Bimekizumab demonstrated a favorable safety profile and high levels of efficacy with up to 2 years of treatment in patients with moderate to severe hidradenitis suppurativa: Pooled results from two phase 3 randomized, controlled trials and their open-label extension

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Background: Hidradenitis suppurativa is a chronic inflammatory disease, requiring treatment with durable efficacy and tolerability.

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Data sharing statement: Underlying data from this manuscript can be requested by qualified researchers 6 months after product approval in the United States of America and Europe, or global development is discontinued, and 18 months after trial completion. Investigators can request access to anonymized individual patient-level data and redacted trial documents, which can include analysis-ready datasets, study protocol, annotated case-report form, statistical analysis plan, dataset specifications, and clinical study report. Before use of the data, proposals need to be approved by an independent review panel at https://Vivli.org/and a signed data-sharing agreement will need to be executed. All documents are available in English only, for a prespecified time, typically 12 months, on a password-protected portal.

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Objective: To report the safety and efficacy of bimekizumab up to 2 years.

Methods: Data from the BE HEARD I&II phase 3 trials and their open-label extension, BE HEARD Extension, were pooled to assess the safety and efficacy of bimekizumab in patients with moderate to severe hidradenitis suppurativa up to 2 years. For safety, exposure-adjusted incidence rates of treatment-emergent adverse events per 100 patient-years (TEAEs/100 PY) were evaluated. For efficacy, lesional-/skin pain-/health-related quality of life (HRQoL) outcomes were assessed.

Results: Five hundred fifty-six patients entered the open-label extension; 446 received bimekizumab to Year 2. TEAEs did not increase with longer bimekizumab exposure (Year 1: 261.6/100 PY; Year 2: 235.7/100 PY). In Year 2, the most common TEAEs were hidradenitis (26.6/100 PY), coronavirus infection (23.1/100 PY), and oral candidiasis (12.5/100 PY). Most patients achieved HiSCR50/75/90/100 at Year 2 (85.4%/77.1%/57.6%/44.2%). Improvements in skin pain and HRQoL achieved at Year 1 were sustained at Year 2.

Limitations: Patient inclusion criteria limit real-world generalizability.

Conclusions: Bimekizumab was well-tolerated up to 2 years; no new safety signals were identified with longer exposure. Bimekizumab provided deep, durable improvements in clinical and HRQoL outcomes. (J Am Acad Dermatol 2026;94:867-78.)

Key words: BE HEARD; bimekizumab; cytokines; hidradenitis suppurativa; IL-17 inhibitors; inflammatory skin disease; open-label extension; randomized controlled trial.

INTRODUCTION

Hidradenitis suppurativa (HS) is a chronic, progressive, inflammatory skin disease characterized by painful nodules, abscesses, and tunnels/fistulae, primarily affecting the axillary, inguinal, gluteal, and perianal areas.[1-4] Characterized as a complex disease, HS is influenced by genetic, environmental, and immunologic factors; proinflammatory cytokines interleukin (IL)-17A and IL-17F have been identified in HS lesions.[5-8]

CAPSULE SUMMARY

- Bimekizumab demonstrated high efficacy with favorable safety among patients with moderate to severe hidradenitis suppurativa for 1 year; here, bimekizumab data are reported for up to 2 years.
- Rates of treatment-emergent adverse events did not increase, no new safety signals were observed, and bimekizumab provided durable and consistent efficacy.

Patients with HS face physical, socioeconomic, and psychological decline, as well as higher mortality, suicidal ideation and behavior (SIB), and comorbidities including cardiovascular disease, diabetes, and inflammatory bowel disease (IBD) versus the general population.[1,9-14]

Recurrent flares can lead to irreversible skin damage and scarring.[15] In severe cases, deep abscesses may develop, which can progress to draining tunnels (DTs).[16] DTs, unique to HS, are associated with a more aggressive disease course and represent a significant challenge for patients and clinicians.[17,18] Compared with patients without DTs, patients with DTs experience more inflammation, discharge, pain, and fatigue.[16] Consequently, DTs are associated with lower health-related quality of life (HRQoL).[18]

Despite guidelines recommending early intervention, patients experience long diagnosis delays.[4] Conventional management includes antibiotics, surgery, and biologics.[19,20] Biologic treatment remains limited, with few approved options and variable tolerability and efficacy.[21-25] Durable and consistent treatments are needed to address the chronic nature of HS.

Bimekizumab is a humanized immunoglobulin G1 (IgG1) monoclonal antibody that selectively inhibits IL-17F in addition to IL-17A.[26] *In vitro* HS models have shown that dual inhibition of IL-17A and IL-17F suppresses proinflammatory cytokine production more than inhibition of either isoform alone.[27]

In the phase 3 BE HEARD I and II trials, bimekizumab was well-tolerated with a safety profile consistent with studies of bimekizumab in other indications and showed clinically meaningful improvements in efficacy, patient-reported symptoms, and HRQoL over 1 year.[28-32] In 2024, bimekizumab received approval in the European Union, Japan, and the United States for patients with moderate to severe HS.[33-35]

Here, the safety and efficacy of bimekizumab are reported up to 2 years using pooled BE HEARD I and II data (Year 1) and their open-label extension (OLE), BE HEARD Extension (Year 2).

