Article Type: Original Article

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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Funding sources:
UCB. UCB contributed to study design, participated in data collection, completed the data analysis, and participated in data interpretation. UCB participated in writing, review, and approval of the manuscript. All authors had full access to the data, reviewed, and approved the final version and were responsible for the decision to submit for publication. A medical writing agency, employed by UCB, assisted with manuscript preparation under the authors' direction.

IRB approval status: Reviewed and approved by the relevant institutional review board (Pro00050006/18 Mar 2021).

Clinicaltrials.gov listing (https://clinicaltrials.gov): BE HEARD I (NCT04242446; registered 2020-01-27), BE HEARD II (NCT04242498; registered 2020-01-27), and BE HEARD EXT (NCT04901195; registered 2021-05-25).

Patient consent on file: Not applicable.

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Word count:
Abstract: 198
Capsule summary: 49
Main text: 2,500/2,500 (excluding capsule summary, abstract, references, figures and tables)

Table and figure count:
Figures: 3
Supplementary Figures: 5
Tables: 2
Supplementary tables: 1

References: 45

Attachments for editor/reviewer reference only: CONSORT checklist, research protocol, IRB approval letter and relevant renewals

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

Previous Presentation: None.

CONSORT Statement: The CONSORT 2025 checklist was used to inform development of this manuscript.

Abstract

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

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

Methods: Data from BE HEARD I&II phase 3 trials and their open-label extension (OLE) BE HEARD EXTENSION were pooled to assess the safety and efficacy of bimekizumab in patients with moderate to severe HS 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: 556 patients entered the OLE; 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.

Capsule Summary (49/50 words)

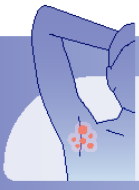
How does this article integrate into what was already known?

- Bimekizumab demonstrated high efficacy with favorable safety among patients with moderate to severe hidradenitis suppurative to 1 year; here, bimekizumab data are reported for up to 2 years.

How does it change practice?

- Rates of treatment-emergent adverse events did not increase, no new safety signals were observed, and bimekizumab provided durable and consistent efficacy.

Bimekizumab for Treating Hidradenitis Suppurativa: **2-Year Findings**



What is Hidradenitis Suppurativa?

- **Hidradenitis suppurativa (HS)** is a severe, inflammatory skin disease with painful skin lesions, requiring **long-term treatment**
- **Bimekizumab** is a drug that can be used to treat moderate to severe HS

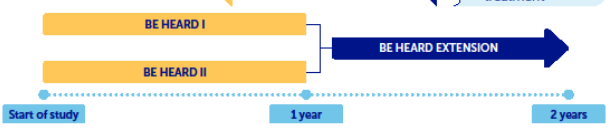
What Did the Studies Do?

- These studies aimed to see the long-term **safety** of bimekizumab, and **how well it worked** for treating patients with moderate to severe HS who had up to 2 years of treatment

In **two clinical trials**, patients with moderate to severe HS received bimekizumab for one year. These trials were blinded so the patients and doctors did not know who received either dose of bimekizumab or placebo during the study

Patients completing the two trials could enter a **third, follow-up trial** where all patients received bimekizumab for a further year (known as an "open-label study")

The results from all **three trials** were combined to see the long-term **safety** of the drug and **how well it worked** following up to **2 years** of treatment



What was the Long-Term Safety of Bimekizumab?

We measured the long-term safety of bimekizumab by assessing side effects and a variety of health measurements

- Patients with moderate to severe HS tolerated the treatment well
- The number of side effects did not increase from Year 1 to Year 2 of treatment, and the types of side effects were similar between the two years
- Few side effects were serious or led to patients dropping out

With up to 2 years of bimekizumab treatment, what were the most common side effects?

Hidradenitis[a]

Coronavirus infection[b]

Yeast infection

[a]This means that the symptoms of HS, such as pain or lesions, got worse which is expected since HS is known to flare
[b]These side effects were expected as the trials took place during the COVID-19 pandemic

How Well Did Bimekizumab Work?

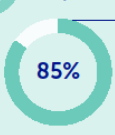
We measured how well bimekizumab worked using the following methods:

HS lesions were counted throughout the study. If the number of certain lesions decreased by at least 50%, or by at least 75%, compared with the number at the start of treatment, and certain other lesions did not increase, the patient achieved a **HS Clinical Response** (**HiSCR50**) or **HiSCR75**

Skin pain was measured on a scale from 0 (no skin pain) to 10 (skin pain as bad as you can imagine), using the HS Symptom Questionnaire (**HSSQ**)

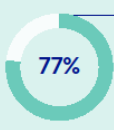
Health-related quality of life was measured by a questionnaire called **DLQI**, which stands for Dermatology Life Quality Index, scored from 0 to 30 where lower scores indicate a lower impact of skin disease on quality of life

In Year 2, most patients had large reductions in HS lesions compared with when they started bimekizumab treatment



HiSCR50 Response

Approximately **8–9 in 10** patients treated with bimekizumab demonstrated at least **50% improvement in HS lesions (HiSCR50)** from the start of treatment



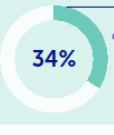
HiSCR75 Response

Almost **8 in 10** patients treated with bimekizumab demonstrated at least **75% improvement in HS lesions (HiSCR75)** from the start of treatment

At Year 2, most of the patients receiving bimekizumab showed improvements in skin pain and about a third reported no effect of HS on their health-related quality of life

Improvements in skin pain (HSSQ)

Almost **8 in 10** patients treated with bimekizumab achieved a meaningful **improvement in skin pain**



No effect of HS on health-related quality of life (DLQI)

A third of patients reported that HS **no longer** had an impact on their **health-related quality of life**

What Does This Mean?

Bimekizumab was **well-tolerated** in patients with **moderate to severe HS**

Introduction

Hidradenitis suppurativa (HS) is a chronic, progressive, inflammatory skin disease characterized by painful nodules, abscesses, and tunnels/fistula, 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]

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 which 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 one 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 is reported up to 2 years using pooled BE HEARD I and II data (Year 1) and their open-label extension (OLE), BE HEARD EXTENSION (BE HEARD EXT; Year 2).

Methods

Study design and treatment

BE HEARD I and II were identically-designed, 48-week randomized controlled trials.[32] BE HEARD EXT 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: 17 Nov 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 EXT (**Figure S1**). 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 320mg every 2 weeks (Q2W); HiSCR90 responders received bimekizumab 320mg every 4 weeks (Q4W).

Patients receiving bimekizumab 320mg Q4W in BE HEARD EXT 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 320mg Q2W were later switched to Q4W after BE HEARD I and II unblinding revealed similar efficacy between the two regimens.

The study was conducted under the auspices of an Institutional Review Board (IRB)/Independent Ethics Committee (IEC), 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 IRB/IEC (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, as well as prespecified safety topics of interest (**Supplementary Methods 1**), are reported. TEAEs were defined as any 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 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; **Figure S2**).

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 (EAIR) are reported per 100 patient-years (100 PY) with associated 95% confidence intervals (CI); coded using Medical Dictionary for Regulatory Activities 19.0.

Efficacy data are reported as observed case (OC). Summaries are descriptive; no formal statistical testing was performed. Multiple non-responder imputation (mNRI; binary outcomes) and multiple imputation (MI; continuous outcomes) data, where an intercurrent event was defined as discontinuation due to an AE or lack of efficacy (AE-LoE), are also reported (**Figure S3**).

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

Results

Patient disposition

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

Of 1,014 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 EXT, with 556 randomized to bimekizumab at baseline; 446 received continuous bimekizumab up to 2 years and were included in the efficacy analysis (**Figure 1**).

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

Baseline characteristics

Demographic and disease characteristics of patients entering the OLE were similar to those randomized to bimekizumab at BE HEARD I and II baseline, except for a numerically higher proportion of females at baseline (57.7%) versus those entering the OLE (53.8%) (**Table 1**). In BE HEARD EXT, 335 patients were allocated to bimekizumab 320mg 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 2**). 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 co-morbidities 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 non-serious; 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 rash pustular 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); post-operative 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 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 two 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 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 (**Figure 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 an OLE entry), similar trends were observed across HiSCR50/75/90/100 (**Table S1**).

