UCB VIRTUAL BRIEFING

Data from the bimekizumab Phase 3 Studies in Hidradenitis Suppurativa (HS)

BE HEARD I and BE HEARD II

Bimekizumab is not approved for use in HS by any regulatory authority worldwide. The safety and efficacy of bimekizumab in HS has not been established.

Bimekizumab is not approved for any indication by the U.S. Food and Drug Administration

Inspired by **patients.**
Driven by **science.**

GL-N-BK-HS-2300006
Date of preparation: March 2023

Intended Audience

- This presentation is intended for analysts and investors invited by UCB to this closed educational event.
- The efficacy and safety of investigational bimekizumab **in the treatment of hidradenitis suppurativa (HS)** has not been established and it is not approved for the treatment of HS by any regulatory authority worldwide.
- Bimekizumab was first approved for moderate to severe plaque psoriasis in adults who are candidates for systemic therapy in the European Union and Great Britain. The label information may differ in other countries where bimekizumab is approved. Please check local prescribing information.
- Bimekizumab is **not approved for any indication by the U.S. Food and Drug Administration.**
- All figures and tables are adapted from cited references/presentations.
- **The slides are for an analyst/investor audience only and were prepared for the purpose of this closed event. They should not be copied or reproduced in any way.**

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Introduction

Emmanuel Caeymaex

Executive Vice President, Immunology Solutions and Head of US, UCB

GL-N-BK-HS-2300006
Date of preparation: March 2023

Agenda

01 Introduction
Emmanuel Caeymaex
Executive Vice President, Immunology Solutions and Head of US, UCB

02 Hidradenitis Suppurativa: A Need for New Therapeutic Approaches
Amit Garg, M.D.
Professor & Founding Chair, Department of Dermatology, Zucker School of Medicine at Hofstra/Northwell, US

03 Data from the Bimekizumab Phase 3 Studies in Hidradenitis Suppurativa (BE HEARD I and BE HEARD II)
Alexa Kimball, M.D.
Beth Israel Deaconess Medical Center and Professor of Dermatology, Harvard Medical School, Boston, MA, U.S.

04 Conclusions
Emmanuel Caeymaex

05 Q&A facilitated by Antje Witte, UCB

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In IL-17 mediated diseases, bimekizumab has delivered 10 consecutive positive Phase 3 studies

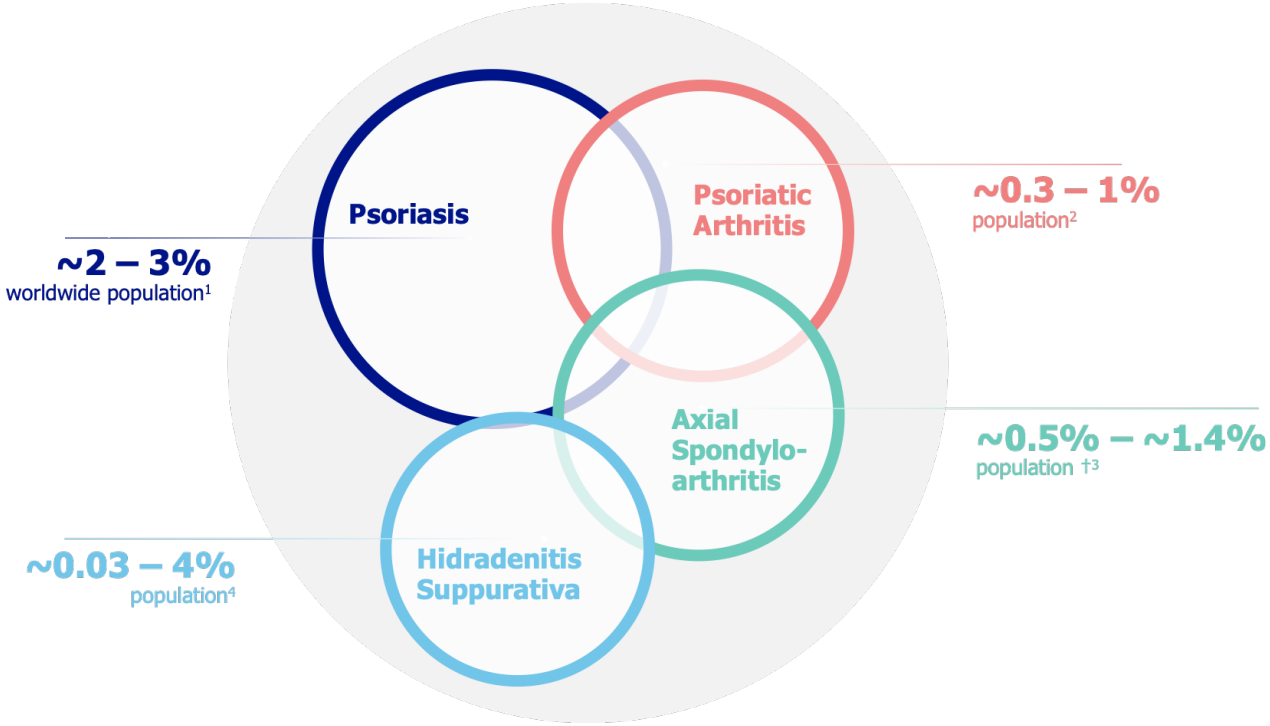
Psoriasis

- **BE VIVID** (PS0009) NCT03370133 (vs ustekinumab*)
- **BE READY** (PS0013) NCT03410992 (vs placebo)
- **BE SURE** (PS0008) NCT03412747 (vs adalimumab)
- **BE RADIANT** (PS0015) NCT03536884 (vs secukinumab)

Hidradenitis Suppurativa

Top-line results expected H2 2022

- **BE HEARD I** (HS0003) NCT04242446 (vs placebo)
- **BE HEARD II** (HS0004) NCT04242498 (vs placebo)



Psoriatic Arthritis

- **BE OPTIMAL** (PA0010) NCT03895203 (vs placebo)
- **BE COMPLETE** (PA0011) NCT03896581 (vs placebo)

Axial Spondyloarthritis

- **BE MOBILE1** (AS0010) NCT03928704 (vs placebo in nr-axSpA)
- **BE MOBILE2** (AS0011) NCT03928743 (vs placebo in AS/r-axSpA)

*Ranked secondary endpoint. †U.S. prevalence.

References: 1. National Psoriasis Foundation. Statistics. Available at: https://www.psoriasis.org/content/statistics. Last accessed: March 23; 2. Gladman DD et al. Ann Rheum Dis. 2005. 64 (Suppl 2);ii14-17; 3. Reveille JD. AM J Med Sci. 2013; 345(6):431-36. 4. Calao M et al. PLoS ONE. 2018;13(7);e0200683.

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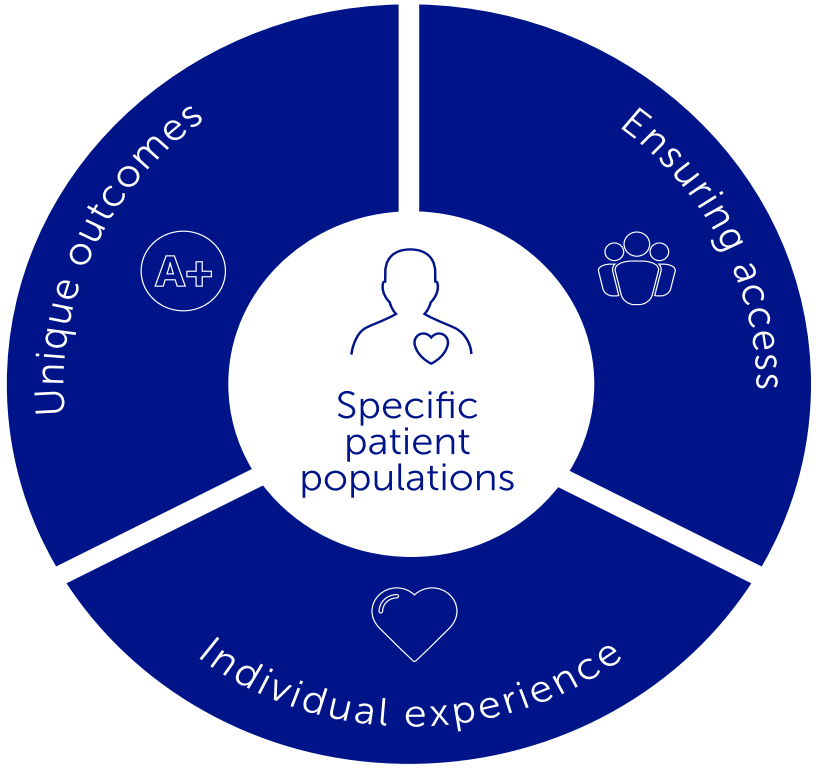
Our focus in HS is aligned with our purpose



Supported by our Partnership Network Including

my Health team

myHSteam

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Hidradenitis Suppurativa: *A Need for New Therapeutic Approaches*

Amit Garg, M.D.

Professor & Founding Chair | Department of Dermatology
Zucker School of Medicine at Hofstra/Northwell

Professor | Center for Health Innovations & Outcomes Research
Feinstein Institutes for Medical Research

SVP | Dermatology Service Line
Northwell Health

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Disclosures

Dr. Garg is an advisor for AbbVie, Aclaris Therapeutics, Anaptys Bio, Aristea Therapeutics, Boehringer Ingelheim, Bristol Myers Squibb, Incyte, Insmed, Janssen, Novartis, Pfizer, Sonoma Biotherapeutics, UCB, Union Therapeutics, Ventyx Biosciences, and Viela Biosciences, and receives honoraria.

