Bimekizumab pharmacokinetics, safety, and efficacy in adolescents 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

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Objectives

In adolescents with moderate to severe plaque psoriasis:

- To assess the pharmacokinetics of bimekizumab (BKZ).
- To evaluate the safety and efficacy of BKZ, and its effect on health-related quality of life.

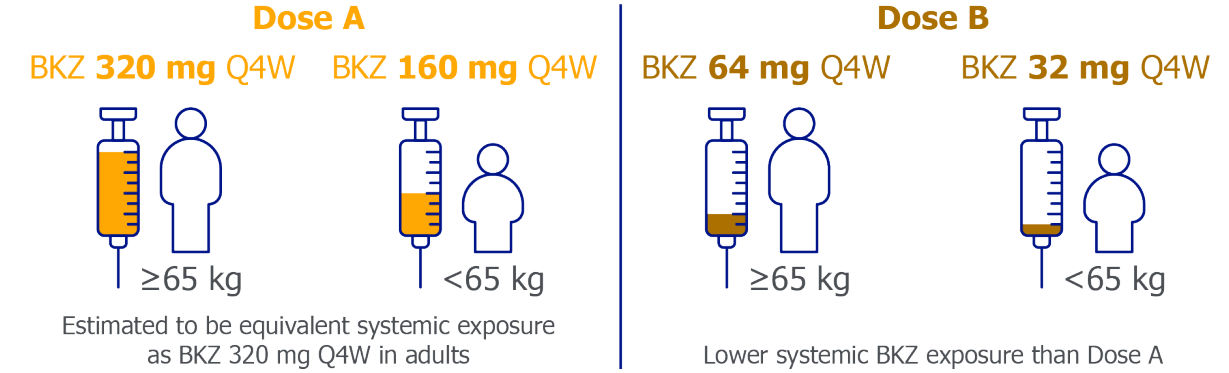
Background

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

Methods

- **BE CONNECTED** enrolled adolescents aged 12–<18 years (≥30 kg) with moderate to severe plaque psoriasis.[8,a]
- 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.

BE CONNECTED Dosing



[a] Moderate to severe defined as: PASI ≥12 (or PASI ≥10 plus clinically relevant involvement in ≥1 of the following regions: face, genital, hand/foot), IGA score ≥3, and ≥10% BSA affected by psoriasis.

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 December 2025]. BKZ: bimekizumab; BSA: body surface area; IGA: Investigator's Global Assessment; PASI: Psoriasis Area Severity Index; Q4W: every 4 weeks.

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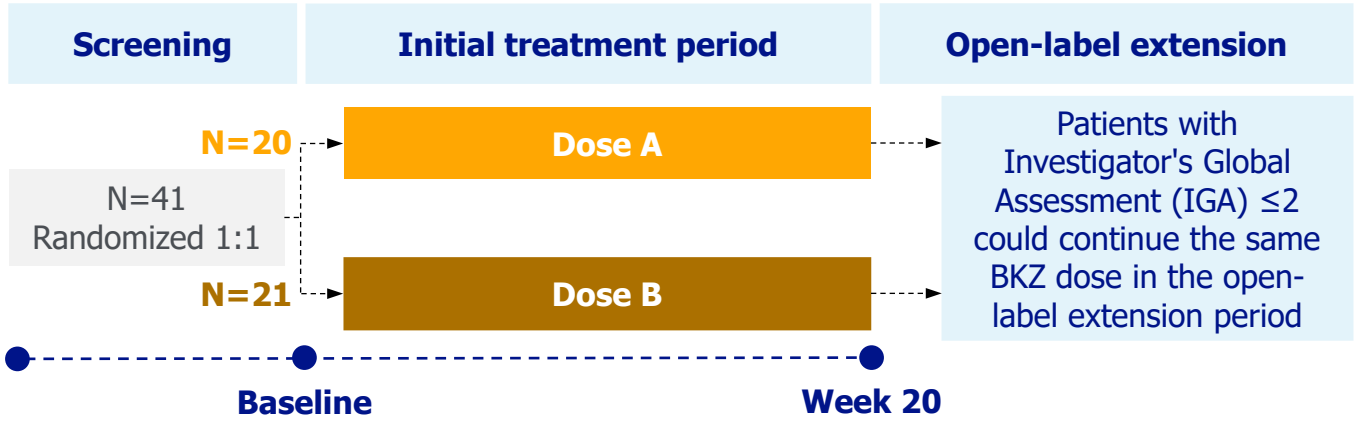
Study Design