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) (**Figure 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) (**Figure 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 (**Figure 3**).

Analyses using mNRI and MI methodology are depicted in **Figures S4**−**S5**.

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 to the BE HEARD I and II baseline population, and to 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 spondylarthritis).[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 coronavirus disease 2019 (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 a 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, Year 2 OLE data may be subject to reporting bias due to lack of blinding and TEAEs of infections may have been impacted by changes in COVID-19 prevention measures. 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 exposure to bimekizumab. Bimekizumab 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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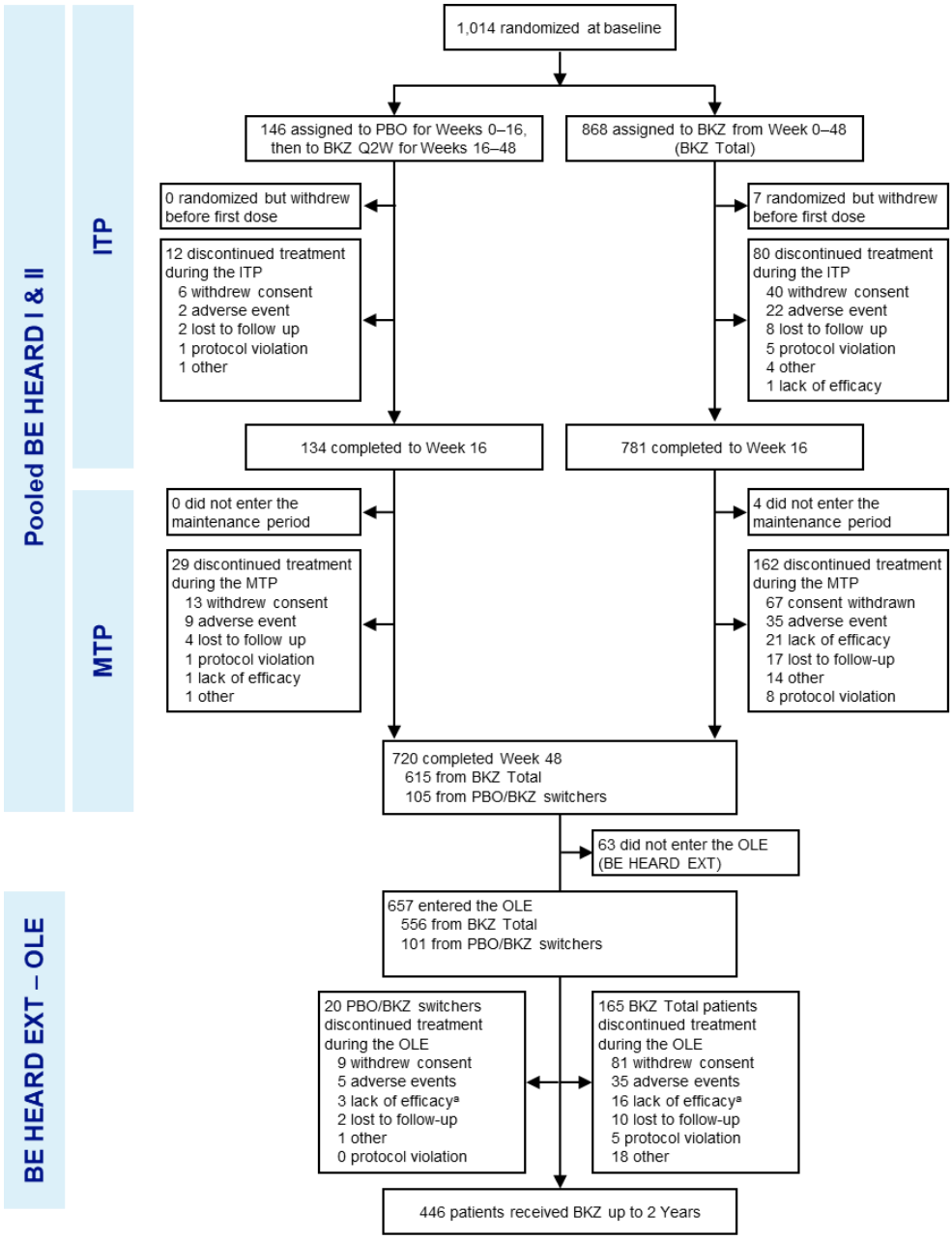
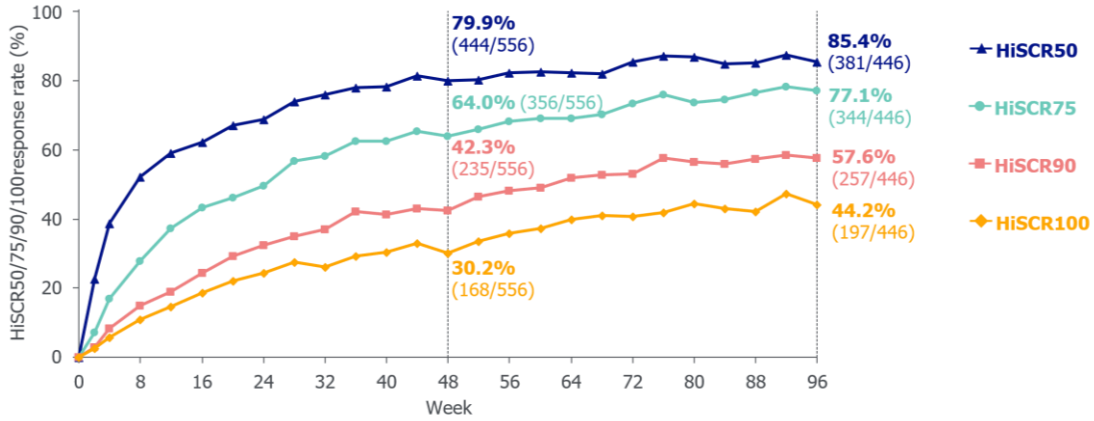
Figures and tables

Figure 1: Patient disposition diagram



Hidradenitis suppurativa. A patient was considered to have started the ITP (Weeks 0–16) if they received their first dose of study medication. 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 one visit in the MTP (Weeks 16−48). A patient was considered to have started the MTP if they had received any dose of bimekizumab 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 one dose of bimekizumab 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; ITP: initial treatment period; MTP: maintenance treatment period; OLE: open-label extension; PBO: placebo; Q2W: every 2 weeks; Q4W: every 4 weeks.

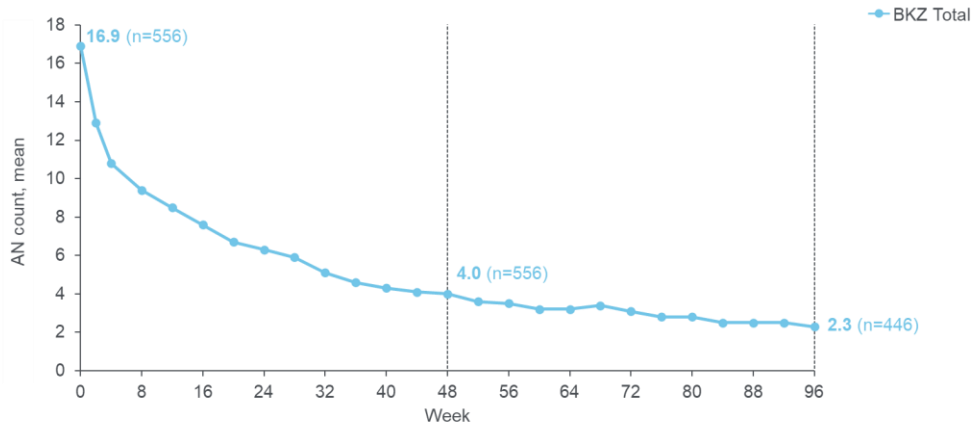
Figure 2: HiSCR50/75/90/100 rates over time for BKZ Total patients (OC)



Hidradenitis suppurativa. OLE set: 657 BE HEARD I and II completers entered BE HEARD EXT 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 non-missing lesion count assessment in the given week, and percentages are calculated accordingly (i.e. 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.