Dr Garg receives research grants from AbbVie, UCB, National Psoriasis Foundation, and CHORD COUSIN Collaboration (C3).

He is co-copyright holder of the HS-IGA and HiSQOL instruments.

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HS has a high burden for patients with significant impact on quality of life

Prevalence[1]

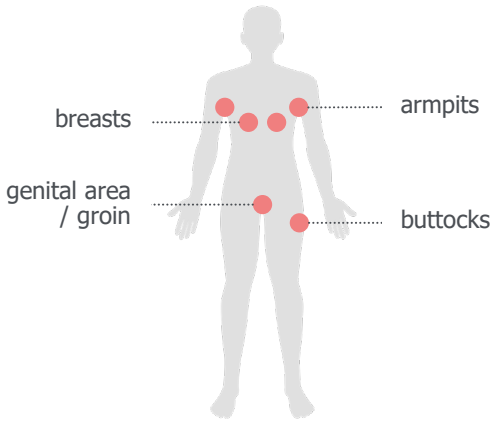
varies ~1% in most studied countries

Comorbidities*[3,4]

- Obesity
- Diabetes
- Axial Spondyloarthritis (axSpA)
- Depression

Others: Generalised Anxiety Disorder, Substance Disorders; Hypertension, Cardiovascular Disease

Affected Areas*[1,2]



Quality of Life*[4]

- Stigma / Embarrassment
- Disruption to Intimacy
- Pain

*not limited to 1. Sabat R, et al. Nat Rev Dis Primers. 2020;6:18; 2. Jemec GBE. N Engl J Med. 2012;366(2):158-164 3. Garg et al JAAD 86 (5) P 1092-P110; 4. Zouboulis et al. J Eur Acad. Dermatol. Venereol. 2015 29(4): 619-44

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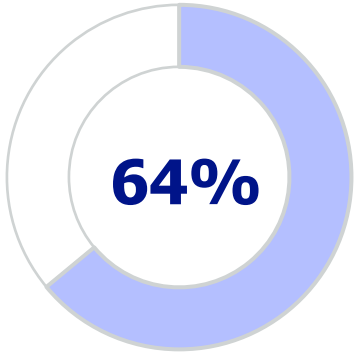
The patient HS journey is challenging

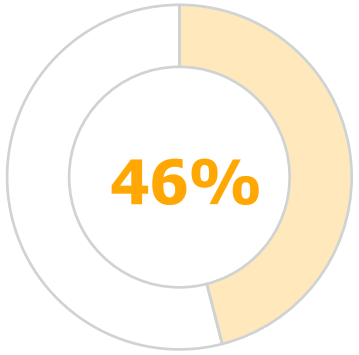
Delays in diagnosis

The Global VOICE survey[1] (N=1,229) reported a **10-year delay in diagnosis with 64% visiting a physician ≥5 times before diagnosis**

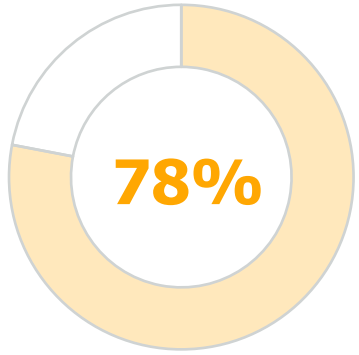


Suboptimal management

In the Global VOICE survey[1] (N=1,229) **45.9% of participants were dissatisfied or very dissatisfied** with current treatment



In an online survey[2] (N=128) with **HS patients 78% had not opened discussion on biologic treatments with their HCP**



- 1. Garg et al. J Am Acad Dermatol. 2020;82:366–76; 2. Kimball et al. Presentation 4059 at SHSA 2021

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Delayed diagnosis can lead to disease progression

- Impairment to quality of life **is greater in HS vs other dermatological conditions**[1–3]

- **Pain, shame, and embarrassment** are closely linked with the severity of symptoms and **greatly impact mental health, sustaining relationships and participating in sexual activity**[1]

- Increased **working disability, greater use of sick leave, and difficulty sustaining employment** have been reported[4,5]

- Patients face **a high burden of disease from multiple comorbidities**, including anxiety, depression and obesity[6]

.
1. Keary et al. Br J Dermatol. 2020;182:342–7. 2. Lindsø Andersen et al. Acta Derm Venereol. 2020;100:adv00107. 3. Storer et al. Int J Womens Dermatol. 2018;4:198–202. 4. Dufour et al. Postgrad Med J. 2014;90:216–21. 5. Matusiak et al. JAAD. 2010;62:706–8. 6. Tzellos and Zouboulis. Dermatol Ther (Heidelb). 2020'10:63–71.

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Delayed access to biologic treatment can further risk disease progression

In moderate to severe disease biologic therapy is an important treatment option[1]

In a US study of **25,966 patients** with HS, only **1.8%** received an anti-TNF prescription[2]

In a study of **225 patients** with HS in the Danish National Patient Registry, **prior to receiving biologics, patients received, on average[3]:**

4 different **systemic therapies**

17 different **treatment series**

8 years
of systemic therapy*
prior to biologic treatment

*Number of years from initiation of first systemic therapy until first biologic therapy, excluding penicillin and dicloxacillin (increases to 15 years when including these therapies).
Standard deviations for mean systemic therapies, treatment series and years: 1.3, 11.3, and 5.9 (or 5.1 including penicillin and dicloxacillin), respectively. HCP, healthcare professional; HS, hidradenitis suppurativa. 1.Čagalj AM et al Int J Mol Sci. 2022; 23(7): 3753. 2. Orenstein et al. J Am Ac Derm. 2021;1399–401. 3. Ring et al. Br J Dermatol. 2022;doi:10.1111/bjd.21673.

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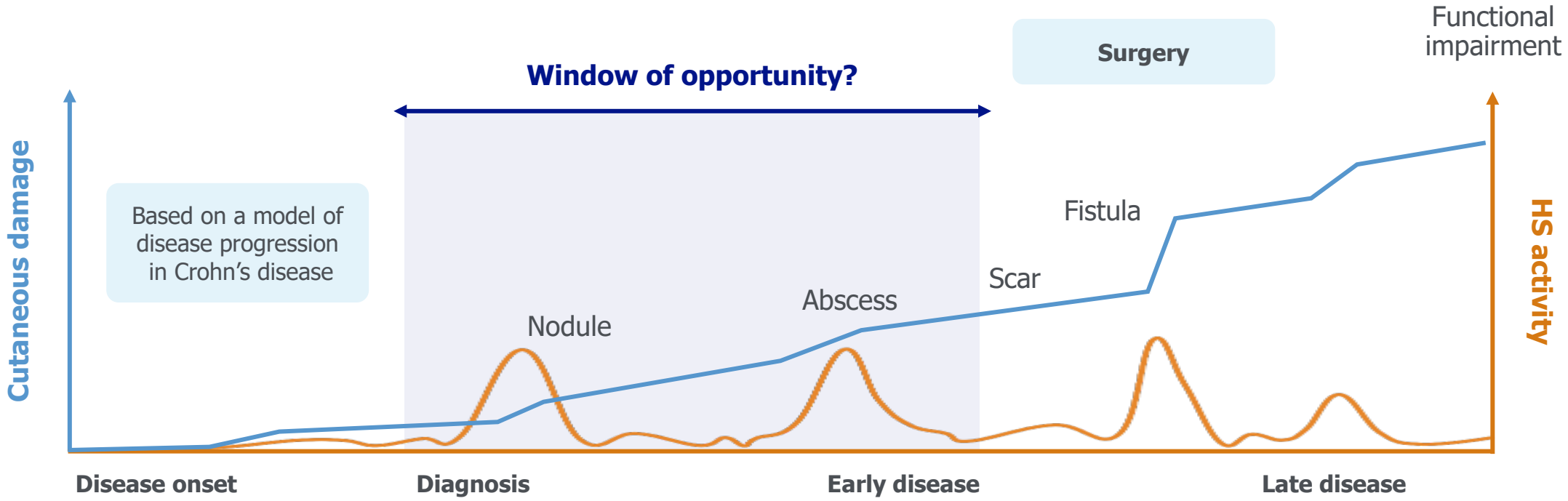
A window of opportunity may exist to support earlier treatment

To improve the quality of life of patients with moderate to severe HS a window of opportunity may exist to support earlier biologic treatment



Adapted from Martorell et al. Actas Dermosifiliogr. 2016;107(Suppl 2):

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Summary

1. HS is a **disabling disease** with great **psychological and functional impact** on patients' lives[1]
2. **Substantial delays in diagnosis and effective treatment** can risk disease progression[2,3]
3. A window of opportunity may exist to **support earlier treatment**
4. There is a **need for new biologic treatment options**

1. Markota Čagalj A et al Int J Mol Sci. 2022 Apr; 23(7): 3753 2. Garg et al. J Am Acad Dermatol. 2020;82:366–76 3. Kearney et al. SHSA 2021. Abstract P4.04

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Data from the Bimekizumab Phase 3 Studies in Hidradenitis Suppurativa

(BE HEARD I and BE HEARD II)

Alexa Kimball, M.D.

