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Bimekizumab Self-Injection Devices: Two Multicenter, Randomized, Open-Label Studies on Self-Administration by Patients With Psoriasis

Jerry Bagel MD,[a] Daljit Tatla,[b] Scarlett Hellot,[c] Bertram Knapp,[d] Charita Murphy,[b] Luke Peterson,[b] Michael Sebastian MD[e]

[a]Psoriasis Treatment Center of Central New Jersey, East Windsor, NJ
[b]UCB Pharma, Raleigh, NC
[c]UCB Pharma, Colombes, France
[d]UCB Pharma, Monheim, Germany
[e]Dermatological Practice Dr. med. Michael Sebastian, Mahlow, Germany

ABSTRACT

Background: Bimekizumab is a monoclonal IgG1 antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A.
Objectives: To assess patients' ability to self-inject bimekizumab subcutaneously using a 1 mL safety syringe or auto-injector.
Methods: DV0002 and DV0006 were sub-studies of BE BRIGHT, a multicenter, phase 3 open-label extension study. Patients with moderate to severe plaque psoriasis received bimekizumab 320 mg (2x160 mg injections) every 4 or 8 weeks and were randomized 1:1 to the safety syringe or the auto-injector. The ability of patients to safely and effectively self-inject bimekizumab was assessed at 8 weeks (primary endpoint) and immediately after self-injection training at Baseline (secondary endpoint). Patient experience was evaluated using the pain visual analog scale (VAS; 0–100 mm; 100 being worst pain), and the Self-Injection Assessment Questionnaire (SIAQ; 0–10; 10 being most positive experience).
Results: All evaluable patients in DV0002 (n=125) and DV0006 (n=86) safely and effectively self-injected bimekizumab at Week 8. All evaluable patients in DV0002 who used the safety syringe (n=64) and 97.1% (n=66/68) who used the auto-injector, as well as all evaluable DV0006 patients (n=88) also self-injected bimekizumab safely and effectively at Baseline. Median VAS scores were low (range: 7.0–20.0), and median pre-injection and post-injection SIAQ scores were high (range: 5.8–10.0 and 7.1–10.0, respectively) across both devices, sub-studies, and timepoints.
Conclusions: Both devices provide a safe and effective option for patients to self-administer bimekizumab. Furthermore, patients reported a positive self-injection experience.
Trial registration: NCT03766685

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INTRODUCTION

Plaque psoriasis is an immune-mediated inflammatory skin disease characterized by erythematous scaly plaques on patients' skin.[1] The treatment of plaque psoriasis with biologics targeting key drivers of chronic inflammation in lesional skin, such as interleukin (IL)-17, is associated with the improvement of symptoms.[2,3]

The most common IL-17 inhibitors used to treat psoriasis target IL-17A alone.[4,5] However, there is evidence that IL-17F also plays an important role in psoriasis pathogenesis and that inhibiting both IL-17A and IL-17F may be more effective.[6,7] Bimekizumab is a monoclonal IgG1 antibody which selectively inhibits IL-17F in addition to IL-17A.[8] In phase 2 and 3 clinical trials, bimekizumab treatment resulted in substantial clinical improvements in patients with moderate to severe plaque psoriasis.[9-12]

Biologics are often administered subcutaneously via self-injection. This offers patients many benefits, including more control over the injection setting and schedule, leading to greater feelings of independence and self-confidence.[13-15] When adhered to, self-injection reduces costs for the healthcare system as patients no longer need to attend the hospital or clinic for regular injections.[15] Nevertheless, there are barriers to self-injection, including needle phobia and patients' lack of confidence.[16,17] The design of self-injection devices can help patients overcome these barriers. For example, hidden needles can reduce needle phobia and larger grips make devices easier to hold and manipulate. Alongside training, these features may also increase treatment adherence.[18,19]

Some patients may prefer having a visible needle and control over self-injection speed.[20] However, others may prefer a more

automated self-injection without a visible needle.[21] To provide options for bimekizumab self-injection, a 1 mL safety syringe, providing greater control, and a 1 mL auto-injector, allowing quick and automatic self-injection, have been developed.

Here, the results from two sub-studies (DV0002 and DV0006) are presented. These studies aimed to evaluate the ability of patients with plaque psoriasis to self-inject bimekizumab using the safety syringe or the auto-injector, and also evaluate patient's experience of self-injection.