448 **Figure 3: Efficacy and lesion-based outcomes for BKZ Total patients (OC)**

449 ***Mean AN count over time (OC)***



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451 ***Mean DT count over time (OC)***

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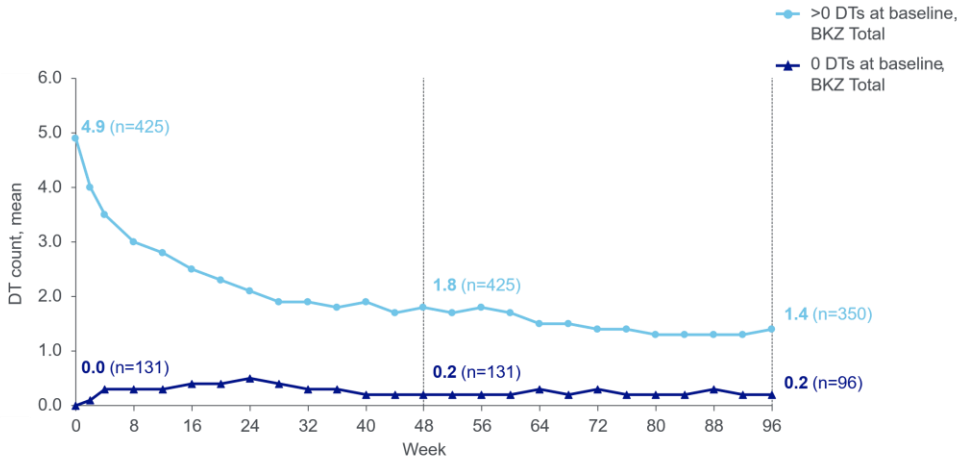
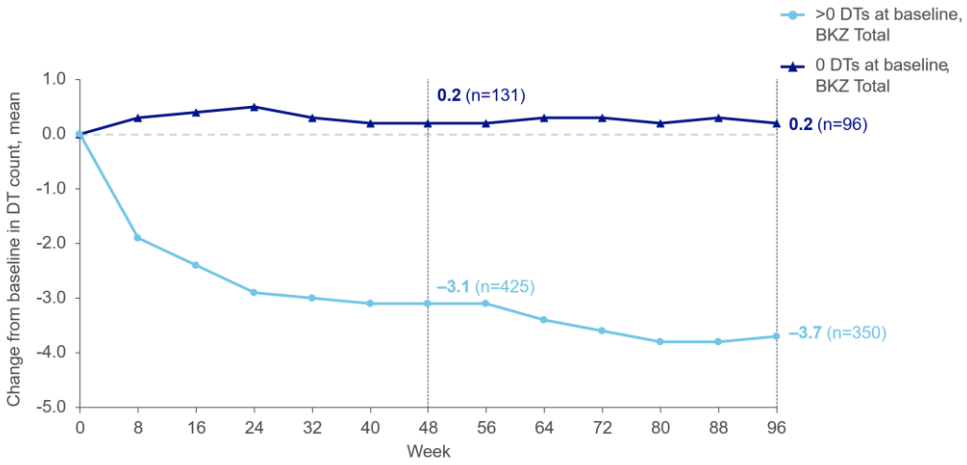
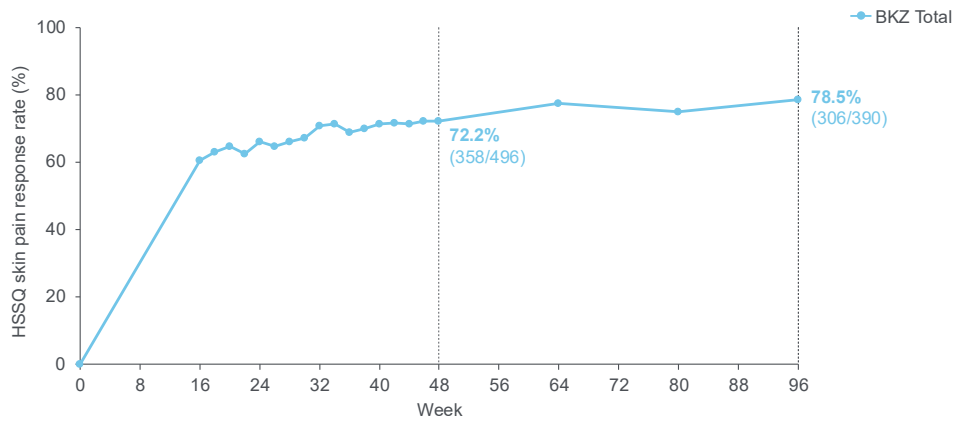


453 ***Mean absolute change from baseline in DT count over time (OC)***

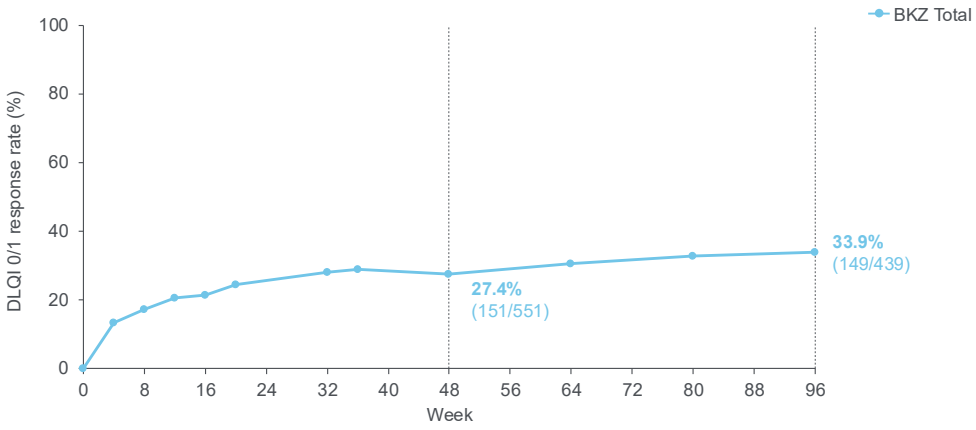
454



HSSQ skin pain response rates over time (OC)[a]



DLQI 0/1 response rates over time (OC)[b]



Hidradenitis suppurativa. OLE set: 657 BE HEARD I and II completers entered BE HEARD EXT at Week 48, of which 556 received BKZ from baseline (BKZ Total). Data for patients in BKZ Total are presented. **[a]** A 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 number of patients with a non-missing data in the given week, and percentages are calculated accordingly (i.e. 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 number of patients with a non-missing data in the given week, and percentages are calculated accordingly (i.e. 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.

471 **Table 1: Demographics and disease characteristics**

	BE HEARD I and II BKZ Total (N=868)	BE HEARD EXT BKZ Total (N=556)
Demographics		
Age (years), mean ± SD	36.5 ± 12.1	36.3 ± 12.2
Age group (years), n (%)		
<40 years	544 (62.7)	348 (62.6)
40 to <65 years	311 (35.8)	201 (36.2)
≥65 years	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[a]	162 (18.7)	112 (20.1)
Disease Characteristics		
Disease duration (years), 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[b], 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[c], n (%)	75 (8.6)	54 (9.7)

	BE HEARD I and II BKZ Total (N=868)	BE HEARD EXT BKZ Total (N=556)
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

Hidradenitis suppurativa. Data are reported for patients randomized to BKZ at BE HEARD I and II baseline (BKZ Total). **[a]** The prior biologic for HS (amended) subgroup covers the following immunosuppressants: adalimumab, anakinra, canakinumab, certolizumab, etanercept, guselkumab, infliximab, iscalimab, risankizumab, secukinumab, and ustekinumab. **[b]** Derived Hurley Stage for each patient is the worst overall Hurley Stage derived from the Hurley Stages recorded across all anatomical regions. **[c]** 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. AN: abscess and inflammatory nodule; BMI: body mass index; DT: draining tunnel; DLQI: Dermatology Life Quality Index; HS: hidradenitis suppurativa; HSSQ: hidradenitis suppurativa symptom questionnaire; IHS4: International Hidradenitis Suppurativa Severity Scoring System; SD: standard deviation.

