Bimekizumab versus Ustekinumab Efficacy Across Subgroups of Patients with Moderate to Severe Plaque Psoriasis: Results from the Multicenter, Randomized, Double-Blinded Phase 3 BE VIVID Trial

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Objective

To assess the efficacy of bimekizumab compared with ustekinumab over 52 weeks of treatment across demographic, disease characteristic, and prior treatment history subgroups of patients with moderate to severe plaque psoriasis from the BE VIVID study.

Background

- Bimekizumab is a monoclonal IgG1 antibody that selectively inhibits IL-17F in addition to IL-17A, both of which play a pivotal role in the pathogenesis of psoriasis (PSO).[1–4]
- Given that the severity of PSO can vary with age, weight and prior treatment exposure,[5] there is a need for therapies that provide consistent and durable skin clearance, regardless of patient/disease characteristics and treatment history.

Methods

- In BE VIVID (NCT03370133), patients were randomized to receive bimekizumab through Week 52, ustekinumab through Week 52, or placebo to Week 16 followed by bimekizumab (patients randomized to placebo were not included in these analyses; **Figure 1**).
- Subgroup analyses were conducted based on patient demographics, disease characteristics, and prior treatment exposure.
- Proportions of bimekizumab- versus ustekinumab-treated patients achieving 90% and 100% improvement from baseline Psoriasis Area and Severity Index (PASI 90 and PASI 100) were calculated at Weeks 16 and 52. Missing data were imputed as non-response (NRI).

Results

Patient Population

- Baseline characteristics for patients randomized to bimekizumab or ustekinumab are shown in **Table 1**.

Bimekizumab Efficacy Across Subgroups

- PASI 90 **(Figure 2)** and PASI 100 **(Figure 3)** response rates were greater in patients randomized to bimekizumab compared with ustekinumab across all subgroups at Week 16.
- Responses were further improved or maintained in bimekizumab-treated patients through Week 52 and remained higher than responses in patients receiving ustekinumab **(Figure 2 and Figure 3)**.

Synopsis

Bimekizumab **vs** Ustekinumab

Subgroup Analyses:

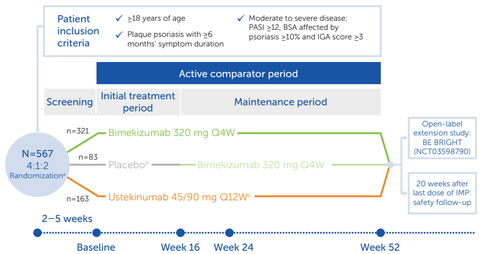
Patient demographics
- Age (<40, 40–<65, ≥65 years)
- Weight (≤100, >100 kg)

Disease characteristics
- Duration (<median, ≥median)
- Severity (PASI<20, PASI≥20; IGA=3, IGA=4)

Prior treatment exposure
- Prior biologic exposure (yes, no)
- Prior anti-TNF exposure (yes, no)
- Prior anti-IL-17 exposure (yes, no)

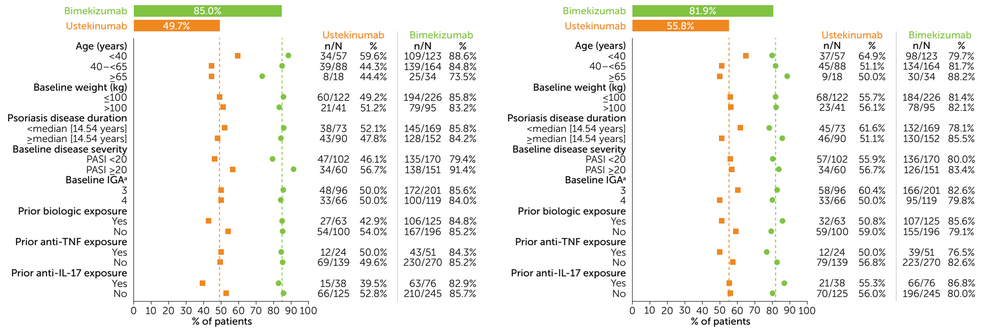
Bimekizumab demonstrated greater skin clearance vs ustekinumab, regardless of patient subgroup.

Figure 1 Study design



[a]Randomization was stratified by prior biologic exposure and region; [b]Patients randomized to placebo were not included in these analyses; [c]Ustekinumab dosing was based on weight: patients ≤100 kg at baseline received one ustekinumab 45 mg injection and one placebo injection; patients >100 kg at baseline received two ustekinumab 45 mg injections (90 mg total).

