P85

Martina L. Porter | mporter3@bidmc.harvard.edu

Four-year efficacy and safety of continuous secukinumab in HS: SUNSHINE/SUNRISE core and extension trials

Martina L. Porter,[1] Christos C. Zouboulis,[2,3] Falk G. Bechara,[4] Alice B. Gottlieb,[5] Ziad Reguiaï,[3,6] Valeria Jordan M.,[7] Betrand Paguet,[7] Artem Zharkov,[7] Vipin N.,[8] Alexa B. Kimball[1]

[1]Harvard Medical School and Clinical Laboratory for Epidemiology and Applied Research in Skin (CLEARS), Department of Dermatology, Beth Israel Deaconess Medical Center, Boston, MA, USA; [2]Departments of Dermatology, Venereology, Allergology and Immunology, Staedtisches Klinikum Dessau, Brandenburg Medical School Theodor Fontane and Faculty of Health Sciences Brandenburg, Dessau, Germany; [3]European Hidradenitis Suppurativa Foundation (EHSF), Dessau, Germany; [4]Department of Dermatology, Venereology and Allergology, Ruhr-University Bochum, Bochum, Germany; ICH – International Center for Hidradenitis Suppurativa / Acne Inversa, Ruhr-University Bochum, Germany; [5]Department of Dermatology, UT Southwestern Medical Center, Dallas, TX, USA; [6]Dermatology Department, Polyclinique Courlancy- Bezannes, Reims, France; [7]Novartis Pharma AG, Basel, Switzerland; [8]Novartis Healthcare Private Limited, Hyderabad, India.

PLAIN LANGUAGE SUMMARY

Why this study was needed:

- Hidradenitis suppurativa (called 'HS' for short) is a debilitating skin disease which usually gets worse over time unless patients receive effective long-term treatments.
- This analysis aimed to show the benefits and safety profile in patients who had received 4 years of continuous secukinumab treatment.

What did this study show:

- In the population of patients that were included in this analysis, 83% were still responding to treatment after 4 years of receiving continuous secukinumab. Patients also had fewer draining tunnels (a severe symptom of HS) after 4 years of continuous treatment with secukinumab.
- Over the 4-years of continuous treatment, secukinumab was well tolerated by patients.

Why this is important:

- These findings highlight the safety and effectiveness of treatment with secukinumab through 4 years of continuous treatment.

INTRODUCTION

- In the SUNSHINE and SUNRISE core and extension trials, secukinumab was effective in improving the clinical signs and symptoms of HS for up to 2 years of treatment, while also demonstrating benefits in reducing skin pain and improving health-related quality of life.[1–4]
- The safety profile of secukinumab through 2 years of treatment during the SUNSHINE and SUNRISE core and extension trials have been consistent with the safety profile observed across multiple other indications.[1,2,5]

OBJECTIVE

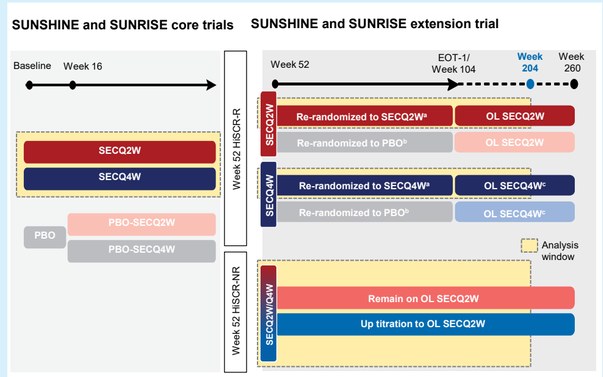
- This post hoc analysis assessed the efficacy and safety of continuous secukinumab treatment through 4 years in the SUNSHINE and SUNRISE core and extension trials.

METHODS

Analysis Design and Patients

- Patients completing the core trials could enter a 4-year extension trial, whereby patients were stratified according to their HS clinical response (HiSCR) status at Week 52 (i.e., HiSCR responders/non-responders; **Figure 1**).
- All patients who received continuous secukinumab treatment between baseline of the core trials (week 0) and week 204 of the extension trial were included in this analysis.
- Outcomes were reported irrespective of secukinumab dose (Q2W or Q4W) or up-titration.
- Data from all visits through week 204 (independent of blinded or open-label treatment status) were considered and are reported as observed without formal hypothesis testing.
- The impact of continuous secukinumab treatment was assessed through week 204 via HiSCR50/75/90/100, mean and percentage change from baseline (cfb) draining tunnel count, and safety outcomes.
- Efficacy analyses are reported for HiSCR-R on continuous secukinumab; safety analyses are reported for all patients on continuous secukinumab (HiSCR-R and HiSCR-NR).