Endpoints

- **Primary:** Observed **BKZ plasma concentration** through Week 20 (patients who received ≥1 BKZ dose and ≥1 plasma concentration measurement).
- **Secondary:**
  - Treatment-emergent adverse events (**TEAEs**) through Week 20 (patients who received ≥1 BKZ dose).
  - Rates of 90% improvement from baseline in Psoriasis Area Severity Index (**PASI 90**) and **IGA 0/1** at Week 16, and **PASI 75** at Week 4 (non-responder imputation [NRI]; all randomized patients).
  - Change from baseline in Children's Dermatology Life Quality Index (**CDLQI**) at Week 16 (observed case [OC]; all randomized patients).
- **Other:** Rates of **PASI 75, PASI 90, PASI 100, IGA 0/1,** and **CDLQI 0/1** over time (NRI).[a]

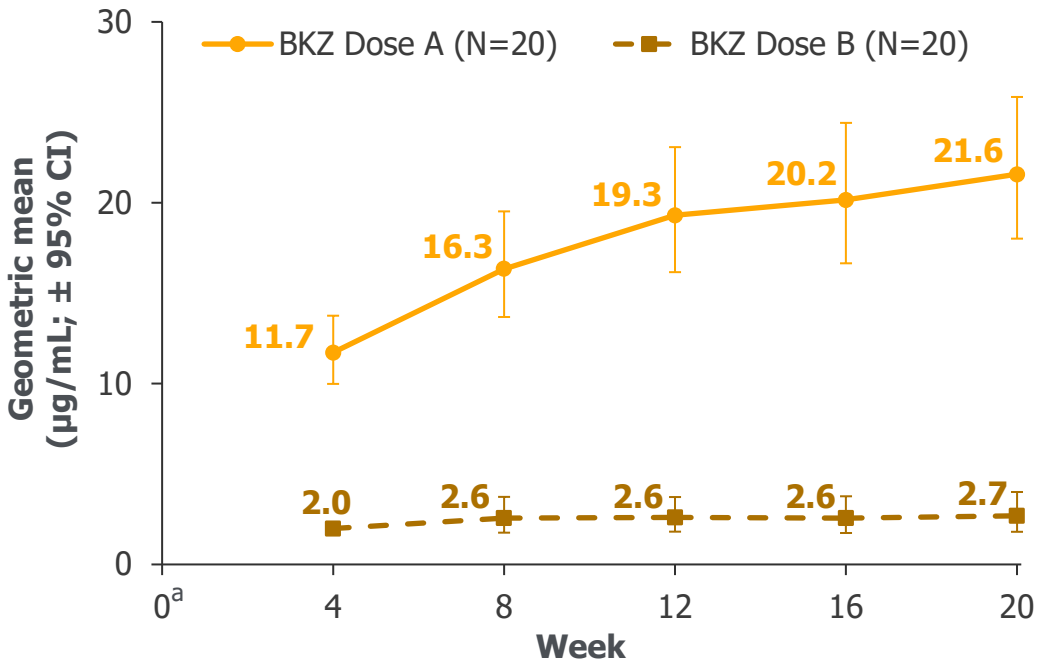
Baseline Characteristics

	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 therapy, n (%)	8 (40.0)	8 (38.1)	16 (39.0)
Any prior biologic therapy, n (%)	1 (5.0)	6 (28.6)	7 (17.1)