Figure 2 Achievement of PASI 90 at Weeks 16 and 52 (ITT, NRI)



[a]In each treatment group, one patient with IGA=2 was mistakenly enrolled and is not shown here.

Figure 3 Achievement of PASI 100 at Weeks 16 and 52 (ITT, NRI)

[a]In each treatment group, one patient with IGA=2 was mistakenly enrolled and is not shown here.

Table 1 Baseline characteristics[a]

	Bimekizumab 320 mg Q4W (n=321)	Ustekinumab 45/90 mg Q12W[b] (n=163)
Age (years), mean ± SD	45.2 ± 14.0	46.0 ± 13.6
<40 years, n (%)	123 (38.3)	57 (35.0)
40–<65 years, n (%)	164 (51.1)	88 (54.0)
≥65 years, n (%)	34 (10.6)	18 (11.0)
Male, n (%)	229 (71.3)	117 (71.8)
Caucasian, n (%)	237 (73.8)	120 (73.6)
Weight (kg), mean ± SD	88.7 ± 23.1	87.2 ± 21.1
≤100 kg, n (%)	226 (70.4)	122 (74.8)
>100 kg, n (%)	95 (29.6)	41 (25.2)
Duration of psoriasis (years), mean ± SD	16.0 ± 11.6	17.8 ± 11.6
<Median (14.54 years), n (%)	169 (52.6)	73 (44.8)
≥Median (14.54 years), n (%)	152 (47.4)	90 (55.2)
PASI, mean ± SD	22.0 ± 8.6	21.3 ± 8.3
PASI<20, n (%)	170 (53.0)	102 (62.6)
PASI≥20, n (%)	151 (47.0)	60 (36.8)
BSA (%), mean ± SD	29.0 ± 17.1	27.3 ± 16.7
IGA[c], n (%)		
3: moderate	201 (62.6)	96 (58.9)
4: severe	119 (37.1)	66 (40.5)
DLQI total, mean ± SD	9.9 ± 6.3	11.0 ± 6.9
Prior biologic therapy, n (%)	125 (38.9)	63 (38.7)
anti-TNF	51 (15.9)	24 (14.7)
anti-IL-17	76 (23.7)	38 (23.3)
anti-IL-23	16 (5.0)	6 (3.7)

[a]Patients randomized to placebo are not shown here; [b]Ustekinumab dosing was based on weight: patients ≤100 kg at baseline received one ustekinumab 45 mg injection and one placebo injection, patients >100 kg at baseline received two ustekinumab 45 mg injections (90 mg total); [c]In each treatment group, one patient with IGA=2 was mistakenly enrolled.

Conclusions

Bimekizumab demonstrated greater skin clearance that was durable in patients with moderate to severe plaque psoriasis as compared with ustekinumab, regardless of patient subgroup.

These results support bimekizumab as a psoriasis treatment suitable for a wide variety of patients given its consistent efficacy across all subgroups analyzed.

BSA: body surface area; DLQI: Dermatology Life Quality Index; IGA: Investigator's Global Assessment; IL: interleukin; IMP: investigational medicinal product; ITT: intention-to-treat; NRI: non-responder imputation; PASI: Psoriasis Area and Severity Index; Q4W: every 4 weeks; Q12W: every 12 weeks; SD: standard deviation; TNF: tumor necrosis factor.

Institutions: [1]Yale University, New Haven, CT, USA; [2]Central Connecticut Dermatology Research, Cromwell, CT, USA; [3]The Rockefeller University, New York, NY, USA; [4]Universitätsklinikum Münster, Münster, Germany; [5]McMaster University, Hamilton, ON, Canada; [6]Probity Medical Research; Windsor, ON, Canada; [7]Institute and Comprehensive Center for Inflammation Medicine, University Hospital of Lübeck, Lübeck, Germany; [8]UCB Pharma, Raleigh, NC, USA; [9]Dermatology Centre, Salford Royal NHS Foundation Trust, Manchester NIHR Biomedical Research Centre, The University of Manchester, Manchester, UK.

