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.
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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Important factors that could result in such differences include but are not limited to: global spread and impacts of wars and pandemics, including COVID-19, changes in general economic, business and competitive conditions, the inability to obtain necessary regulatory approvals or to obtain them on acceptable terms or within expected timing, costs associated with research and development, changes in the prospects for products in the pipeline or under development by UCB, effects of future judicial decisions or governmental investigations, safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, product liability claims, challenges to patent protection for products or product candidates, competition from other products including biosimilars, changes in laws or regulations, exchange rate fluctuations, changes or uncertainties in tax laws or the administration of such laws, and hiring and retention of its employees. There is no guarantee that new product candidates will be discovered or identified in the pipeline, or that new indications for existing products will be developed and approved. Movement from concept to commercial product is uncertain; preclinical results do not guarantee safety and efficacy of product candidates in humans. So far, the complexity of the human body cannot be reproduced in computer models, cell culture systems or animal models. The length of the timing to complete clinical trials and to get regulatory approval for product marketing has varied in the past and UCB expects similar unpredictability going forward. Products or potential products which are the subject of partnerships, joint ventures or licensing collaborations may be subject to disputes between the partners or may prove to be not as safe, effective or commercially successful as UCB may have believed at the start of such partnership. UCB’s efforts to acquire other products or companies and to integrate the operations of such acquired companies may not be as successful as UCB may have believed at the moment of acquisition. Also, UCB or others could discover safety, side effects or manufacturing problems with its products and/or devices after they are marketed. The discovery of significant problems with a product similar to one of UCB’s products that implicate an entire class of products may have a material adverse effect on sales of the entire class of affected products. Moreover, sales may be impacted by international and domestic trends toward managed care and health care cost containment, including pricing pressure, political and public scrutiny, customer and prescriber patterns or practices, and the reimbursement policies imposed by third-party payers as well as legislation affecting biopharmaceutical pricing and reimbursement activities and outcomes. Finally, a breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of UCB’s data and systems.

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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
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**
- **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.

Our focus in HS is aligned with our purpose

Supported by our Partnership Network Including

Specific patient populations

Unique outcomes

Ensuring access

Individual experience

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Hidradenitis Suppurativa: A Need for New Therapeutic Approaches

Amit Garg, M.D.
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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
Disclosures

Dr. Garg is an advisor for AbbVie, Aclaris Therapeutics, Anaptys Bio, Arista 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.
HS has a high burden for patients with significant impact on quality of life

Prevalence
varies ~1% in most studied countries

Comorbidities
Obesity
Diabetes
Axial Spondyloarthritis (axSpA)
Depression

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

Affected Areas
breasts
armpits
genital area / groin

Quality of Life
Stigma / Embarrassment
Disruption to Intimacy
Pain

The patient HS journey is challenging

Delays in diagnosis

The Global VOICE survey¹ (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 survey¹ (N=1,229) 45.9% of participants were dissatisfied or very dissatisfied with current treatment

In an online survey² (N=128) with HS patients 78% had not opened discussion on biologic treatments with their HCP


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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\(^6\)

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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 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).
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.

Based on a model of disease progression in Crohn's disease.

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

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1. Markota Čagalj A et al Int J Mol Sci. 2022 Apr; 23(7): 3753
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
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, Christos C. Zouboulis, Christopher Sayed, Joslyn S. Kirby, Errol Prens, John R. Ingram, Amit Garg, Robert Rolleri, Edward Muller, Paulatsya Joshi, Gregor Jemec

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

- 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 Ingelheim, Ventyx, Moonlake, Concert, EvolImmune, Sonoma Bio, Sanofi, and receives fellowship funding from Janssen and AbbVie; serves on Board of Directors for Almirall.

- CCZ: Honorary 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: Honorary as a consultant for AbbVie, Aclaris Therapeutics, AnaptysBio, Arista 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: Honorary 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.

