Bimekizumab Pharmacokinetics, Safety, and Efficacy in Adolescent Patients with Moderate to Severe Plaque Psoriasis: Data from the Initial Treatment Period of the Open-label BE CONNECTED Phase 2 Study

Amy Paller,[1] Jacek C. Szepietowski,[2,3] Jolanta Węgłowska,[2,4] Philippa Charlton,[5] Fabienne Staelens,[6] Delphine Deherder,[6] Merran MacPherson,[7] Asim Datye,[8] Andreas Pinter[9]

[1]Departments of Dermatology and Pediatrics, Northwestern University Feinberg School of Medicine, Chicago, IL, USA; [2]Division of Dermatology, Venereology and Clinical Immunology, Faculty of Medicine, Wrocław University of Science and Technology, Wrocław, Poland; [3]Cityclinic: Medical and Psychological Center, Wrocław, Poland; [4]dermMedica sp.z o.o., Wrocław, Poland; [5]UCB, Morrisville, NC, USA; [6]UCB, Braine-l'Alleud, Belgium; [7]UCB, Slough, UK; [8]UCB, Oakville, ON, Canada; [9]University Hospital Frankfurt, Frankfurt am Main, Germany

Objectives

To assess the pharmacokinetics of bimekizumab (BKZ) and to evaluate the safety and efficacy of BKZ in adolescent patients with moderate to severe plaque psoriasis.

Background

- Approximately 30% of psoriasis cases begin in childhood, negatively impacting children's quality of life and psychological health, with 16% of pediatric psoriasis cases being moderate to severe.[1–3]
- BKZ has previously demonstrated high efficacy levels and was well tolerated in adult patients with moderate to severe plaque psoriasis.[4–7]

Methods

- BE CONNECTED enrolled adolescent patients aged 12–<18 years (≥30 kg) with moderate to severe plaque psoriasis.[8]
- Patients were stratified by weight and randomized 1:1 to one of two doses of open-label BKZ in a 20-week initial treatment period (**Figure 1**).
- The **primary endpoint** was observed BKZ plasma concentration through Week 20 among patients who received ≥1 BKZ dose and had ≥1 plasma concentration measurement.
- **Secondary endpoints** included:
  - Treatment-emergent adverse events (TEAEs) through Week 20 among patients who received ≥1 BKZ dose.
  - Achievement of ≥90% improvement from baseline in Psoriasis Area Severity Index (PASI 90) at Week 16, Investigator's Global Assessment (IGA) 0/1 at Week 16, and ≥75% improvement from baseline in PASI (PASI 75) at Week 4 (non-responder imputation [NRI]) among all randomized patients.
  - Change from baseline in Children's Dermatology Life Quality Index (CDLQI) at Week 16 (observed case [OC]) among all randomized patients.
- Other endpoints included rates of PASI 75, PASI 90, 100% improvement from baseline in PASI (PASI 100), IGA 0/1, and CDLQI 0/1 over time among all randomized patients (NRI).

Results

Baseline characteristics

- In total, 41 patients were randomized in the study (Dose A: n=20; Dose B: n=21). Mean age was 14.8 (standard deviation: 1.9) years; 58.5% of patients were female and 97.6% were White (**Table 1**).

Pharmacokinetics and safety

- Steady-state BKZ plasma concentrations were reached by Weeks 16–20, with lower BKZ plasma concentrations for Dose B compared with Dose A (**Figure 2**).
- Rates of any TEAEs were 45.0% with Dose A and 38.1% with Dose B. One serious, non-treatment-related TEAE was reported in the Dose A group (**Table 2**).
- No Candida infections, serious infections, or TEAEs of inflammatory bowel disease were reported (**Table 2**).

Efficacy and quality of life outcomes

- Rates of achievement of PASI 90, IGA 0/1, PASI 75, and PASI 100 (NRI) through Week 20 are presented in **Figure 3**.
  - At Week 4, after one dose of BKZ, 80.0% and 70.0% of patients receiving Dose A achieved PASI 75 and PASI 90, respectively; 52.4% and 38.1% of patients receiving Dose B achieved PASI 75 and PASI 90, respectively (**Figure 3A**; **Figure 3C**).
  - At Week 16 PASI 90 and IGA 0/1 were achieved by 95.0% of patients receiving Dose A and 90.5% of patients receiving Dose B (**Figure 3A**; **Figure 3B**).
  - PASI 100 was achieved by 80.0% of patients receiving Dose A and 81.0% of patients receiving Dose B at Week 16 (**Figure 3D**).
- At Week 16, mean improvement from baseline in CDLQI was 75.2% with Dose A and 70.2% with Dose B (OC); 75.0% and 61.9% of patients achieved CDLQI 0/1, respectively (NRI).

