Bimekizumab and secukinumab comparative effectiveness in hidradenitis suppurativa: Indirect treatment comparisons at Week 16 and 1 Year

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OBJECTIVE:

- In the absence of head-to-head evidence, to assess the relative efficacy at both Week 16 and 1 year of bimekizumab (BKZ) vs. secukinumab (SEC) in the treatment of patients with moderate to severe hidradenitis suppurativa (HS).

Background:

- HS is a painful, recurring skin condition that impacts patients' **quality of life**.[1,2]
- **BKZ** is a monoclonal IgG1 antibody which selectively inhibits interleukin **(IL)-17F in addition to IL-17A**.[3]
- In contrast, **SEC** inhibits **IL-17A only**.[4]

Methods:

- A **systematic literature review** was performed to identify randomized controlled trials (RCTs) in HS (25 April 2023).[3–6]
- We include trials **BE HEARD I&II (BKZ), HS0001 (BKZ)** and **SUNRISE/SUNSHINE (SEC)**.[3–6]
- Patients with **moderate to severe HS** were included.

Indirect Treatment Comparison Methodology

- The primary endpoints of RCTs (HS Clinical Response 50% [HiSCR50]) are compared using a Week 16 **Bayesian anchored indirect comparison** and a 1-year unanchored **matching-adjusted indirect comparison (MAIC)**.

1. Garg A et al. J Am Acad Dermatol. 2020;82(2):366–76; **2.** Chernyshov PV et al. Int J Environ Res Public Health. 2021;18:6131; **3.** Glatt S et al. JAMA Dermatol. 2021;157:1279–88; **4.** Kimball AB et al. Lancet. 2023;401(10378):747–61. **5.** BE HEARD I: www.clinicaltrials.gov/study/NCT04242446; **6.** BE HEARD II: www.clinicaltrials.gov/study/NCT04242498. BKZ: bimekizumab; HS: hidradenitis suppurativa; HiSCR: HS Clinical Response Score; IL: interleukin; MAIC: matching-adjusted indirect comparison; RCT: randomized controlled trial; SEC: secukinumab.

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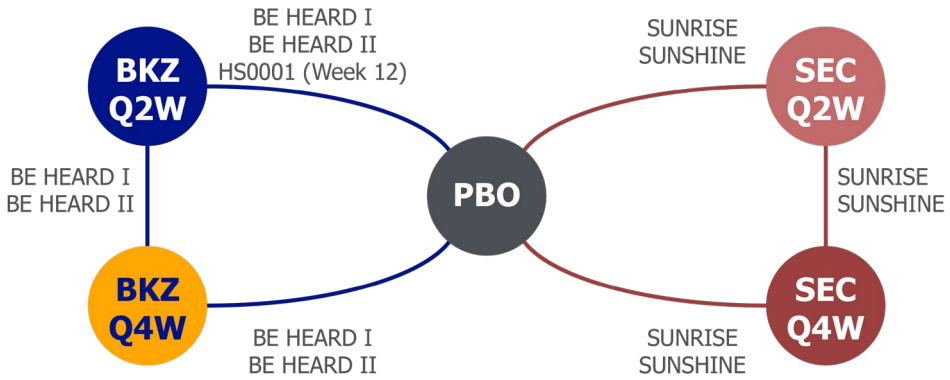
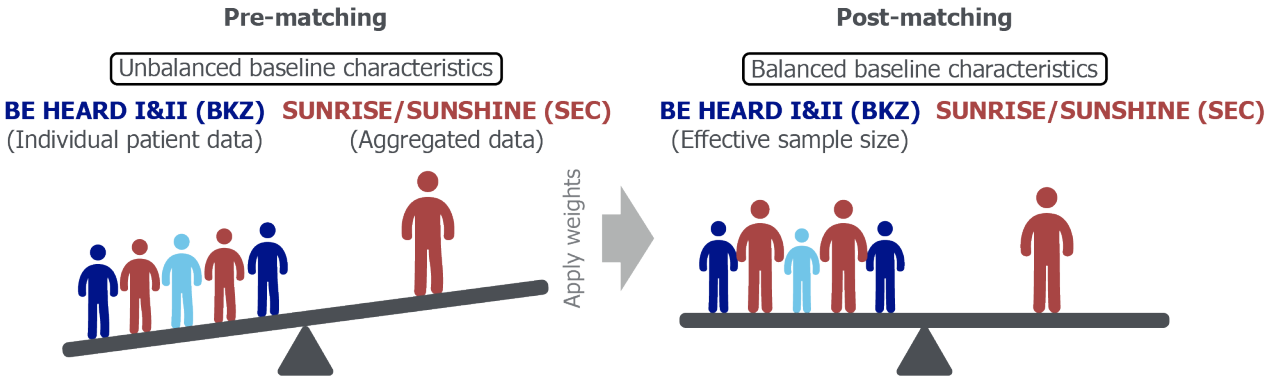
Bayesian Anchored Indirect Comparison



