Bimekizumab clinical efficacy responses translate into improvements in patient outcomes to Week 48 in patients with moderate to severe hidradenitis suppurativa: Results from BE HEARD I&II

Alexa B. Kimball,[1] Amit Garg,[2] Hadar Lev-Tov,[3] Kelsey R. van Straalen,[4] Evangelos J. Giamarellos-Bourboulis,[5,6] Koremasa Hayama,[7] Bartosz Lukowski,[8] Robert Rolleri,[9] Jérémy Lambert,[10] Tom Vaux,[11] Linnea Thorlacius[12]

[1]Beth Israel Deaconess Medical Center and Harvard Medical School, Boston, MA, USA; [2]Northwell, New Hyde Park, NY, USA; [3]Dr. Phillip Frost Department of Dermatology and Cutaneous Surgery, University of Miami Miller School of Medicine, Miami, FL, USA; [4]Department of Dermatology, Erasmus University Medical Center, Rotterdam, The Netherlands; [5]European Hidradenitis Suppurativa Foundation (EHSF), Dessau, Germany; [6]4th Department of Internal Medicine, National and Kapodistrian University of Athens, Medical School, Athens, Greece; [7]Division of Cutaneous Science, Department of Dermatology, Nihon University School of Medicine, Tokyo, Japan; [8]Vedim/UCB, Warsaw, Poland; [9]UCB, Morrisville, NC, USA; [10]UCB, Colombes, France; [11]UCB, Slough, UK; [12]Department of Dermatology, Zealand University Hospital, Roskilde, Denmark

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OBJECTIVE

- To report how achieving increasingly higher hidradenitis suppurativa (HS) Clinical Response (HiSCR) thresholds associates with improvements in health-related quality of life (HRQoL) and patient-reported skin pain with bimekizumab (BKZ) treatment.

Background

- HS is a chronic skin disease whereby debilitating symptoms **reduce patients' HRQoL**.[1,2]
- Achievement of **higher HiSCR thresholds** has translated into **better patient outcomes**, including QoL and skin pain.[3,4]
- **BKZ** is a humanized IgG1 monoclonal antibody that selectively inhibits interleukin (IL)-17F and IL-17A and has previously demonstrated **depth** and **durability** of response.[5,6]

Methods

- BKZ-treated patients were grouped by achievement of **mutually exclusive HiSCR thresholds** at Week 16 and 48.
- Associations between HiSCR thresholds and **HS QoL questionnaire (HiSQOL) response** or **HS symptom questionnaire (HSSQ) skin pain response** were assessed at Week 16 and 48.
- Data are reported for patients randomized to BKZ 320 mg from baseline in BE HEARD I&II (**BKZ Total**).[6]
- Data are reported as observed case (OC).

Associations investigated:

1. Chernyshov PV et al. J Eur Acad Dermatol Venereol 2019;33;1633–43; **2.** Matusiak Ł et al. Acta Derm Venereol 2018;98:191–4; **3.** Gottlieb AB et al. ISPOR-US 2024; Poster 138629; **4.** Horváth B et al. ISPOR-EU 2024; Poster PCR53; **5.** Adams R et al. Front Immunol 2020;11:1894; **6.** Kimball AB at al. Lancet 2024;403:2504–19 (NCT04242446, NCT04242498). BKZ: bimekizumab; HS: hidradenitis suppurativa; HiSCR: HS Clinical Response; HiSQOL: HS QoL questionnaire; HSSQ: HS symptom questionnaire; IL: interleukin; OC: observed case; QoL: quality of life.

