnels, is frequently used as the primary endpoint in HS clinical trials.^{2,3} However, the HiSCR has demonstrated high placebo (PBO) response rates;^{4,5} to minimise these rates, high-impact efficacy endpoints have been proposed. Herein, the treatment effects of SEC on high-impact efficacy endpoints in patients with moderate to severe HS from the SUNSHINE and SUNRISE trials are reported.

Materials & Methods:

SUNSHINE (NCT03713619) and SUNRISE (NCT03713632) are identical multicentre, phase 3 clinical trials of SEC in patients with moderate to severe HS. Patients were randomised to receive s.c. SEC 300 mg every 2 (SECQ2W) or 4 weeks (SECQ4W), or PBO in a 1:1:1 ratio between week 0 and 16. Patients receiving PBO were switched to SECQ2W or SECQ4W, while patients receiving SECQ2W or SECQ4W remained on the same treatment from weeks 16 to 52. The high-impact efficacy endpoints included HiSCR 75, HiSCR 90, and HiSCR 100, representing a $\geq 75\%$, $\geq 90\%$, and 100% decrease in AN count, respectively, with no increase in the number of abscesses and/or draining tunnels versus baseline. Data from week 0 to 16 are based on imputed data, and data from week 16 to 52 are based on observed data. Sustainability of response was assessed by investigating the proportion of patients who achieved a HiSCR 75/90/100 response at week 16, and at week 52 in patients with available response data, based on observed data at both timepoints.

Results:

Overall, 1084 patients were enrolled in SUNSHINE and SUNRISE; mean (standard deviation) age was 36.2 (11.5) years, and 56.3% were female. At week 16, a numerically greater proportion of patients treated with SEC achieved HiSCR 75 versus PBO in SUNSHINE (26.4% [SECQ2W]; 22.6% [SECQ4W]; 16.5% [PBO]) and SUNRISE (23.2% [SECQ2W]; 30.6% [SECQ4W]; 13.5% [PBO]). Similarly, at week 16, a numerically greater proportion of patients treated with SEC achieved HiSCR 90 and HiSCR 100 versus PBO in SUNSHINE (HiSCR90: 14.3% [SECQ2W]; 13.5% [SECQ4W]; 7.1% [PBO]; HiSCR 100: 12.0% [SECQ2W]; 10.4% [SECQ4W]; 4.8% [PBO]) and SUNRISE (HiSCR90: 11.6% [SECQ2W]; 16.0% [SECQ4W]; 5.8% [PBO]; HiSCR100: 7.5% [SECQ2W]; 8.1% [SECQ4W]; 4.6% [PBO]). Response rates for high-impact efficacy endpoints seen at week 16 were sustained, with a trend for improvement, to week 52 in both SEC arms (**Table 1**). The majority of patients achieving high-impact efficacy endpoint responses at week 16 maintained this response at week 52 (**Figure 1**).

Conclusion:

SEC treatment provided better HiSCR 75, HiSCR 90, and HiSCR 100 versus PBO at week 16; these responses were sustained with a trend for improvement to week 52, highlighting the long-term benefits of SEC treatment in patients with moderate to severe HS.

References:

- 1. Sabat R, et al. Nat Rev Dis Primers 2020;6:18.
- 2. Kimball AB, et al. Lancet 2023;401(10378):747–61.
- 3. Kimball AB, et al. NEJM 2016;375(5):422–34.
- 4. Kimball AB. JAAD 2020;83(6):e431.
- 5. Frew et al. JAAD Int 2020;1:208–21.

Figure 1: Proportion of patients (%) in the secukinumab arms of the SUNSHINE and SUNRISE trials achieving (A) HiSCR 75, (B) HiSCR 90 and (C) HiSCR 100 at both week 16 and week 52 based on observed data at both visits
HiSCR, hidradenitis suppurativa clinical response; n, number of responders at week 16; Q2W, every 2 weeks; Q4W, every 4 weeks; SEC, secukinumab 300mg.

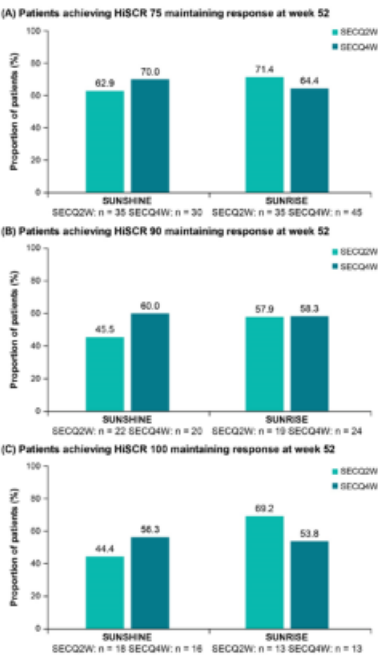


Table 1: Patient response rates in the SUNSHINE and SUNRISE trials for HiSCR 75, HiSCR 90 and HiSCR 100 at week 16 and week 52

| Patients achieving <u>HiSCR</u> 75 at week 16 (%) | | | | Patients achieving <u>HiSCR</u> 75 at week 52 (%) | | | |
|---|--------|--------|------|--|--------|----------------|----------------|
| | SECQ2W | SECQ4W | PBO | SECQ2W | SECQ4W | PBO- SECQ2W | PBO- SECQ4W |
| SUNSHINE | 26.4 | 22.6 | 16.5 | 41.9 | 37.5 | 37.9 | 36.6 |
| SUNRISE | 23.2 | 30.6 | 13.5 | 43.8 | 43.3 | 46.9 | 32.3 |
| Patients achieving <u>HiSCR</u> 90 at week 16 (%) | | | | Patients achieving <u>HiSCR</u> 90 at week 52 (%) | | | |
| | SECQ2W | SECQ4W | PBO | SECQ2W | SECQ4W | PBO- SECQ2W | PBO- SECQ4W |
| SUNSHINE | 14.3 | 13.5 | 7.1 | 24.8 | 25.0 | 20.7 | 16.9 |
| SUNRISE | 11.6 | 16.0 | 5.8 | 26.3 | 26.8 | 25.0 | 15.4 |
| Patients achieving <u>HiSCR</u> 100 at week 16 (%) | | | | Patients achieving <u>HiSCR</u> 100 at week 52 (%) | | | |
| | SECQ2W | SECQ4W | PBO | SECQ2W | SECQ4W | PBO- SECQ2W | PBO- SECQ4W |
| SUNSHINE | 12.0 | 10.4 | 4.8 | 17.1 | 18.0 | 17.2 | 12.7 |
| SUNRISE | 7.5 | 8.1 | 4.6 | 18.2 | 19.7 | 20.3 | 9.2 |
| <u>HiSCR</u> , hidradenitis suppurativa clinical response; PBO, placebo; Q2W, every 2 weeks; Q4W, every 4 weeks; SEC, secukinumab 300mg. | | | | | | | |

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