Beth Israel Deaconess Medical Center
and Harvard Medical School, Boston, MA, U.S

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Bimekizumab in patients with moderate-to-severe hidradenitis suppurativa: 48-week efficacy and safety from BE HEARD I & II, two phase 3, randomized, double-blind, placebo-controlled, multicenter studies

Alexa B. Kimball,[1] Christos C. Zouboulis,[2,3] Christopher Sayed,[2,4] Joslyn S. Kirby,[5] Errol Prens,[2,6] John R. Ingram,[2,7] Amit Garg,[8] Robert Rolleri,[9] Edward Muller,[10] Paulatsya Joshi,[10] Gregor Jemec[2,11]

[1]Beth Israel Deaconess Medical Center and Harvard Medical School, Boston, MA, USA; [2]European Hidradenitis Suppurativa Foundation (EHSF), Dessau, Germany; [3]Departments of Dermatology, Venereology, Allergology and Immunology, Staedtisches Klinikum Dessau, Brandenburg Medical School Theodor Fontane and Faculty of Health Sciences Brandenburg, Dessau, Germany; [4]Department of Dermatology, University of North Carolina School of Medicine, Chapel Hill, NC, USA; [5]Department of Dermatology, Penn State University, Hershey, PA, USA; [6]Department of Dermatology, Erasmus University Medical Center Rotterdam, Rotterdam, The Netherlands; [7]Department of Dermatology & Academic Wound Healing, Division of Infection & Immunity, Cardiff University, Cardiff, UK; [8]Donald and Barbara Zucker School of Medicine at Hofstra/Northwell, Hempstead, NY, USA; [9]UCB Pharma, Morrisville, NC, USA; [10]UCB Pharma, Slough, UK; [11]Department of Dermatology, Zealand University Hospital, Roskilde, Denmark; [12]Department of Clinical Medicine, Faculty of Health and Medical Science, University of Copenhagen, Copenhagen, Denmark.
University of Copenhagen, Copenhagen, Denmark.

Data presented as oral platform presentation at AAD 2023 – Session S042

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- **ABK:** Consultant and investigator for AbbVie, Bristol Myers Squibb, Eli Lilly, Janssen, Novartis, Pfizer, and UCB Pharma; investigator for Incyte and AnaptysBio; consultant for Bayer, Boehringer Ingleheim, Ventyx, Moonlake, Concert, EvoImmune, Sonoma Bio, Sanofi, and receives fellowship funding from Janssen and AbbVie; serves on Board of Directors for Almirall.
- **CCZ:** Honoraria as an advisor and speaker for studies or lectures associated with hidradenitis suppurativa (HS) from AbbVie, Almirall, Boehringer Ingelheim, Idorsia, Incyte, InflaRx, Janssen, Novartis, Regeneron, UCB Pharma, and Viatris; department has received grants from AbbVie, Boehringer Ingelheim, InflaRx, Novartis, and UCB Pharma for his participation as an investigator.
- **CS:** Investigator for AbbVie, Chemocentryx, GSK, Incyte, InflaRx, Novartis, and UCB Pharma; consultancy fees from AbbVie, Alumis, InflaRx, Incyte, Logical Images, Sonoma Biotherapeutics, and UCB Pharma; speaker for AbbVie and Novartis.
- **JSK:** Reports personal fees from AbbVie, ChemoCentryx, CSL Behring, DermTech, Incyte, Insmed, Janssen, Moonlake, Novartis, and UCB Pharma; received personal fees and grants from Incyte; co-copyright holder of HiSQOL.
- **EP:** Consultant, advisory board member, speaker for and received honoraria from Almirall, GSK, Janssen-Cilag, Moonlake, Novartis, and UCB Pharma; department received investigator-initiated grant support from AbbVie, Celgene, CHDR, Citryll, Janssen-Cilag, Kymera, and UCB Pharma.
- **JRI:** Receives stipend as Editor-in-Chief of the British Journal of Dermatology and authorship honorarium from UpToDate; consultant for Boehringer Ingelheim, ChemoCentryx, Citryll, Novartis, and UCB Pharma and has served on advisory boards for Insmed, Kymera Therapeutics, and Viela Bio; co-copyright holder of the Hidradenitis Suppurativa Quality of Life questionnaire, Investigator Global Assessment (IGA), and Patient Global Assessment instruments for HS; department receives income from copyright of the Dermatology Life Quality Instrument (DLQI) and related instruments.
- **AG:** Honoraria as a consultant for AbbVie, Aclaris Therapeutics, AnaptysBio, Aristea Therapeutics, Bristol Myers Squibb, Boehringer Ingelheim, Incyte, Insmed, Janssen, Novartis, Pfizer, Sonoma Biotherapeutics, UCB Pharma, Union Therapeutics, Ventyx biosciences, and Viela Biosciences; received research grants from AbbVie, UCB Pharma, National Psoriasis Foundation, and C3; co-copyright holder of HiSQOL and HS-IGA.
- **RR, EM, PJ:** Employees and shareholders of UCB Pharma.
- **GJ:** Honoraria from AbbVie, Boehringer Ingelheim, Chemocentryx, Incyte, Janssen-Cilag, LEO Pharma, Novartis, and UCB Pharma for participation on advisory boards; investigator for AbbVie, InflaRx, Janssen-Cilag, Leo Pharma, Novartis, Regeneron, Sanofi, and UCB Pharma; speaker honoraria from AbbVie and Novartis; research grants from LEO Pharma and Novartis.

Acknowledgements

This study was funded by UCB Pharma. We would like to thank the patients and their caregivers in addition to all the investigators and their teams who contributed to these studies, including clinical project managers, Rob Byerly and Sarah Knowles. The authors acknowledge Susanne Wiegratz, MSc, UCB Pharma, Monheim, Germany, for publication coordination, and Phoebe Kennedy, MSc, Costello Medical, Bristol, UK, for medical writing and editorial assistance. All costs associated with development of this presentation were funded by UCB Pharma.

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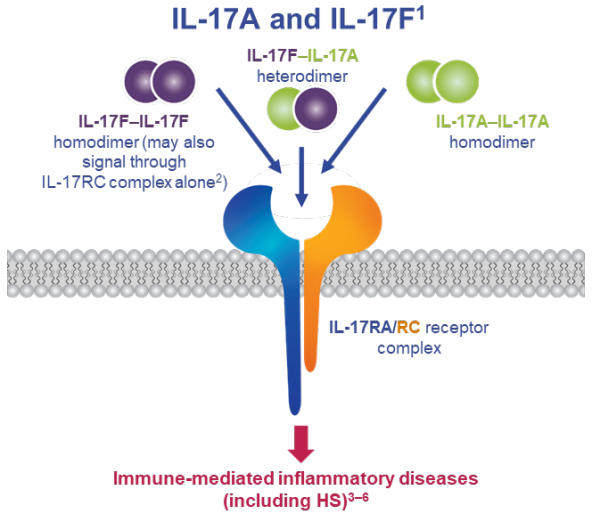
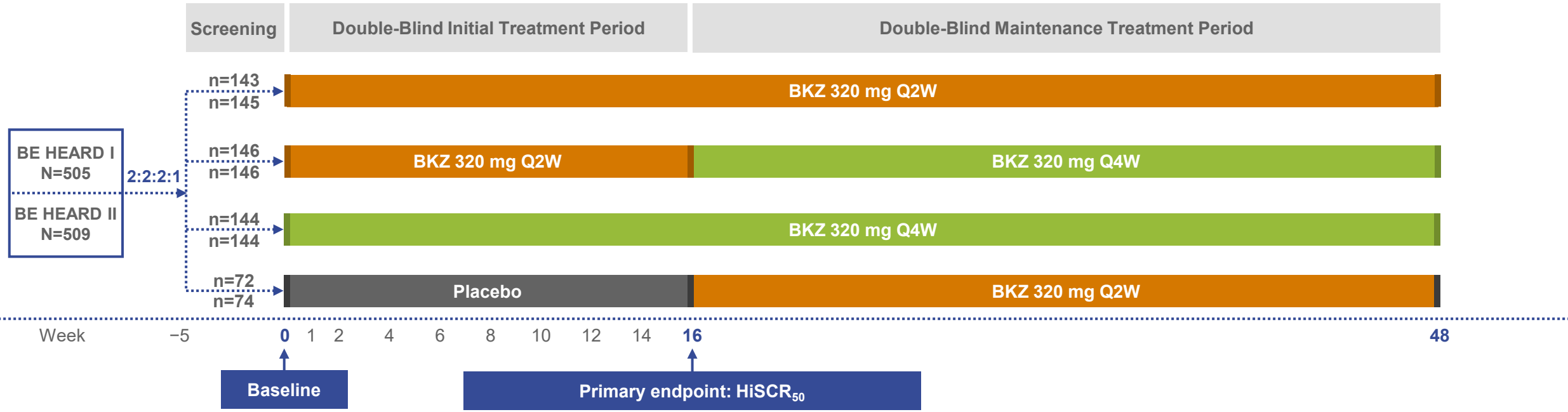
Background and BE HEARD I and II Study Design

Patients

- **Included**: patients with a diagnosis of moderate to severe HS with ≥5 inflammatory lesions (abscess and inflammatory nodule [AN] count)
- **Excluded**: patients with >20 draining tunnels



Study Design



1. Yang XO et al. *J Exp Med* 2008;205:1063–75; **2.** Goepfert A et al. *Immunity* 2020;52:499–512; **3.** Glatt S et al. *Ann Rheum Dis* 2018;77:523−32; **4.** Zouboulis CC et al. *J Eur Acad Dermatol Venereol* 2020;34:846–61; **5.** Schlapbach C et al. *J Am Acad Dermatol* 2011;65:790–98; **6.** Maroof A et al. *Translational data suggesting a pivotal role for IL-17A and IL-17F in hidradenitis suppurativa*. Poster 3776; SHSA 2022. AN: abscess and inflammatory nodule; BKZ: bimekizumab; $HiSCR_{50}$: ≥50% reduction from baseline in the total AN count with no increase from baseline in abscess or draining tunnel count; HS: hidradenitis suppurativa; IL: interleukin; Q2W: every two weeks; Q4W: every four weeks; RA: receptor A; RC: receptor C.

