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Bimekizumab efficacy and safety in patients with moderate to severe hidradenitis suppurativa: Analysis of pooled data from BE HEARD I and II phase 3, randomised, double-blind, placebo-controlled, multicentre studies

Christos C. Zouboulis^{*1}, Alice B. Gottlieb², Seth Forman³, Jamie Weisman⁴, Jacek Szepietowski⁵, Errol Prens⁶, Hideki Fujita⁷, Pratiksha Dokhe⁸, Edward Muller⁸, Cynthia Madden⁹, Robert Roller⁹, Alexa B. Kimball¹⁰

¹Departments of Dermatology, Venereology, Allergology and Immunology, Staedtisches Klinikum Dessau, Brandenburg Medical School Theodor Fontane and Faculty of Health Sciences Brandenburg, Dessau, Germany,

²Department of Dermatology, The Icahn School of Medicine at Mount Sinai, New York, United States, ³ForCare Clinical Research, Tampa, United States, ⁴Medical Dermatology Specialists, Inc., Atlanta, United States,

⁵Department of Dermatology, Venereology and Allergology, Wroclaw Medical University, Wroclaw, Poland,

⁶Department of Dermatology, Erasmus University Medical Center Rotterdam, Rotterdam, Netherlands, ⁷Division of Cutaneous Science, Department of Dermatology, Nihon University School of Medicine, Tokyo, Japan, ⁸UCB Pharma, Slough, United Kingdom, ⁹UCB Pharma, Morrisville, United States, ¹⁰Beth Israel Deaconess Medical Center and Harvard Medical School, Boston, United States

Introduction & Objectives:

Hidradenitis suppurativa (HS) is a debilitating skin disease; treatment options are limited.¹ Bimekizumab (BKZ), a humanised IgG1 monoclonal antibody that selectively inhibits interleukin (IL)17F in addition to IL-17A, has demonstrated clinically meaningful improvements in patients (pts) with HS.² Here, pooled efficacy and safety data are presented to Week (Wk) 48 for the phase 3 BE HEARD I and II studies.^{3,4}

Materials & Methods:

Data were pooled from BE HEARD I and II which included an initial (Wks 0–16) and maintenance treatment period (Wks 16–48). Adult pts with moderate to severe HS were randomised 2:2:2:1 (initial/maintenance) to BKZ 320 mg every 2 wks (Q2W)/Q2W, BKZ Q2W/every 4 wks (Q4W), BKZ Q4W/Q4W or placebo (PBO)/BKZ Q2W. We report the proportions of pts with $\geq 50/75/90/100\%$ HS Clinical Response (HiSCR50/75/90/100), and a safety overview through Wk 48. Modified non-responder imputation reported at Wk 16 and observed case at Wks 16/48.

Results:

In total, 1,014 pts were randomised: BKZ Q2W/Q2W (n=288), BKZ Q2W/Q4W (n=292), BKZ Q4W/Q4W (n=288) and PBO/BKZ Q2W (n=146). Baseline demographics were comparable across treatment arms; mean age: 35.8–37.3 years, female pts: 51.4–60.8% and mean weight: 95.9–99.0 kg. Baseline clinical characteristics were similar; mean abscess and inflammatory nodule count: 14.4–17.7, mean draining tunnel count: 3.3–3.8.

BKZ-treated pts showed higher response rates in the primary endpoint HiSCR50 at Wk 16 vs PBO (PBO/BKZ Q2W 33.4%, Q4W/Q4W 56.1%, Q2W/Q4W 55.9%, Q2W/Q2W 58.0% [mNRI]). Responses improved at Wk 48 for BKZ pts (Q4W/Q4W 79.5%, Q2W/Q4W 80.6%, Q2W/Q2W 76.8%) (**Table**). At Wk 48, response in PBO/BKZ switchers approached that reached by pts on BKZ from baseline (70.5%). A similar trend was seen in the more stringent HiSCR75/90 endpoints through Wk 48 (**Table**). Analysis of the most stringent HiSCR100 endpoint showed numerically higher responses in BKZ pts vs PBO at Wk 16 (PBO/BKZ Q2W 5.6%, Q4W/Q4W 15.8%, Q2W/Q4W 16.6%; Q2W/Q2W 15.6% [mNRI]). BKZ-treated pts had improved responses at Wk 48; PBO/BKZ switchers demonstrated similarly high HiSCR100 rates at Wk 48 (**Table**).