Figure 1. Post hoc analysis of the impact of continuous secukinumab design



The complete study designs for the SUNSHINE and SUNRISE core[1] and extension[2] trials have been reported. Patients in the extension trial were stratified according to their HS clinical response at week 52 of the core trials (HiSCR-R/HiSCR-NR). HiSCR-R entered a randomized withdrawal period at week 52 until end-of-treatment-1 (EOT-1), defined as either week 104 or meeting the primary endpoint of time to loss of response (LOR; if before or at week 104). If a patient met LOR before or at week 104, they could remain in the trial by switching to open-label treatment (see symbols for treatment switching). From week 104, all treatment was open-label. This analysis reports outcomes from baseline of the core trials to week 204 only in patients receiving continuous secukinumab, including patients meeting LOR and switching from randomized treatment to open-label treatment. Patients originally assigned to placebo in the core trials and those re-randomized to receive placebo at week 52 were excluded.

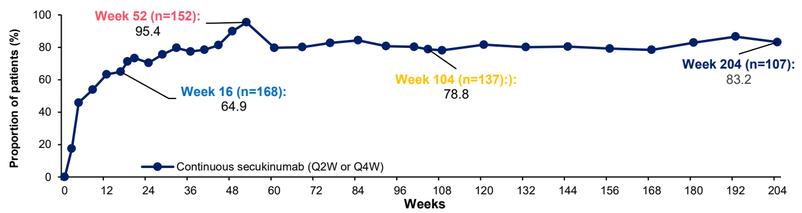
[a]Switched to OL SECQ2W if LOR occurred before week 104; [b]Switched to OL SECQ4W if LOR occurred before or at week 104; [c]May be up-titrated to the SECQ2W at the discretion of the principal investigator.

EOT, end of treatment period; HiSCR, Hidradenitis Suppurativa Clinical Response; LOR, loss of response; NR, HiSCR non-responder at week 52 of the core trial; PBO, placebo; Q2W, every 2 weeks; Q4W, every 4 weeks; R, HiSCR responder at week 52 of the core trial; SEC, secukinumab 300 mg.

RESULTS

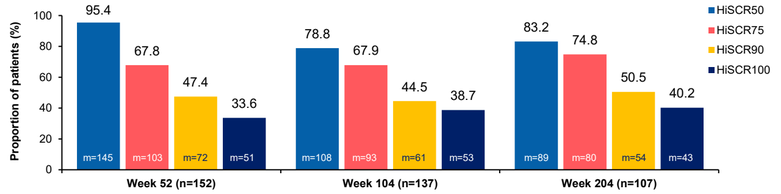
- Overall, 172 HiSCR-R and 200 HiSCR-NR received continuous secukinumab between Week 0 up to week 204 and were eligible for efficacy and safety analyses.
- HiSCR-R demonstrated sustained clinical responses on continuous secukinumab through 4 years as measured by the proportion of patients achieving HiSCR50 (83.2% [89/107]; **Figure 2**), and responses at higher clinical thresholds (**Figure 3**). Analyses of the HiSCR-NR population demonstrated a similar trend.
- In HiSCR-R patients on continuous secukinumab, 81.3% maintained HiSCR50 between weeks 52 and 204. A further 72.9%, 46.9% and 35.4% improved their response from HiSCR50 to HiSCR75, HiSCR90 and HiSCR100, respectively, between weeks 52 and 204.
- At baseline, the mean draining tunnel count was 2.3, which had notably decreased by week 16, and remained persistently low through week 204 (mean draining tunnel count: 0.8; % cfb: −68.5%; **Figure 4**).
- Treatment with continuous secukinumab was well tolerated through week 204 by both HiSCR-R and HiSCR-NR patients with a trend towards reduced exposure-adjusted incidence rates (EAIR) at week 204 (**Table 1**).
- The EAIR of safety topics of interest were generally reduced following 4-years of continuous secukinumab treatment compared to the EAIRs observed after 1-year.