Patient Demographics and Characteristics at Baseline were Generally Balanced Across Studies

	BE HEARD I All Patients N=505	BE HEARD II All Patients N=509
Age, years, mean (SD)	36.7 (12.0)	36.6 (12.4)
Sex, female, n (%)	318 (63.0)	258 (50.7)
Racial group, white, n (%)	393 (77.8)	415 (81.5)
BMI, kg/m^2, mean (SD)	33.8 (8.2)	32.3 (8.0)
Smoking status, current, n (%)	217 (43.0)	245 (48.1)
Duration of HS, years, mean (SD)	9.0 (8.3)	7.0 (7.1)
AN count, mean (SD)	16.0 (17.5)	16.5 (14.6)
DT count, mean (SD)	3.8 (4.8)	3.4 (3.7)
Hurley stage,[a] n (%)		
II	254 (50.3)	311 (61.1)
III	251 (49.7)	198 (38.9)
DLQI Total Score, mean (SD)	12.0 (7.1)[b]	10.8 (6.6)[c]
Prior biologic use,[d] n (%)	126 (25.0)	67 (13.2)
Baseline antibiotic use (antibiotic strata),[e] n (%)	40 (7.9)	46 (9.0)

Randomized set. [a] Derived Hurley stage for each patient is the worst overall Hurley stage derived from the Hurley stages recorded across all anatomical regions; [b] n=496; [c] n=500; [d] Patients received prior biologic therapy for any indication; [e] Derived antibiotic use at baseline is defined as 'yes' if the patient has a recorded systemic antibiotic started at least 28 days prior to the baseline visit in BE HEARD I, and for patients who reported at least one ongoing systemic antibiotic at baseline in BE HEARD II. AN: abscess and inflammatory nodule; BMI: body mass index; DLQI: Dermatology Life Quality Index; DT: draining tunnel; HS: hidradenitis suppurativa; SD: standard deviation.

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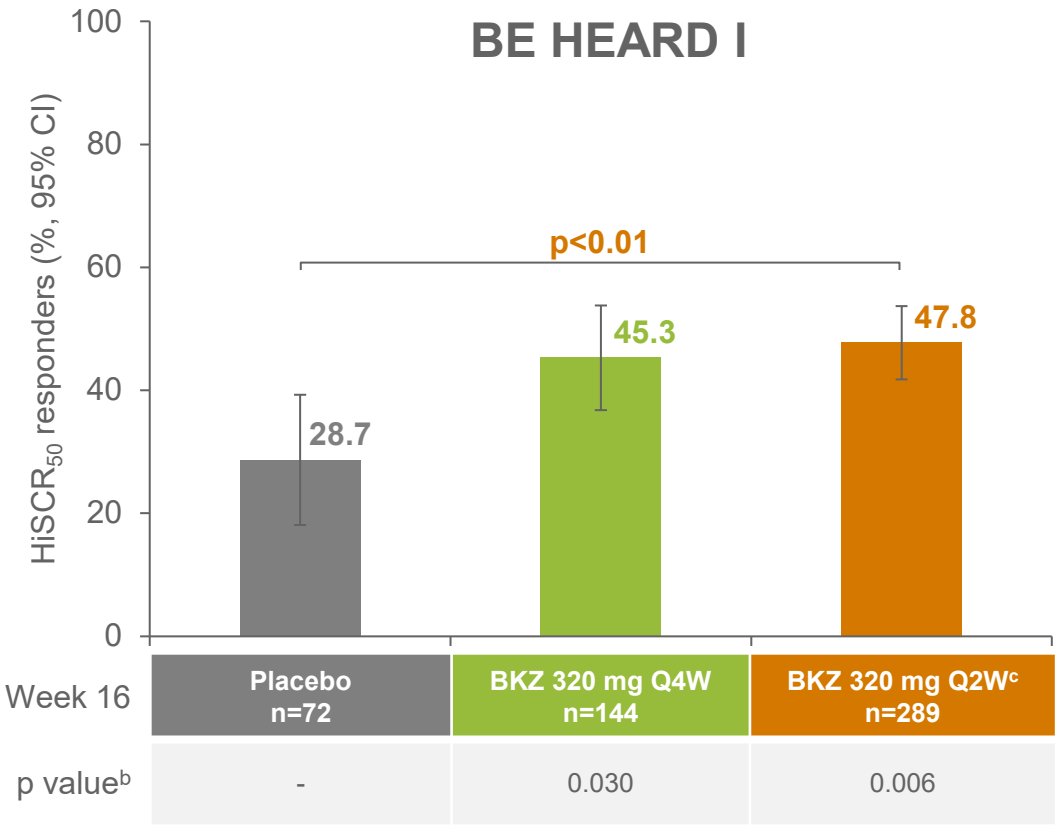
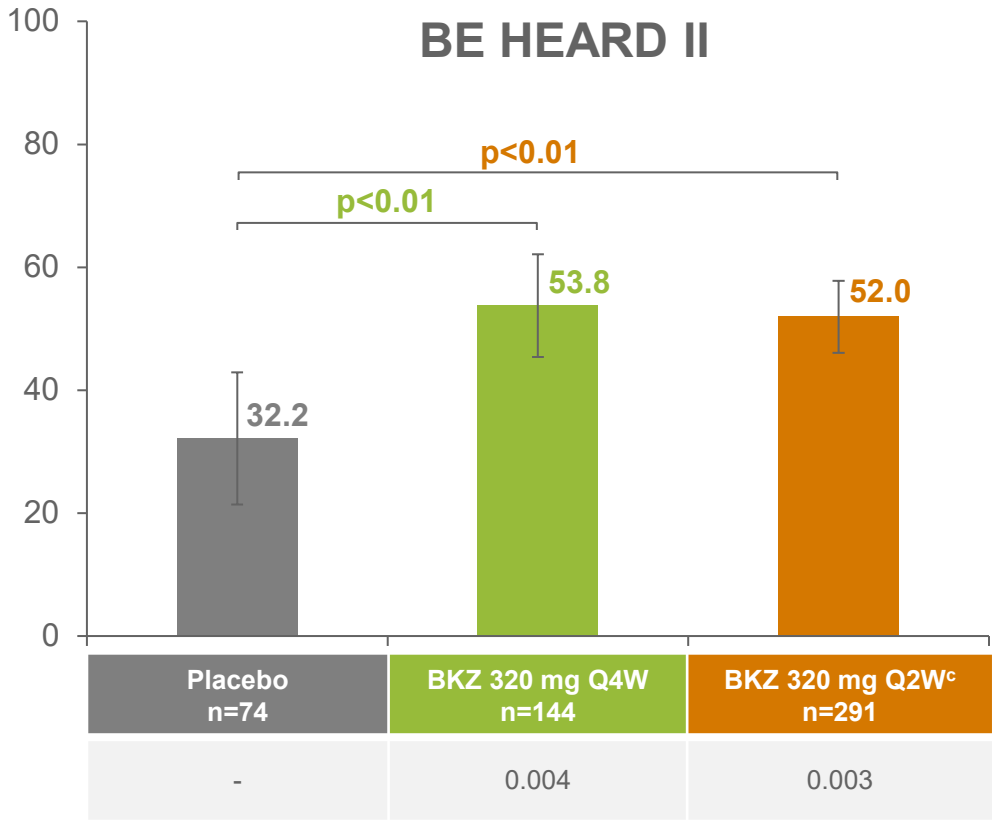
Patients treated with Bimekizumab Achieved Clinically Meaningful Improvements over Placebo at Week 16 as Measured by the Primary Endpoint, $HiSCR_{50}$ (mNRI [All-ABX][a])

BE HEARD I met the primary endpoint of $HiSCR_{50}$ for BKZ 320 mg Q2W versus placebo
BE HEARD II met the primary endpoint of $HiSCR_{50}$ for both BKZ dose regimens versus placebo



Week 16	Placebo n=72	BKZ 320 mg Q4W n=144	BKZ 320 mg Q2W[c] n=289
p value[b]	-	0.030	0.006



	Placebo n=74	BKZ 320 mg Q4W n=144	BKZ 320 mg Q2W[c] n=291
	-	0.004	0.003

Randomized set. [a] **mNRI (All-ABX): Patients who take any systemic antibiotic (new or increased dose)** or who discontinue due to AE or lack of efficacy **are treated as non-responders at all subsequent visits**. Other missing data were imputed via multiple imputation. Primary analysis method; [b] p value (from Wald test) reported for **adjusted responder rates**, obtained from logistic regression with treatment, Hurley stage at baseline and baseline antibiotic use as factors; the significance level for each dose regimen versus placebo was 0.025; [c] Data were pooled for all patients who received ≥1 BKZ 320 mg Q2W dose to Week 16 (BKZ 320 mg Q2W). ABX: antibiotics; AE: adverse event; AN: abscess and inflammatory nodule; BKZ: bimekizumab; CI: confidence interval; HiSCR: Hidradenitis Suppurativa Clinical Response; $HiSCR_{50}$: ≥50% reduction from baseline in the total AN count with no increase from baseline in abscess or draining tunnel count; mNRI: modified non-responder imputation; Q2W: every two weeks; Q4W: every four weeks.