MATERIALS AND METHODS

Study Objectives

The primary and secondary objectives of DV0002/6 were to evaluate, for each device, the ability of patients to safely and effectively self-administer bimekizumab 8 weeks after receiving training in self-injection and immediately after training (at Baseline), respectively. Other objectives were to evaluate: (i) patient experience of self-injection via the pain visual analog scale (VAS) and the Self-Injection Assessment Questionnaire (SIAQ) and (ii) the structural and mechanical integrity of each device after self-injection.

Patients

DV0002/6 were sub-studies of BE BRIGHT (NCT03598790), an open-label extension of three phase 3 randomized control studies.[9,10,12] DV0002 was conducted in North America (USA and Canada), while DV0006 was conducted in the European Union (Germany, Hungary, Poland) and Japan. Patients participating in BE BRIGHT were informed of the DV0002/6 sub-studies and were able to voluntarily sign-up; sample size was not powered with respect to any endpoint but was based on practical considerations.

All patients involved in DV0002/6 were adults (≥18 years) diagnosed with moderate to severe plaque psoriasis, willing to self-inject bimekizumab, and considered reliable and capable of adhering to the protocol by the investigator (Table 1).

All patients signed an informed consent form approved by an International Review Board/Independent Ethics Committee, which complied with all regulatory requirements.

Devices

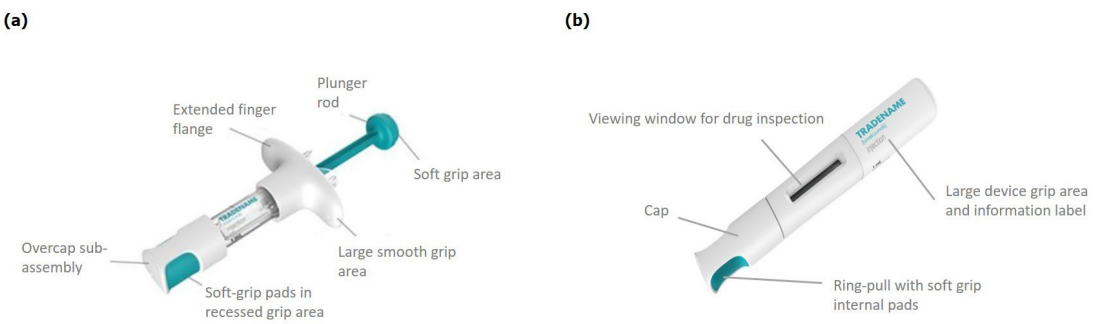
The bimekizumab safety syringe was designed with an extended finger flange and plunger rod with a soft grip thumb area (Figure 1a). To self-inject, patients positioned the safety syringe at the injection site, pushed the needle tip into the subcutaneous space under the skin, and depressed the plunger.

TABLE 1.

DV0002 and DV0006 Inclusion and Exclusion Criteria	
Inclusion Criteria	**Exclusion Criteria**
• Informed consent • Willing to self-inject bimekizumab • Considered reliable and capable of adhering to the protocol according to the judgement of the Investigator • Female patients must be either postmenopausal, unable to fall pregnant or willing to use an effective method of contraception throughout the study • Completion of the feeder study (BE VIVID [NCT03370133], BE READY [NCT03410992] or BE SURE [NCT03412747]) without meeting any withdrawal criteria	• A medical or psychiatric condition that, in the opinion of the investigator, would compromise the patient's ability to participate in the study • Patient may not participate in another study of a medicinal product or device • History of chronic alcohol or drug abuse 6 months prior to Baseline • Female patients planning to become pregnant during the study or 20 weeks following the final dose • Patient has had a positive or indeterminate IGRA in a feeder study

As DV0002 and DV0006 were sub-studies, aside from willingness to self-inject, all other inclusion and exclusion criteria were derived from BE BRIGHT (NCT03598790). To participate in the sub-studies patients had to meet all the inclusion criteria and none of the exclusion criteria. IGRA: interferon gamma release assay.

FIGURE 1. The self-injection devices evaluated in DV0002 and DV0006. (a) The bimekizumab safety syringe; (b) The bimekizumab auto-injector.