- **Bayesian anchored indirect comparison** is performed based on the proportion of patients who achieve HiSCR50 using a regression model with a binomial likelihood and logit link. Fixed effects model results are expressed as odds ratios (OR).
- **BKZ data were re-analyzed to match** handling of intercurrent events and imputation approach (modified non-responder imputation [mNRI] with rescue antibiotics for HS, adverse events and lack of efficacy as intercurrent events) in SEC trials.[1–4]
- BKZ- vs. SEC-only comparison was chosen due to study imputation differences.

Unanchored MAIC



- **To adjust for cross-trial differences**, individual patient data from BE HEARD I&II were **weighted to match** baseline characteristics in SEC trials (SUNRISE/SUNSHINE).[2–4]
- Weights were determined by propensity score, based on age, sex, body mass index, race, region, Hurley Stage, smoking, abscess and inflammatory nodule (AN) count, draining tunnel count, disease duration, prior biologics and concomitant antibiotics.[a]
- The analyses followed MAIC methodology described by Signorovitch et al. in accordance with the NICE Decision Support Unit Technical Support Document.[5,6]

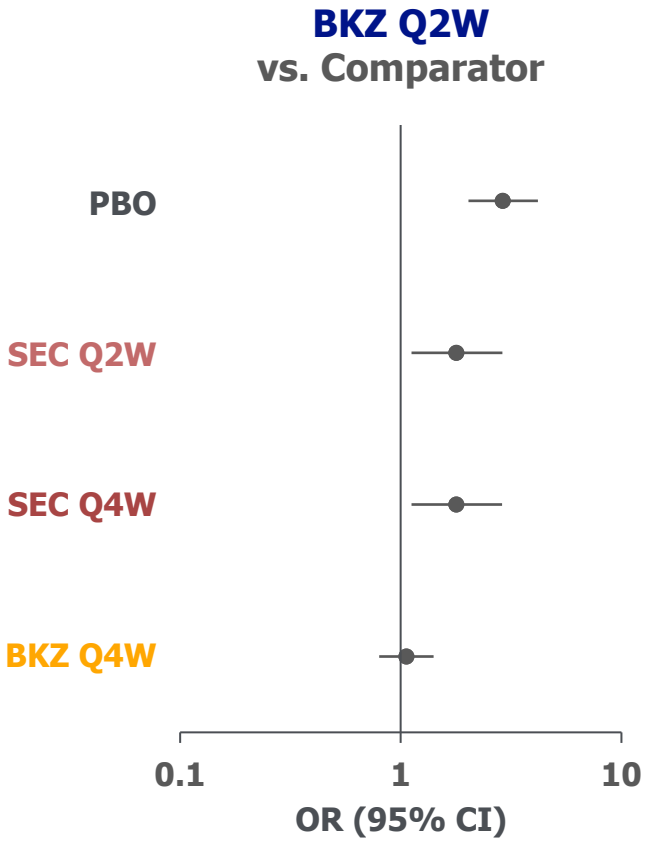
[a] Baseline inflammatory nodule and abscess count were not adjusted for, as they were collinear with baseline AN count. **1.** Glatt S et al. JAMA Dermatol. 2021;157:1279–88; **2.** BE HEARD I: www.clinicaltrials.gov/study/NCT04242446; **3.** BE HEARD II: www.clinicaltrials.gov/study/NCT04242498; **4.** Kimball AB et al. Lancet. 2023;401(10378):747–61; **5.** NICE Decision Support Unit Technical Support Document 18.; **6.** Signorovitch JE et al. Value Health. 2012;15(6):940–7. AN: abscess and inflammatory nodule; BKZ: bimekizumab; HS: hidradenitis suppurativa; HiSCR: HS Clinical Response Score; MAIC: matching-adjusted indirect comparison; mNRI: modified non-responder imputation; OR: odds ratio; Q2W: every 2 weeks; Q4W: every 4 weeks; SEC: secukinumab.