Abbreviations used:

DT:	draining tunnel
EAIR:	exposure-adjusted incidence rate
HRQoL:	health-related quality of life
HS:	hidradenitis suppurativa
IBD:	inflammatory bowel disease
IL:	interleukin
MACE:	major adverse cardiac events
SIB:	suicidal ideation and behavior
TEAE:	treatment-emergent adverse event

METHODS

Study design and treatment

BE HEARD I and II were identically-designed, 48-week randomized controlled trials.[32] BE HEARD Extension was conducted at 143 centers from regions that enrolled patients in BE HEARD I and II (Europe, North America, Asia/Australia, and the Middle East). The OLE is ongoing (interim cut-off: November 17, 2023) and planned to continue for up to 188 weeks in ongoing centers.

Patients completing Week 48 of BE HEARD I and II could enroll in BE HEARD Extension (Supplemenatry Fig 1, available via Mendeley at https://data.mendeley.com/datasets/8bjtsp9cf2/1). Treatment allocation was based on BE HEARD I and II ≥90% HS Clinical Response (HiSCR90) status (≥90% reduction in abscess and inflammatory nodule [AN] count from baseline with no increase from baseline in abscess or DT count, averaged from Weeks 36, 40, and 44). HiSCR90 non-responders received subcutaneous bimekizumab 320 mg every 2 weeks (Q2W); HiSCR90 responders received bimekizumab 320 mg every 4 weeks (Q4W).

Patients receiving bimekizumab 320 mg Q4W in BE HEARD Extension who could not sustain either an average improvement from baseline in AN count of ≥90% over any consecutive 8-week period or ≥75% improvement at any single visit could have their dose increased to Q2W at investigator discretion. Patients receiving bimekizumab 320 mg Q2W were later switched to Q4W after BE HEARD I and II unblinding revealed similar efficacy between the 2 regimens.

The study was conducted under the auspices of an institutional review board/independent ethics committee, as defined in local regulations, International Council for Harmonisation Good Clinical Practice, and in accordance with the ethical principles that have their origin in the Declaration of Helsinki. The study protocol, informed consent forms, and other patient-related documents were reviewed and approved by the institutional review board/independent ethics committee (Pro00050006). All patients provided written informed consent before screening.

Procedures

Full inclusion/exclusion criteria for BE HEARD I and II have been published previously.[32]

Treatment-emergent adverse events (TEAEs), serious TEAEs, TEAEs leading to discontinuation, and prespecified safety topics of interest (Supplementary Methods 1, available via Mendeley at https://data.mendeley.com/datasets/8bjtsp9cf2/1) are reported. TEAEs were defined as any adverse event (AE) with an onset from the first dose of bimekizumab up to 140 days after the final dose. If partial dates made it unclear whether an AE was treatment-emergent, it was assumed to be a TEAE. Patient data related to suicidality and depression were extensively monitored using questionnaires. IBD, liver function test elevation, SIB, and major adverse cardiac events (MACE) were adjudicated by independent external committees.

Safety data were analyzed for patients who received ≥1 bimekizumab dose. TEAEs are reported in Year 1 (Weeks 0-48), Year 2 (Weeks 52-96), and for up to 2 years of bimekizumab exposure, measuring from first bimekizumab dose (Week 0 for patients randomized to bimekizumab at BE HEARD I and II baseline and Week 16 for patients randomized to placebo at baseline; Supplementary Fig 2, available via Mendeley at https://data.mendeley.com/datasets/8bjtsp9cf2/1).

Efficacy outcomes included HiSCR50/75 achievement to Week 96. Skin pain over the past 7 days was assessed using the skin pain item from the HS Symptom Questionnaire (HSSQ), an 11-point numeric scale, where lower scores indicate lower pain.[36] For patients with baseline HSSQ skin pain scores ≥3, proportions achieving an HSSQ skin pain response (≥30% improvement and ≥1-point reduction from baseline) were evaluated to Week 96. Exploratory efficacy outcomes included HiSCR90/100 achievement and mean AN count to Week 96. Mean DT count and mean change from baseline in DT count were calculated, stratified by patients with/without DTs at baseline, to Week 96. The impact of skin disease on HRQoL was assessed by the Dermatology Life Quality Index (DLQI; scored 0-30, higher scores indicate more severe impact), with proportions of patients achieving scores of 0 or 1 (indicating no impact) evaluated to Week 96.[37]

Statistical analysis

Pooled data were analyzed using SAS v9.4 for patients who received ≥1 dose of bimekizumab. For safety, exposure-adjusted incidence rates (EAIRs) are reported per 100 patient-years (100 PY) with associated 95% confidence intervals (CIs); coded using Medical Dictionary for Regulatory Activities 19.0.

Efficacy data are reported as observed case. Summaries are descriptive; no formal statistical

testing was performed. Multiple non-responder imputation (binary outcomes) and multiple imputation (continuous outcomes) data, where an intercurrent event was defined as discontinuation due to an AE or lack of efficacy (AE-LoE), are also reported (Supplementary Fig 3, available via Mendeley at https://data.mendeley.com/datasets/8bjtsp9cf2/1).

All trials are registered with ClinicalTrials.gov: BE HEARD I (NCT04242446), BE HEARD II (NCT04242498), and BE HEARD Extension (NCT04901195).