The bimekizumab auto-injector was designed with a large grip area to facilitate manipulation of the device, a hidden needle, and a window through which the contents of the enclosed syringe could be seen to confirm complete dose delivery (Figure 1b). To self-inject, patients removed the cap, positioned the auto-injector at the injection site, and depressed it against the skin surface to activate the device to automatically administer bimekizumab.

Study Design

Patients received bimekizumab 320 mg every 4 weeks (Q4W) or every 8 weeks (Q8W) depending on the Psoriasis Area Severity Index (PASI) score achieved in the feeder trials. At Baseline (Week 0) patients were randomized 1:1 to the safety syringe or auto-injector group and received training on self-injection technique for their assigned device (Figure 2). The protocol specified that the bimekizumab 320 mg dose was to be administered as 2x1 mL 160 mg self-injections to either the left/right lateral abdomen or outer thigh, rotating sites between each injection. Patients self-injected at Baseline (Week 0) immediately after training, and at Week 8 (without further training). Other injections of bimekizumab were administered by study personnel (as per the BE BRIGHT study protocol).[22]

Before the first self-injection at Baseline, patients were required to complete the pre-injection SIAQ. After self-injection, patients completed the post-injection SIAQ and reported pain associated with self-injection using the pain VAS. A safety follow-up telephone call was made 1 week after the last bimekizumab self-injection.

Study Procedures and Evaluations

Safe and effective self-injection

Safe and effective self-injection was defined by complete delivery of bimekizumab, assessed by visual inspection of the device by study personnel, and the absence of adverse events (AEs) related to the device (ADEs) that led to withdrawal from the sub-study. To meet study endpoints, both self-injections (2x160 mg dose) had to be evaluated as safe and effective by the study personnel. Evaluable patients must have self-injected at least one dose of bimekizumab.

Only ADEs were reported in these sub-studies, other AEs were reported in a common database for BE BRIGHT. ADEs were defined as AEs resulting from inadequacies or incorrect use of the device as assessed by the investigator. After each self-injection, the structural and mechanical integrity of each device was evaluated by trained personnel.

Injection site pain VAS

Patients recorded injection site pain by placing a mark on a 100 mm line from 0 (no pain) to 100 (worst possible pain) within 15 minutes of completing both self-injections.

Pre- and post-injection SIAQ

Patients completed the pre-injection SIAQ before the first self-injection at Baseline only. The pre-injection SIAQ is composed of 7 items grouped into 3 domains: 'feelings about injections', 'self-confidence', and 'satisfaction with current mode of administration'.

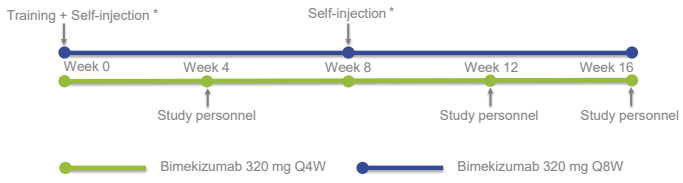
After each self-injection patients completed the post-injection SIAQ to evaluate their experience with the new device. The post-injection SIAQ is composed of 21 items grouped into 6 domains: 'feelings about injections', 'self-image', 'self-confidence', 'injection site reactions', 'ease of use', and 'satisfaction with self-injection'.

Patients who used the safety syringe answered Version 2.0 of the SIAQ; patients who used the auto-injector answered Version 2.1.[15] The questionnaires were identical except for Question 11, with Version 2.0 referring to the use of a plunger, and Version 2.1 referring to the depression of the investigational device presentation.

Statistical Analysis

The pre- and post-injection SIAQ items were rated on a scale of 1–5 (excluding 'ease of use', which was rated 1–6). To allow comparison between items, domains, and questionnaires, individual item scores were converted to a 10-point scale.[15] Higher scores indicated higher levels of confidence, satisfaction, fewer concerns with self-injection and an absence of injection site reactions. SIAQ domain scores for each patient were calculated as a mean of the item scores in that domain, if ≥50% of the items in the domain had been completed. The median and range of the pre- and post-injection SIAQ domain scores, and VAS scores, were reported.

