EA DV CONGRESS
BERLIN 11-14 OCTOBER 2023
EUROPEAN ACADEMY OF DERMATOLOGY AND VENEREOLOGY

Abstract N°: 3512

IHS4 outcomes with bimekizumab in patients with moderate to severe hidradenitis suppurativa: Pooled results from the BE HEARD I and II phase 3 trials

Christos Zouboulis*[1], Joslyn Kirby[2], Thrasyvoulos Tzellos[3], Saakshi Khattri[4], Afsaneh Alavi[5], Maurizio Podda[6], Veronique Del Marmol[7], Lynda Spelman[8], Robert Rolleri[9], Paulatsya Joshi[10], Leah Davis[9], Ingrid Pansar[11], John Frew[12, 13, 14]

[1]Departments of Dermatology, Venereology, Allergology and Immunology, Staedtisches Klinikum Dessau, Brandenburg Medical School Theodor Fontane and Faculty of Health Sciences Brandenburg, Dessau, Germany, [2]Department of Dermatology, Penn State University, Hershey, United States, [3]Department of Dermatology, Nordland Hospital Trust, Bodø, Norway, [4]The Mount Sinai Hospital, New York, United States, [5]Mayo Clinic, Rochester, United States, [6]Darmstadt Hospital, Darmstadt, Germany, [7]Department of Dermatology, Hôpital Erasme, Université Libre de Bruxelles, Brussels, Belgium, [8]Veracity Clinical Research and Probity Medical, Brisbane, Australia, [9]UCB Pharma, Morrisville, United States, [10]UCB Pharma, Slough, United Kingdom, [11]UCB Pharma, Brussels, Belgium, [12]Department of Dermatology, Liverpool Hospital, Sydney, Australia, [13]Laboratory of Translational Cutaneous Medicine, Ingham Institute for Applied Medical Research, Sydney, Australia, [14]School of Clinical Medicine, UNSW Medicine and Health, Sydney, Australia

Introduction & Objectives:

Hidradenitis suppurativa (HS) severity can be dynamically assessed using the International Hidradenitis Suppurativa Severity Score System (IHS4), a validated clinician-rated tool that includes the number of inflammatory nodules, abscesses and draining tunnels.1 Treatment with bimekizumab (BKZ), a humanised IgG1 monoclonal antibody that selectively inhibits IL-17F in addition to IL-17A, has previously led to clinical improvements in IHS4 at phase 2.2 In this post hoc analysis, improvements in HS disease severity, as measured by IHS4, are reported for patients (pts) with moderate to severe HS who received up to 48 weeks (wks) of BKZ treatment pooled across the phase 3 BE HEARD I and II trials.3,4

Materials & Methods:

Pooled data from the randomised, double-blind, placebo (PBO)-controlled, multicentre BE HEARD I and II trials included an initial (Wks 0–16) and maintenance treatment period (Wks 16–48). Adult pts were randomised 2:2:2:1 (initial/maintenance) to receive BKZ 320 mg every 2 wks (Q2W)/Q2W, BKZ Q2W/Q4W, BKZ Q4W/Q4W or PBO/BKZ Q2W. IHS4 scores are reported by category through Wk 48, in addition to change from baseline (CfB) in IHS4; mild HS was defined as a score of ≤3, moderate HS as 4–10 and severe HS ≥11.1 Missing data were imputed using multiple imputation.

Results:

At baseline, 1,014 pts were randomised to PBO/BKZ Q2W (n=146), BKZ Q4W/Q4W (n=288), BKZ Q2W/Q4W (n=292) or BKZ Q2W/Q2W (n=288). Mean baseline IHS4 scores ranged from 30.6 (PBO/BKZ Q2W) to 36.0 (BKZ Q2W/Q4W). According to IHS4, one pt (0.3%, BKZ Q4W/Q4W) had mild HS and 11.6–16.3% had moderate HS across BKZ dose regimens at baseline, vs 83.7–88.4% with severe HS (**Figure**).

Over time, the proportion of pts with mild or moderate HS, as defined by IHS4, increased when treated with BKZ, with a corresponding decrease in the proportion of pts with severe HS (**Figure**). At Wk 16, higher proportions of BKZ-treated pts had mild HS vs PBO-treated pts: 24.6–27.2% vs 15.3%. Similar trends were observed for pts with

moderate HS: 25.8–28.0% (BKZ) vs 17.1% (PBO). Pts treated with BKZ to Wk 16 also saw numerically greater improvements vs PBO from baseline in IHS4 scores: −16.8 (BKZ Q4W/Q4W), −17.4 (BKZ Q2W/Q4W) and −17.0 (BKZ Q2W/Q2W) versus −6.0 (PBO).