RESULTS

Patient disposition

BE HEARD I and II were conducted between February 19, 2020, and February 19, 2023, and March 02, 2020, and September 28, 2022, respectively. BE HEARD Extension, conducted from May 27, 2021, is ongoing.

Of 1014 patients enrolled in BE HEARD I and II, 868 were randomized to bimekizumab and 146 to placebo at baseline; 720 completed treatment to Week 48. Of these, 657 entered BE HEARD Extension, with 556 randomized to bimekizumab at baseline; 446 received continuous bimekizumab up to 2 years and were included in the efficacy analysis (Fig 1).

Between Weeks 48 and 96, 165 patients randomized to bimekizumab at baseline discontinued treatment, of which approximately 10% discontinued due to lack of efficacy (Fig 1).

Baseline characteristics

At BE HEARD I and II baseline, demographics and disease characteristics were similar between all patients randomized to bimekizumab and the cohort that entered the OLE (Table I). In BE HEARD Extension, 335 patients were allocated to bimekizumab 320 mg Q2W, and 221 patients to Q4W.

Safety

The EAIR of any TEAE did not increase with longer bimekizumab exposure (Year 1: 261.6/100 PY; Year 2: 235.7/100 PY) (Table II). No increase was observed from Year 1 to Year 2 for serious TEAEs (8.2/100 to 7.9/100 PY), severe TEAEs (10.4/100 to 7.2/100 PY), drug-related TEAEs (80.9/100 to 44.5/100 PY), and TEAEs leading to discontinuation (8.9/100 to 5.0/100 PY). In Year 1, one fatal TEAE of congestive heart failure (adjudicated MACE) was reported in a patient with multiple comorbidities and cardiovascular risk factors.[32] A death occurred in Year 2 due to a possible central nervous system infection in the context of deteriorating HS. Neither death was assessed as bimekizumab-related by the investigator.

In Year 2, hidradenitis (combination of reported terms related to HS abscesses, pain, and worsening) was the most common TEAE occurring at 26.6/100 PY (Year 1: 25.5/100 PY). COVID-19 infection was commonly reported, with an EAIR of 23.1/100 PY in Year 2 (Year 1: 13.6/100 PY). Most COVID-19 infections were mild/moderate and nonserious, with one serious case in both Year 2 and Year 1. In Year 2, oral candidiasis was the third most commonly reported TEAE at 12.5/100 PY (Year 1: 15.2/100 PY). Hypersensitivity reactions, mostly related to skin (dermatitis and eczema), did not increase with longer bimekizumab exposure (Year 2: 19.8/100 PY; Year 1: 26.5/100 PY). Most hypersensitivity reactions were mild/moderate and non-serious; one serious case of a pustular rash was reported in Year 1. No anaphylactic reactions were reported.

In Year 2, the EAIR of serious infections remained low (Year 2: 1.7/100 PY vs Year 1: 1.9/100 PY); postoperative wound infections were most commonly reported (2 patients; 0.3/100 PY). Incidence of fungal infections was 25.3/100 PY in Year 2 (Year 1: 34.8/100 PY). In Year 2, the most commonly reported fungal infection preferred terms were oral candidiasis (12.5/100 PY), vulvovaginal mycotic infections (2.6/100 PY), and vulvovaginal candidiasis (2.1/100 PY). While all were mild/moderate in Year 2, one case of oral candidiasis led to discontinuation.

For the overall population with/without a history of IBD, the EAIR of adjudicated definite or probable IBD did not increase from Year 1 (0.5/100 PY) to Year 2 (0.2/100 PY). Among the 8 patients with a history of IBD up to 2 years, 2 patients experienced a flare in Year 2. Of these, one patient discontinued the study in Year 2.

The EAIR for adjudicated SIB remained stable from Year 1 (0.8/100 PY) to Year 2 (0.9/100 PY), and there were no completed suicides in either year. In Year 1, there were 2 reported cases of suicidal ideation that were adjudicated as suicide attempts (0.3/100 PY) in patients with a history of neuropsychiatric disorders; these were assessed as not bimekizumab-related by the investigator. There were no attempts in Year 2.

EAIRs remained low for neutropenia from Year 1 (0.1/100 PY) to Year 2 (0.2/100 PY), adjudicated MACE (0.4/100 PY to 0.2/100 PY), and malignancies excluding nonmelanoma skin cancer (0.3/100 PY to 1.0/100 PY). There were no cases of active tuberculosis.

EAIRs of liver function elevations (aspartate aminotransferase or alanine aminotransferase) >3 or >5 times the upper limit of normal did not