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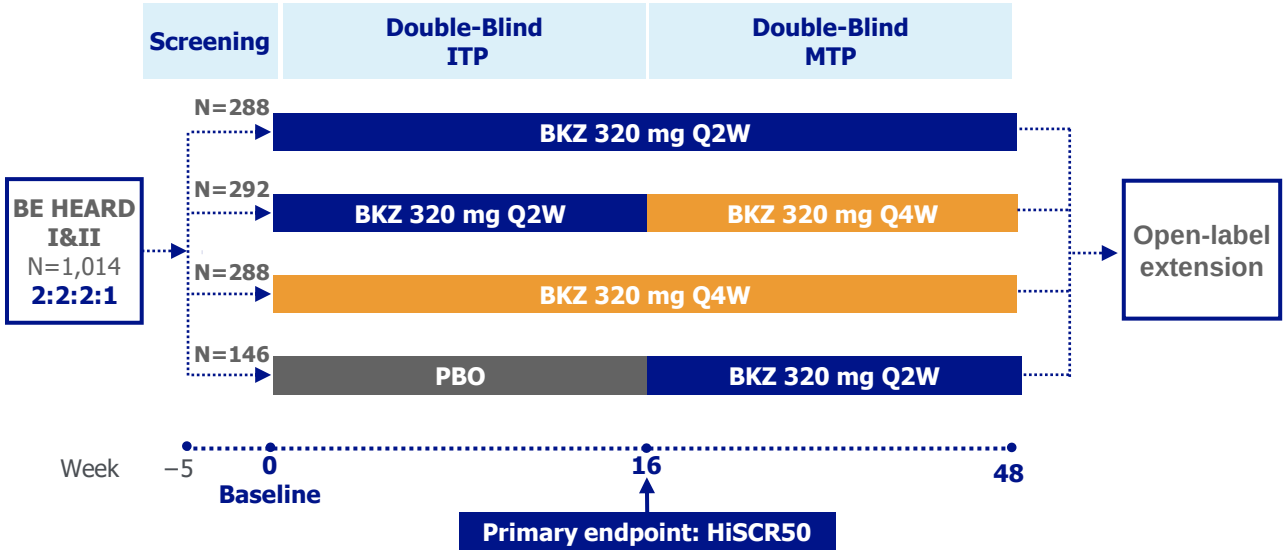
Study Design



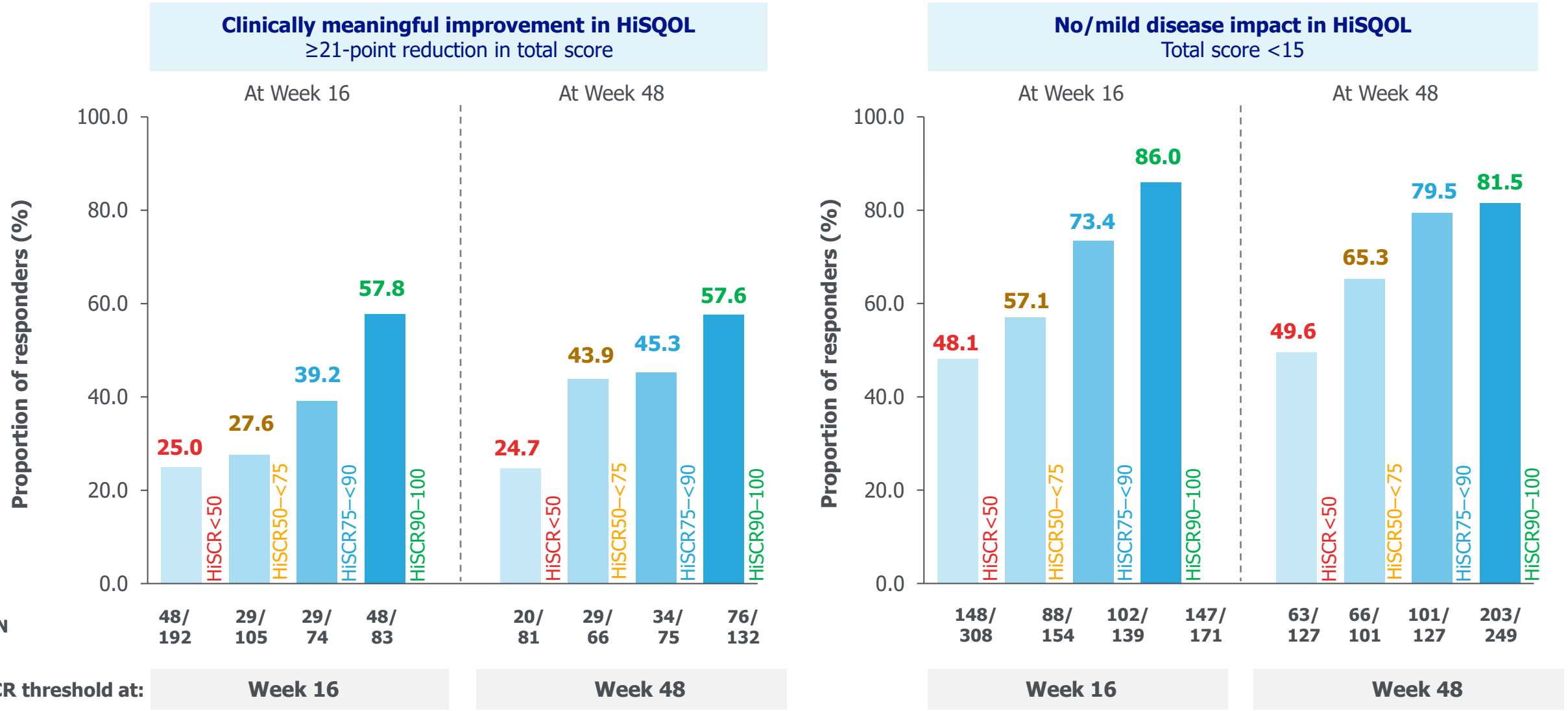
- Data were pooled from the phase 3 trials BE HEARD I&II for patients with moderate to severe HS.[1] BKZ Total comprises all patients randomized to BKZ from baseline.

