P3080

Bimekizumab safe and effective self-administration using 2 mL devices by patients with moderate to severe plaque psoriasis: Results from two multicentre, randomised, open-label studies

Jerry Bagel,[1,2] Bertram Knapp,[3] Thomas Vaux,[4] Bengt Hoepken,[3] Michael Sebastian[5]

Objective

To assess the ability of patients to safely and effectively self-administer subcutaneous bimekizumab (BKZ) using a 2 mL safety syringe or auto-injector (AI).

Introduction

- Safe and effective self-injection of subcutaneous BKZ in patients with moderate to severe plaque psoriasis using a 1 mL safety syringe or AI has previously been associated with a positive overall patient experience.[1]
- The 2 mL safety syringe and AI devices provide an alternative injection regimen to 1 mL devices, giving patients the choice to self-administer one injection instead of two, which may be preferable for patients.[2]

Methods

- DV0002 (US and Canada) and DV0006 (Germany, Hungary, and Poland) were sub-studies of the phase 3 open-label extension study, BE BRIGHT.[1,3]
- Included patients received BKZ 320 mg every 4 weeks (Q4W) or every 8 weeks (Q8W) based on treatment regimen and Psoriasis Area Severity Index (PASI) response at BE BRIGHT entry.
- Patients were randomised 1:1 to BKZ-safety syringe-2 mL or BKZ-AI-2 mL, and performed self-injection at sub-study baseline and Week 8, following training in the self-injection technique.
- Safe and effective self-injection was defined as complete dose delivery of BKZ and absence of adverse device events that precluded continued use of the device and/or led to study withdrawal.
- Primary and secondary objectives were to assess patients' ability to safely and effectively self-administer BKZ at Week 8 and baseline, respectively.
- Other objectives were to evaluate patient experience of self-injection using the following measures:
  - Injection site-related pain visual analogue scale (VAS), ranging from 0 to 100 mm;
  - Self-Injection Assessment Questionnaire (SIAQ), ranging from 0 to 10, with higher scores indicating higher confidence and less concern with self-injection, and higher satisfaction with current mode of administration.
- A further objective was to evaluate post-use structural and mechanical integrity of each device.
- Data were analysed using two full analysis sets (BKZ-safety syringe-2 mL and BKZ-AI-2 mL) and are reported for the combined BKZ dose groups (BKZ Total) using observed cases (OC).

Results

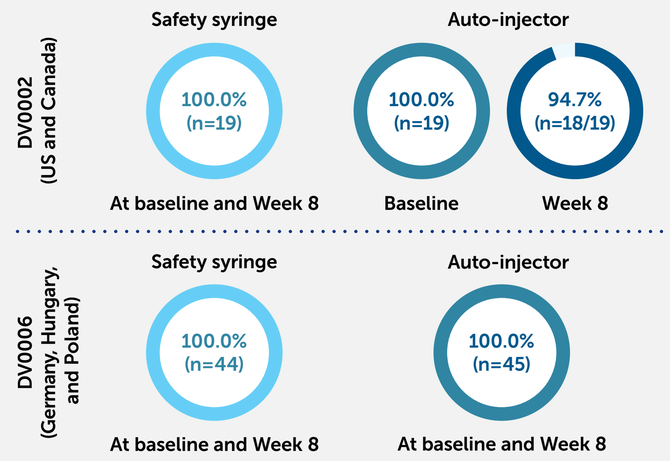
- Baseline characteristics are shown in **Table 1**.
- In DV0002, 19 patients were randomised to use BKZ-safety syringe-2 mL and 19 to BKZ-AI-2 mL.
  - All patients using BKZ-safety syringe-2 mL (n=19) self-injected BKZ safely and effectively at baseline and Week 8.
  - All patients using BKZ-AI-2 mL self-injected BKZ safely and effectively at baseline (n=19), and 94.7% (n=18/19) at Week 8.
- In DV0006, 44 patients were randomised to use BKZ-safety syringe-2 mL and 45 to BKZ-AI-2 mL.
  - All patients using BKZ-safety syringe-2 mL (n=44) and BKZ-AI-2 mL (n=45) safely and effectively self-injected BKZ at baseline and Week 8.
- In DV0002/6, median pre-injection and post-injection SIAQ scores were ≥7.5 for all subscales across both devices, and were >9.0 for feelings about injections, self-image, and injection-site reactions subscales (**Figure 1** and **2**).
- In DV0002, median VAS scores numerically decreased with BKZ-safety syringe-2 mL and remained stable with BKZ-AI-2 mL, from baseline to Week 8 (**Figure 3A**).
- In DV0006, median VAS scores remained stable with BKZ-safety syringe-2 mL and BKZ-AI-2 mL, from baseline to Week 8 (**Figure 3B**).
  - Results from both sub-studies indicate variable but generally low injection site-related pain.
- All devices maintained their structural and functional integrity post-use.
- One device deficiency complaint was received for a BKZ-AI-2 mL device presentation after its use at DV0002 Week 8 resulted in a non-serious adverse drug event (injection site-related pain), and the complete dose of BKZ was not administered.