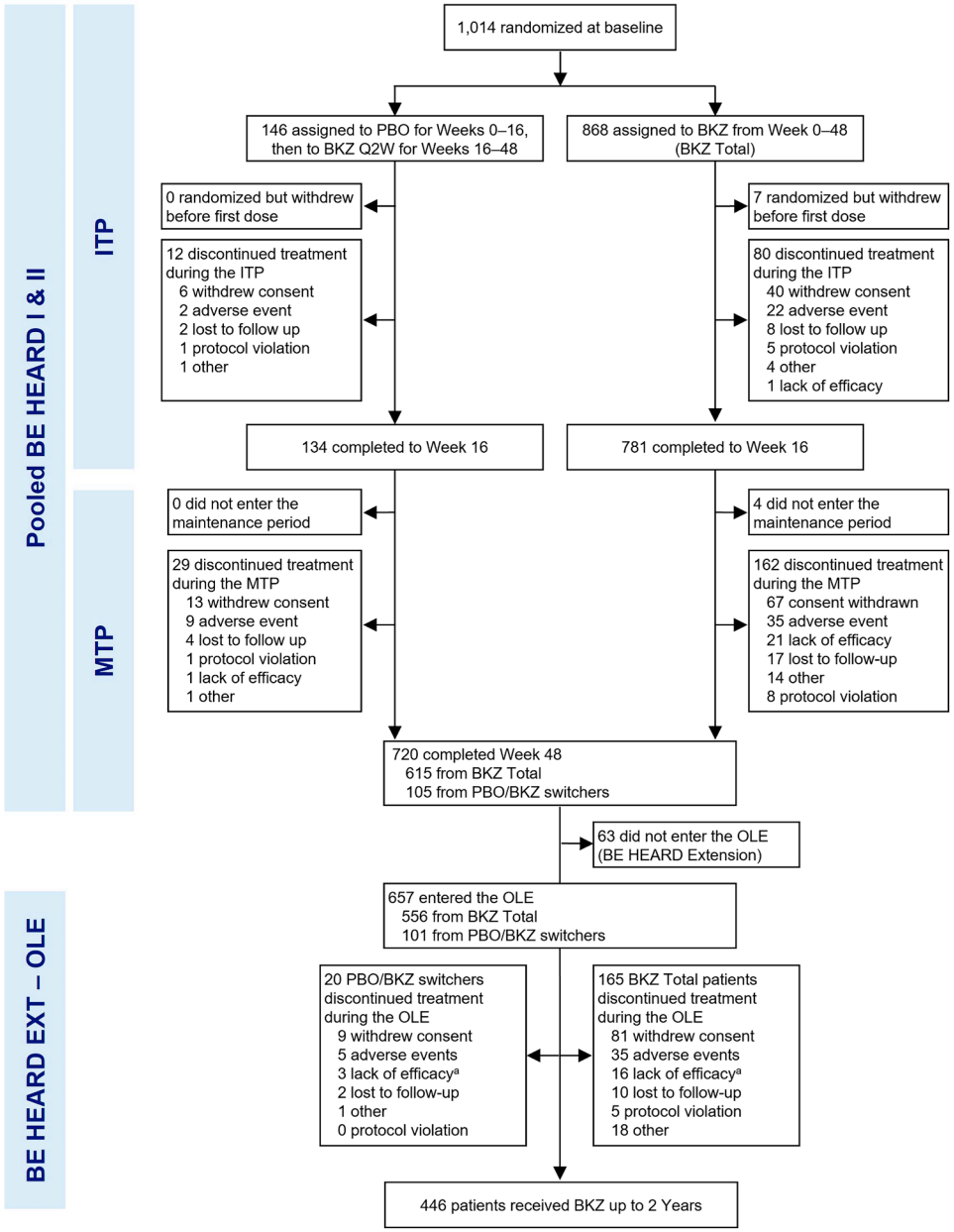

Fig 1. Patient disposition diagram. A patient was considered to have started the ITP (Weeks 0-16) if they received their first dose of BKZ. A patient was considered to have completed the ITP if they had a Week 16 visit or if they failed to attend the Week 16 visit but attended at least 1 visit in the MTP (Weeks 16-48). A patient was considered to have started the MTP if they had received any dose of BKZ in the MTP. A patient was considered to have completed the MTP if they had completed Week 48 of BE HEARD I or II. A patient was considered to have started the OLE if they received at least 1 dose of BKZ during the OLE time period (Weeks 48-96). [a]At the time of discontinuation during the OLE, for the BKZ Total population, 27.3% (n = 45) achieved <HiSCR50, 15.8% (n = 26) achieved HiSCR50, 15.8% (n = 26) achieved HiSCR75, 7.9% (n = 13) achieved HiSCR90, and 33.3% (n = 55) achieved HiSCR100. *BKZ*, Bimekizumab; *HiSCR*, hidradenitis suppurativa clinical response; *HiSCR50/75/90/100*, ≥50/75/90/100% reduction from baseline in the total abscess and inflammatory nodule count with no increase from baseline in abscess or draining tunnel count; *ITP*, initial treatment period; *MTP*, maintenance treatment period; *OLE*, open-label extension; *PBO*, placebo; *Q2W*, every 2 weeks.