FIGURE 2. Study design for DV0002 and DV0006.*Each 320 mg dose of bimekizumab was administered as 2x160 mg self-injections. Patients received training in self-injection at Week 0 prior to their first self-injections (Baseline) and then self-injected a second time at Week 8. The ability of patients to safely and effectively self-administer each bimekizumab injection and patient experience of self-injection was evaluated at the time of self-injection. All other doses required for the patient's dosing regimen were carried out by study personnel. Q4W: every 4 weeks; Q8W: every 8 weeks.



RESULTS

Patient Disposition and Baseline Characteristics

DV0002

In total, 134 patients enrolled in DV0002, with 66 (46 Q4W and 20 Q8W) patients randomized to the safety syringe and 68 (47 Q4W and 21 Q8W) to the auto-injector arm. One patient randomized to the safety syringe arm did not perform any self-injections and was excluded from subsequent analysis sets.

Among patients who used the safety syringe: one did not self-inject at Baseline but continued the study, one was lost to follow-up before Week 8, and another did not receive bimekizumab at Week 8 but continued the study. Therefore, among patients randomized to the safety syringe arm, 98.5% (64/65) completed the study, with 64 and 63 evaluable patients at Baseline and Week 8, respectively (Figure 3).

Among patients who used the auto-injector: five discontinued prior to Week 8, one did not receive bimekizumab at Week 8 but continued the study, and two further patients discontinued after Week 8. Reasons for discontinuation included withdrawn consent, non-compliance, protocol violation, lost to follow-up and one AE (not device related). Therefore, of the patients randomized to the auto-injector arm, 89.7% (61/68) completed the study with 68 and 62 evaluable patients at Baseline and Week 8, respectively (Figure 3).

The mean age of patients in the safety syringe and auto-injector arms was 49.7 years and 46.8 years, and mean disease duration was 21.1 years and 20.9 years, respectively. Most patients in both the safety syringe and auto-injector arms were male (66.2% and 72.1%, respectively) and Caucasian (92.3% and 89.7%, respectively; Table 2).

DV0006

In total, 88 patients were enrolled in DV0006 with 45 (36 Q4W and 9 Q8W) randomized to use the safety syringe and 43 (32 Q4W and 11 Q8W) randomized to use the auto-injector. Two patients in the safety syringe arm withdrew consent prior to Week 8, therefore 95.6% (43/45) completed the study with 45 and 43 evaluable patients at Baseline and Week 8, respectively. All patients randomized to the auto-injector arm in DV0006 completed the study (100% [43/43]) and were evaluable at both time points (Figure 4).

FIGURE 3. DV0002 patient flow diagram.