Table 2: Exposure-adjusted incidence rates of treatment-emergent adverse events per 100 patient-years in BE HEARD I & II and BE HEARD EXT

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[a]			
Hidradenitis	25.5 (21.9, 29.5)	26.6 (22.4, 31.4)	23.2 (20.5, 26.1)
COVID-19 infection[b]	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[c]	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)

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
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[e]	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)

Hidradenitis suppurativa. **[a]** Most common TEAEs are organized in descending order based on the Up to 2 Years data. **[b]** These trials were conducted during the COVID-19 pandemic. **[c]** 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 flare. **[d]** n represents the number of patients with newly diagnosed IBD at the specified timepoint, N represents the number of patients without a history of IBD at baseline. **[e]** No elevations of greater than five times the ULN were adjudicated to be highly likely or definitely related to bimekizumab. ALT: alanine aminotransferase; AST: aspartate aminotransferase; CI: confidence interval; COVID-19: coronavirus disease 2019; EAIR: exposure-adjusted incidence rate; IBD: inflammatory bowel disease; MACE: major adverse cardiac event; NMSC: non-melanoma skin cancer; PYAR: patient-years at risk; SIB: suicidal ideation and behavior; TEAE: treatment-emergent adverse event; ULN: upper limit of normal.

SUPPLEMENTARY

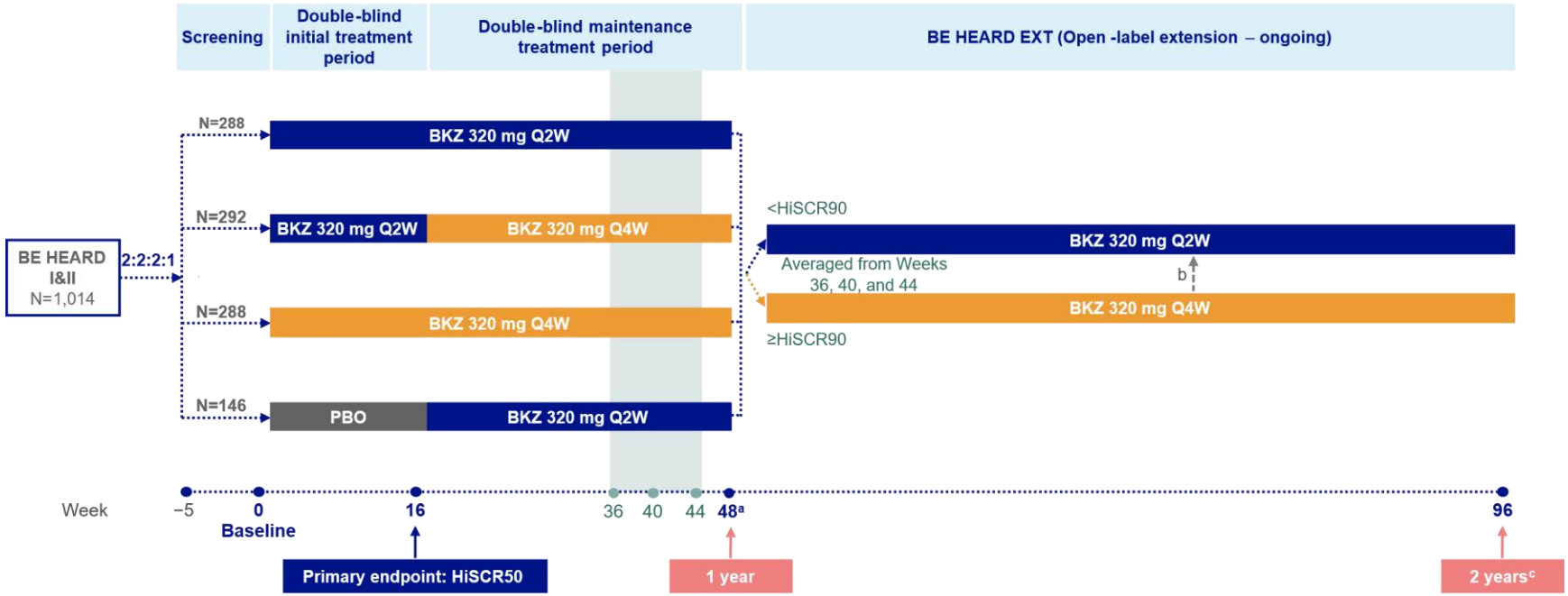
Table of Contents

Supplementary Methods 1. Prespecified safety topics of interest

Prespecified safety topics of interest were infections (serious, opportunistic, including tuberculosis and fungal infections), inflammatory bowel disease (IBD), malignancies, major adverse cardiac events (MACE), liver function test changes and enzyme elevations, suicidal ideation and behavior (SIB), neutropenia, hypersensitivity reactions, and injection site reactions.

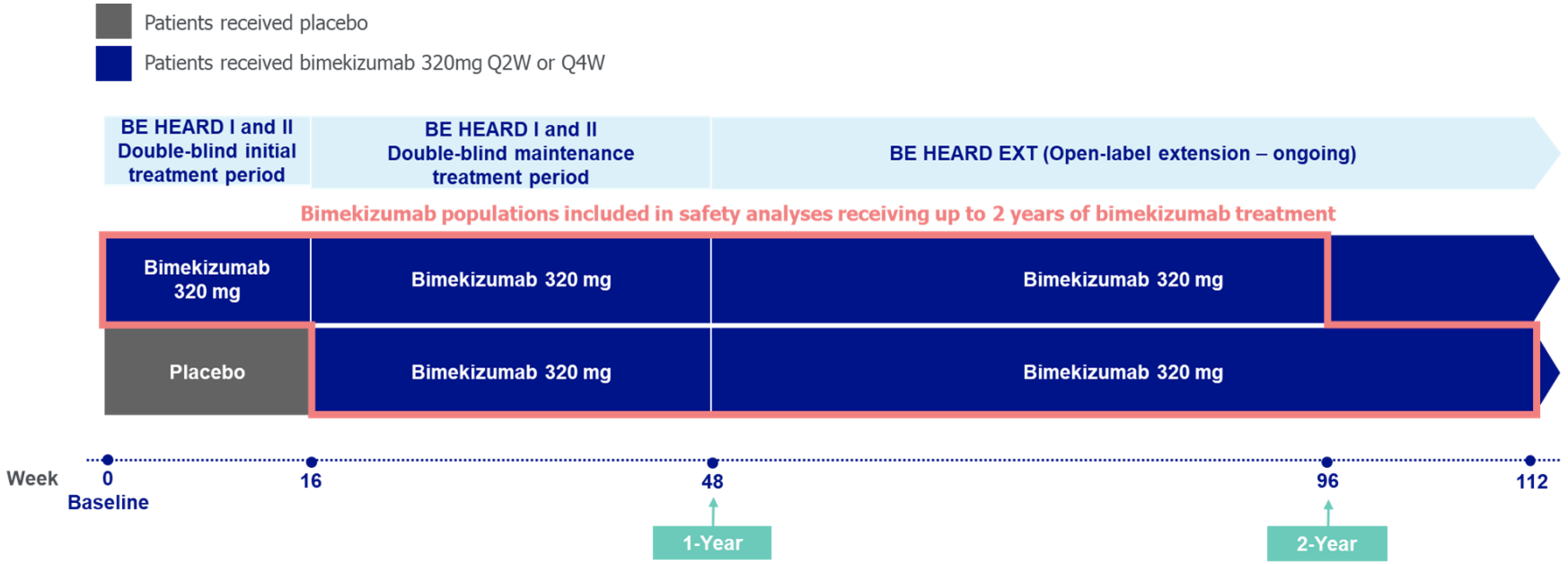
Predefined cardiovascular, gastrointestinal, neuropsychiatric, and hepatic events were reviewed and adjudicated by independent Cardiovascular, IBD, Neuropsychiatric, and Hepatology Adjudication Committees.