Baseline Characteristics

	BKZ 320 mg Total N=868
Age (years), mean (SD)	36.5 (12.1)
Sex, female, n (%)	501 (57.7)
Racial group, n (%)	
White	689 (79.4)
Black	97 (11.2)
BMI (kg/m²), mean (SD)	33.1 (8.1)
Duration of HS (years), mean (SD)	7.7 (7.4)
AN Count, mean (SD)	16.6 (16.9)
DT Count, mean (SD)	3.6 (4.3)
Hurley Stage, n (%)	
II	486 (56.0)
III	382 (44.0)
DLQI total score, mean (SD)	11.2 (6.9)
HiSQOL total score, mean (SD)	25.0 (13.3)
HSSQ skin pain score, mean (SD)	5.8 (2.4)
Prior biologic use,[a] n (%)	162 (18.7)
Baseline antibiotic use, n (%)	75 (8.6)

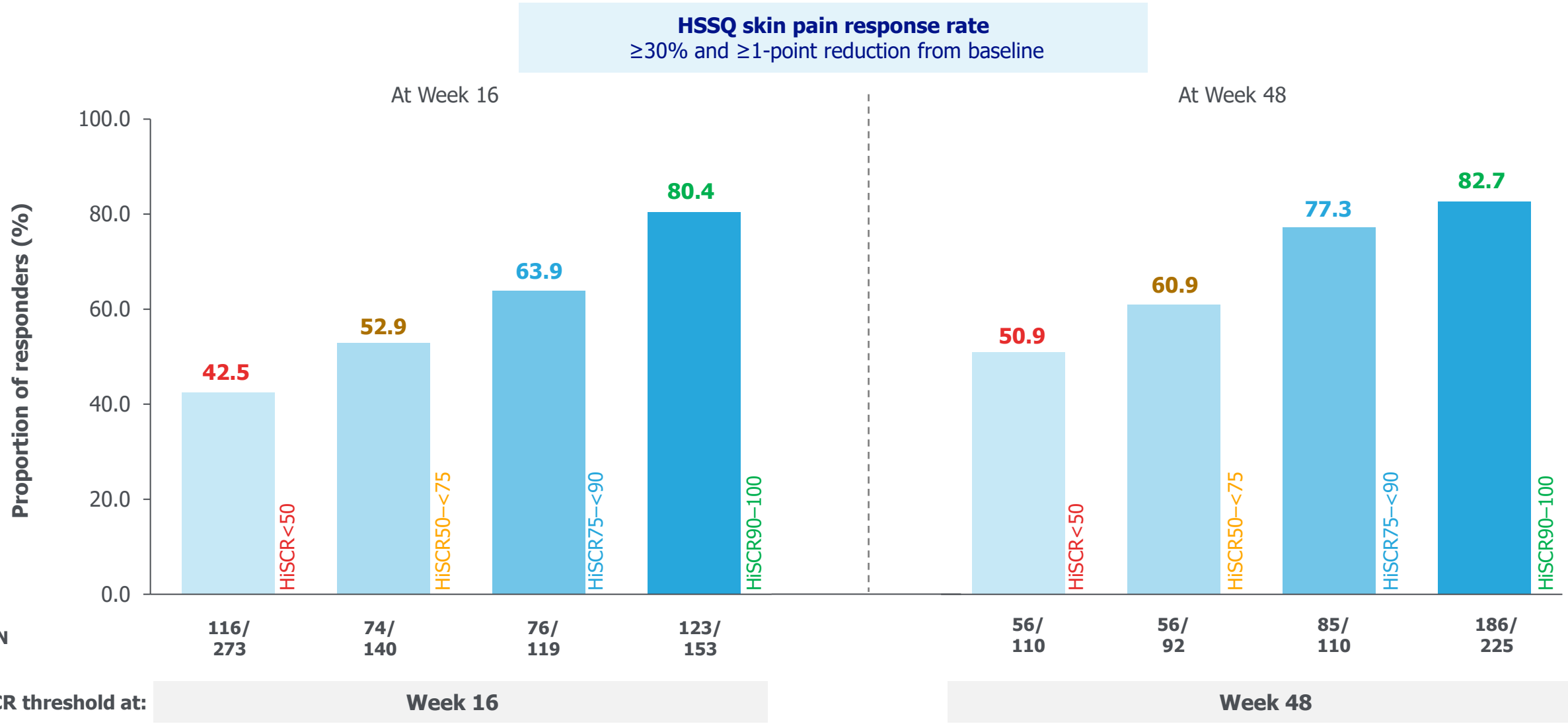
1. Kimball AB at al. Lancet 2024;403:2504–19 (NCT04242446, NCT04242498). **[a]** Patients received prior biologic therapy for any indication. AN: abscess and inflammatory nodule; BKZ: bimekizumab; BMI: body mass index; DLQI: Dermatology Life Quality Index; DT: draining tunnel; HiSCR50: ≥50% reduction in total abscess and inflammatory nodule count from baseline with no increase from baseline in abscess or draining tunnel count; HiSQOL: hidradenitis suppurativa quality of life; HS: hidradenitis suppurativa; HSSQ: HS symptom questionnaire; ITP: initial treatment period; MTP: maintenance treatment period; Q2W: every 2 weeks; Q4W: every 4 weeks; PBO: placebo; SD: standard deviation.

HiSQOL Total Score Responses at Week 16/48 by HiSCR Threshold in BKZ Total Patients (OC)