Table I. Demographics and disease characteristics at BE HEARD I and II baseline

	All BKZ total patients (*N* = 868)	All BKZ total patients who entered BE HEARD Extension (*N* = 556)
Demographic characteristics		
Age (y), mean ± SD	36.5 ± 12.1	36.3 ± 12.2
Age group (y), *n* (%)		
<40 y	544 (62.7)	348 (62.6)
40 to <65 y	311 (35.8)	201 (36.2)
≥65 y	13 (1.5)	7 (1.3)
Sex, (*n*, %)		
Female	501 (57.7)	299 (53.8)
Male	367 (42.3)	257 (46.2)
Body weight, kg, mean ± SD	97.2 ± 24.4	96.2 ± 23.5
BMI, kg/m^2, mean ± SD	33.1 ± 8.1	32.5 ± 7.8
Smoking status, *n* (%)		
Never	336 (38.7)	206 (37.1)
Current	387 (44.6)	260 (46.8)
Former	134 (15.4)	89 (16.0)
Missing	11 (1.3)	1 (0.2)
Race, *n* (%)		
American Indian or Alaska Native	3 (0.3)	1 (0.2)
Asian	34 (3.9)	29 (5.2)
Black	97 (11.2)	55 (9.9)
Native Hawaiian or Other Pacific Islander	2 (0.2)	2 (0.4)
White	689 (79.4)	448 (80.6)
Other or Mixed	39 (4.5)	17 (3.1)
Missing	4 (0.5)	4 (0.7)
Prior biologic use*	162 (18.7)	112 (20.1)
Disease characteristics		
Disease duration (y), mean ± SD	7.7 ± 7.4	7.4 ± 7.1
AN count, mean ± SD	16.0 ± 14.5	16.9 ± 18.5
DT count, mean ± SD	3.8 ± 4.4	3.8 ± 4.3
Hurley stage†, *n* (%)		
II	486 (56.0)	303 (54.5)
III	382 (44.0)	253 (45.5)
IHS4 score, mean ± SD	34.8 ± 31.4	35.6 ± 31.5
Concomitant antibiotic use‡, *n* (%)	75 (8.6)	54 (9.7)
HSSQ skin pain score, mean ± SD	5.8 ± 0.1	5.8 ± 2.4
DLQI total score, mean ± SD	11.2 ± 6.9	11.0 ± 6.8

Patient characteristics at BE HEARD I and II baseline are reported for all patients randomized to BKZ at baseline (BKZ total) and the subset of BKZ total patients who entered BE HEARD Extension.

AN, Abscess and inflammatory nodule; *BKZ*, bimekizumab; *BMI*, body mass index; *DLQI*, Dermatology Life Quality Index; *DT*, draining tunnel; *HS*, hidradenitis suppurativa; *HSSQ*, Hidradenitis Suppurativa Symptom Questionnaire; *IHS4*, International Hidradenitis Suppurativa Severity Scoring System.

*The prior biologic for HS (amended) subgroup covers the following immunosuppressants: adalimumab, anakinra, canakinumab, certolizumab, etanercept, guselkumab, infliximab, iscalimab, risankizumab, secukinumab, and ustekinumab.

†Derived Hurley Stage for each patient is the worst overall Hurley Stage derived from the Hurley Stages recorded across all anatomical regions.

‡Derived antibiotic use at baseline is defined as "Yes" if the patient has a recorded systemic antibiotic started ≥28 days prior to the baseline visit.

increase from Year 1 (3.6/100 PY and 1.0/100 PY) to Year 2 (3.1/100 PY and 1.0/100 PY, respectively).

Efficacy

At Year 2, 85.4% (381/446) of patients achieved HiSCR50 and 77.1% (344/446) achieved HiSCR75 (Fig 2). Further, 57.6% (257/446) of patients achieved HiSCR90, and 44.2% (197/446) achieved HiSCR100. Among patients receiving the approved bimekizumab dose (Q2W/Q4W at Week 16/48; Q4W at OLE entry), similar trends were observed across HiSCR50/75/90/100 (Supplementary Table I, available via Mendeley at https://data.mendeley.com/datasets/8bjtsp9cf2/1).

Table II. Exposure-adjusted incidence rates of treatment-emergent adverse events per 100 patient-years in BE HEARD I & II and BE HEARD Extension