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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

<table>
<thead>
<tr>
<th>Screening</th>
<th>Double-Blind Initial Treatment Period</th>
<th>Double-Blind Maintenance Treatment Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>BE HEARD I: N=505</td>
<td>BKZ 320 mg Q2W</td>
<td>BKZ 320 mg Q2W</td>
</tr>
<tr>
<td>n=143</td>
<td>n=146</td>
<td></td>
</tr>
<tr>
<td>BE HEARD II: N=509</td>
<td>BKZ 320 mg Q2W</td>
<td>BKZ 320 mg Q4W</td>
</tr>
<tr>
<td>n=144</td>
<td>n=146</td>
<td></td>
</tr>
<tr>
<td>Placebo</td>
<td>BKZ 320 mg Q4W</td>
<td>BKZ 320 mg Q2W</td>
</tr>
<tr>
<td>n=72</td>
<td>n=74</td>
<td></td>
</tr>
</tbody>
</table>

Week: -5 0 1 2 4 6 8 10 12 14 16 48

Baseline | Primary endpoint: HiSCR50

Screening: 2:2:2:1


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Date of preparation: March 2023
Patient Demographics and Characteristics at Baseline were Generally Balanced Across Studies

<table>
<thead>
<tr>
<th></th>
<th>BE HEARD I All Patients N=505</th>
<th>BE HEARD II All Patients N=509</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age, years, mean (SD)</strong></td>
<td>36.7 (12.0)</td>
<td>36.6 (12.4)</td>
</tr>
<tr>
<td><strong>Sex, female, n (%)</strong></td>
<td>318 (63.0)</td>
<td>258 (50.7)</td>
</tr>
<tr>
<td><strong>Racial group, white, n (%)</strong></td>
<td>393 (77.8)</td>
<td>415 (81.5)</td>
</tr>
<tr>
<td><strong>BMI, kg/m², mean (SD)</strong></td>
<td>33.8 (8.2)</td>
<td>32.3 (8.0)</td>
</tr>
<tr>
<td><strong>Smoking status, current, n (%)</strong></td>
<td>217 (43.0)</td>
<td>245 (48.1)</td>
</tr>
<tr>
<td><strong>Duration of HS, years, mean (SD)</strong></td>
<td>9.0 (8.3)</td>
<td>7.0 (7.1)</td>
</tr>
<tr>
<td><strong>AN count, mean (SD)</strong></td>
<td>16.0 (17.5)</td>
<td>16.5 (14.6)</td>
</tr>
<tr>
<td><strong>DT count, mean (SD)</strong></td>
<td>3.8 (4.8)</td>
<td>3.4 (3.7)</td>
</tr>
<tr>
<td><strong>Hurley stage, a n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>254 (50.3)</td>
<td>311 (61.1)</td>
</tr>
<tr>
<td>III</td>
<td>251 (49.7)</td>
<td>198 (38.9)</td>
</tr>
<tr>
<td><strong>DLQI Total Score, mean (SD)</strong></td>
<td>12.0 (7.1)b</td>
<td>10.8 (6.6)c</td>
</tr>
<tr>
<td><strong>Prior biologic use, d n (%)</strong></td>
<td>126 (25.0)</td>
<td>67 (13.2)</td>
</tr>
<tr>
<td><strong>Baseline antibiotic use (antibiotic strata), e n (%)</strong></td>
<td>40 (7.9)</td>
<td>46 (9.0)</td>
</tr>
</tbody>
</table>

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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Date of preparation: March 2023
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

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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Date of preparation: March 2023
HiSCR\textsubscript{50} Responses Showed Sustained Improvements over 48 Weeks

HiSCR\textsubscript{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

**mNRI (HS-ABX)\textsuperscript{a}**

- **Initial treatment period**
  - BE HEARD I: n=144
  - Placebo/BKZ 320 mg Q2W: n=72
  - BKZ 320 mg Q2W/Q2W: n=143
  - BKZ 320 mg Q2W/Q4W: n=146

- **Maintenance treatment period**
  - BE HEARD I: n=144
  - Placebo/BKZ 320 mg Q2W: n=72
  - BKZ 320 mg Q2W/Q2W: n=143
  - BKZ 320 mg Q2W/Q4W: n=146