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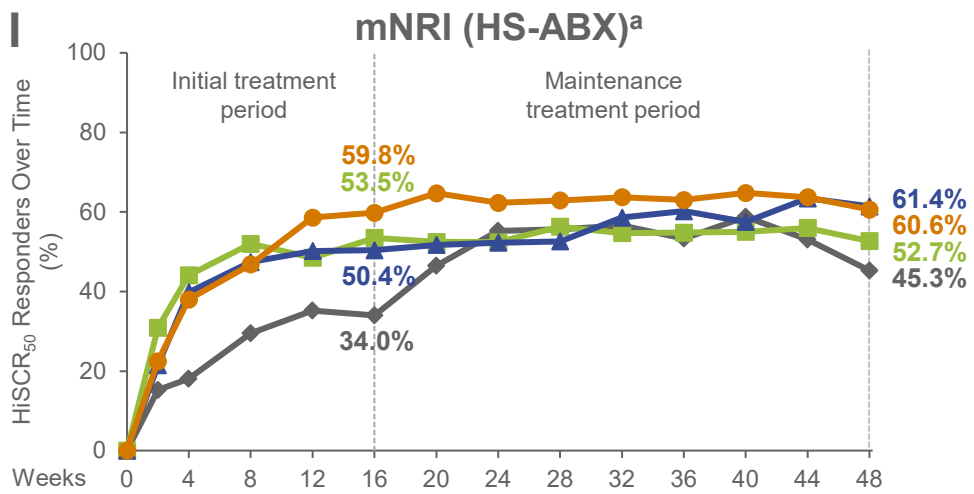
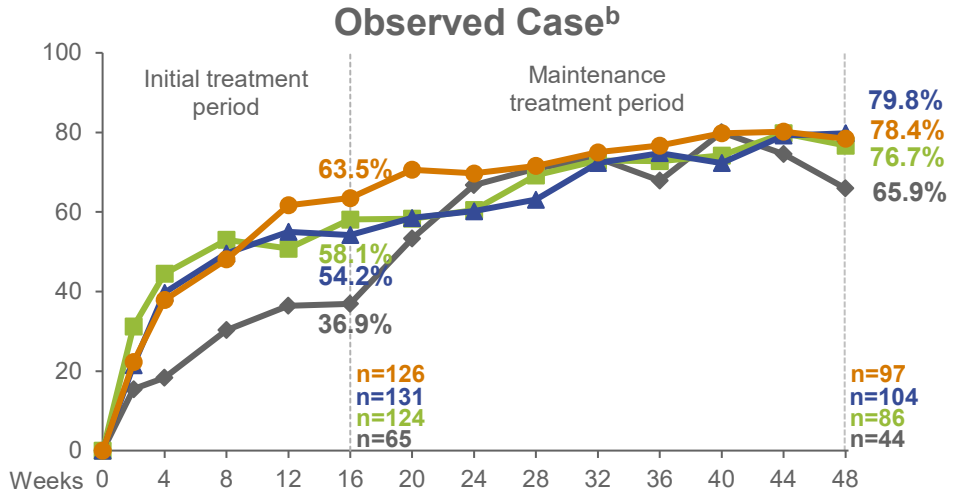
GL-N-BK-HS-2300006
Date of preparation: March 2023

$HiSCR_{50}$ Responses Showed Sustained Improvements over 48 Weeks

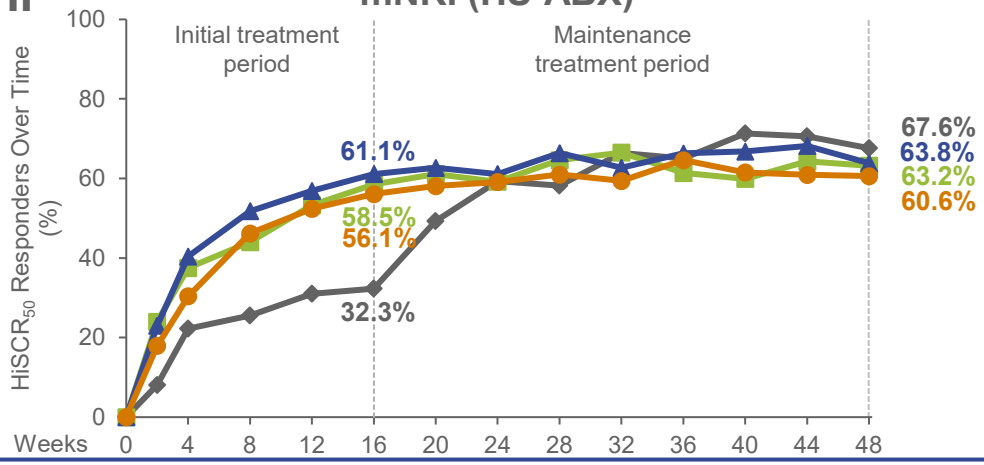
$HiSCR_{50}$ was sustained over time across BKZ groups in BE HEARD I and II, and patients switching from placebo to bimekizumab had a rapid increase in response within the first four weeks across both studies

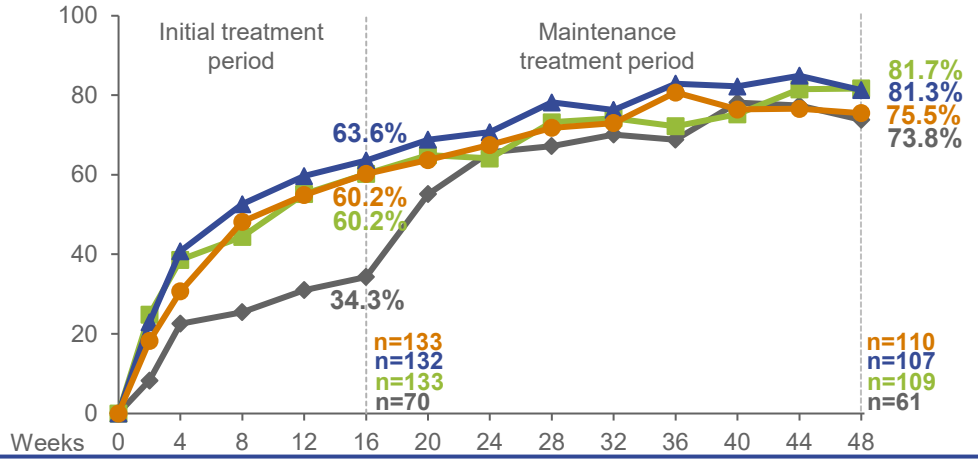
BE HEARD I





BE HEARD II





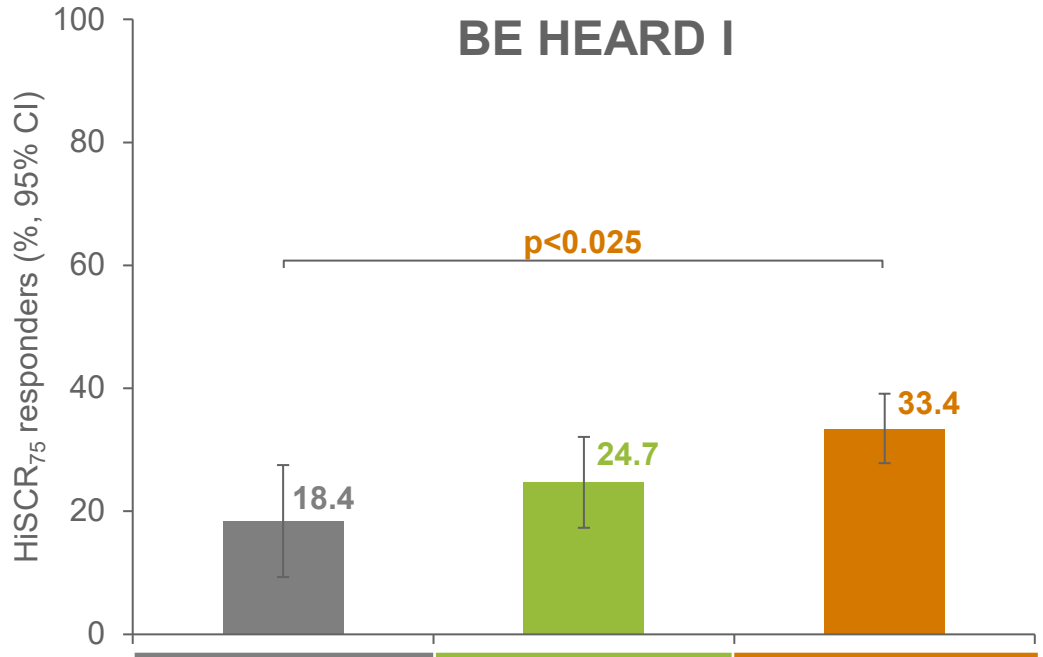
- **BKZ 320 mg Q2W/Q2W**
  BHI: n=143
  BHII: n=145
- **BKZ 320 mg Q2W/Q4W**
  BHI: n=146
  BHII: n=146
- **BKZ 320 mg Q4W/Q4W**
  BHI: n=144
  BHII: n=144
- **Placebo/BKZ 320 mg Q2W**
  BHI: n=72
  BHII: n=74

Randomized set. [a] **mNRI (HS-ABX): Patients who take systemic antibiotics as rescue medication for HS** as defined by the PI or who discontinue due to AE or lack of efficacy **are treated as non-responders at all subsequent visits**. Other missing data were imputed via multiple imputation; [b] Observed case (OC): All available data after an intercurrent event were summarized as recorded in the database, and all missing data were left missing. ABX: antibiotics; AE: adverse event; AN: abscess and inflammatory nodule; BHI: BE HEARD I; BHII: BE HEARD II; BKZ: bimekizumab; HiSCR: Hidradenitis Suppurativa Clinical Response; $HiSCR_{50}$: ≥50% reduction from baseline in the total AN count with no increase from baseline in abscess or draining tunnel count; HS: hidradenitis suppurativa; mNRI: modified non-responder imputation; OC: observed case; PI: principal investigator; Q2W: every two weeks; Q4W: every four weeks.