Figure 2. Proportion of HiSCR-R achieving HiSCR50 through week 204



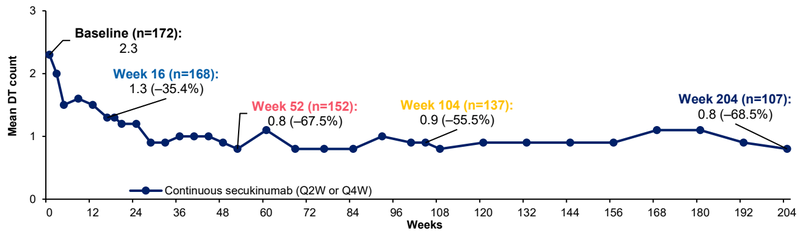
HiSCR50, hidradenitis suppurativa clinical response with a ≥50%reduction in abscess and inflammatory nodule count with no increase in abscess and/or draining tunnel number versus core trials baseline; n, number of evaluable patients with non-missing and non-zero value at core trial baseline and at the associated baseline; Q2W, every 2 weeks; Q4W, every 4 weeks.

Figure 3. HiSCR responses at greater clinical thresholds (HiSCR-50/75/90/100) at weeks 52, 104 and 204 in HiSCR-R



HiSCR50/75/90/100, Hidradenitis Suppurativa Clinical Response with a ≥50%/≥75%/≥90%/100% reduction in abscess and nodule count with no increase in abscess and/or draining tunnel number compared with baseline.
HS, hidradenitis suppurativa; m, number of evaluable patients with observed response; n, number of evaluable patients with non-missing and non-zero value at core trials baseline and at the associated visit; R, HiSCR responder at week 52 of the core trial.

Figure 4. Percentage cfb in mean draining tunnel count from core baseline to week 204 in HiSCR-R patients



cfb, change from baseline; DT, draining tunnel; HiSCR, Hidradenitis Suppurativa Clinical Response; n, number of evaluable patients with non-missing and non-zero value at core trials baseline and at the associated visit; R, HiSCR responder at week 52 of the core trial.

Table 1. Safety of treatment with secukinumab through 4 years of continuous treatment (HiSCR-R and HiSCR-NR)

Characteristic	Week 52: HiSCR-R and HiSCR-NR (N=372)[a]		Week 104: HiSCR-R and HiSCR-NR (N=372)[a]		Week 204: HiSCR-R and HiSCR-NR (N=372)[a]	
Patients with any AEs, n (%)	308 (82.8)		345 (92.7)		351 (94.4)	
Death[b]	0 (0.0)		0 (0.0)		2 (0.5)	
Non-fatal SAEs	21 (5.6)		65 (17.5)		79 (21.2)	
Discontinued study treatment due to any AEs	0 (0.0)		14 (3.8)		19 (5.1)	
Cumulative exposure (weeks), median (IQR)	52.3 (52.1, 53.3)		116.1 (114.3, 117.3)		215.1 (148.6, 217.0)	
Most common TEAEs by PT[c]	EAIR	n / EX	EAIR	n / EX	EAIR	n / EX
COVID-19	5.39	20 / 3.7	12.76	97 / 7.6	9.28	102 / 11.0
Hidradenitis	12.81	45/3.5	11.96	84 / 7.0	8.97	96 / 10.7
Headache	19.70	65 / 3.3	11.82	80 / 6.8	7.73	81 / 10.5
Nasopharyngitis	13.25	46 / 3.5	9.48	68 / 7.2	7.34	81 / 11.0
Upper respiratory tract infection	6.03	22 / 3.7	4.81	37 / 7.7	4.18	50 / 11.9
Diarrhea	7.84	28 / 3.6	4.68	35 / 7.5	3.13	37 / 11.8
Pyrexia	6.03	22 / 3.7	4.60	35 / 7.6	3.10	37 / 11.9
Safety topics of interest[c]						
Infections and infestations[d]	86.63	206 / 2.4	70.60	280 / 4.0	58.30	293 / 5.0
Upper respiratory tract infection[e]	6.03	22 / 3.7	4.81	37 / 7.7	4.18	50 / 11.9
Fungal infectious disorders[f]	10.90	39 / 3.6	8.48	62 / 7.3	6.08	69 / 11.4
Candida infections[e]	0.26	1 / 3.8	0.62	5 / 8.0	0.47	6 / 12.8
Hypersensitivity[g]	14.11	49 / 3.5	11.84	84 / 7.1	8.41	91 / 10.8
Eczema[e]	4.05	15 / 3.7	3.62	28 / 7.7	2.79	34 / 12.2
Rash[e]	2.14	8 / 3.7	1.40	11 / 7.9	0.88	11 / 12.5
Dermatitis[e]	1.06	4 / 3.8	0.75	6 / 8.0	0.47	6 / 12.7
Dermatitis contact[e]	2.67	10 / 3.7	2.03	16 / 7.9	1.36	17 / 12.5
Malignant or unspecified tumors[g]	0.26	1 / 3.8	0.62	5 / 8.0	0.47	6 / 12.8
MACE (MI, stroke, Cardiovascular death)[h]	0	0	0.12	1 / 8.0	0.23	3 / 12.9
IBD[i]	0	0	0.12	1 / 8.0	0.08	1 / 12.9