**Observed Case\textsuperscript{b}**

- **Initial treatment period**
  - BE HEARD I: n=144
  - Placebo/BKZ 320 mg Q2W: n=72
  - BKZ 320 mg Q2W/Q2W: n=143
  - BKZ 320 mg Q2W/Q4W: n=146

- **Maintenance treatment period**
  - BE HEARD I: n=144
  - Placebo/BKZ 320 mg Q2W: n=72
  - BKZ 320 mg Q2W/Q2W: n=143
  - BKZ 320 mg Q2W/Q4W: n=146

**BE HEARD II**

**mNRI (HS-ABX)\textsuperscript{a}**

- **Initial treatment period**
  - BE HEARD II: n=145
  - Placebo/BKZ 320 mg Q2W: n=74
  - BKZ 320 mg Q2W/Q2W: n=124
  - BKZ 320 mg Q2W/Q4W: n=131

- **Maintenance treatment period**
  - BE HEARD II: n=145
  - Placebo/BKZ 320 mg Q2W: n=74
  - BKZ 320 mg Q2W/Q2W: n=124
  - BKZ 320 mg Q2W/Q4W: n=131

**Observed Case\textsuperscript{b}**

- **Initial treatment period**
  - BE HEARD II: n=145
  - Placebo/BKZ 320 mg Q2W: n=74
  - BKZ 320 mg Q2W/Q2W: n=124
  - BKZ 320 mg Q2W/Q4W: n=131

- **Maintenance treatment period**
  - BE HEARD II: n=145
  - Placebo/BKZ 320 mg Q2W: n=74
  - BKZ 320 mg Q2W/Q2W: n=124
  - BKZ 320 mg Q2W/Q4W: n=131

Randomized set. \(\text{[a]}\) 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. \(\text{[b]}\) 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; HS: hidradenitis suppurativa; HiSCR: Hidradenitis Suppurativa Clinical Response; HiSCR\textsubscript{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.

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GL-N-BK-HS-2300016
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

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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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GL-N-BK-HS-2300006
Date of preparation: March 2023
HiSCR<sub>75</sub> Responses Showed Sustained Improvements over 48 Weeks

HiSCR<sub>75</sub> 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**

![Graph showing HiSCR<sub>75</sub> responders over time for BE HEARD I with mNRI (HS-ABX)<sup>a</sup>](image1)

**BE HEARD II**

![Graph showing HiSCR<sub>75</sub> responders over time for BE HEARD II with mNRI (HS-ABX)<sup>a</sup>](image2)

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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<sub>75</sub>: ≥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.

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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.

**BE HEARD I**

- **Placebo**
  - n=72
  - Mean CfB in DLQI Total Score: 0

- **BKZ 320 mg Q4W**
  - n=144
  - Mean CfB in DLQI Total Score: -5.51

- **BKZ 320 mg Q2W**
  - n=289
  - Mean CfB in DLQI Total Score: -5.01

Minimum clinically important difference (MCID)[b]: -2.67

**BE HEARD II**

- **Placebo**
  - n=74
  - Mean CfB in DLQI Total Score: 0

- **BKZ 320 mg Q4W**
  - n=144
  - Mean CfB in DLQI Total Score: -4.14

- **BKZ 320 mg Q2W**
  - n=291
  - Mean CfB in DLQI Total Score: -4.49

Minimum clinically important difference (MCID)[b]: -3.07

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; [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.
**Overview of TEAEs: Weeks 0–16**