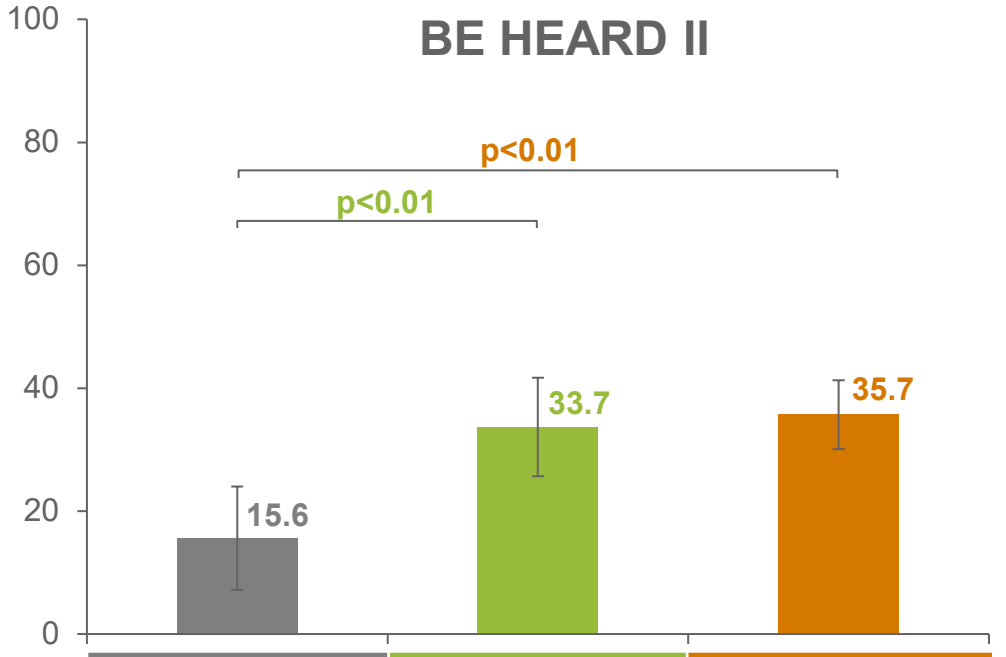
GL-N-BK-HS-2300006
Date of preparation: March 2023

Bimekizumab Demonstrated Deep Levels of Clinical Response over Placebo at Week 16, as Measured by HiSCR$_{75}$, a Key Secondary Endpoint (mNRI [All-ABX][a])

BE HEARD I met the secondary endpoint of HiSCR$_{75}$ for BKZ 320 mg Q2W versus placebo
BE HEARD II met the secondary endpoint of HiSCR$_{75}$ for both BKZ dose regimens versus placebo



Week 16	Placebo n=72	BKZ 320 mg Q4W n=144	BKZ 320 mg Q2W[c] n=289
p value[b]	-	0.350	0.021



	Placebo n=74	BKZ 320 mg Q4W n=144	BKZ 320 mg Q2W[c] n=291
	-	0.007	0.002

Randomized set. [a] **mNRI (All-ABX): Patients who take any systemic antibiotic (new or increased dose)** or who discontinue due to AE or lack of efficacy **are treated as non-responders at all subsequent visits**. Other missing data were imputed via multiple imputation. Primary analysis method; [b] p value (from Wald test) reported for **adjusted responder rates**, obtained from logistic regression with treatment, Hurley stage at baseline and baseline antibiotic use as factors; the significance level for each dose regimen versus placebo was 0.025; [c] Data were pooled for all patients who received ≥1 BKZ 320 mg Q2W dose to Week 16 (BKZ 320 mg Q2W). ABX: antibiotics; AE: adverse event; AN: abscess and inflammatory nodule; BKZ: bimekizumab; CI: confidence interval; HiSCR: Hidradenitis Suppurativa Clinical Response; HiSCR$_{75}$: ≥75% reduction from baseline in the total AN count with no increase from baseline in abscess or draining tunnel count; mNRI: modified non-responder imputation; Q2W: every two weeks; Q4W: every four weeks.

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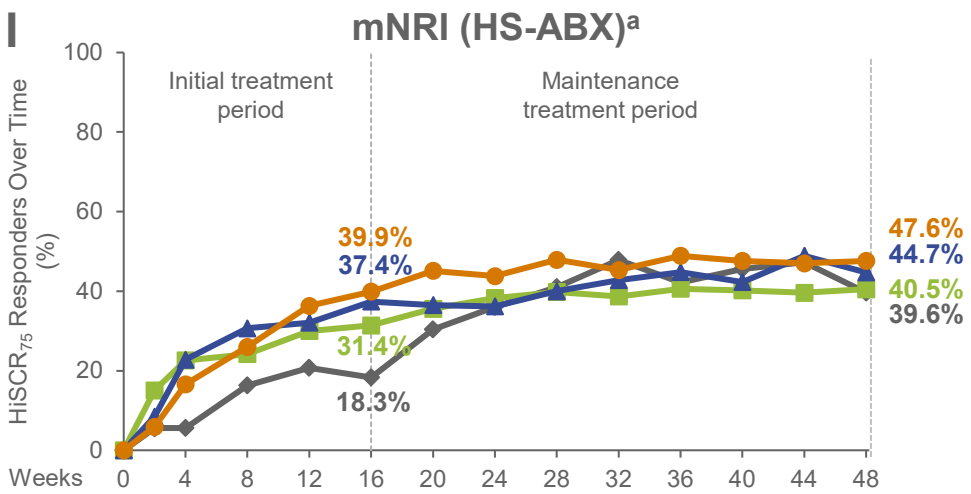
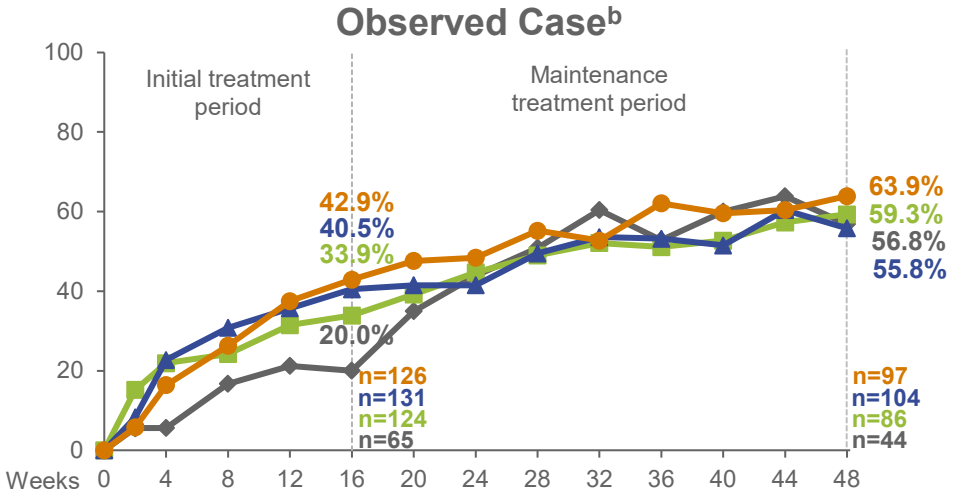
$HiSCR_{75}$ Responses Showed Sustained Improvements over 48 Weeks

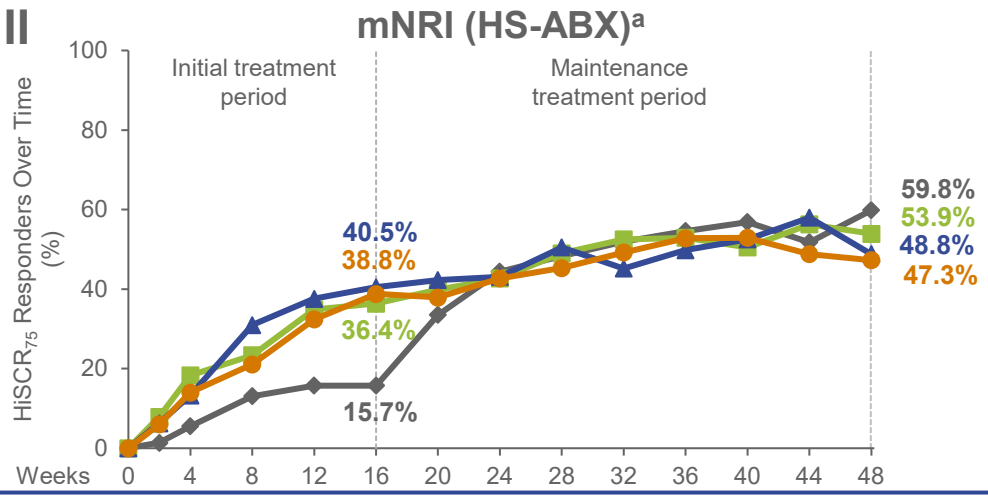
$HiSCR_{75}$ was sustained over time across BKZ groups in BE HEARD I and II, and patients switching from placebo to bimekizumab had a rapid increase in response within the first four weeks across both studies