[a]Safety data are provided in a cumulative manner and includes all eligible patients through the associated timepoint and are inclusive of patients who may have discontinued treatment with secukinumab early; [b]Two deaths were reported and were both considered unrelated to treatment with secukinumab by the investigator. [c]Patients with multiple occurrences of a level under one treatment is counted only once for the same risk for that treatment. Furthermore, exposure time is censored at time of first event; [d]system organ class (SOC); [e]preferred term (PT); [f]high-level group term (HLGT); [g]standard MeDRA query (SMQ); [h]Novartis MeDRA query (NMQ); [i]customized MeDRA query (NMQ).
AE, adverse event; COVID-19, 2019 coronavirus; EAIR, exposure adjusted incidence rate per 100 patient treatment years; EX, exposure in 100 patient treatment years; HS, hidradenitis suppurativa; IQR, interquartile range; MACE, major adverse cardiovascular event; MI, myocardial infarction; N, number of evaluable patients with non-missing and non-zero value at core trial baseline; n, number of patients with observed adverse event; NR, HiSCR non-responder at week 52 of the core trial; R, HiSCR responder at week 52 of the core trial; SOC, system organ class; TEAE, treatment- emergent adverse event.

CONCLUSIONS

- Sustained clinical responses, as measured by HiSCR50, were observed with continuous secukinumab treatment through 4 years in patients with moderate to severe HS. These responses were sustained even when measured at higher clinical thresholds (HiSCR-75/90/100).
- Notable reductions to the draining tunnel count of patients persisted over the 4-year period of continuous treatment with secukinumab.
- Continuous treatment with secukinumab through 4 years demonstrated consistent benefits in efficacy for patients with moderate to severe HS and was well tolerated and in line with the known safety profile of secukinumab.

Scan to obtain:
- Poster
- Oral Presentation

https://medicalcongressposters.com/Default.aspx?doc=5c4ec

The study was sponsored by Novartis Pharma AG, Basel, Switzerland.

Poster presented at the 10th Annual Symposium on Hidradenitis Suppurativa Advances (SHSA), Nashville, TN, USA, October 31–November 02, 2025.

References

1. Kimball, AB, et al. The Lancet. 2023;401(10378): 747–61.
2. Kimball AB, et al. Br J Dermatol. 2025;192(4): 629–640.
3. Kimball AB, et al. P64857. Poster presented at: AAD Congress, Orlando, FL, USA; March 7–11, 2025.
4. Kimball AB, et al. P64674. Poster presented at: AAD Congress, Orlando, FL, USA; March 7–11, 2025.
5. Sun R, et al. Dermatol Ther (Heidelb). 2024;14(3):729–43

Acknowledgements

All authors participated in the development of this presentation. The authors thank **Priti Pandey**, MSc, for her contributions to the statistical analyses and providing thoughtful reviews of this publication. The authors also thank **Sam Ffrench-Mullen**, BSc, and **Trudy McGarry**, PhD (Novartis Ireland Ltd.) for editorial and medical writing support, which was funded by Novartis Pharma AG, Basel, Switzerland, in accordance with the Good Publication Practice (GPP 2022) guidelines (http://www.ismpp.org/gpp-2022).