Supplementary Figure 1: BE HEARD I and II and BE HEARD EXT study design



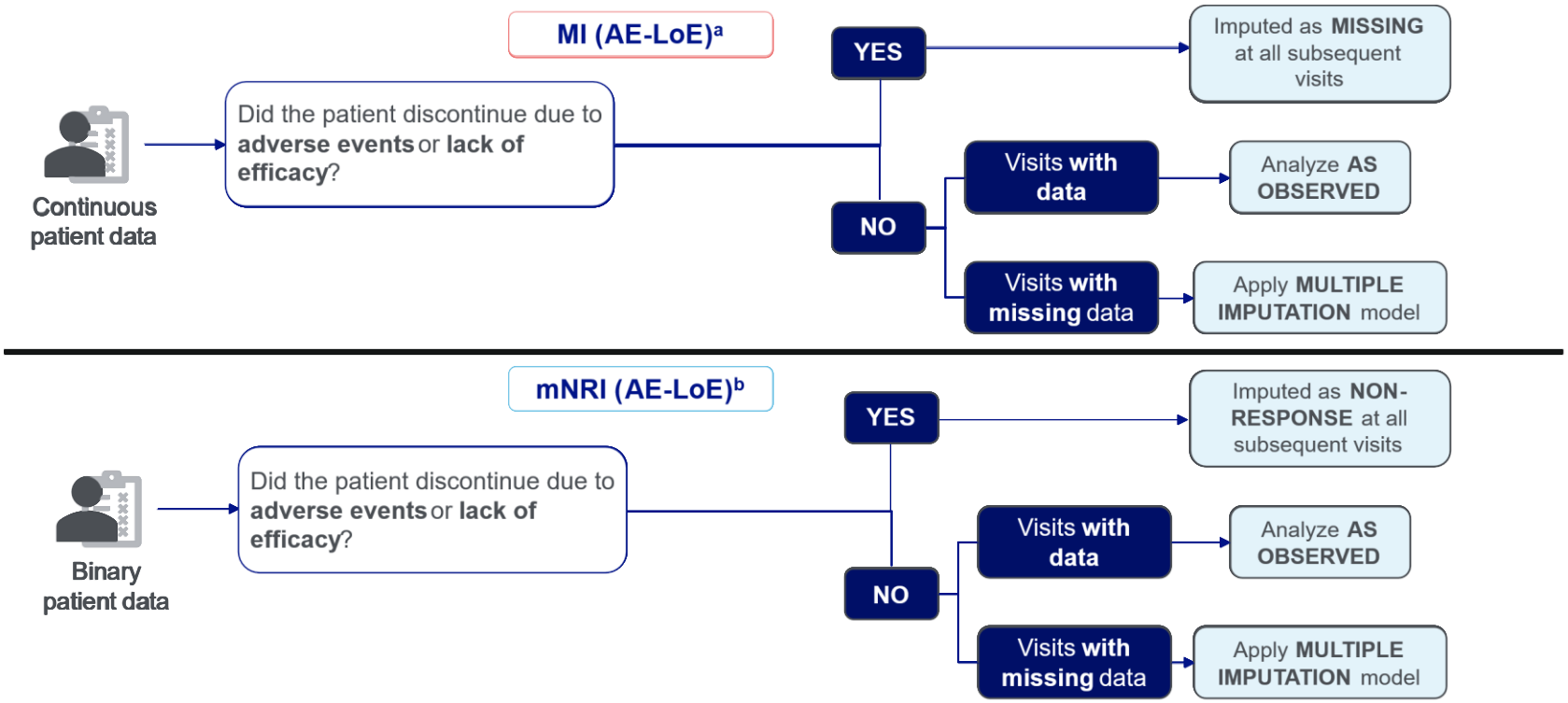
Hidradenitis suppurativa. **[a]** Patients who completed Week 48 of BE HEARD I and II could enroll in BE HEARD EXT and receive open-label BKZ Q2W or BKZ Q4W based on HiSCR90 responder status using the average lesion counts from Weeks 36, Week 40, and Week 44 of BE HEARD I and II; **[b]** In the first 48 weeks of the ongoing BE HEARD EXT, dose adjustment from BKZ Q4W to BKZ Q2W was permitted based on prespecified criteria for reduction in improvement from baseline in AN count; **[c]** Cumulative 2-year data (48 weeks in BE HEARD I and II and 48 weeks in BE HEARD EXT). AN: abscess and inflammatory nodule; BKZ: bimekizumab; HiSCR50/90: ≥50%/90% reduction from baseline in the total AN count with no increase from baseline in abscess or draining tunnel count; Q2W: every two weeks; Q4W: every four weeks.

Supplementary Figure 2: Safety pooled data



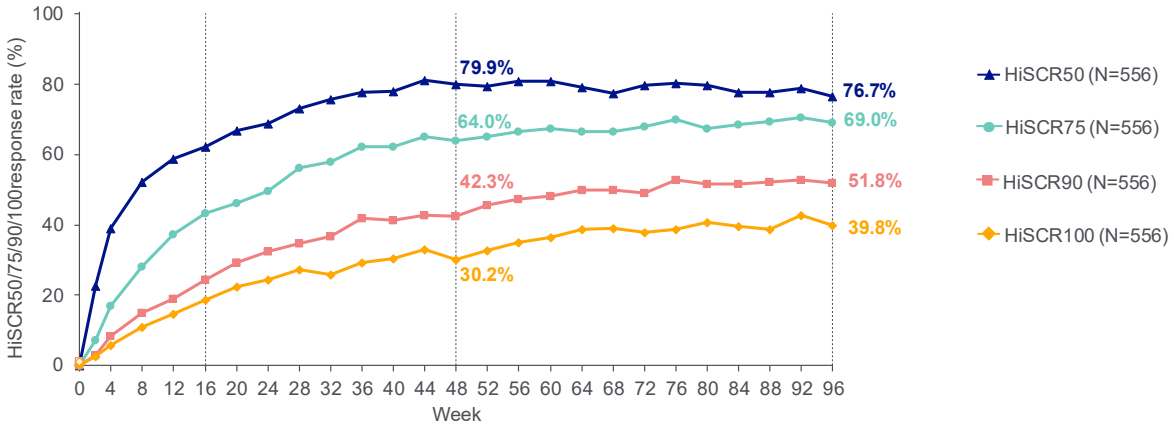
Hidradenitis suppurativa. Safety pool for patients who received up to 2 years of bimekizumab treatment. Q2W: every 2 weeks; Q4W: every 4 weeks.

Supplementary Figure 3: Missing data handling



Hidradenitis suppurativa. For AE-LoE, discontinuation due to adverse event of lack of efficacy constitutes as an intercurrent event**. [a]** Intermittent missing data were imputed using multiple imputation with MCMC method followed by monotone regression for monotone missing data. Patients who experienced an intercurrent event were treated as missing following the intercurrent event and imputed using the multiple imputation method for missing data. **[b]** Intermittent missing data were imputed using multiple imputation with MCMC method followed by monotone regression for monotone missing data. Lesion counts were imputed and then dichotomized to obtain the response status. Patients who experienced an intercurrent event were treated as non-responders following the intercurrent event. Observed case reflects the patients who remained on treatment and missing data were not considered. AE-LoE: adverse event or lack of efficacy; MCMC: Markov Chain Monte Carlo; mNRI: modified non-responder imputation; MI: multiple imputation.