Conclusions

A positive self-administration experience was associated with the 2 mL devices, as reported with 1 mL devices,[1] providing patients with an option to self-administer a single injection of bimekizumab, which may benefit those who experience needle phobia or prefer fewer needlesticks for a single dose.[2,4]

Summary

Safe and effective self-injection of BKZ using 2 mL devices:



Patients' experience of self-injection using either device was **positive** and **injection site-related pain** was **generally low/mild**.

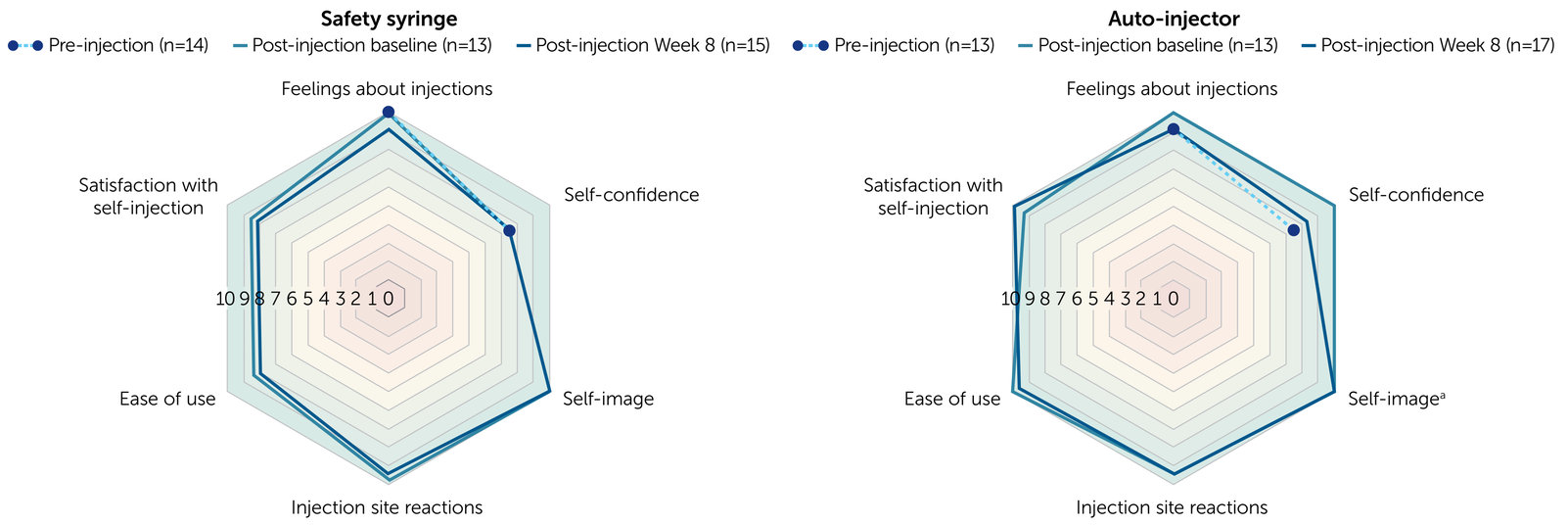
Almost all patients with moderate to severe plaque psoriasis could **safely and effectively self-administer bimekizumab** using the **2 mL safety syringe or auto-injector**, as demonstrated previously with 1 mL devices.[1]