References: [1]Durham L. Curr Rheumatol Reports 2015;17:55; [2]Fujishima S. Arch Dermatol Res 2010;302:499–505; [3]Glatt S. Br J Clin Pharmacol 2017;83:991–1001; [4]Papp KA. J Am Acad Dermatol 2018;79:277–86.e10; [5]Kamiya K. Int J Mol Sci 2019;20:4347. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **BS, JGK, NM, RV, DPT, DT, MW, CC, CM, RBW;** drafting of the publication, or revising it critically for important intellectual content: **BS, JGK, NM, RV, DPT, DT, MW, CC, CM, RBW;** final approval of the publication: **BS, JGK, NM, RV, DPT, DT, MW, CC, CM, RBW**. **Author Disclosures: BS:** Consultant (honoraria) from AbbVie, Almirall, Amgen, Arcutis, Arena, Aristea, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Dermavant, Dermira, Eli Lilly, Equillium, GSK, Janssen, LEO Pharma, Meiji Seika Pharma, Mindera, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sanofi-Genzyme, Sun Pharma and UCB Pharma; speaker for AbbVie, Amgen, Eli Lilly, Janssen and Ortho Dermatologics; Scientific Director (consulting fee) for Corrona Psoriasis Registry; Investigator for AbbVie, Cara, Corrona Psoriasis Registry, Dermavant, Dermira and Novartis; Editor-in-Chief (honorarium) for Journal of Psoriasis and Psoriatic Arthritis; **JGK:** Grants paid to institution from AbbVie, Akros, Allergan, Amgen, Avillion, Biogen MA, Boehringer Ingelheim, Botanix, Bristol Myers Squibb, Celgene, Eli Lilly, Exicure, Incyte, Innovaderm, Janssen, LEO Pharma, Novan, Novartis, Paraxel, Pfizer, Regeneron, Sienna, UCB Pharma and Vitae; personal fees from AbbVie, Allergan, Almirall, Amgen, Arena, Aristea, Asana, Aurigne, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly, Escalier, LEO Pharma, Nimbus, Novartis, Menlo, Pfizer, Sanofi, Sienna, Sun Pharma, UCB Pharma and Valeant; **NM:** Honoraria, advisor, and/or paid speaker for and/or participated as principal investigator in clinical trials for AbbVie, Almirall, Asana, Biogen, Bristol Myers Squibb, Boehringer Ingelheim, Celgene Corporation, Dermira, Dr. Reddy's Laboratories, Eli Lilly, Galderma, Genentech, Incyte, Janssen-Cilag, Kyowa Kirin, LEO Pharma, Merck, Novartis, Pfizer, Regeneron, Sun Pharma and UCB Pharma; **RV:** Consultant, and/or scientific advisor, and/or investigator, and/or speaker for AbbVie, Amgen, Astellas, Bausch Health/Valeant, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Dermira, Eli Lilly, Galderma, GSK, Janssen, LEO Pharma, Merck (MSD), Merck Serono, Novartis, Pfizer, Regeneron, Roche, Sanofi-Aventis/Genzyme, Sun Pharma, Takeda and UCB Pharma; **DPT:** Investigator and/or speaker for AbbVie, Amgen, Arcutis, Avillion, Bausch Health, Bristol Myers Squibb, Boehringer Ingelheim, Celgene, Dermira, Eli Lilly, Galderma, GSK, Incyte, Janssen, LEO Pharma, Merck-Serono, Novartis, Pfizer, Regeneron, Sanofi-Aventis/Genzyme, Sun Pharma and UCB Pharma; **DT:** Honoraria for participation on advisory boards, as a speaker and for consultancy from AbbVie, Almirall, Amgen, Biogen-Idec, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, DS-Biopharma, Eli Lilly, Galapagos, Janssen, LEO Pharma, Morphosis, Novartis, Pfizer, Regeneron, Samsung, Sandoz-Hexal, Sanofi and UCB Pharma; Research grants received from Celgene and Novartis; **MW:** Employee of UCB Pharma; **CC, CM:** Employees and shareholders of UCB Pharma; **RBW:** Research grants from AbbVie, Almirall, Amgen, Celgene, Eli Lilly, Janssen, LEO Pharma, Novartis, Pfizer and UCB Pharma; Consultant for AbbVie, Almirall, Amgen, Arena, Avillion, Bristol Myers Squibb, Boehringer Ingelheim, Celgene, Eli Lilly, Janssen, LEO Pharma, Novartis, Pfizer, Sanofi and UCB Pharma. **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 this study. The authors acknowledge Mylene Serna, PharmD, UCB Pharma, Smyrna, GA, USA and Susanne Wiegratz, MSc, UCB Pharma, Monheim am Rhein, Germany for publication coordination; Eva Cullen, PhD, UCB Pharma, Brussels, Belgium for critical review; Kristian Clausen, MPH, Costello Medical, Cambridge, UK for medical writing and editorial assistance; and the Costello Medical Design Team for design support. All costs associated with development of this presentation were funded by UCB Pharma.

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