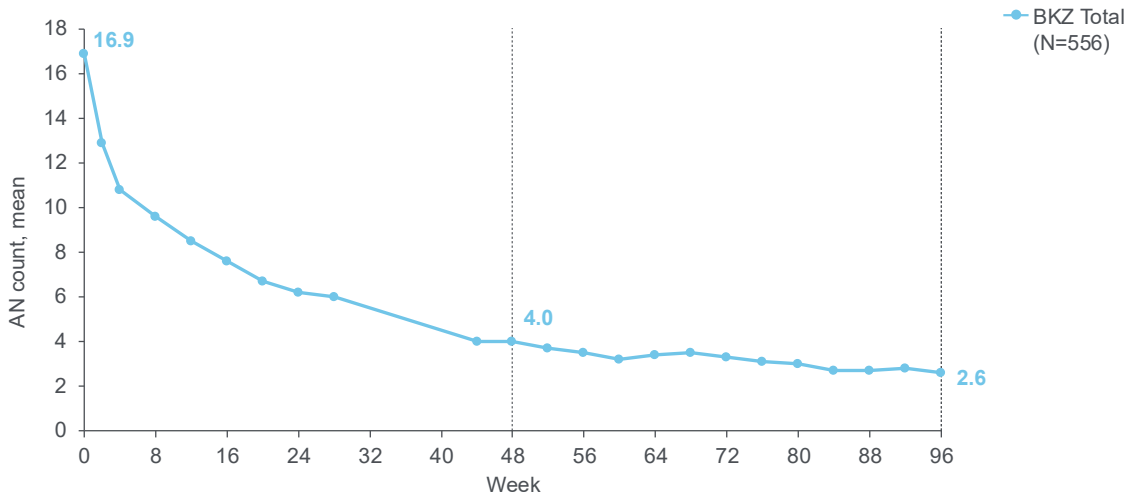
Supplementary Figure 4: HiSCR50/75/90/100 over time in BKZ Total patients (mNRI [AE-LoE])



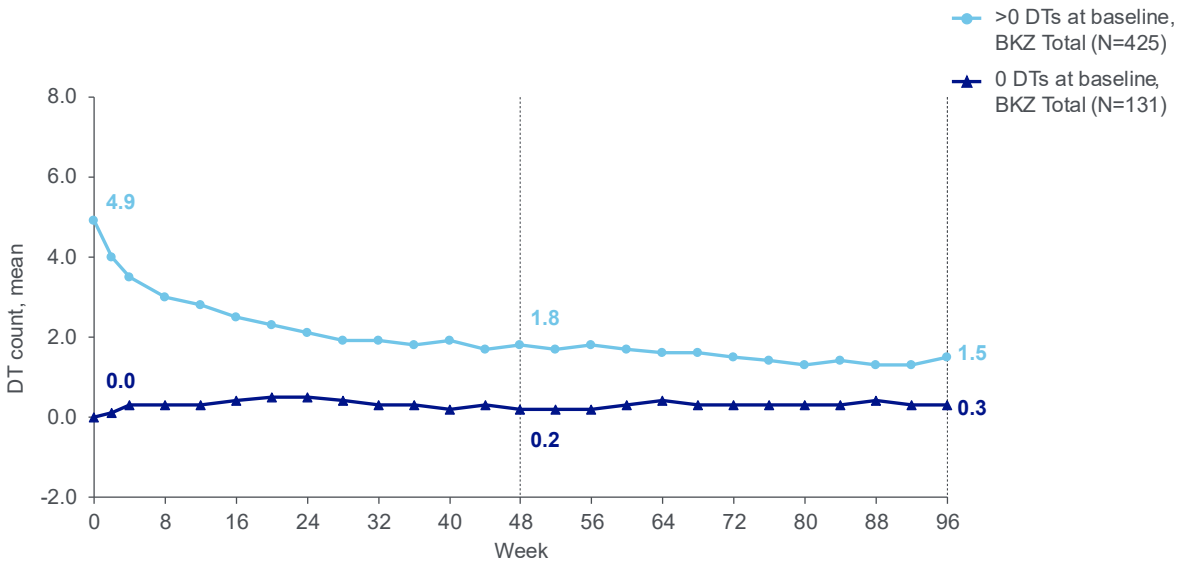
Hidradenitis suppurativa. OLE set: 657 BE HEARD I and II completers entered BE HEARD EXT at Week 48, of which 556 received BKZ from baseline (BKZ Total). Data for patients in BKZ Total are presented. BKZ Total comprised patients randomized to BKZ from baseline in BE HEARD I and II who entered BE HEARD EXT. Intermittent missing data were imputed using multiple imputation with MCMC method followed by monotone regression for monotone missing data. Lesion counts were imputed and then dichotomized to obtain the response status. For AE-LoE, discontinuation due to adverse event or lack of efficacy constituted as an intercurrent event. Patients who experienced an intercurrent event were treated as non-responders following the intercurrent event. AE-LoE: adverse event or lack of efficacy; 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; MCMC: Markov Chain Monte Carlo; mNRI: multiple non-responder imputation; OLE: open-label extension.

Supplementary Figure 5: Efficacy and lesion based outcomes over time in BKZ Total patients (MI [AE-LoE] and mNRI [AE-LoE])

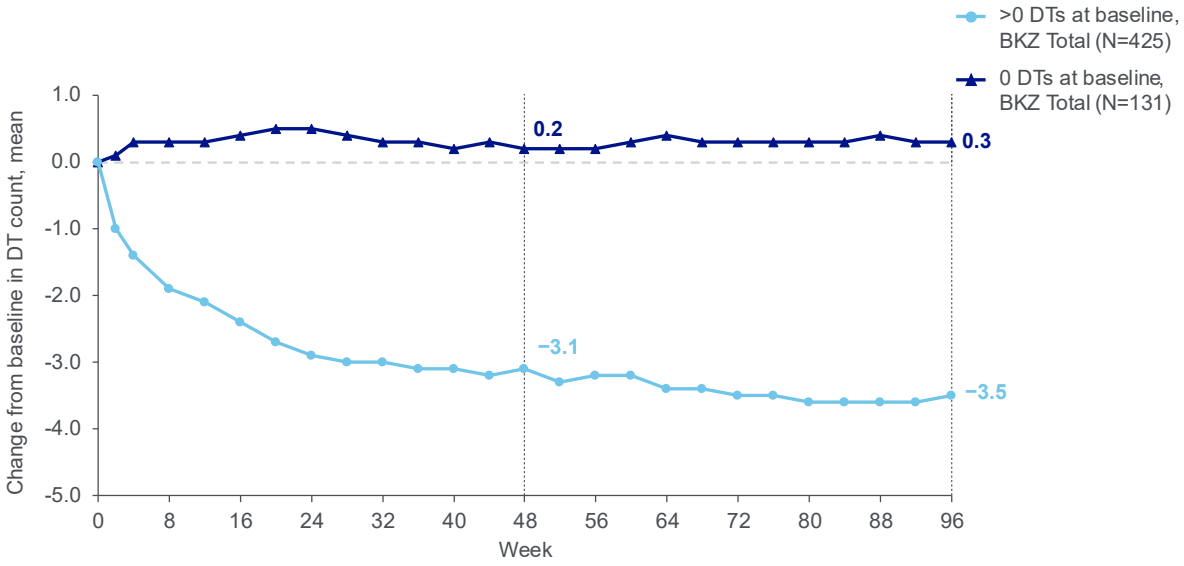
Mean AN count over time (MI [AE-LoE])[a]