<table>
<thead>
<tr>
<th></th>
<th>Placebo n=72</th>
<th>BKZ 320 mg Q4W n=143</th>
<th>BKZ 320 mg Q2W&lt;sup&gt;a&lt;/sup&gt; n=286</th>
<th>BKZ Total&lt;sup&gt;b&lt;/sup&gt; n=429</th>
<th>Placebo n=74</th>
<th>BKZ 320 mg Q4W n=142</th>
<th>BKZ 320 mg Q2W&lt;sup&gt;a&lt;/sup&gt; n=290</th>
<th>BKZ Total&lt;sup&gt;b&lt;/sup&gt; n=432</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Any TEAE</strong></td>
<td>48 (66.7)</td>
<td>94 (65.7)</td>
<td>192 (67.1)</td>
<td>286 (66.7)</td>
<td>42 (56.8)</td>
<td>73 (51.4)</td>
<td>187 (64.5)</td>
<td>260 (60.2)</td>
</tr>
<tr>
<td><strong>Serious TEAEs</strong></td>
<td>0</td>
<td>4 (2.8)</td>
<td>6 (2.1)</td>
<td>10 (2.3)</td>
<td>0</td>
<td>3 (2.1)</td>
<td>9 (3.1)</td>
<td>12 (2.8)</td>
</tr>
<tr>
<td><strong>TEAEs leading to discontinuation</strong></td>
<td>1 (1.4)</td>
<td>6 (4.2)</td>
<td>10 (3.5)</td>
<td>16 (3.7)</td>
<td>0</td>
<td>3 (2.1)</td>
<td>12 (4.1)</td>
<td>15 (3.5)</td>
</tr>
</tbody>
</table>

**Top three most common TEAEs for each study<sup>c</sup>**

<table>
<thead>
<tr>
<th></th>
<th>Placebo</th>
<th>BKZ 320 mg Q4W</th>
<th>BKZ 320 mg Q2W&lt;sup&gt;a&lt;/sup&gt;</th>
<th>BKZ Total&lt;sup&gt;b&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hidradenitis</strong></td>
<td>10 (13.9)</td>
<td>12 (8.4)</td>
<td>19 (6.6)</td>
<td>31 (7.2)</td>
</tr>
<tr>
<td><strong>Oral candidiasis</strong></td>
<td>0</td>
<td>2 (1.4)</td>
<td>17 (5.9)</td>
<td>19 (4.4)</td>
</tr>
<tr>
<td><strong>Headache</strong></td>
<td>3 (4.2)</td>
<td>8 (5.6)</td>
<td>22 (7.7)</td>
<td>30 (7.0)</td>
</tr>
<tr>
<td><strong>Diarrhea</strong></td>
<td>1 (1.4)</td>
<td>12 (8.4)</td>
<td>18 (6.3)</td>
<td>30 (7.0)</td>
</tr>
<tr>
<td><strong>Infections and infestations</strong></td>
<td>18 (25.0)</td>
<td>52 (36.4)</td>
<td>98 (34.3)</td>
<td>150 (35.0)</td>
</tr>
<tr>
<td><strong>Serious infections</strong></td>
<td>0</td>
<td>0</td>
<td>1 (0.3)</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td><strong>Opportunistic infections&lt;sup&gt;d&lt;/sup&gt;</strong></td>
<td>0</td>
<td>1 (0.7)</td>
<td>1 (0.3)</td>
<td>2 (0.5)</td>
</tr>
<tr>
<td><strong>Fungal infections</strong></td>
<td>1 (1.4)</td>
<td>17 (11.9)</td>
<td>34 (11.9)</td>
<td>51 (11.9)</td>
</tr>
<tr>
<td><strong>Candida infections</strong></td>
<td>0</td>
<td>7 (4.9)</td>
<td>22 (7.7)</td>
<td>29 (6.8)</td>
</tr>
<tr>
<td><strong>Hypersensitivity reaction&lt;sup&gt;e&lt;/sup&gt;</strong></td>
<td>4 (5.6)</td>
<td>12 (8.4)</td>
<td>30 (10.5)</td>
<td>42 (9.8)</td>
</tr>
<tr>
<td><strong>Dermatitis and eczema</strong></td>
<td>3 (4.2)</td>
<td>6 (4.2)</td>
<td>14 (4.9)</td>
<td>20 (4.7)</td>
</tr>
<tr>
<td><strong>Definite or probable adjudicated IBD&lt;sup&gt;f&lt;/sup&gt;</strong></td>
<td>0</td>
<td>1 (0.7)</td>
<td>1 (0.2)</td>
<td>2 (1.4)</td>
</tr>
</tbody>
</table>

---

Safety set, MedDRA (Version 19.0). One case of malignancy (excluding non-melanoma 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 Total); [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.