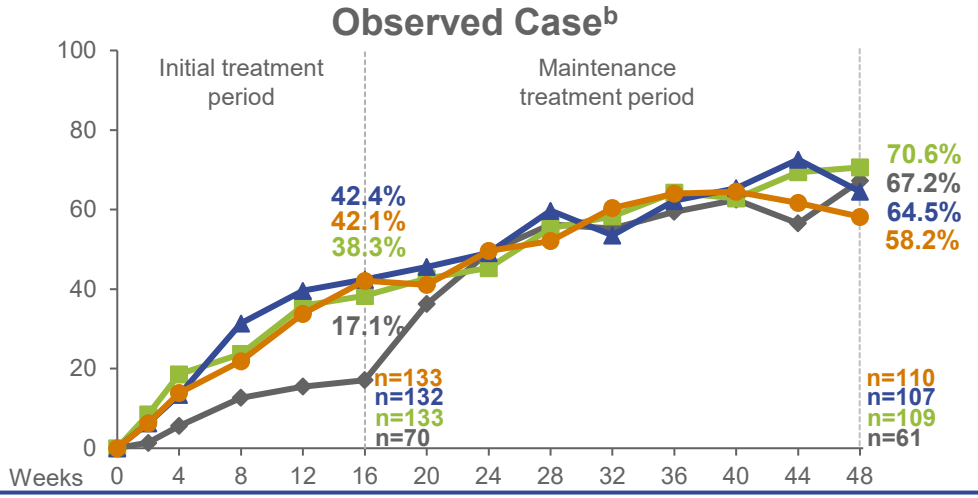
BE HEARD I





BE HEARD II





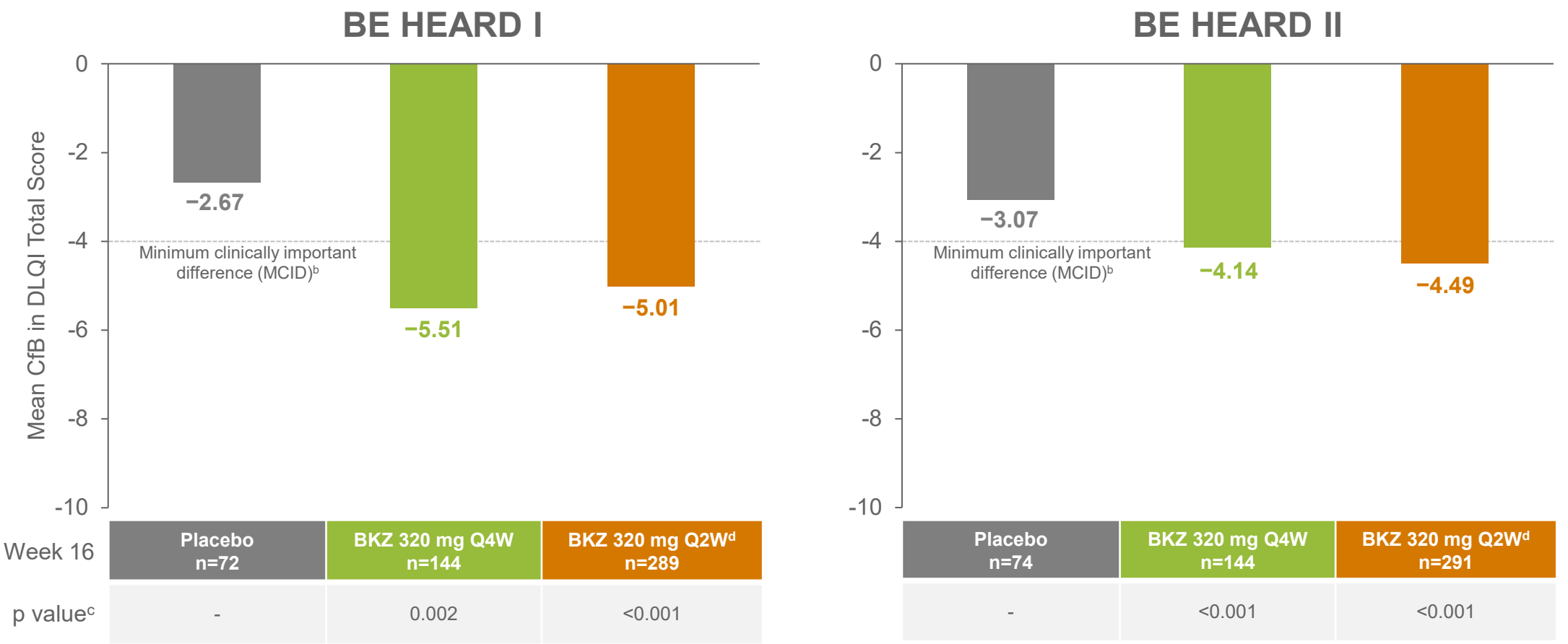
- **BKZ 320 mg Q2W/Q2W**
  BHI: n=143
  BHII: n=145
- **BKZ 320 mg Q2W/Q4W**
  BHI: n=146
  BHII: n=146
- **BKZ 320 mg Q4W/Q4W**
  BHI: n=144
  BHII: n=144
- **Placebo/BKZ 320 mg Q2W**
  BHI: n=72
  BHII: n=74

Randomized set. [a] **mNRI (HS-ABX): Patients who take systemic antibiotics as rescue medication for HS** as defined by the PI or who discontinue due to AE or lack of efficacy **are treated as non-responders at all subsequent visits**. Other missing data were imputed via multiple imputation; [b] Observed case (OC): All available data after an intercurrent event were summarized as recorded in the database, and all missing data were left missing. ABX: antibiotics; AE: adverse event; AN: abscess and inflammatory nodule; BHI: BE HEARD I; BHII: BE HEARD II; BKZ: bimekizumab; HiSCR: Hidradenitis Suppurativa Clinical Response; $HiSCR_{75}$: ≥75% reduction from baseline in the total AN count with no increase from baseline in abscess or draining tunnel count; HS: hidradenitis suppurativa; mNRI: modified non-responder imputation; OC: observed case; PI: principal investigator; Q2W: every two weeks; Q4W: every four weeks.

GL-N-BK-HS-2300006
Date of preparation: March 2023

Patients Treated with Bimekizumab Experienced Improved Health-Related Quality of Life Compared with Placebo at Week 16 (MI [All-ABX][a])

An improvement in DLQI Total Score was observed for BKZ 320 mg Q2W versus placebo in BE HEARD I
Improvement in DLQI was also observed for both BKZ dose regimens versus placebo in BE HEARD II



Randomized set. [a] MI (All-ABX): Patients who discontinued study treatment due to lack of efficacy or adverse events, or who received any systemic antibiotics during the study (new or increased dose), were set to missing and subsequently imputed using multiple imputation. All other missing data also imputed using multiple imputation; [b] MCID defined as a four-point reduction in DLQI Total Score;[1] [c] p values based on an ANCOVA with fixed effects of treatment, Hurley Stage at baseline, baseline antibiotic use and baseline DLQI Total Score as covariates. p values for Q4W vs placebo in BE HEARD I and both Q2W and Q4W vs placebo in BE HEARD II were not eligible for assessing statistical significance due to the testing procedure; [d] Data were pooled for all patients who received ≥1 BKZ 320 mg Q2W dose to Week 16 (BKZ 320 mg Q2W). **1.** Basra MKA et al. *Dermatology* 2015;230:27–33. ABX: antibiotics; ANCOVA: analysis of covariance; BKZ: bimekizumab; CI: confidence interval; CfB: change from baseline; DLQI: dermatology life quality index; MI: multiple imputation; MCID: minimum clinically important difference; Q2W: every two weeks; Q4W: every four weeks.

