

Bimekizumab Efficacy by Patient Subgroups in Moderate to Severe Hidradenitis Suppurativa: 3-Year Phase 3 Results From BE HEARD EXT

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Objective

- To report bimekizumab (BKZ) **efficacy and maintenance of clinical response over 3 years** across **different subgroups** of patients with moderate to severe hidradenitis suppurativa (HS) using phase 3 (BE HEARD I&II) and open label extension (BE HEARD EXT) data.

Background

- HS disease varies between individuals based on patient and disease characteristics, such as sex and disease duration.¹
- Biological therapies which provide **consistent efficacy**, regardless of patient characteristics, are needed.
- BKZ** is a humanized IgG1 monoclonal antibody that selectively inhibits interleukin (IL)-17A and IL-17F.²

Methods

- Data were pooled from the **phase 3 BE HEARD I&II** trials and their open-label extension, **BE HEARD EXT** (full study details available via QR code).^{3,4}
- Patients completing the 48-week BE HEARD I&II studies could enrol in BE HEARD EXT and receive open-label BKZ 320 mg every 2 weeks (Q2W) or every 4 weeks (Q4W) based on **HS Clinical Response (HiSCR)-90** response, averaged from Weeks 36, 40, and 44.
- We report the rates of patients achieving HiSCR50/90 for subgroups at Years 1, 2, and 3 (Weeks 48, 96, and 148).
- Data are reported as observed case (OC) for patients randomized to BKZ 320 mg from baseline in BE HEARD I&II who entered BE HEARD EXT and continued to receive BKZ (**BKZ Total**).

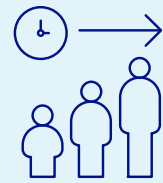
1. Schrader AMR. et al. J Am Acad Dermatol 2014;71:460–7; 2. Adams R. et al. Front Immunol 2020;11:1894; 3. Kimball AB. et al. Lancet 2024;403:2504–19 (NCT04242446, NCT04242498); 4. BE HEARD EXT (NCT04901195): www.clinicaltrials.gov/study/NCT04901195. BKZ: bimekizumab; HiSCR: HS Clinical Response; HiSCR50/90: ≥50/90% reduction from baseline in total abscess and inflammatory nodule count, with no increase from baseline in abscess or draining tunnel count; HS: hidradenitis suppurativa; IL: interleukin; OC: observed case; Q2W: every 2 weeks; Q4W: every 4 weeks.

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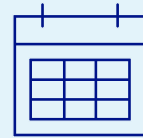
Summary

Bimekizumab-treated patients achieved **high clinical response rates across** the following **subgroups** at **1 year**, with **responses maintained** through to **3 years**.



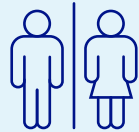
Age:^a

<median, 35 years
≥median, 35 years



Duration of HS:^a

<median, 5.02 years
≥median, 5.02 years



Sex:

Male
Female



Hurley stage:

II
III



Weight:

≤100 kg
>100 kg



BMI:

<30 kg/m²
30–35 kg/m²
≥35 kg/m²



Prior biologic use:^b

Yes
No

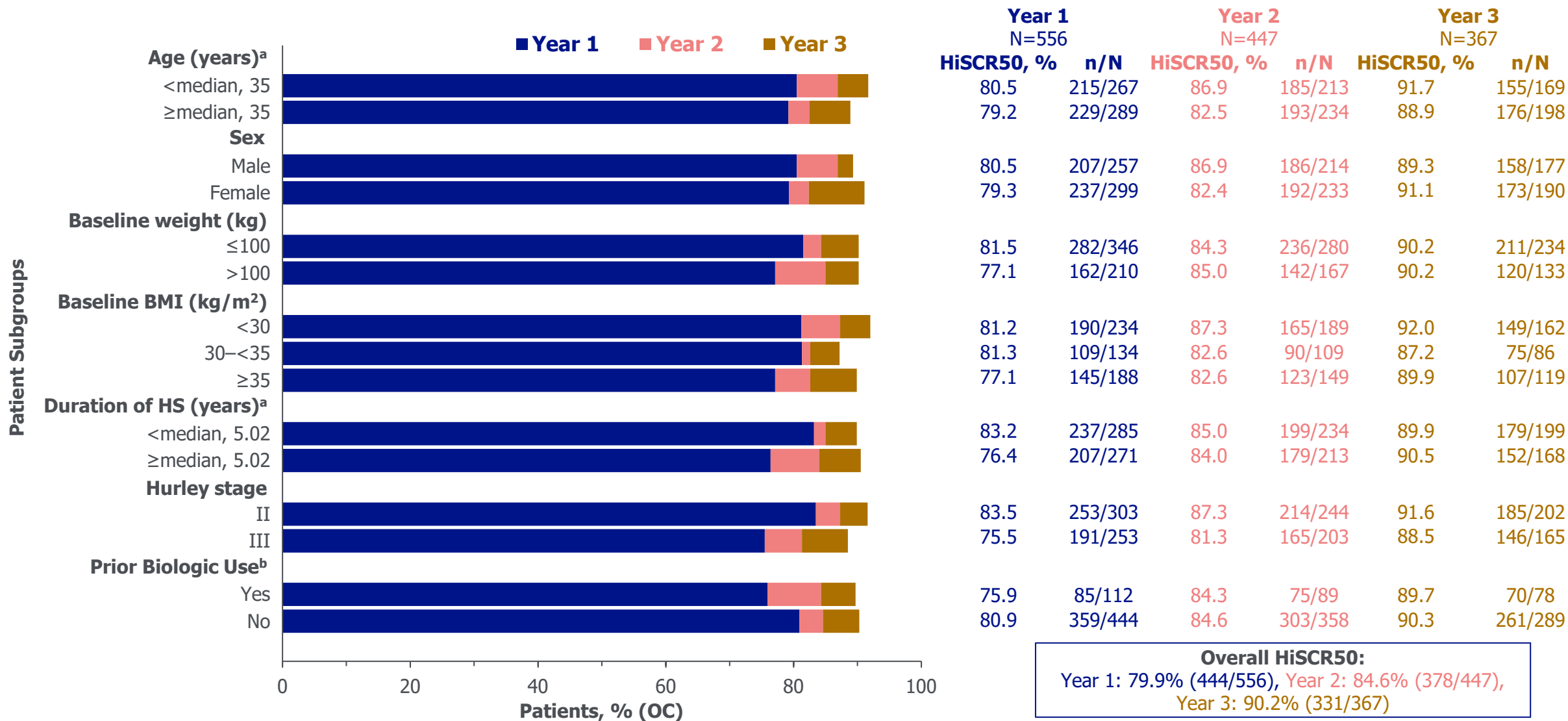
At Year 3 in all presented subgroups, **HiSCR50 achievement** was **≥87.2%**, while **HiSCR90 achievement** was **≥59.3%**.

Baseline Characteristics

	BKZ Total N=556
Age (years) , mean (SD)	36.3 (12.2)
Sex, female , n (%)	299 (53.8)
Racial group, white , n (%)	448 (80.6)
Weight (kg) , mean (SD)	96.2 (23.5)
BMI (kg/m²) , mean (SD)	32.5 (7.8)
Duration of HS (years) , mean (SD)	7.4 (7.1)
Hurley stage , n (%)	
II	303 (54.5)
III	253 (45.5)
Prior biologic use^b , n (%)	112 (20.1)
IHS4 severity , n (%)	
Mild: ≤3	0
Moderate: 4–10	70 (12.6)
Severe: ≥11	486 (87.4)