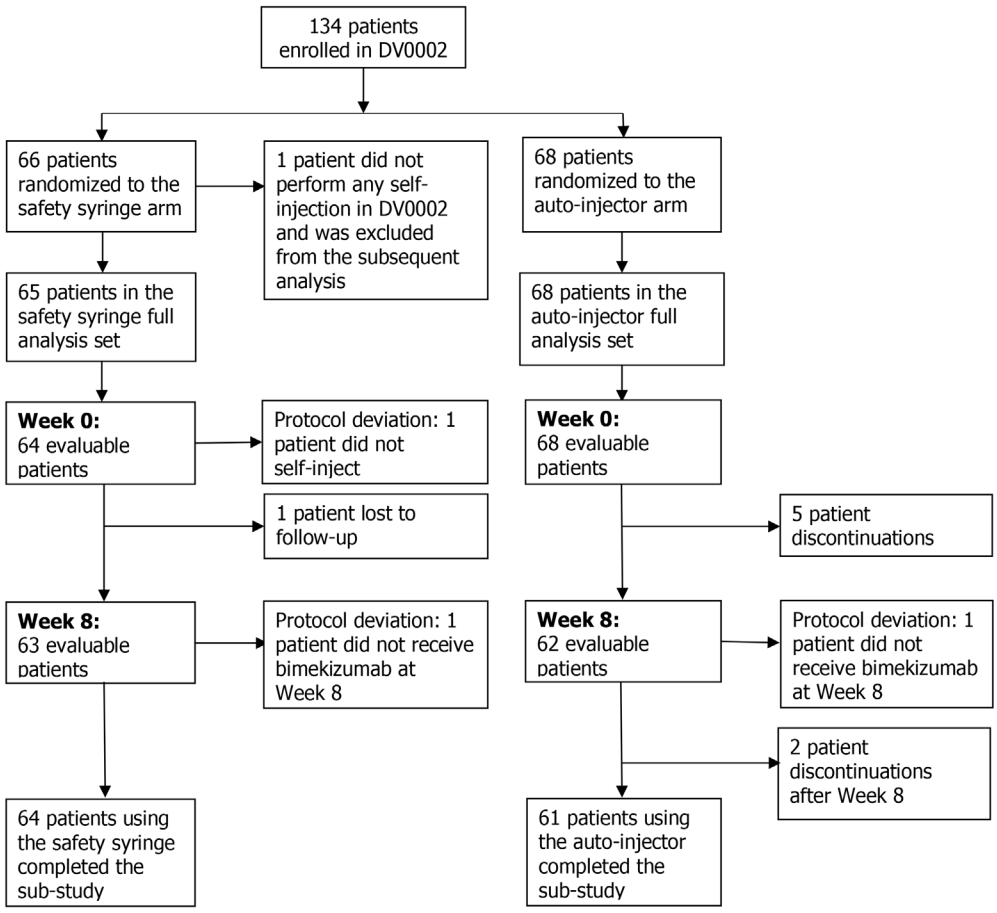


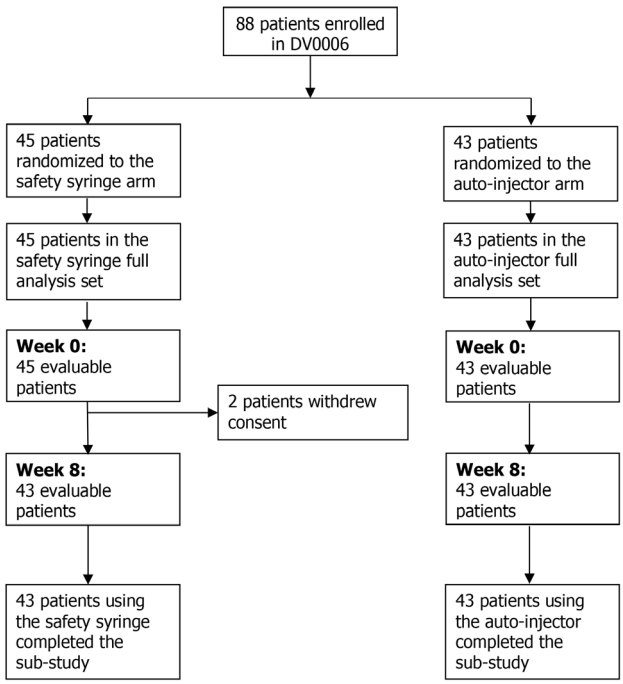
TABLE 2.

Patient Baseline Characteristics						
DV0002 (N=133)	Bimekizumab Safety Syringe			Bimekizumab Auto-Injector		
	Q8W (N=20)	Q4W (N=45)	Total (N=65)	Q8W (N=21)	Q4W (N=47)	Total (N=68)
Age (years), mean (SD)	51.6 (14.6)	48.9 (12.9)	49.7 (13.4)	50.1 (13.9)	45.3 (13.9)	46.8 (14.0)
Male, n (%)	14 (70.0)	29 (64.4)	43 (66.2)	14 (66.7)	35 (74.5)	49 (72.1)
BMI (kg/m^2), mean (SD)	31.5 (7.3)	32.1 (7.4)	31.9 (7.3)	32.5 (6.3)	32.7 (7.1)	32.6 (6.8)
Caucasian, n (%)	20 (100)	40 (88.9)	60 (92.3)	20 (95.2)	41 (87.2)	61 (89.7)
Disease duration (years), mean (SD)	19.5 (16.2)	21.8 (15.2)	21.1 (15.4)	21.8 (15.5)	20.6 (14.8)	20.9 (14.9)
DV0008 (N=88)	Bimekizumab Safety Syringe			Bimekizumab Auto-Injector		
	Q8W (N=9)	Q4W (N=36)	Total (N=45)	Q8W (N=11)	Q4W (N=32)	Total (N=43)
Age (years), mean (SD)	36.3 (11.7)	49.1 (11.8)	46.6 (12.8)	46.8 (11.7)	44.6 (12.4)	45.2 (12.2)
Male, n (%)	5 (55.6)	29 (80.6)	34 (75.6)	9 (81.8)	26 (81.3)	35 (81.4)
BMI (kg/m^2), mean (SD)	25.8 (5.0)	29.5 (6.4)	28.8 (6.3)	27.8 (4.6)	29.4 (5.7)	28.9 (5.4)
Caucasian, n (%)	8 (88.9)	28 (77.8)	36 (80.0)	9 (81.8)	25 (78.1)	34 (79.1)
Disease duration (years), mean (SD)	17.2 (8.9)	19.5 (12.3)	19.0 (11.6)	23.3 (14.6)	17.9 (12.4)	19.3 (13.0)