Disclosures

MLP has acted as a consultant and investigator for AbbVie, Eli Lilly and Company, Incyte, Janssen, MoonLake Immunotherapeutics, Novartis, Pfizer, Prometheus, Sanofi, Sonoma Biotherapeutics and UCB; consultant for Alumis, FIDE, Trifecta Clinical/WCG and Zura Bio; investigator for Anaptys Bio, Bayer, Bristol Myers Squibb, OASIS Pharmaceuticals and Regeneron; received royalties from Beth Israel Deaconess Medical Center. **CCZ** has received advisory board and consultation fees from Almirall, Biogen, Boehringer Ingelheim, CLS Behring, Eli Lilly and Company, Estée Lauder, Idorsia, Incyte, Leo, L'OREAL, MSD, NAOS-BIODERMA, Novartis, PPM, Sanofi, ShiRhom, Takeda, UCB, and ZuraBio and lecture honoraria from Almirall, Amgen, Biogen, Bristol Myers Squibb, NAOS-BIODERMA, L'Oréal, Novartis, Pfizer, and UCB. His departments have received grants from Astra Zeneca, Boehringer Ingelheim, Bristol Myers Squibb, Brandenburg Medical School Theodor Fontane, EADV, European Union, German Federal Ministry of Education and Research, GSK, Incyte, Inflarx, MSD, Novartis, Relaxera, Sanofi, and UCB for his participation as clinical and research investigator. He is president of the EHSF e.V., the Deutsches Register Morbus Adamantiades-Behçet e.V., coordinator of the ALLOCATE Skin group of the European Reference Network for Rare and Complex Skin Diseases (ERN Skin), chair of the ARHS Task Force group of the EADV, and board member of the International Society for Behçet's Disease. He is editor of the EADV News and co-copyright holder of IHS4 on behalf of the EHSF e.V. **FGB** has received honoraria for participation in advisory boards, in clinical trials, and/or as a speaker for AbbVie Inc., AbbVie Deutschland GmbH & Co. KG, Acelyrin, Avalo, Boehringer Ingelheim Pharma GmbH & Co. KG, Celltrion, Incyte Corporation, Merck, Mölnlycke, Moonlake Immunotherapeutics, Novartis Pharma GmbH, Sitala, UCB, and Janssen-Cilag GmbH. **ABG** received research/educational grants from Bristol-Myers Squibb, Janssen, Moonlake, and UCB, (all paid to Mount Sinai School of Medicine until May 1, 2025). At UTSW she is Sub I on studies from Janssen, Bristol Myers Squibb and UCB; received honoraria as an advisory board member and consultant for Bristol Myers Squibb, Eli Lilly, Janssen, Novartis, Oruka, Sanofi, SunPharma, Takeda, Teva, UCB. **ZR** has received consulting fees and honoraria from AbbVie, Almirall, Amgen, Bristol Myers Squibb, Celltrion, Eli Lily, Janssen-Cilag, Leo-Pharma, Novartis, Pfizer, Sanofi, UCB; received personal fees for attending meetings and/or travel from AbbVie, Almirall, Eli Lily, Janssen-Cilag, Novartis, Pfizer, UCB, Sanofi; received fees as an investigator from AbbVie, Amgen, Almirall, Bayer, Boehringer Ingelheim, Celltrion, Incyte, Janssen-Cilag, Leo-Pharma, Novartis, Pfizer, Regeneron, Sanofi, UCB. **VJM, BP, AZ** and **VN** are employees of Novartis and hold company stocks. **ABK** has received consulting fees or honoraria from AbbVie, Avalo, Boehringer Ingelheim, Cellarity, Citryll, Eli Lilly, Evommune, Janssen, Merck, Moonlake, Novartis, Nurix, Pfizer, Sanofi, Sonoma Bio, Takeda, Target RWE, UCB, Union Therapeutics, Ventyx, and Zura Bio. Her institution has received grants from Acelyrin, AnaptysBio, Avalo, Bristol Myers Squibb, Eli Lilly, Incyte, Janssen, Moonlake, Novartis, Pfizer, Prometheus, Regeneron, Sanofi, Sonoma Bio, and UCB. Serves on the board of directors for Almirall.