Dose A: BKZ 320 mg Q4W in patients ≥65 kg, BKZ 160 mg Q4W in patients <65 kg; Dose B: BKZ 64 mg Q4W in patients ≥65 kg, BKZ 32 mg Q4W in patients <65 kg. **[a]** For rates of CDLQI 0/1, only Week 16 values are reported here. BKZ: bimekizumab; BSA: body surface area; CDLQI: Children's Dermatology Life Quality Index; IGA: Investigator's Global Assessment; NRI: non-responder imputation; OC: observed case; PASI: Psoriasis Area Severity Index; PASI 75/90/100: ≥75%/≥90%/100% improvement from baseline in PASI; SD: standard deviation; TEAE: treatment-emergent adverse event.

Pharmacokinetics and Safety Through Week 20

BKZ plasma concentration



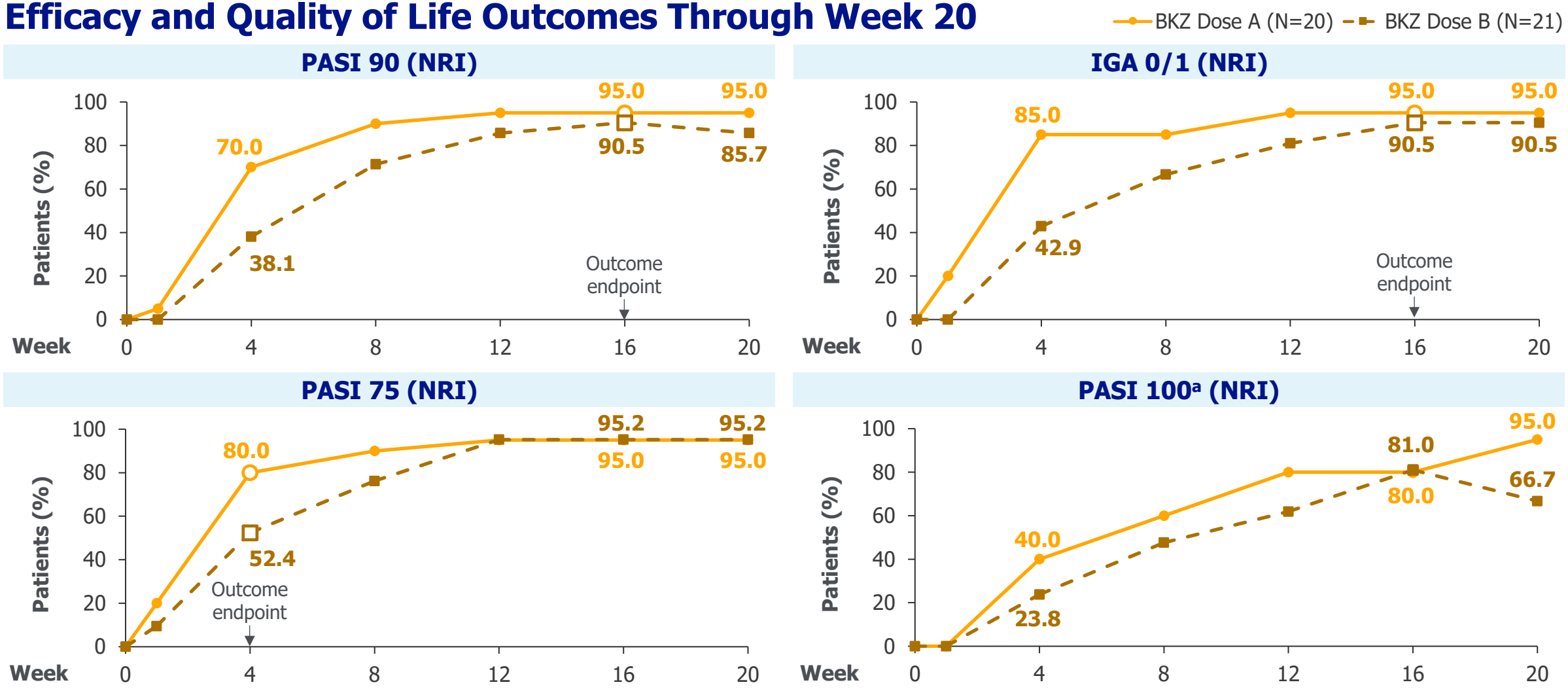
- **Steady-state** BKZ plasma concentrations were reached by Weeks 16–20.
- As expected, BKZ plasma concentrations were **lower for Dose B** compared with Dose A.