Table 1 Baseline characteristics

	DV0002		DV0006	
	BKZ-safety syringe-2 mL BKZ Total N=19	BKZ-AI-2 mL BKZ Total N=19	BKZ-safety syringe-2 mL BKZ Total N=44	BKZ-AI-2 mL BKZ Total N=45
Age (years), mean ± SD	50.3 ± 15.8	43.0 ± 12.4	46.0 ± 12.4	48.3 ± 12.4
Sex, **male**, n (%)	10 (52.6)	10 (52.6)	31 (70.5)	34 (75.6)
Racial group, **white**, n (%)	16 (84.2)	16 (84.2)	44 (100)	45 (100)
Weight (kg), mean ± SD	93.2 ± 30.9	95.8 ± 23.9	90.6 ± 18.0	91.3 ± 17.9
BMI (kg/m²), mean ± SD	32.4 ± 8.0	33.3 ± 7.3	29.6 ± 5.3	29.9 ± 5.7
Disease duration (years), mean ± SD	19.1 ± 13.0	25.2 ± 14.4	21.1 ± 11.5	23.9 ± 12.8
Country, n (%)				
Canada	11 (57.9)	7 (36.8)	–	–
United States	8 (42.1)	12 (63.2)	–	–
Germany	–	–	11 (25.0)	16 (35.6)
Hungary	–	–	11 (25.0)	7 (15.6)
Poland	–	–	22 (50.0)	22 (48.9)

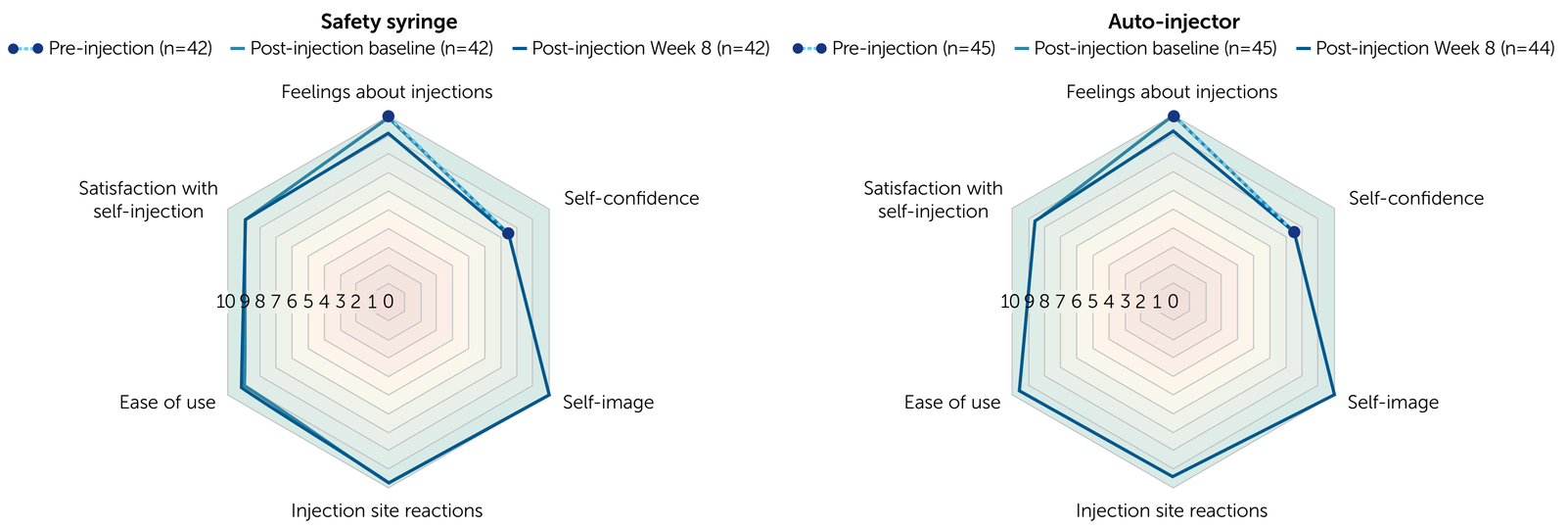
Age was summarised based on age at the time of feeder study entry. Weight was summarised based on the last visit in the feeder study/BE BRIGHT baseline visit. Disease duration (years) was calculated based on the date of enrollment in DV0002/DV0006.