Incidence per 100 PY (95% CI)	Year 1 100 PYAR = 7.84 *N* = 995	Year 2 100 PYAR = 5.84 *N* = 762	Up to 2 years 100 PYAR = 13.68 *N* = 995
Incidence of TEAEs			
Any TEAE	261.6 (244.2, 280.0)	235.7 (217.0, 255.7)	236.4 (221.3, 252.2)
Serious TEAE	8.2 (6.3, 10.5)	7.9 (5.8, 10.6)	7.4 (6.0, 9.0)
Severe TEAE	10.4 (8.2, 12.9)	7.2 (5.2, 9.8)	8.3 (6.8, 10.0)
Drug-related TEAE	80.9 (73.6, 88.8)	44.5 (38.7, 50.8)	60.1 (55.1, 65.6)
TEAEs leading to discontinuation	8.9 (6.9, 11.2)	5.0 (3.4, 7.2)	7.2 (5.9, 8.8)
TEAEs leading to death	0.1 (0.0, 0.7)	0.2 (0.0, 1.0)	0.1 (0.0, 0.5)
Most common TEAEs*			
Hidradenitis	25.5 (21.9, 29.5)	26.6 (22.4, 31.4)	23.2 (20.5, 26.1)
COVID-19 infection†	13.6 (11.1, 16.5)	23.1 (19.2, 27.6)	17.5 (15.2, 20.0)
Oral candidiasis	15.2 (12.5, 18.2)	12.5 (9.7, 15.8)	12.1 (10.3, 14.2)
Nasopharyngitis	10.2 (8.0, 12.7)	12.0 (9.3, 15.3)	10.0 (8.3, 11.9)
Headache	11.4 (9.1, 14.1)	5.1 (3.4, 7.3)	8.2 (6.7, 10.0)
TEAEs of interest			
Infections and infestations	112.2 (103.2, 121.8)	115.5 (104.8, 127.1)	101.2 (93.8, 109.0)
Serious infections	1.9 (1.1, 3.2)	1.7 (0.8, 3.2)	1.7 (1.1, 2.5)
Fungal infections	34.8 (30.5, 39.6)	25.3 (21.2, 30.0)	27.8 (24.8, 31.2)
Oral candidiasis	15.2 (12.5, 18.2)	12.5 (9.7, 15.8)	12.1 (10.3, 14.2)
Vulvovaginal mycotic infection	3.5 (2.3, 5.1)	2.6 (1.5, 4.3)	3.0 (2.1, 4.1)
Vulvovaginal candidiasis	3.8 (2.5, 5.4)	2.1 (1.1, 3.6)	2.9 (2.1, 4.0)
Active tuberculosis	0	0	0
Adjudicated definite or probable IBD‡	0.5 (0.1, 1.3)	0.2 (0.0, 1.0)	0.4 (0.1, 0.9)
Malignancies	0.5 (0.1, 1.3)	1.0 (0.4, 2.2)	0.7 (0.4, 1.3)
Excluding NMSC	0.3 (0.0, 0.9)	1.0 (0.4, 2.2)	0.6 (0.3, 1.2)
Adjudicated SIB	0.8 (0.3, 1.7)	0.9 (0.3, 2.0)	0.8 (0.4, 1.4)
Suicide attempts	0.3 (0.0, 0.9)	0	0.2 (0.0, 0.5)
Neutropenia events	0.1 (0.0, 0.7)	0.2 (0.0, 1.0)	0.1 (0.0, 0.5)
Adjudicated MACE	0.4 (0.1, 1.1)	0.2 (0.0, 1.0)	0.3 (0.1, 0.8)
Hepatic events	5.9 (4.3, 7.9)	5.8 (4.0, 8.2)	5.3 (4.2, 6.8)
ALT or AST >3X ULN	3.6 (2.4, 5.2)	3.1 (1.8, 4.9)	3.3 (2.4, 4.5)
ALT or AST >5X ULN‖	1.0 (0.4, 2.0)	1.0 (0.4, 2.3)	1.0 (0.6, 1.7)
Hypersensitivity reactions	26.5 (22.8, 30.6)	19.8 (16.2, 23.9)	22.1 (19.5, 25.0)
Dermatitis and eczema	16.3 (13.5, 19.5)	15.1 (12.0, 18.7)	14.5 (12.4, 16.8)
Serious hypersensitivity reactions	0.1 (0.0, 0.7)	0	0.1 (0.0, 0.4)
Administration and injection site reactions	8.9 (6.9, 11.3)	2.3 (1.2, 3.9)	6.0 (4.7, 7.5)

ALT, Alanine aminotransferase; *AST*, aspartate aminotransferase; *EAIR*, exposure-adjusted incidence rate; *IBD*, inflammatory bowel disease; *MACE*, major adverse cardiac event; *NMSC*, nonmelanoma skin cancer; *PYAR*, patient-years at risk; *SIB*, suicidal ideation and behavior; *TEAE*, treatment-emergent adverse event; *ULN*, upper limit of normal; *PY*, patient-years.

*Most common TEAEs are organized in descending order based on up to 2 years of data.

†These trials were conducted during the COVID-19 pandemic.

‡Only patients who did not have active symptomatic IBD and who did not require prohibited medications at screening or baseline were permitted to enter the study. Among patients with a history of IBD up to 2 years (n = 8), 2 patients experienced a flare.

‖No elevations of greater than 5 times the ULN were adjudicated to be highly likely or definitely related to bimekizumab.

Mean AN count decreased from 16.9 (standard deviation [SD]: 18.5) at baseline (n = 556) to 4.0 (8.5) at Year 1 (n = 556) and 2.3 (4.3) at Year 2 (n = 446) (Fig 3). Among patients with DTs at baseline, mean DT count reduced from 4.9 (4.3) at baseline (n = 425) to 1.8 (2.8) at Year 1 (n = 425). Reductions in mean DT count were maintained at Year 2, with a mean of 1.4 (2.5) and a mean change from baseline of −3.7 (3.7, n = 350). For patients without DTs at baseline, mean DT count minimally increased to 0.2 (0.5) at both Year 1 (n = 131) and Year 2 (n = 96) (Fig 3).

HSSQ skin pain response rates were sustained from Year 1 (72.2% [358/496]) to Year 2 (78.5% [306/390]). At Year 1 and Year 2, 27.4% (151/551) and 33.9% (149/439) of patients reported DLQI scores of 0/1, respectively (Fig 3).