GL-N-BK-HS-2300006
Date of preparation: March 2023

Overview of TEAEs: Weeks 0–16

n (%)	BE HEARD I				BE HEARD II			
	Placebo n=72 100 PY=0.22	BKZ 320 mg Q4W n=143 100 PY=0.43	BKZ 320 mg Q2W[a] n=286 100 PY=0.87	BKZ Total[b] n=429 100 PY=1.30	Placebo n=74 100 PY=0.23	BKZ 320 mg Q4W n=142 100 PY=0.44	BKZ 320 mg Q2W[a] n=290 100 PY=0.88	BKZ Total[b] n=432 100 PY =1.32
Any TEAE	48 (66.7)	94 (65.7)	192 (67.1)	286 (66.7)	42 (56.8)	73 (51.4)	187 (64.5)	260 (60.2)
Serious TEAEs	0	4 (2.8)	6 (2.1)	10 (2.3)	0	3 (2.1)	9 (3.1)	12 (2.8)
TEAEs leading to discontinuation	1 (1.4)	6 (4.2)	10 (3.5)	16 (3.7)	0	3 (2.1)	12 (4.1)	15 (3.5)
Top three most common TEAEs for each study[c]								
Hidradenitis	10 (13.9)	12 (8.4)	19 (6.6)	31 (7.2)	5 (6.8)	13 (9.2)	25 (8.6)	38 (8.8)
Oral candidiasis	0	2 (1.4)	17 (5.9)	19 (4.4)	0	5 (3.5)	24 (8.3)	29 (6.7)
Headache	3 (4.2)	8 (5.6)	22 (7.7)	30 (7.0)	7 (9.5)	7 (4.9)	18 (6.2)	25 (5.8)
Diarrhea	1 (1.4)	12 (8.4)	18 (6.3)	30 (7.0)	6 (8.1)	5 (3.5)	18 (6.2)	23 (5.3)
Infections and infestations	18 (25.0)	52 (36.4)	98 (34.3)	150 (35.0)	12 (16.2)	39 (27.5)	95 (32.8)	134 (31.0)
Serious infections	0	0	1 (0.3)	1 (0.2)	0	0	0	0
Opportunistic infections[d]	0	1 (0.7)	1 (0.3)	2 (0.5)	0	1 (0.7)	0	1 (0.2)
Fungal infections	1 (1.4)	17 (11.9)	34 (11.9)	51 (11.9)	0	18 (12.7)	41 (14.1)	59 (13.7)
Candida infections	0	7 (4.9)	22 (7.7)	29 (6.8)	0	15 (10.6)	26 (9.0)	41 (9.5)
Hypersensitivity reaction[e]	4 (5.6)	12 (8.4)	30 (10.5)	42 (9.8)	1 (1.4)	9 (6.3)	32 (11.0)	41 (9.5)
Dermatitis and eczema	3 (4.2)	6 (4.2)	14 (4.9)	20 (4.7)	1 (1.4)	8 (5.6)	21 (7.2)	29 (6.7)
Definite or probable adjudicated IBD[f]	0	1 (0.7)	0	1 (0.2)	0	2 (1.4)	1 (0.3)	3 (0.7)

Safety set, MedDRA (Version 19.0). One case of malignancy (excluding non-melanomic skin cancers) occurred during Weeks 0–16 in BE HEARD II (BKZ 320 mg Q2W group). [a] Data were pooled for all patients who received ≥1 BKZ 320 mg Q2W dose to Week 16 (BKZ 320 mg Q2W); [b] Data were pooled for all patients who received ≥1 BKZ 320 mg dose to Week 16 (BKZ Total); [c] Top three most common TEAEs are presented for BKZ treatment groups in each study (BE HEARD I: hidradenitis, headache, diarrhea; BE HEARD II: hidradenitis, oral candidiasis, headache); [d] Opportunistic infections were localized mucocutaneous events, as defined by internal company conventions; [e] There were no incidences of anaphylactic reactions; [f] In patients with no history of IBD. BKZ: bimekizumab; IBD: inflammatory bowel disease; PY: patient-year; Q2W: every two weeks; Q4W:every four weeks; TEAE: treatment-emergent adverse event.

GL-N-BK-HS-2300006
Date of preparation: March 2023

Safety Topics of Interest: Weeks 0–48

n (%)	BE HEARD I				BE HEARD II			
	Placebo/BKZ 320 mg Q2W[a] (n=65) 100 PY=0.59	BKZ 320 mg Q4W/Q4W (n=143) 100 PY=1.18	BKZ 320 mg Q2W/Q4W (n=145) 100 PY=1.24	BKZ 320 mg Q2W/Q2W (n=141) 100 PY=1.21	Placebo/BKZ 320 mg Q2W[a] (n=69) 100 PY=0.68	BKZ 320 mg Q4W/Q4W (n=142) 100 PY=1.31	BKZ 320 mg Q2W/Q4W (n=146) 100 PY=1.35	BKZ 320 mg Q2W/Q2W (n=144) 100 PY=1.33
Infections and infestations	43 (66.2)	87 (60.8)	89 (61.4)	91 (64.5)	34 (49.3)	76 (53.5)	85 (58.2)	85 (59.0)
Serious infections	1 (1.5)	2 (1.4)	3 (2.1)	5 (3.5)	1 (1.4)	1 (0.7)	1 (0.7)	2 (1.4)
Opportunistic infections[c]	1 (1.5)	3 (2.1)	3 (2.1)	1 (0.7)	0	3 (1.4)	1 (0.7)	1 (0.7)
Fungal infections	12 (18.5)	35 (24.5)	32 (22.1)	33 (23.4)	10 (14.5)	35 (24.6)	39 (26.7)	40 (27.8)
Candida infections	4 (6.2)	22 (15.4)	21 (14.5)	20 (14.2)	4 (5.8)	26 (18.3)	29 (19.9)	27 (18.8)
Oral candidiasis	3 (4.6)	13 (9.1)	16 (11.0)	15 (10.6)	3 (4.3)	14 (9.9)	25 (17.1)	22 (15.3)
Neutropenia	0	0	1 (0.7)	0	0	0	0	0
Any hypersensitivity reaction[d]	15 (23.1)	26 (18.2)	30 (20.7)	38 (27.0)	10 (14.5)	23 (16.2)	28 (19.2)	23 (16.0)
Dermatitis and eczema	8 (12.3)	15 (10.5)	20 (13.8)	22 (15.6)	9 (13.0)	17 (12.0)	20 (13.7)	14 (9.7)
Adjudicated suicidal ideation/behavior	1 (1.5)	2 (1.4)	0	1 (0.7)	0	0	1 (0.7)	0
Adjudicated MACE	0	0	1 (0.7)	2 (1.4)	0	0	0	0
Hepatic events	7 (10.8)	2 (1.4)	7 (4.8)	12 (8.5)	2 (2.9)	7 (4.9)	7 (4.8)	3 (2.1)
>5 x ULN elevation of AST/ALT	0	0[e]	2 (1.4)[f]	2 (1.4)[e]	1 (1.4)	2 (1.4)	0[g]	1 (0.7)[h]
Malignancies	1 (1.5)	0	0	0	0	1 (0.7)	0	2 (1.4)
Definite or probable adjudicated IBD[i]	1 (1.5)	1 (0.7)	1 (0.7)	0	0	2 (1.4)	1 (0.7)	1 (0.7)

Across the program, one patient with significant cardiovascular history died of congestive heart failure (BE HEARD I: BKZ Q2W/Q2W group).

Active medication set, MedDRA (Version 19.0). Hepatic events category includes events in the SMQ "Drug related hepatic disorders - comprehensive search (SMQ)", excluding the following two sub-SMQs: "Liver neoplasms, benign (incl. cysts and polyps) (SMQ)" and "Liver neoplasms, malignant and unspecified (SMQ)"; Hepatic events and DILI category includes all post-baseline assessments including those at unscheduled visits but excluding any that occur more than 140 days after the last administration of study medication, counting a patient only once. [a] TEAEs reported for the Placebo/BKZ 320 mg group may have occurred while the patient was receiving either placebo or BKZ; [b] Data were pooled for all patients who received ≥1 BKZ 320 mg dose to Week 48 (BKZ Total); [c] Opportunistic infections were localized mucocutaneous events, as defined by internal company conventions; [d] There were no incidences of anaphylactic reactions related to BKZ; [e] n=140; [f] n=144; [g] n=145; [h] n=143; [i] In patients with no history of IBD. ALT: alanine aminotransferase; AST: aspartate aminotransferase; BKZ: bimekizumab; IBD: inflammatory bowel disorder; MACE: major adverse cardiac event; PY: patient-years; Q2W: every two weeks; Q4W: every four weeks; SMQ: standardized MedDRA queries; TEAE: treatment-emergent adverse event; ULN: upper limit of normal.

GL-N-BK-HS-2300006
Date of preparation: March 2023

BE HEARD I & II Conclusions

In patients with moderate to severe HS, bimekizumab achieved at Week 16:

- The primary endpoint **$HiSCR_{50}$**, providing **greater improvements in HS clinical response** versus placebo
- A key secondary endpoint **$HiSCR_{75}$**, **a more stringent outcome**, versus placebo
- **Clinically meaningful improvements** in patients' **quality of life** versus placebo

$HiSCR_{50}$ and $HiSCR_{75}$ responses showed **sustained improvements** over 48 weeks

Bimekizumab was generally **well-tolerated**, and the overall safety profile was consistent with prior studies[1-3]

The results support bimekizumab, which targets IL-17F in addition to IL-17A, as a promising new therapeutic option for moderate to severe HS

1. Reich K et al. *N Engl J Med* 2021;385:142–52; **2.** Merola JF et al. *Lancet* 2023;401:38–48; **3.** van der Heijde D et al. *Ann Rheum Dis* 2023;doi:10.1136/ard-2022-223595 (Epub ahead of print). AN: abscess and inflammatory nodule; $HiSCR_{50/75}$: ≥50/75% reduction from baseline in the total AN count with no increase from baseline in abscess or draining tunnel count; HS: hidradenitis suppurativa; IL: interleukin.

GL-N-BK-HS-2300006
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Conclusions

Emmanuel Caeymaex

Executive Vice President, Immunology Solutions and Head of US, UCB

GL-N-BK-HS-2300006
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Emmanuel Caeymaex

Executive Vice President, Immunology Solutions and Head of US, UCB

Q&A

Amit Garg, M.D.

Professor & Founding Chair | Department of Dermatology, Zucker School of Medicine at Hofstra/Northwell, US

Alexa Kimball, M.D.

Beth Israel Deaconess Medical Center and Professor of Dermatology, Harvard Medical School, Boston, MA, U.S.

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Thank you

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GL-N-BK-HS-230006
Date of preparation: March 2023

Inspired by **patients.**
Driven by **science.**