Figure 1 DV0002 median SIAQ responses pre-injection at baseline and post-injection at baseline and Week 8 (OC)



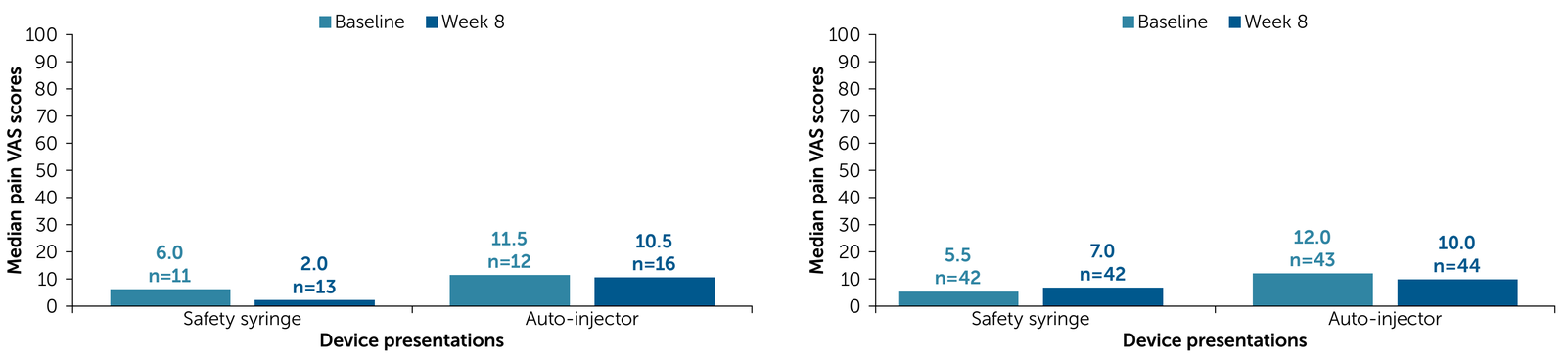
N numbers indicate the number of patients with an observed SIAQ subscale score at a given visit. Pre-injection scores were not collected for the self-image, injection site-reactions, ease of use, and satisfaction with self-injection subscales. Subscale scores ranged from 0 to 10; higher scores indicated higher confidence and less concern with self-injections, and higher satisfaction with self-injection. Assessments where the self-injection was not performed by the patient, or the assessment was not done on the day of the injection were not included. **[a]** n=16 at the post-injection Week 8 visit.

Figure 2 DV0006 median SIAQ responses pre-injection at baseline and post-injection at baseline and Week 8 (OC)



N numbers indicate the number of patients with an observed SIAQ subscale score at a given visit. Pre-injection scores were not collected for the self-image, injection site-reactions, ease of use, and satisfaction with self-injection subscales. Subscale scores ranged from 0 to 10; higher scores indicated higher confidence and less concern with self-injections, and higher satisfaction with self-injection. Assessments where the self-injection was not performed by the patient, or the assessment was not done on the day of the injection, were not included.

Figure 3 Injection site-related pain VAS at baseline and Week 8 (OC)



Numbers indicate the number of patients with an observed pain VAS score at a given visit. Scores on the VAS for pain could range from 0 (no pain) to 100 (worst possible pain). Assessments where the self-injection was not performed by the patient, or the assessment was not done on the day of the injection, were not included.

AI: auto-injector; **BKZ:** bimekizumab; **BKZ-AI-2 mL:** 2 mL bimekizumab auto-injector; **BKZ-safety syringe-2 mL:** 2 mL bimekizumab safety syringe; **BMI:** body mass index; **OC:** observed case; **PASI:** Psoriasis Area Severity Index; **Q4W:** every 4 weeks; **Q8W:** every 8 weeks; **SD:** standard deviation; **SIAQ:** Self-Injection Assessment Questionnaire; **VAS:** visual analogue scale.

Institutions: [1]Psoriasis Treatment Center of Central New Jersey, East Windsor, New Jersey, USA; [2]CorEvitas, LLC, Waltham, Massachusetts, USA; [3]UCB, Monheim am Rhein, Germany; [4]UCB, Slough, UK; [5]Dermatologie Mahlow Practice Dr. med. Michael Sebastian, Mahlow, Germany.

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