Serious TEAEs were reported in 7.0% Q4W/Q4W, 4.5% Q2W/Q4W and 8.1% Q2W/Q2W pts. One pt died across 48 wks (congestive heart failure, significant cardiovascular history). The most frequently reported TEAEs in 995 pts receiving ≥ 1 dose of BKZ were hidradenitis (18.7%), oral candidiasis (11.2%) and corona virus infection (10.8%). Adjudicated definite or probable inflammatory bowel disease occurred in 0.7% of BKZ pts.

Conclusion:

BKZ treatment resulted in clinically meaningful improvements in HiSCR50 and the more stringent HiSCR75/90/100 endpoints vs PBO at Wk 16. Improvements increased for pts remaining in the study through Wk 48.** BKZ was generally well tolerated with a safety profile that was consistent with previous studies.5** These data, together with confirmatory results from the individual studies, support the efficacy of IL-17F and IL17A blockade in treating moderate to severe HS, and support BKZ as a promising new therapeutic option.

References

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Table. Proportion of patients achieving HiSCR responses at Weeks 16 and 48 by treatment sequence (mNRI,^a OC^b)

	PBO/BKZ Q2W (n=146)			BKZ Q4W/Q4W (n=288)			BKZ Q2W/Q4W (n=292)			BKZ Q2W/Q2W (n=288)		
	Week 16 % [mNRI]	Week 16 % (n/N) [OC]	Week 48 % (n/N) [OC]	Week 16 % [mNRI]	Week 16 % (n/N) [OC]	Week 48 % (n/N) [OC]	Week 16 % [mNRI]	Week 16 % (n/N) [OC]	Week 48 % (n/N) [OC]	Week 16 % [mNRI]	Week 16 % (n/N) [OC]	Week 48 % (n/N) [OC]
HiSCR ₅₀	33.4	35.6 (48/135)	70.5 (74/105)	56.1	59.1 (152/257)	79.5 (155/195)	55.9	58.9 (155/263)	80.6 (170/211)	58.0	61.8 (160/259)	76.8 (159/207)
HiSCR ₇₅	17.0	18.5 (25/135)	62.9 (66/105)	34.0	36.2 (93/257)	65.6 (128/195)	39.2	41.4 (109/263)	60.2 (127/211)	39.3	42.5 (110/259)	60.9 (126/207)
HiSCR ₉₀	8.5	9.6 (13/135)	40.0 (42/105)	20.6	21.4 (55/257)	42.1 (82/195)	22.0	22.8 (60/263)	41.7 (88/211)	21.0	21.6 (56/259)	39.6 (82/207)
HiSCR ₁₀₀	5.6	5.9 (8/135)	31.4 (33/105)	15.8	16.3 (42/257)	30.8 (60/195)	16.6	17.1 (45/263)	28.9 (61/211)	15.6	15.4 (40/259)	30.0 (62/207)

Randomised set. [a] mNRI: 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] OC: the denominator represents the number of patients with a non-missing lesion count assessment at the given week, and percentages are calculated accordingly. BKZ: bimekizumab; HiSCR: Hidradenitis Suppurativa Clinical Response; HiSCR_{50/75/90/100}: $\geq 50\%$, $\geq 75\%$, $\geq 90\%$ and 100% reduction in the total abscess and inflammatory nodule count with no increase from baseline in abscess or draining tunnel count; HS: hidradenitis suppurativa; mNRI: modified non-responder imputation; OC: observed case; PBO: placebo; Q2W: every two weeks; Q4W: every four weeks.

