Mean percent PASI improvement with bimekizumab in patients with moderate to severe plaque psoriasis: Pooled results from four phase 3/3b trials

Andrew Blauvelt,[1] George Han,[2] Stephen K. Tyring,[3] Jennifer Soung,[4] Tae Oh,[5] Leah Davis,[6] Veerle Vanvoorden,[7] Mark Lebwohl[2]

Presented at the Fall Clinical Dermatology Conference 2021 | October 21–24 | Las Vegas, NV

Objective

To evaluate the clinical efficacy of bimekizumab, using the mean percent change from baseline Psoriasis Area and Severity Index (PASI) through 16 weeks of treatment across four trials.

Introduction

- Bimekizumab is a monoclonal IgG1 antibody that selectively inhibits both interleukin (IL)-17A and IL-17F.[1,2]
- Individual phase 3/3b clinical trials have demonstrated the clinical efficacy of bimekizumab, including fast onset of response durable over two years as measured by PASI cutoff thresholds, for the treatment of patients with moderate to severe plaque psoriasis.[3–6]
- Mean percent change from baseline PASI can be used by clinicians to characterize expected improvements in skin symptoms over time in patients initiating treatment with bimekizumab.

Methods

- Data from the bimekizumab treatment arms of four phase 3/3b trials, BE READY (NCT03410992)[3], BE VIVID (NCT03370133)[4], BE SURE (NCT03412747)[5], and BE RADIANT (NCT03536884)[6], were pooled.
- Included patients received bimekizumab 320 mg every four weeks (Q4W) through Week 16 **(Figure 1)**.
- Mean percent improvements from baseline PASI through Week 16 are reported for the pooled cohort. Pooled results from Week 2 do not include BE SURE data, as PASI was not assessed at this timepoint.
- Missing data were imputed as last observation carried forward (LOCF).

Results

- Patient demographics and baseline characteristics for the pooled cohort are reported in **Table 1**.
- A total of 1,362 bimekizumab-treated patients were pooled. Among these patients, mean percent improvements from baseline PASI at Weeks 1, 2, 4, and 16 were 42.2%, 64.6%, 82.1%, and 95.9%, respectively **(Figure 2)**.
- Across all trials, the percentage of bimekizumab-treated patients who completed treatment through Week 16 ranged from 95.3–97.4%.

Conclusions

Marked mean percent PASI improvements were observed as early as Week 1 and continued to increase to Week 16, showing that high levels of skin clearance were rapidly achieved in patients receiving bimekizumab.

By showing average patient responses to bimekizumab, these data inform clinicians regarding expectations for bimekizumab treatment, allowing clinicians to clearly communicate the expectations of response to patients receiving bimekizumab.

Summary

Data were pooled from the bimekizumab treatment arms of four phase 3/3b trials

BE READY (NCT03410992)

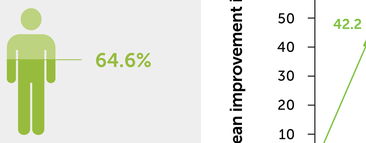
BE VIVID (NCT03370133)

BE SURE (NCT03412747)

BE RADIANT (NCT03536884)

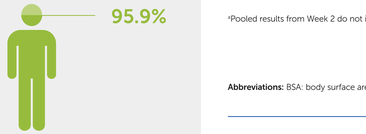
Mean percent PASI improvement with bimekizumab 320 mg Q4W (N=1,362)

Week 1



Week 2

Week 4



Week 16

Figure 1 Study design

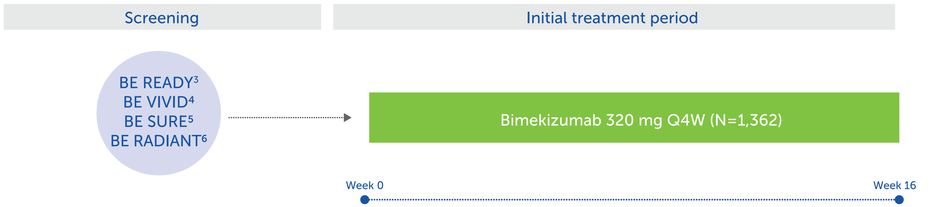
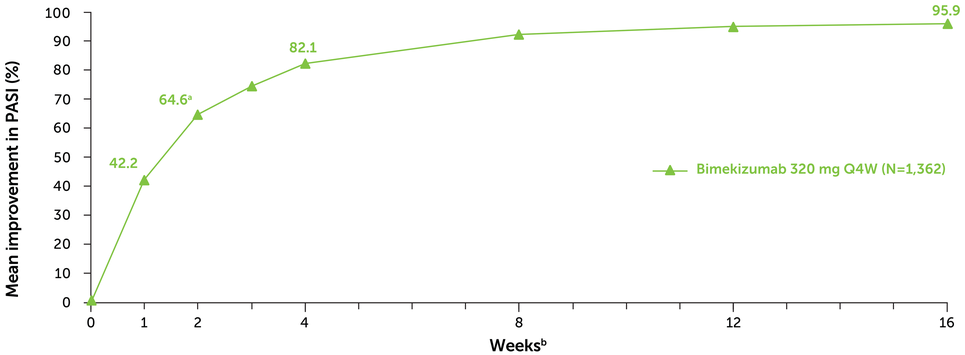


Figure 2 Pooled mean percent improvements from baseline PASI (LOCF)



[a]Pooled results from Week 2 do not include BE SURE data, as PASI was not assessed at this timepoint; [b]Across all trials, bimekizumab was dosed at baseline, and Weeks 4, 8, 12, and 16.