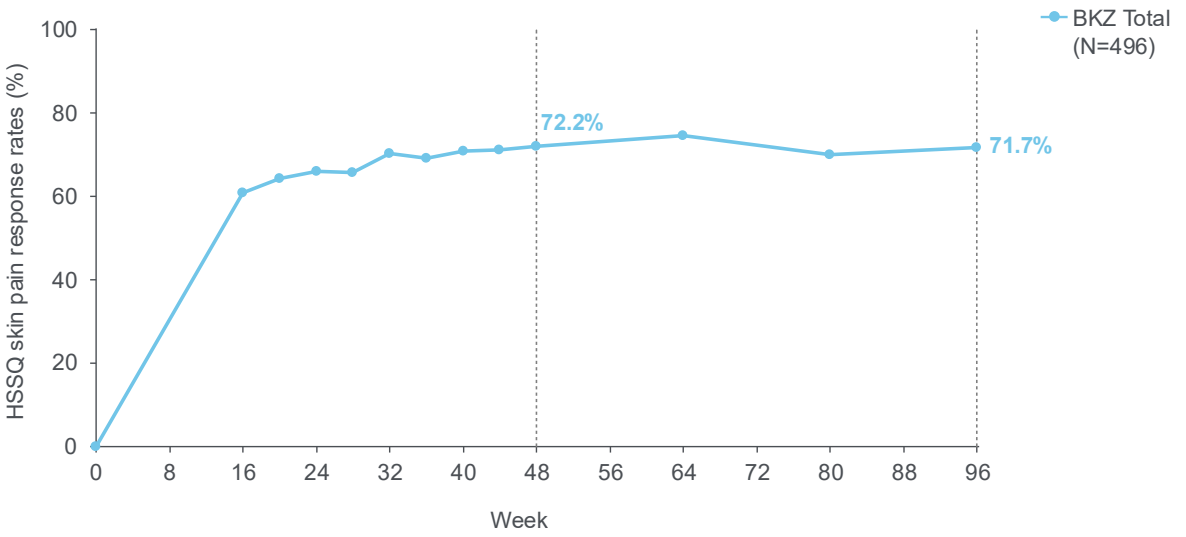
Mean DT count over time (MI [AE-LoE])[a]



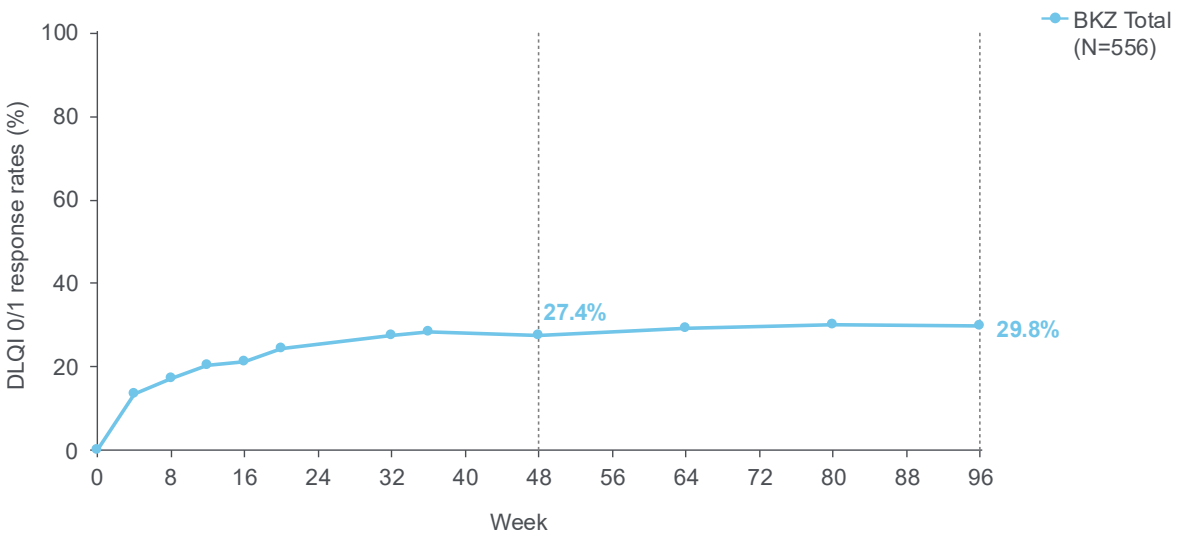
Mean absolute change from baseline in DT over time (MI [AE-LoE])[a]



HSSQ skin pain response rates (mNRI [AE-LoE])[b,c]



DLQI 0/1 Response Rates (mNRI [AE-LoE])[b,d]



Hidradenitis suppurativa. OLE set: 657 BE HEARD I and II completers entered BE HEARD EXT at Week 48, of which 556 received BKZ from baseline (BKZ Total). Data for patients in BKZ Total are presented. For AE-LoE, discontinuation due to adverse event or lack of efficacy constitutes an intercurrent event. **[a]** Intermittent missing data were imputed using multiple imputation with MCMC method followed by monotone regression for monotone missing data. Patients who experienced an intercurrent event were treated as missing following the intercurrent event and imputed using the multiple imputation method for missing data. **[b]** Intermittent missing data were imputed using multiple imputation with MCMC method followed by monotone regression for monotone missing data. Lesion counts were imputed and then dichotomized to obtain the response status. Patients who experienced an intercurrent event were treated as non-responders following the intercurrent event. **[c]** HSSQ response defined as at least a 30% reduction and ≥1 point reduction in HSSQ skin pain score, among patients with a baseline score of ≥3. **[d]** A DLQI response was defined as total scores of 0 or 1 (no impact of disease on HRQoL). AE-LoE: adverse event or lack of efficacy; AN: abscess and inflammatory nodule; BKZ: bimekizumab; DT: draining tunnel; DLQI: Dermatology Quality of Life Index; HRQoL: health-related quality of life; HSSQ: Hidradenitis Suppurativa Symptom Questionnaire; MCMC: Markov Chain Monte Carlo; MI: multiple imputation; mNRI: multiple non-responder imputation; OLE: open-label extension.

Supplementary Table 1. HiSCR50/75/90/100 over time in patients receiving BKZ Q2W/Q4W/Q4W[a] (OC)

Week	HiSCR50 % (n/N)	HiSCR75 % (n/N)	HiSCR90 % (n/N)	HiSCR100 % (n/N)
2	33.8 (25/74)	16.2 (12/74)	8.1 (6/74)	6.8 (5/74)
4	56.8 (42/74)	28.4 (21/74)	14.9 (11/74)	10.8 (8/74)
8	70.8 (51/72)	44.4 (32/72)	34.7 (25/72)	29.2 (21/72)
12	75.7 (56/74)	55.4 (41/74)	40.5 (30/74)	31.1 (23/74)
16	87.8 (65/74)	75.7 (56/74)	45.9 (34/74)	35.1 (26/74)
20	91.9 (68/74)	73.0 (54/74)	50.0 (37/74)	36.5 (27/74)
24	88.0 (66/75)	73.3 (55/75)	56.0 (42/75)	41.3 (31/75)
28	94.7 (71/75)	90.7 (68/75)	68.0 (51/75)	52.0 (39/75)
32	91.8 (67/73)	84.9 (62/73)	72.6 (53/73)	49.3 (36/73)
36	100 (74/74)	98.6 (73/74)	87.8 (65/74)	58.1 (43/74)
40	100 (72/72)	100 (72/72)	91.7 (66/72)	68.1 (49/72)
44	100 (73/73)	100 (73/73)	91.8 (67/73)	78.1 (57/73)
48	98.7 (74/75)	93.3 (70/75)	81.3 (61/75)	60.0 (45/75)
52	90.5 (67/74)	83.8 (62/74)	77.0 (57/74)	64.9 (48/74)
56	93.2 (69/74)	85.1 (63/74)	67.6 (50/74)	58.1 (43/74)
60	96.0 (72/75)	82.7 (62/75)	66.7 (50/75)	56.0 (42/75)
64	93.2 (69/74)	85.1 (63/74)	75.7 (56/74)	62.2 (46/74)
68	84.1 (58/69)	82.6 (57/69)	76.8 (53/69)	62.3 (43/69)
72	85.9 (61/71)	77.5 (55/71)	70.4 (50/71)	56.3 (40/71)
76	93.0 (66/71)	83.1 (59/71)	67.6 (48/71)	59.2 (42/71)
80	92.9 (65/70)	78.6 (55/70)	68.6 (48/70)	64.3 (45/70)

84	93.9 (62/66)	87.9 (58/66)	68.2 (45/66)	60.6 (40/66)
88	89.6 (60/67)	83.6 (56/67)	71.6 (48/67)	58.2 (39/67)
92	92.2 (59/64)	85.9 (55/64)	78.1 (50/64)	73.4 (47/64)
96	90.8 (59/65)	87.7 (57/65)	76.9 (50/65)	69.2 (45/65)

Hidradenitis suppurativa. OLE set: 657 BE HEARD I and II completers entered BE HEARD EXT at Week 48. **[a]** Data are reported for patients who were randomized to receive Q2W/Q4W in the initial/maintenance period and received Q4W on OLE entry. The denominator for n/N represents the number of patients with a non-missing lesion count assessment at the given week and percentages are calculated accordingly (i.e. 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; Q2W: every 2 weeks; Q4W: every 4 weeks.