Conclusions

Bimekizumab pharmacokinetics were within the expected range, aligning with the established pharmacokinetic profile in adult patients.

Bimekizumab was well tolerated, with no safety signals identified.

Moreover, bimekizumab treatment in adolescent patients led to rapid, high-level improvements in clinical outcomes and quality of life that were consistent with studies in adult patients.[4–7]

Summary

We report results up to Week 20 from the BE CONNECTED phase 2 clinical trial of BKZ in adolescent patients with moderate to severe plaque psoriasis

Primary endpoint: Pharmacokinetics

Steady-state BKZ plasma concentrations were reached by **Weeks 16–20**, and lower for **Dose B** compared with **Dose A**, aligning with adult patient pharmacokinetics

Secondary endpoint: TEAEs through Week 20

Overall, BKZ was **well-tolerated** with **no safety signals** identified

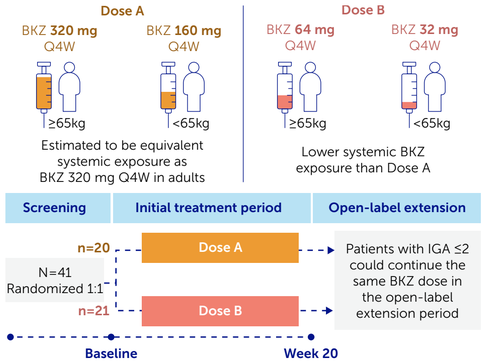
Secondary endpoint: Efficacy at Week 16

>90% achieved **PASI 90**

≥80% achieved **PASI 100**

≥70% mean **improvement** from baseline in **CLDQI**

Figure 1 BE CONNECTED dosing and study design



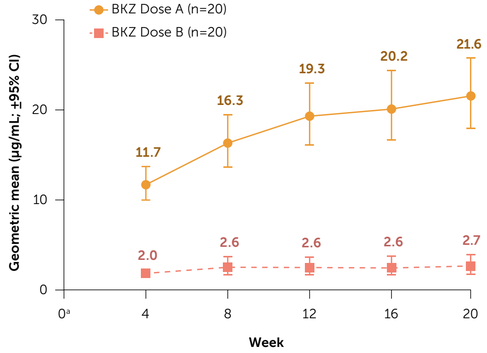
Enrolled patients were aged 12–<18 years (≥30 kg) with moderate to severe plaque psoriasis, defined as PASI ≥12 (or PASI ≥10 plus clinically relevant involvement in ≥1 of the following regions: face, genital, and hand/foot), IGA ≥3, and ≥10% BSA.

Table 1 Baseline characteristics

	BKZ Dose A n=20	BKZ Dose B n=21	All patients N=41
Age (years), mean (SD)	15.1 (1.9)	14.6 (2.0)	14.8 (1.9)
Sex, female, n (%)	11 (55.0)	13 (61.9)	24 (58.5)
Racial group, White, n (%)	19 (95.0)	21 (100)	40 (97.6)
Weight (kg), mean (SD)	65.7 (16.8)	70.2 (20.0)	68.0 (18.4)
Duration of psoriasis (years), mean (SD)	5.0 (3.8)	5.8 (3.0)	5.4 (3.4)
PASI, mean (SD)	16.7 (5.4)	18.2 (6.2)	17.5 (5.8)
BSA (%), mean (SD)	22.8 (13.6)	23.4 (9.5)	23.1 (11.5)
IGA, n (%)			
3: Moderate	20 (100)	19 (90.5)	39 (95.1)
4: Severe	0	2 (9.5)	2 (4.9)
CDLQI Total Score, mean (SD)	5.2 (5.9)	7.3 (6.5)	6.3 (6.2)
Any prior systemic treatment, n (%)	8 (40.0)	8 (38.1)	16 (39.0)
Any prior biologic treatment, n (%)	1 (5.0)	6 (28.6)	7 (17.1)

Dose A was BKZ 320 mg Q4W in patients ≥65 kg and BKZ 160 mg Q4W in patients <65 kg. Dose B was BKZ 64 mg Q4W in patients ≥65 kg and BKZ 32 mg Q4W in patients <65 kg.