Table 1 Baseline demographics and disease characteristics

	Pooled bimekizumab 320 mg Q4W (N=1,362)
Age (years), mean ± SD	45.1 ± 13.6
Male, n (%)	949 (69.7)
Caucasian, n (%)	1,188 (87.2)
Weight (kg), mean ± SD	89.7 ± 21.9
Duration of psoriasis (years), mean ± SD	18.2 ± 12.6
PASI, mean ± SD	20.7 ± 7.6
BSA (%), mean ± SD	26.0 ± 15.6
IGA, n (%)	
3: moderate	896 (65.8)
4: severe	463 (34.0)
DLQI, mean ± SD	10.5 ± 6.4
Prior biologic therapy, n (%)	505 (37.1)

Abbreviations: BSA: body surface area; DLQI: Dermatology Life Quality Index; IGA: Investigator's Global Assessment; IL: interleukin; LOCF: last observation carried forward; PASI: Psoriasis Area and Severity Index; Q4W: every 4 weeks; SD: standard deviation.

Institutions: [1]Oregon Medical Research Center, Portland, Oregon, USA; [2]Icahn School of Medicine at Mount Sinai, New York, New York, USA; [3]Department of Dermatology University of Texas Health Science Center, Houston, Texas, USA; [4]Southern California Dermatology, Santa Ana, California, USA; [5]UCB Pharma, Smyrna, Georgia, USA; [6]UCB Pharma, Raleigh, North Carolina, USA; [7]UCB Pharma, Brussels, Belgium

References: [1]Glatt S *et al.* Br J Clin Pharmacol 2017;83:991–1001; [2]Papp KA *et al.* J Am Acad Dermatol 2018;79:277–286.e10; [3]Gordon KB *et al.* Lancet 2021;397:475–86; [4]Reich K *et al.* Lancet 2021;397:487–498; [5]Warren R *et al.* N Engl J Med 2021;385(2):130–141; [6]Reich K *et al.* N Eng J Med 2021; DOI: 10.1056/NEJMoa2102383. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **AB, GH, SKT, JS, TO, LD, VV, ML;** Drafting of the publication, or revising it critically for important intellectual content: **AB, GH, SKT, JS, TO, LD, VV, ML;** Final approval of the publication: **AB, GH, SKT, JS, TO, LD, VV, ML.** **Author Disclosures: AB:** Scientific adviser and/or clinical study investigator for AbbVie, Abcentra, Aligos, Almirall, Amgen, Arcutis, Arena, Athenex, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Eli Lilly, Evommune, Forte, Galderma, Incyte, Janssen, Landos, LEO Pharma, Novartis, Pfizer, Rapt, Regeneron, Sanofi Genzyme, Sun Pharma, and UCB Pharma; **GH:** Consultant, speaker, or research support for AbbVie, Amgen, Athenex, Boehringer Ingelheim, Bond Avillion, Bristol Myers Squibb, Castle Biosciences, Celgene, Dermavant, Dermtech, Eli Lilly, Janssen, LEO Pharma, MedX, MC2, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sanofi Genzyme, Sun Pharma, and UCB Pharma; **SKT:** Clinical study investigator for UCB Pharma; **JS:** Honoraria and/or consulting fees from Amgen, Celgene, Dermavant, National Psoriasis Foundation, Ortho Dermatologics and Regeneron; grants and consulting fees from Abbvie, Actelion, Boeringher Ingelheim, Dermira, Eli Lilly, Janssen, Leo Pharma, Novartis Pharma and UCB, research grants from Cassiopeia, Galderma, and Pfizer; **TO, LD:** Employees of UCB Pharma; **VV:** Employee and shareholder of UCB Pharma; **ML:** Employee of Mount Sinai and receives research funds from Abbvie, Amgen, Arcutis, Avotres, Boehringer Ingelheim, Dermavant, Eli Lilly, Incyte, Janssen Research & Development, LLC, Ortho Dermatologics, Regeneron, and UCB Pharma; consultant for Aditum Bio, AnaptysBio, Almirall, Arcutis, Aristea, Arrive technology, Avotres Therapeutics, BioMx, Boehringer Ingelheim, Bristol Myers Squibb, Cara Therapeutics, Castle Biosciences, Corrona, Dermavant Sciences, Dr.Reddy, Evelo, Evommune, Facilitate International Dermatologic Education, Forte, Foundation for Research and Education in Dermatology, Helsinn, LEO Pharma, Meiji, Mindera, Pfizer, Seanergy, and Verrica. **Acknowledgments:** This study was funded by UCB Pharma. We would like to thank the patients and their caregivers in addition to all of the investigators and their teams who contributed to this study. The authors acknowledge Mylene Serna, PharmD, UCB Pharma, Smyrna, GA, USA for publication coordination, and Emily Kaiser, BS, Costello Medical, Boston, MA, USA for medical writing and editorial assistance. All costs associated with development of this presentation were funded by UCB Pharma.