ACKNOWLEDGMENTS

These studies were funded by UCB. The authors thank the patients and their caregivers in addition to all the investigators and their teams who contributed to these studies. The authors acknowledge Susanne Wiegratz, MSc, UCB, Monheim am Rhein, Germany for publication coordination, May-Li MacKinnon, PhD, Costello Medical, Manchester, UK and Isabel Katz, BA, Costello Medical, London, UK for medical writing support and editorial assistance in accordance with Good Publication Practice (GPP 2022) guidelines (http://www.ismpp.org/gpp-2022).

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.

FUNDING

These studies were funded by UCB.

AUTHORS' CONTRIBUTIONS

Substantial contributions to study conception and design: **CJS**, **BK**, **AG**, **HBN**, **ABK**, **CCZ**, **GBEJ**, **GK, JRI**, **AM**, **DD**, **CC**, **RLR**, **TV, JL**, **BL**, and **FGB** ; substantial contributions to analysis and interpretation of the data; **CJS**, **BK**, **AG**, **HBN**, **ABK**, **CCZ**, **GBEJ**, **GK, JRI**, **AM**, **DD**, **CC**, **RLR**, **TV, JL**, **BL**, and **FGB** ; drafting the article or revising it critically for important intellectual content; **CJS**, **BK**, **AG**, **HBN**, **ABK**, **CCZ**, **GBEJ**, **GK, JRI**, **AM**, **DD**, **CC**, **RLR**, **TV, JL**, **BL**, and **FGB**; final approval of the version of the article to be published: **CJS**, **BK**, **AG**, **HBN**, **ABK**, **CCZ**, **GBEJ**, **GK, JRI**, **AM**, **DD**, **CC**, **RLR**, **TV, JL**, **BL**, and **FGB.**

DISCLOSURES

CJS: Investigator for AbbVie, AstraZeneca, ChemoCentryx, Incyte, InflaRx, Novartis, and UCB; consultancy fees from AbbVie, Alumis, AstraZeneca, InflaRx, Incyte, Logical Images, MoonLake Immunotherapeutics, Sandoz, Sanofi, Sonoma Biotherapeutics, and UCB; speaker for AbbVie and Novartis.

BK: Received research support from or has been a principal investigator (clinical trials) for AbbVie, Almirall, Janssen, Merck, MoonLake Immunotherapeutics, Novartis, Pfizer and UCB; has been a consultant for AbbVie, Almirall, Celgene, Janssen, Merck, MC2 Therapeutics, MoonLake Immunotherapeutics, Novartis, Pfizer and UCB; has received honoraria from AbbVie, Almirall, Celgene, Eli Lilly and Company, Janssen, MoonLake Immunotherapeutics, Novartis, Pfizer, UCB, and Union Therapeutics; has been on scientific advisory boards for AbbVie, Almirall, Celgene, Eli Lilly and Company, Janssen, MoonLake Immunotherapeutics, Novartis, Pfizer, and UCB.

AG: Receives honoraria as an advisor for AbbVie, Almirall, Boehringer Ingelheim, Engitix, Immunitas Therapeutics, Incyte, Insmed, Novartis, Pfizer, Sonoma Biotherapeutics, UCB, Union Therapeutics, and Zura Bio; receives research grants from AbbVie, CHORD COUSIN Collaboration (C3), and UCB.

HBN: Received consulting fees from AbbVie, Medscape, Sonoma Biotherapeutics, Union Chimique Belge (UCB), and Novartis; received grant from Union Chimique Belge (UCB); and holds shares in Radera, Inc. She is on the JAMA Dermatology Editorial Board and Vice President of the Hidradenitis Suppurativa Foundation.

ABK: Received institution grants from AbbVie, Admirx, AnaptysBio, Aristea, Bristol Myers Squibb, Eli Lilly and Company, Incyte, Janssen, MoonLake Immunotherapeutics, Novartis, Pfizer, Prometheus, Sonoma Biotherapeutics, and UCB; received consulting fees from AbbVie, Alumis, Avalo, Bayer, Boehringer Ingelheim, Eli Lilly and Company, Janssen, MoonLake Immunotherapeutics, Novartis, Pfizer, Priovant, Sanofi, Sonoma Biotherapeutics, Target RWE, UCB, Union Therapeutics, and Ventyx; serves on the board of directors of Almirall.

CCZ: Received institution grants as a clinical and research investigator for AbbVie, AstraZeneca, 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; received honoraria as a consultant for AccureAcne, Almirall, Biogen, Boehringer Ingelheim, CSL Behring, Eli Lilly and Company, Estée Lauder, Idorsia, Incyte, L'Oréal, MSD, NAOS-BIODERMA, Novartis, PPM, Sanofi, SciRhom, Takeda, UCB, and ZuraBio; received lecture fees from Almirall, Amgen, Biogen, Bristol Myers Squibb, L'Oréal, NAOS-BIODERMA, Novartis, Pfizer, and UCB. He is president of the EHSF e.V., president of the Deutsches Register Morbus Adamantiades-Behçet e.V., board member of the International Society for Behçet's Disease, coordinator of the ALLOCATE Skin group of the ERN Skin and chair of the ARHS Task Force group of the EADV; editor of the EADV News; co-copyright holder of IHS4 on behalf of the EHSF e.V.

GBEJ: Honoraria from AbbVie, Boehringer Ingelheim, ChemoCentryx, Incyte, Janssen, LEO Pharma, Novartis and UCB for participation on advisory boards; investigator for AbbVie, CSL, InflaRx, Janssen, LEO Pharma, Novartis, Regeneron, Sanofi, and UCB; speaker honoraria from AbbVie and Novartis; research grants from LEO Pharma and Novartis.

GK: Received travel grants or honoraria, has been a consultant member of advisory boards and speaker bureaus or has served as an investigator for AbbVie, Actelion, Almirall, Amgen, Basilea, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly and Company, Hexal-Sandoz, Janssen, LEO Pharma, MSD, Novartis, Pfizer, Sanofi, Takeda, and UCB.

JRI: Received a stipend as recent Editor-in-Chief of the British Journal of Dermatology and an authorship honorarium from UpToDate; consultant for AbbVie, Boehringer Ingelheim, Cantargia, ChemoCentryx, Citryll, Elasmogen, Engitix, Incyte, Indero, Insmed, Kymera Therapeutics, MoonLake, Novartis, UCB, UNION Therapeutics, and Viela Bio; co-copyright holder of HiSQOL©, HS Patient Global Assessment, and HS-IGA; his department receives income from copyright of the Dermatology Life Quality Instrument (DLQI), and related instruments.

AM: Research grants, consulting fees, and/or speaker's fees from AbbVie, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eisai, Eli Lilly and Company, Janssen, Kyowa Hakko Kirin, LEO Pharma, Maruho, Mitsubishi Tanabe Pharma, Nichi-Iko, Nippon Kayaku, Novartis, Pfizer, Sun Pharma, Taiho Pharmaceutical, Torii Pharmaceutical, UCB, and Ushio.

DD, CC, RLR, TV, JL, and **BL:** Employees and shareholders of UCB.

FGB: Received honoraria for participation in advisory boards, in clinical trials, and/or as a speaker from AbbVie, Acelyrin, Beiersdorf, Boehringer Ingelheim, Celltrion, Dr. Wolff, Incyte, Janssen, Johnson & Johnson, Merck, Mölnlycke, MoonLake Immunotherapeutics, Novartis, Sanofi, Sitala, and UCB.