Pooled data; BKZ Total (N=868) comprised patients randomized to BKZ from baseline, **90.0%/70.9% of patients completed Week 16/48**. OC n/N: denominator represents number of patients with a non-missing HiSQOL assessment in the given week, and percentages are calculated accordingly. BKZ: bimekizumab; HiSCR: hidradenitis suppurativa Clinical Response; HiSCR50/75/90/100: 50%/75%/90%/100% reduction in total abscess and inflammatory nodule count from baseline with no increase from baseline in abscess or draining tunnel count; HiSQOL: hidradenitis suppurativa quality of life; OC: observed case.

HSSQ Skin Pain Responses at Week 16/48 by HiSCR Threshold in BKZ Total Patients (OC)



Pooled data; BKZ Total (N=868) comprised patients randomized to BKZ from baseline, **90.0%/70.9% of patients completed Week 16/48**. HSSQ response for the skin pain item is defined as **≥30% reduction and ≥1-point reduction** from baseline. Only study participants with a score of ≥3 at baseline are included. OC n/N: denominator represents number of patients with a non-missing HSSQ assessment in the given week, and percentages are calculated accordingly. BKZ: bimekizumab; HiSCR: hidradenitis suppurativa Clinical Response; HiSCR50/75/90/100: 50%/75%/90%/100% reduction in total abscess and inflammatory nodule count from baseline with no increase from baseline in abscess or draining tunnel count; HSSQ: hidradenitis suppurativa symptom questionnaire; OC: observed case.

CONCLUSIONS:

With bimekizumab treatment over 1 year, **higher efficacy** measured by HiSCR, translated into **greater improvements** in HS-specific skin pain and health-related quality of life outcomes.

Higher treatment goals should be targeted to provide better **patient-reported outcomes**.

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