Analyses using multiple nonresponder imputation and multiple imputation methodology are depicted in

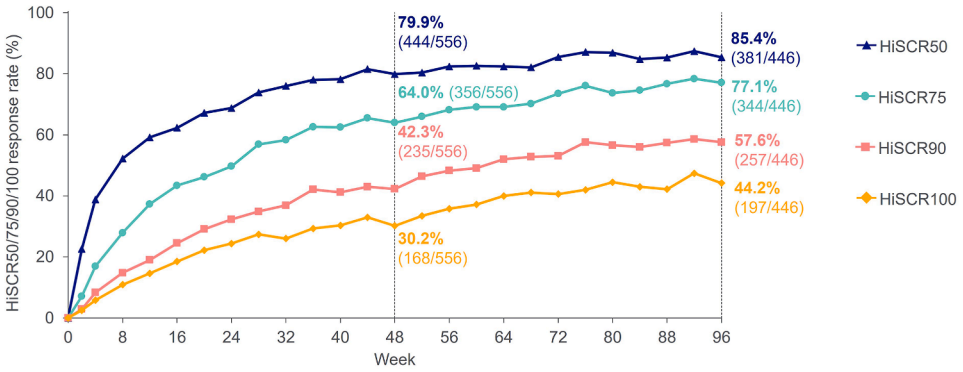

Fig 2. HiSCR50/75/90/100 rates over time for BKZ total patients (OC) with hidradenitis suppurativa. OLE set: 657 BE HEARD I and II completers entered BE HEARD Extension at Week 48, of which 556 received BKZ from baseline (BKZ total). Data for patients in BKZ total are presented. OC, *n/N*: denominator represents number of patients with a nonmissing lesion count assessment in the given week, and percentages are calculated accordingly (ie, where data recorded after an intercurrent event are included as recorded). *BKZ*, Bimekizumab; *HiSCR*, hidradenitis suppurativa clinical response; *HiSCR50/75/90/100*, ≥50/75/90/100% reduction from baseline in the total abscess and inflammatory nodule count with no increase from baseline in abscess or draining tunnel count; *OC*, observed case; *OLE*, open-label extension.

Supplementary Figs 4 and 5, available via Mendeley at https://data.mendeley.com/datasets/8bjtsp9cf2/1.

DISCUSSION

Development of effective and highly tolerable long-term treatments for HS would benefit clinicians and patients. Here, the safety and efficacy of the newly approved biologic bimekizumab were evaluated following up to 2 years of continuous treatment. In Year 2, no new safety signals were observed, and bimekizumab demonstrated durable and deep efficacy among a substantial number of patients with moderate to severe HS.

The population entering the OLE was consistent with the BE HEARD I and II baseline population and with populations in other phase 3 HS trials.[22,32,38] However, compared with these aforementioned studies, the proportion of female patients entering the OLE was numerically lower. Sex-based differences may impact therapeutic outcomes due to variations in comorbidities and clinical manifestations.[39,40]

Bimekizumab was well-tolerated in Year 2, with a safety profile consistent with Year 1 and that of bimekizumab in other indications (psoriasis, psoriatic arthritis, and axial spondyloarthritis).[28-30,32]

The EAIR of any TEAE did not increase with longer bimekizumab exposure. In Year 2, the most commonly reported TEAEs were hidradenitis, COVID-19 infections, and oral candidiasis. Hidradenitis was expected, considering the recurrent nature of HS.[1] As the trials were conducted during the COVID-19 pandemic, it was also expected that COVID-19 infections would be a common TEAE. In this study, the COVID-19 term combined multiple terms including symptomatic and asymptomatic infections identified through COVID-19 testing; no systematic testing was performed. Hidradenitis and COVID-19 were also commonly reported TEAEs for secukinumab treatment of HS.[41]

Rates of fungal infections did not increase with longer bimekizumab exposure. Most cases of oral candidiasis were mild/moderate and did not lead to discontinuation. In Year 2, no new safety concerns were identified across the safety topics of interest.

Bimekizumab demonstrated consistent efficacy across lesion-, skin pain-, and HRQoL-based outcomes, with high proportions of patients achieving HiSCR50/75/90/100 at Year 2. DTs are a hallmark of advanced HS, leading to permanent scarring and impaired HRQoL.[16,17] Here, clinically important reductions in DT count achieved at Year 1 were maintained at Year 2 among patients with DTs at baseline. In patients without DTs at baseline, DT count minimally increased to Year 2. Effective control over DTs may prevent related downstream sequelae. Skin pain also greatly impacts HRQoL; most patients reported reductions in skin pain, which translated into HRQoL improvements, as demonstrated by high proportions achieving an HSSQ skin pain response and DLQI 0/1.[42-45]

These findings may have limited real-world generalizability due to specific patient inclusion and exclusion criteria. Further, OLE studies may be subject to reporting bias due to lack of blinding, and as patient numbers tend to decrease over time in clinical trials. Hence, OLE data are supportive of blinded safety and efficacy assessments. TEAEs of