Figure 2 BKZ plasma concentration through Week 20



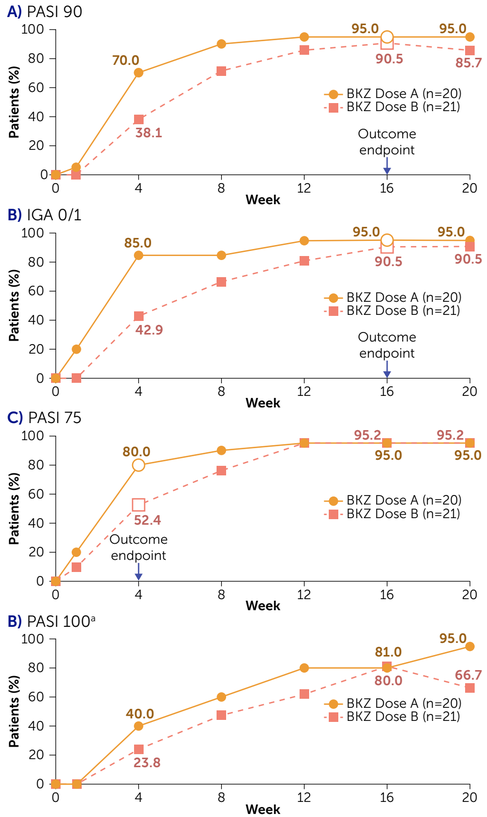
Pharmacokinetics set included all patients who received ≥1 BKZ dose and had ≥1 plasma concentration assessment. Dose A was BKZ 320 mg Q4W in patients ≥65 kg and BKZ 160 mg Q4W in patients <65 kg. Dose B was BKZ 64 mg Q4W in patients ≥65 kg and BKZ 32 mg Q4W in patients <65 kg. **[a]** Baseline values were below the limit of quantification.

Table 2 TEAEs reported through Week 20

TEAE, n (%)	BKZ Dose A n=20	BKZ Dose B n=21	All patients N=41
Any TEAE	9 (45.0)	8 (38.1)	17 (41.5)
Serious TEAE	1 (5.0)[a]	0	1 (2.4)[a]
TEAE leading to treatment discontinuation	0	0	0
TEAE leading to death	0	0	0
Most common TEAEs (≥2 incidences)			
Nasopharyngitis	2 (10.0)	2 (9.5)	4 (9.8)
Arthralgia	1 (5.0)	1 (4.8)	2 (4.9)
Rhinitis	2 (10.0)	0	2 (4.9)
Upper respiratory tract infection	0	2 (9.5)	2 (4.9)
Serious infection	0	0	0
Fungal infection (including Candida)	0	0	0
Opportunistic infection (including TB)	0	0	0
Adjudicated inflammatory bowel disease	0	0	0
Injection site reaction	1 (5.0)[b]	0	1 (2.4)[b]
Adjudicated suicidal ideation and behavior	0	0	0
Cardiovascular event	0	0	0
Neutropenia	0	0	0
Any malignancy	0	0	0
Hypersensitivity	0	1 (4.8)	1 (2.4)
Serious hypersensitivity	0	0	0
Hepatic event	1 (5.0)[c]	0	1 (2.4)[c]
Alanine aminotransferase increased	1 (5.0)[c]	0	1 (2.4)[c]

Safety set included all patients who received ≥1 BKZ dose. Dose A was BKZ 320 mg Q4W in patients ≥65 kg and BKZ 160 mg Q4W in patients <65 kg. Dose B was BKZ 64 mg Q4W in patients ≥65 kg and BKZ 32 mg Q4W in patients <65 kg. **[a]** One patient experienced a case of syncope (assessed as not related to treatment), which was classified as a serious TEAE due to hospitalization for investigations; **[b]** This was injection site erythema; **[c]** This was in a patient with obesity who was later diagnosed with hepatic steatosis.

Figure 3 Rates of achievement of PASI 90, IGA 0/1, PASI 75, and PASI 100 through Week 20 (NRI)



Randomized set included all randomized patients. Dose A was BKZ 320 mg Q4W in patients ≥65 kg and BKZ 160 mg Q4W in patients <65 kg. Dose B was BKZ 64 mg Q4W in patients ≥65 kg and BKZ 32 mg Q4W in patients <65 kg. **[a]** PASI 100 was evaluated over time, with no designated endpoint week.