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GL-N-BK-HS-2300006
Date of preparation: March 2023
### Safety Topics of Interest: Weeks 0–48

#### Infections and infestations

<table>
<thead>
<tr>
<th>Category</th>
<th>Placebo/BKZ 320 mg Q2W</th>
<th>BKZ 320 mg Q4W/Q4W</th>
<th>BKZ 320 mg Q2W/Q2W</th>
<th>BKZ 320 mg Q2W/Q2W</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infections and infestations</td>
<td>43 (66.2)</td>
<td>87 (60.8)</td>
<td>89 (61.4)</td>
<td>91 (64.5)</td>
</tr>
<tr>
<td>Serious infections</td>
<td>1 (1.5)</td>
<td>2 (1.4)</td>
<td>3 (2.1)</td>
<td>5 (3.5)</td>
</tr>
<tr>
<td>Opportunistic infections</td>
<td>1 (1.5)</td>
<td>3 (2.1)</td>
<td>3 (2.1)</td>
<td>1 (0.7)</td>
</tr>
<tr>
<td>Fungal infections</td>
<td>12 (18.5)</td>
<td>35 (24.5)</td>
<td>32 (22.1)</td>
<td>33 (23.4)</td>
</tr>
<tr>
<td>Candida infections</td>
<td>4 (6.2)</td>
<td>22 (15.4)</td>
<td>21 (14.5)</td>
<td>20 (14.2)</td>
</tr>
<tr>
<td>Oral candidiasis</td>
<td>3 (4.6)</td>
<td>13 (9.1)</td>
<td>16 (11.0)</td>
<td>15 (10.6)</td>
</tr>
<tr>
<td>Neutropenia</td>
<td>0</td>
<td>0</td>
<td>1 (0.7)</td>
<td>0</td>
</tr>
<tr>
<td>Any hypersensitivity reaction</td>
<td>15 (23.1)</td>
<td>26 (18.2)</td>
<td>30 (20.7)</td>
<td>38 (27.0)</td>
</tr>
<tr>
<td>Dermatitis and eczema</td>
<td>8 (12.3)</td>
<td>15 (10.5)</td>
<td>20 (13.8)</td>
<td>22 (15.6)</td>
</tr>
<tr>
<td>Adjudicated suicidal ideation/behavior</td>
<td>1 (1.5)</td>
<td>2 (1.4)</td>
<td>0</td>
<td>1 (0.7)</td>
</tr>
<tr>
<td>Adjudicated MACE</td>
<td>0</td>
<td>0</td>
<td>1 (0.7)</td>
<td>2 (1.4)</td>
</tr>
<tr>
<td>Hepatic events</td>
<td>7 (10.8)</td>
<td>2 (1.4)</td>
<td>7 (4.8)</td>
<td>12 (8.5)</td>
</tr>
<tr>
<td>&gt;5 x ULN elevation of AST/ALT</td>
<td>0</td>
<td>0e</td>
<td>2 (1.4)f</td>
<td>2 (1.4)e</td>
</tr>
<tr>
<td>Malignancies</td>
<td>1 (1.5)</td>
<td>0</td>
<td>0</td>
<td>1 (0.7)</td>
</tr>
<tr>
<td>Definite or probable adjudicated IBD</td>
<td>1 (1.5)</td>
<td>1 (0.7)</td>
<td>1 (0.7)</td>
<td>0</td>
</tr>
</tbody>
</table>

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

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**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=146; [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.

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**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 \( \text{HiSCR}_{50} \), providing **greater improvements in HS clinical response** versus placebo
- A key secondary endpoint \( \text{HiSCR}_{75} \), a more stringent outcome, versus placebo
- **Clinically meaningful improvements** in patients’ **quality of life** versus placebo

\( \text{HiSCR}_{50} \) and \( \text{HiSCR}_{75} \) 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**

Conclusions

Emmanuel Caeymaex
Executive Vice President, Immunology Solutions and Head of US, UCB
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GL-N-BK-HS-2300006
Date of preparation: March 2023
Thank you
Inspired by patients.
Driven by science.