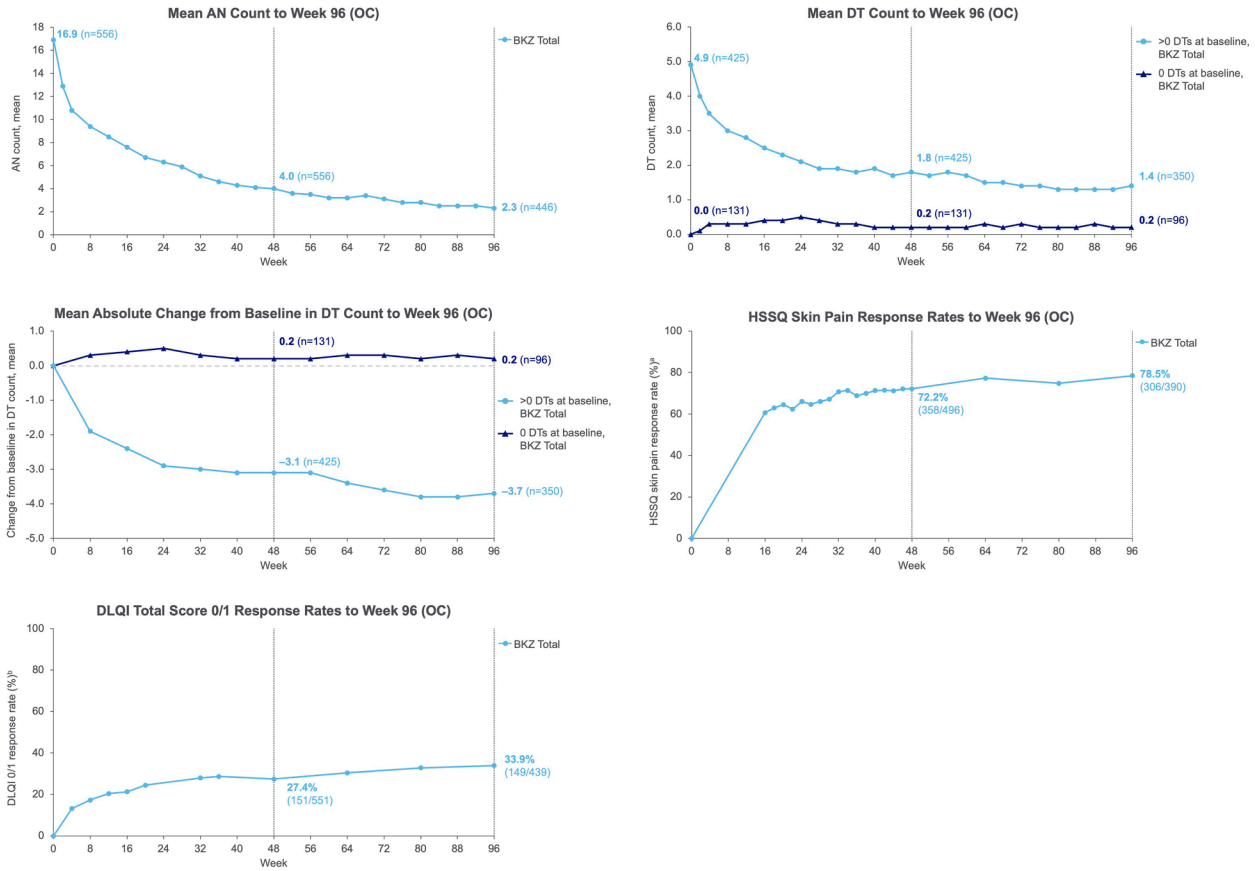

Fig 3. Efficacy and lesion-based outcomes for BKZ total patients (OC) with hidradenitis suppurativa. OLE set: 657 BE HEARD I and II completers entered BE HEARD Extension at Week 48, of which 556 received BKZ from baseline (BKZ total). Data for patients in BKZ total are presented. [a]An HSSQ skin pain response was defined as at least a 30% reduction and ≥1 point reduction in HSSQ skin pain score among patients with a score of ≥3 at baseline. *n/N*: denominator represents the number of patients with nonmissing data in the given week, and percentages are calculated accordingly (ie, where data recorded after an intercurrent event are included as recorded). [b]A DLQI response was defined as total scores of 0 or 1 (no impact of disease on HRQoL). *n/N*: denominator represents the number of patients with nonmissing data in the given week, and percentages are calculated accordingly (ie, where data recorded after an intercurrent event are included as recorded). *AN*, Abscess and inflammatory nodule; *BKZ*, bimekizumab; *DLQI*, Dermatology Life Quality Index; *DT*, draining tunnel; *HRQoL*, health-related quality of life; *HSSQ*, Hidradenitis Suppurativa Symptom Questionnaire; *OC*, observed case; *OLE*, open-label extension.

infections may have been impacted by changing COVID-19 prevention measures. Finally, without direct comparative (head-to-head) studies, comparisons of bimekizumab with other IL-17 inhibitors should be made cautiously.

In conclusion, bimekizumab was well-tolerated for up to 2 years of treatment among patients with moderate to severe HS. No new safety signals were observed, and EAIRs of TEAEs did not increase with longer bimekizumab exposure. Bimekizumab's dual inhibition of IL-17F in addition to IL-17A provided deep and durable reductions of key lesions characteristic of HS, including DTs, along with improvements in skin pain and health-related quality of life.

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Conflicts of interest

All details of authors' affiliation or involvement in an organization or entity with a financial or nonfinancial interest in the subject matter or materials discussed in this manuscript are disclosed. Prof Sayed is an investigator for AbbVie, AstraZeneca, ChemoCentryx, Incyte, InflaRx, Novartis, and UCB; receives consultancy fees from AbbVie, Alumis, AstraZeneca, InflaRx, Incyte, Logical Images, MoonLake Immunotherapeutics, Sandoz, Sanofi, Sonoma Biotherapeutics, and UCB; and is a speaker for AbbVie and Novartis. 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