BKZ: bimekizumab; **BSA:** body surface area; **CI:** confidence interval; **CLDQI:** Children's Dermatology Life Quality Index; **IGA:** Investigator's Global Assessment; **NRI:** non-responder imputation; **OC:** observed case; **PASI 75/90/100:** ≥75%/≥90%/100% improvement from baseline in Psoriasis Area and Severity Index; **Q4W:** every 4 weeks; **SD:** standard deviation; **TB:** tuberculosis; **TEAE:** treatment-emergent adverse event.

References: [1]Menter A et al. J Am Acad Dermatol 2020;82:161–201; [2]Yang A et al. Am J Clin Dermatol 2025;26:695–710; [3]Ramond A et al. Dermatol Ther (Heidelb) 2025;15:3765–76; [4]Reich K et al. N Engl J Med 2021;385:142–52 (NCT03536884); [5]Gordon KB et al. Lancet 2021;397:475–86 (NCT03410992); [6]Warren RB et al. N Engl J Med 2021;385:130–41 (NCT03412747); [7]Reich K et al. Lancet 2021;397:487–98 (NCT03370133); [8]BE CONNECTED (NCT04718896). Available at: https://clinicaltrials.gov/study/NCT04718896 [Accessed March 2026]. **Author Contributions:** All authors had substantial contributions to the study conception/design or acquisition/analysis/interpretation of data, drafted the publication or reviewed it critically for important intellectual content, and approved the final publication. **Author Disclosures: AmP:** Investigator, consultant, and/or data and safety monitoring board member for AbbVie, Abeona Therapeutics, Arcutis, BioCryst, BioMendics, Boehringer Ingelheim, Castle Creek Biosciences, Chiesi, Daiichi Sankyo, Dermavant, Eli Lilly and Company, Galderma, Incyte, Johnson & Johnson Innovative Medicine, Krystal Biotech, LEO Pharma, L'Oréal, MoonLake Immunotherapeutics, Pelthos, Quoin, Regeneron Pharmaceuticals, and Sanofi. **JCS:** Consultant and advisory board member of AbbVie, Almirall, Boehringer Ingelheim, Galderma, LEO Pharma, Novartis, Pierre Fabre, Sandoz, Sanofi, and UCB; speaker for AbbVie, Almirall, Boehringer Ingelheim, Eli Lilly and Company, Janssen, LEO Pharma, Novartis, Pfizer, Pierre Fabre, Sanofi–Genzyme, and UCB; investigator for AbbVie, Acelyrin, Almirall, Amgen, AnaptysBio, Argenx, Aslan, Boehringer Ingelheim, Biocom, Bio Thera, Bristol Myers Squibb, Celltrion, CuraTeQ Biologics, DICE Therapeutics, Eli Lilly and Company, Galapagos, Galderma, Helm AG, Incyte, InflaRx, Janssen, Kiniksa, Kymab Limited, LEO Pharma, Medimmune, Menlo Therapeutics, Merck, MoonLake Immunotherapeutics, Novartis, Pierre Fabre, Pfizer, Regeneron Pharmaceuticals, Takeda, Teva, Trevi Therapeutics, UCB, Uni Therapeutics, and Ventyx Bioscience. **JW:** Investigator, speaker and/or advisor for Acelyrin, Almirall, Amgen, AnaptysBio, Celgene, Coherus, Dermira, Dong, Eli Lilly and Company, Galderma, Incyte, Janssen, LEO Pharma, Merck, MoonLake Immunotherapeutics, Novartis, Pfizer, Regeneron Pharmaceuticals, Sandoz, Sanofi-Genzyme, Takeda, Teva, and UCB. **PC, FS, DD, MM:** Employees and shareholders of UCB. **AD:** Employee of UCB. **AnP:** Investigator, speaker, and/or advisor for AbbVie, Almirall, Amgen, Biogen, Boehringer Ingelheim, Celgene, Eli Lilly and Company, Galderma, GSK, Hexal, Janssen, LEO Pharma, MC2 Therapeutics, Medac, Merck Serono, Mitsubishi Pharma, MSD, MoonLake Immunotherapeutics, Novartis, Pfizer, Regeneron, Roche, Sandoz, Schering-Plough, Tigercat Pharma, UCB, and Zuellig Pharma. **Acknowledgments:** 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 Inés Dueñas Pousa, UCB, Madrid, Spain for publication coordination, Oscar Jenkyn-Jones, MSc, Costello Medical, London, UK for medical writing and editorial assistance, and the Costello Medical Creative team for design support. This study was funded by UCB. All costs associated with development of this poster were funded by UCB.

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