Baseline Characteristics

Trial	SUNRISE/SUNSHINE Aggregated	BE HEARD I&II POOLED Pre-Adjustment	BE HEARD I&II POOLED Post-Adjustment[a]
Treatment regimen	SEC Q2W	BKZ Q2W/Q4W	BKZ Q2W/Q4W
N or ESS	361	291	226[b]
Age, mean ± SD	37.2 ± 12.0	37.0 ± 12.4	37.2 ± 12.0
Male, n (%)	162 (45.0)	118 (40.5)	102 (45.0)
White, n (%)	278 (77.0)	232 (79.7)	174 (77.0)
BMI, mean ± SD	32.3 ± 7.9	32.7 ± 7.9	32.3 ± 7.9
AN count, mean ± SD	13.4 ± 9.8	17.1 ± 16.7	13.4 ± 9.8
DT count, mean ± SD	3.0 ± 3.5	3.8 ± 4.4	3.0 ± 3.5
Smoking, n (%)	193 (53.4)	134 (46.0)	121 (53.5)
Hurley Stage III, n (%)	153 (42.5)	131 (45.0)	96 (42.5)
Region (US), n (%)	55 (15.2)	87 (29.9)	34 (15.2)
Disease duration (years), mean ± SD	7.3 ± 7.5	8.2 ± 7.6	7.3 ± 7.5
Prior biologics, n (%)	79 (22.0)	56 (19.2)	50 (22.0)
Concomitant antibiotics, n (%)	43 (12.0)	28 (9.6)	27 (12.0)

[a] Adjustment performed as part of the 1-year unanchored MAIC analysis. **[b]** Adjusting for: age, sex, body mass index, race, region, Hurley Stage, smoking, AN count, DT count, disease duration, prior biologics and concomitant antibiotics. AN: abscess and inflammatory nodule; BKZ: bimekizumab; BMI: body mass index; DT: draining tunnels; ESS: effective sample size; Q2W: every 2 weeks; Q4W: every 4 weeks; SEC: secukinumab; SD: standard deviation; US: United States.