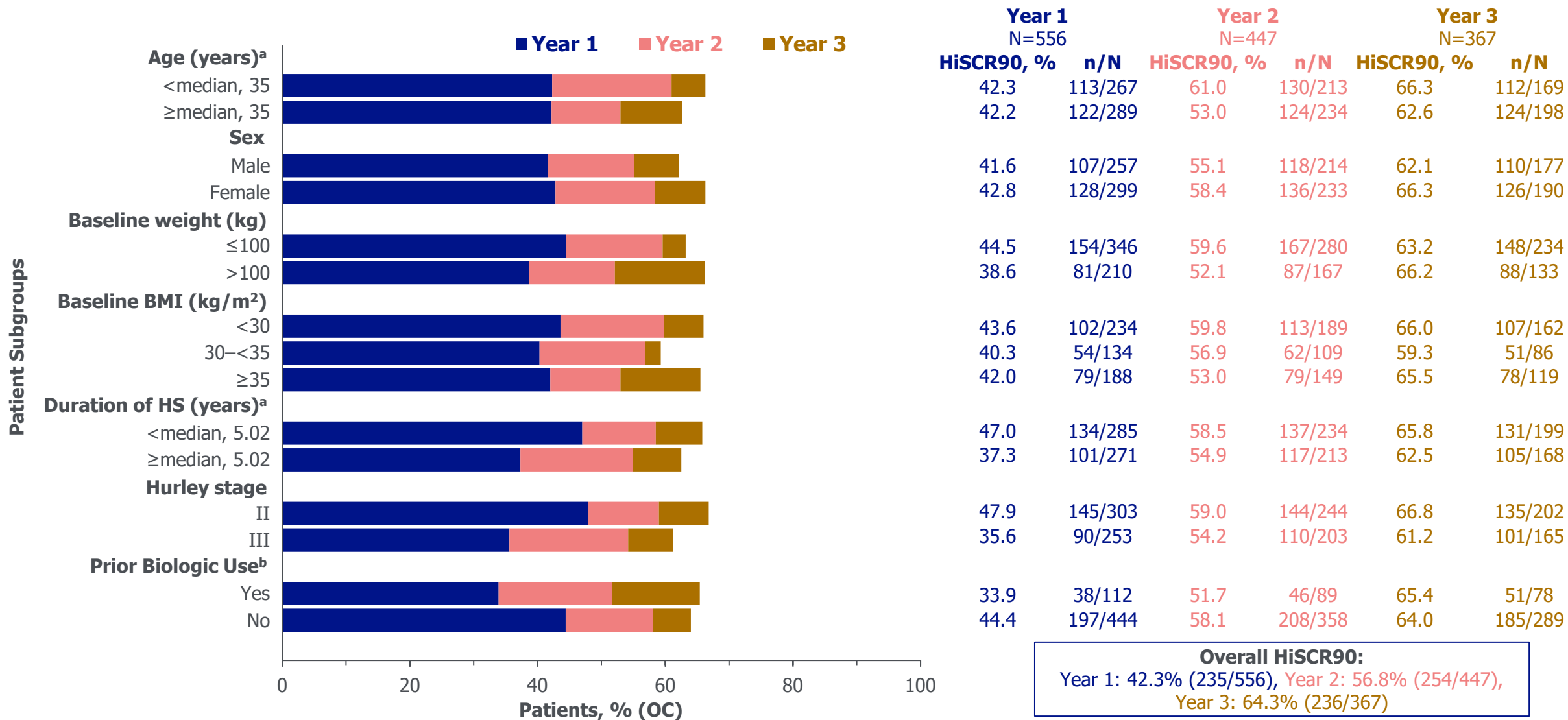
OLE set; only included patients who entered BE HEARD EXT at Week 48. BKZ Total (N=556) comprised patients randomized to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT and continued to receive BKZ. **[a]** Median years calculated based on all subjects who entered BE HEARD I&II at baseline (N=657); **[b]** Patients received prior biologic therapy for any indication. BKZ: bimekizumab; BMI: body mass index; HiSCR: HS Clinical Response; HiSCR50/90: ≥50/90% reduction from baseline in the total abscess and inflammatory nodule count, with no increase from baseline in abscess or draining tunnel count; HS: hidradenitis suppurativa; IHS4: International Hidradenitis Suppurativa Severity Score System; OLE: open-label extension; SD: standard deviation.

Most Patients Across Subgroups Achieved HiSCR50 at Year 1, With Responses Maintained Through to Year 3



OLE set; only included patients who entered BE HEARD EXT at Week 48. BKZ Total (N=556) comprised patients randomized to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT and continued to receive BKZ. n/N: denominator represents number of patients with a non-missing lesion count assessment in the given week, and percentages are calculated accordingly. **[a]** Median value calculated based on all subjects who entered BE HEARD I&II at baseline (N=657); **[b]** Patients received prior biologic therapy for any indication. BKZ: bimekizumab; BMI: body mass index; HiSCR50: ≥50% reduction from baseline in the total abscess and inflammatory nodule (AN) count, with no increase from baseline in abscess or draining tunnel (DT) count; HS: hidradenitis suppurativa; OC: observed case; OLE: open-label extension.

Most Patients Across Subgroups Achieved HiSCR90 at Year 2, With Responses Maintained Through to Year 3, Indicating That Deeper Responses Take Longer



OLE set; only included patients who entered BE HEARD EXT at Week 48. BKZ Total (N=556) comprised patients randomized to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT and continued to receive BKZ. n/N: denominator represents number of patients with a non-missing lesion count assessment in the given week, and percentages are calculated accordingly. **[a]** Median value calculated based on all subjects who entered BE HEARD I&II at baseline (N=657); **[b]** Patients received prior biologic therapy for any indication. BKZ: bimekizumab; BMI: body mass index; HiSCR90: ≥90% reduction from baseline in the total abscess and inflammatory nodule (AN) count, with no increase from baseline in abscess or draining tunnel (DT) count; HS: hidradenitis suppurativa; OC: observed case; OLE: open-label extension.

Conclusions



Patients treated with bimekizumab demonstrated high clinical response rates across all subgroups at 1 year, with responses maintained through to 3 years.



These results emphasize the long-term benefit of bimekizumab as an effective treatment option for patients with hidradenitis suppurativa, regardless of patient demographics and disease characteristics.

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