Safety

	Weeks 0–20		
Safety Event, 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)[b]	0	1 (2.4)[b]
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	0	0	0
Opportunistic infection (including TB)	0	0	0
Adjudicated inflammatory bowel disease	0	0	0
Injection site reaction	1 (5.0)[c]	0	1 (2.4)[c]
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)[d]	0	1 (2.4)[d]
Alanine aminotransferase increased	1 (5.0)[d]	0	1 (2.4)[d]

Pharmacokinetics Set: all patients who received ≥1 BKZ dose and ≥1 plasma concentration assessment. Safety Set: all patients who received ≥1 BKZ dose. Dose A: BKZ 320 mg Q4W in patients ≥65 kg, BKZ 160 mg Q4W in patients <65 kg; Dose B: BKZ 64 mg Q4W in patients ≥65 kg, BKZ 32 mg Q4W in patients <65 kg. **[a]** Baseline values were below the limit of quantification; **[b]** 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; **[c]** Injection site erythema; **[d]** Patient with obesity who was later diagnosed with hepatic steatosis. BKZ: bimekizumab; CI: confidence interval; Q4W: every 4 weeks; TB: tuberculosis; TEAE: treatment-emergent adverse event.

Efficacy and Quality of Life Outcomes Through Week 20



Improvement in health-related **quality of life** at **Week 16**:

- Mean **improvement** from baseline in **CDLQI** was **75.2%** with Dose A and **70.2%** with Dose B (OC).
- Response rate of **CDLQI 0/1** was **75.0%** with Dose A and **61.9%** with Dose B (NRI).

Randomized Set: all randomized patients. Dose A: BKZ 320 mg Q4W in patients ≥65 kg, BKZ 160 mg Q4W in patients <65 kg; Dose B: BKZ 64 mg Q4W in patients ≥65 kg, BKZ 32 mg Q4W in patients <65 kg. **[a]** PASI 100 was evaluated over time, with no designated endpoint week. BKZ: bimekizumab; CDLQI: Children's Dermatology Life Quality Index; NRI: non-responder imputation; OC: observed case; PASI 75/90/100: ≥75%/≥90%/100% improvement in Psoriasis Area Severity Index; IGA: Investigator's Global Assessment.

Conclusions

In adolescents with moderate to severe psoriasis:

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

Bimekizumab was well tolerated, with no safety signals identified.

Bimekizumab treatment led to rapid, high-level improvements in clinical outcomes and quality of life that were consistent with adult studies.[1–4]

Author Contributions: Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **AmP, JCS, JW, PC, FS, DD, MM, AD, AnP**; Drafting of the publication, or reviewing it critically for important intellectual content: **AmP, JCS, JW, PC, FS, DD, MM, AD, AnP**; Final approval of the publication: **AmP, JCS, JW, PC, FS, DD, MM, AD, AnP**.

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1. Reich K et al. N Engl J Med 2021;385:142–52 (NCT03536884); **2.** Gordon KB et al. Lancet 2021;397:475–86 (NCT03410992); **3.** Warren RB et al. N Engl J Med 2021;385:130–41 (NCT03412747); **4.** Reich K et al. Lancet 2021;397:487–98 (NCT03370133).