Bayesian Anchored Indirect Comparison: BKZ vs. Comparator HiSCR50 Week 16



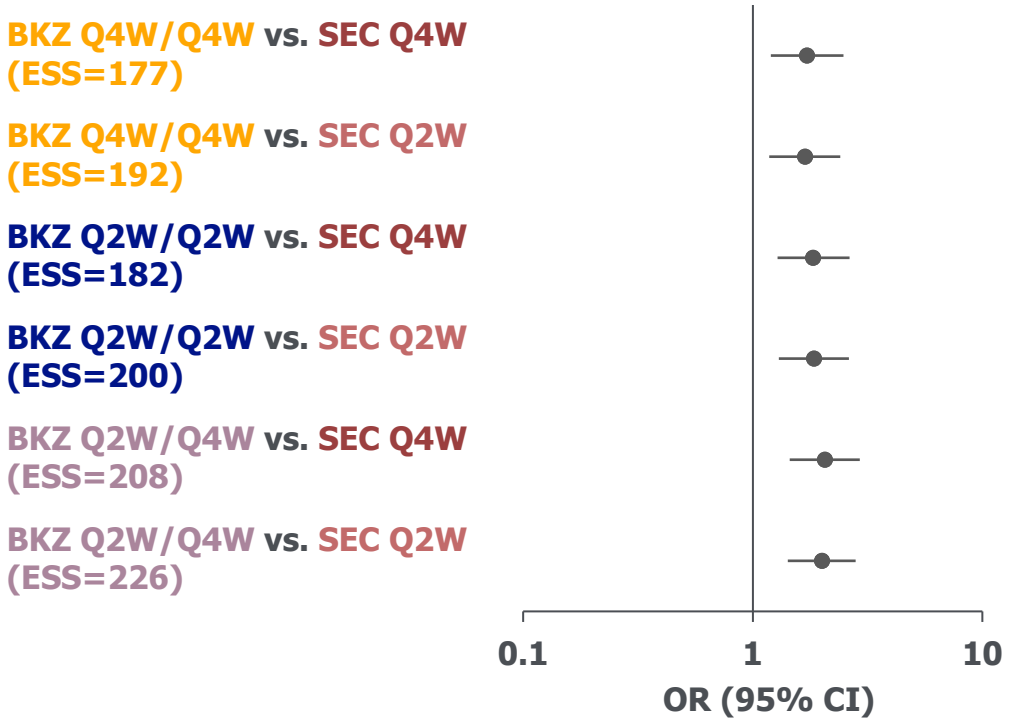
BKZ Q2W or BKZ Q4W vs. SEC

	OR (95% CrI)[a]
BKZ Q2W vs. SEC Q2W	1.79 (1.12, 2.89)
BKZ Q2W vs. SEC Q4W	1.79 (1.12, 2.88)
BKZ Q4W vs. SEC Q2W	1.69 (1.02, 2.83)
BKZ Q4W vs. SEC Q4W	1.69 (1.02, 2.82)

BKZ Q2W and Q4W showed **higher HiSCR50 responses** when indirectly compared with SEC.

MAIC: BKZ vs. SEC HiSCR50 1 Year

BKZ Q2W or BKZ Q4W vs. SEC Q4W or SEC Q2W (NRI)



BKZ demonstrated **higher HiSCR50 responses** when compared with SEC in the MAIC analysis.

[a] Blue outline indicates difference favoring BKZ in comparison to SEC. BKZ: bimekizumab; CI: confidence interval; CrI: credible interval; ESS: effective sample size; HiSCR: HS Clinical Response Score; MAIC: matching-adjusted indirect comparison; NRI: non-responder imputation; OR: odds ratio; PBO: placebo; Q2W: every 2 weeks; Q4W: every 4 weeks; SEC: secukinumab.

CONCLUSIONS:

- Both bimekizumab Q2W and Q4W showed **higher HiSCR50 responses** when indirectly compared to secukinumab, according to **Bayesian anchored indirect comparison** performed at Week 16.
- Results of the MAIC analysis at 1 year were consistent with those of Week 16, and bimekizumab showed a **higher likelihood** of a **HiSCR50 response** than secukinumab.

LIMITATIONS:

- The small number of SLR-identified studies used varied methodologies and imputation methods; this could have resulted in heterogeneity that could not be accounted for.
- The MAIC was potentially limited as the analysis could only adjust for the baseline variables reported in the secukinumab studies.
- Differences in study design were another source of uncertainty.

Author Contributions: Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **AG, LD, VT, SK, VP;** Drafting of the publication, or revising it critically for important intellectual content: **AG, LD, VT, SK, VP;** Final approval of the publication: **AG, LD, VT, SK, VP**. **Disclosures: AG:** Consultant for AbbVie, Aclaris Therapeutics, AnaptysBio, Aristea Therapeutics, Bristol Myers Squibb, Boehringer Ingelheim, Incyte, Insmed, Janssen, Novartis, Pfizer, Sonoma Biotherapeutics, UCB Pharma, Union Therapeutics, Ventyx Biosciences and Viela Biosciences, and receives honoraria. Received research grants from AbbVie, C3, National Psoriasis Foundation and UCB Pharma. Co-copyright holder of HiSQOL and HS-IGA. **LD, VT, SK:** Employees and shareholders of UCB Pharma. **VP:** Consulting fees from AbbVie, Amgen, Boehringer Ingelheim, Celgene, Dermira, Janssen, Eli Lilly, Medimmune, Novartis, Pfizer, Sun Pharma, UCB Pharma and Valeant.

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