Improvements in IHS4 categories were sustained over time across BKZ groups: at Wk 48, 37.3–40.1% had mild HS and 23.8–25.3% had moderate HS, compared with 34.7–39.0% with severe HS (**Figure**). Similarly, pts saw further improvements in IHS4 scores with BKZ treatment over time; at Wk 48, IHS4 scores reduced across BKZ groups, with the greatest CfB seen in the group that received BKZ Q2W/Q4W: −21.5 (PBO/BKZ Q2W), −22.5 (BKZ Q4W/Q4W), −23.8 (BKZ Q2W/Q4W) and −22.3 (BKZ Q2W/Q2W).

Conclusion:

Over 48 wks of BKZ treatment, the majority of pts with severe HS at baseline shifted to mild or moderate disease, as defined by the clinician-rated IHS4 tool. Pts who initially received PBO saw improvements in HS severity after switching to BKZ at Wk 16. These data suggest that blocking IL-17F in addition to IL-17A was efficacious in treating moderate to severe HS and support BKZ as a promising new therapeutic option in development.

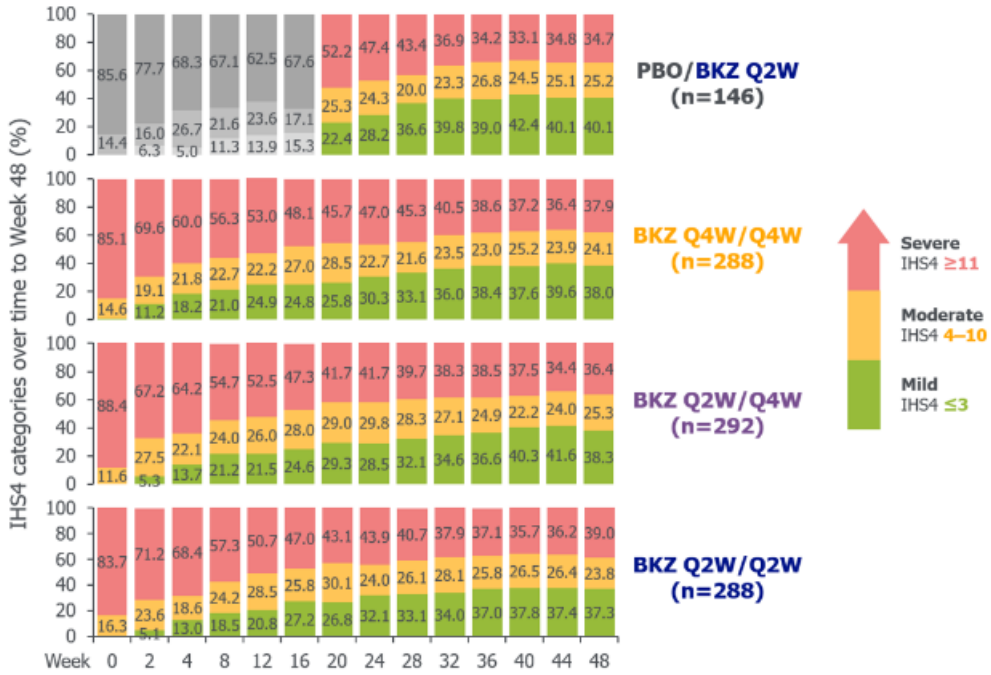
References

1. Zouboulis CC. Br J Dermatol 2017;177:1401–9. **2.** Glatt S. JAMA Dermatol 2021;157;1279–88; **3.** BE HEARD I: https://clinicaltrials.gov/ct2/show/NCT04242446; **4.** BE HEARD II: https://clinicaltrials.gov/ct2/show/NCT04242498.

Funding

These studies were funded by UCB Pharma. Medical writing support was provided by Costello Medical.

Figure. IHS4 categories to Week 48 by treatment group (MI)[a]



Randomised set. [a] Note that these values have been rounded and so may not add to 100%. MI: Intermittent missing data were imputed using multiple imputation with the Markov Chain Monte Carlo method followed by monotone regression for monotone missing data. Participants who experienced an intercurrent event were treated as missing following the intercurrent event. Patients who took systemic antibiotics as rescue medication for HS as defined by the principal investigator or who discontinued due to adverse event or lack of efficacy were treated as missing at all subsequent visits. Treatment switch after the initial treatment period for the PBO/BKZ 320mg Q2W and BKZ 320mg Q2W/Q4W groups started at Week 16. BKZ: bimekizumab; HS: hidradenitis suppurativa; IHS4: International Hidradenitis Suppurativa Severity Score System; MI: multiple imputation; PBO: placebo; Q2W: every 2 weeks; Q4W: every 4 weeks.