BMI: body mass index; Q4W: every 4 weeks; Q8W: every 8 weeks; SD: standard deviation.

The mean age of patients in the safety syringe and auto-injector arms was 46.6 years and 45.2 years, and mean disease duration was 19.0 years and 19.3 years, respectively. Most patients were male (75.6% and 81.4%, respectively) and Caucasian (80.0% and 79.1%, respectively; Table 2).

FIGURE 4. DV0006 patient flow diagram.

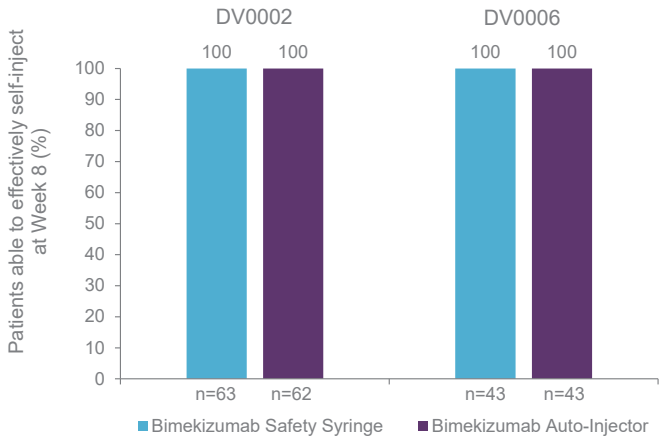


Safe and Effective Self-Injection

DV0002

In DV0002, 100% of evaluable patients who used the safety syringe (n=63) and the auto-injector (n=62) were able to safely and effectively self-inject bimekizumab at Week 8 (Figure 5). Furthermore, 100% of evaluable patients who used the safety syringe (n=64) and 97.1% of evaluable patients (n=66/68) who used the auto-injector were able to safely and effectively self-inject bimekizumab immediately after training at Baseline (Figure 6). The two evaluable patients who did not effectively self-inject bimekizumab were administered one bimekizumab injection by study personnel in error.

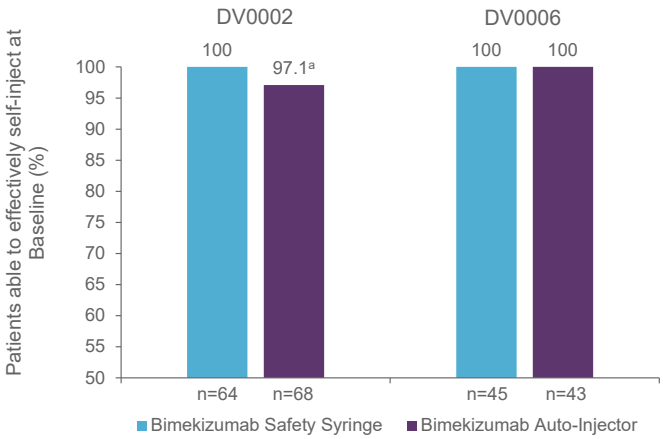
FIGURE 5. Safe and effective self-injection at Week 8. Safe and effective self-injection was defined by the absence of any residual bimekizumab left in the device, which was assessed by visual inspection, and the absence of any adverse device effects leading to discontinuation.



Eight injection site reactions (four each in the safety syringe and auto-injector arms) were reported across six patients. All were evaluated as not device related, not severe and none led to discontinuation (Table 3).

Of the 254 safety syringes used in DV0002 none showed signs of impaired structural integrity, product quality, or functional compromise. Of the 258 auto-injectors used, two (0.8%) showed signs of functional compromise during inspection after the first self-injection at Baseline. One was reported to have malfunctioned post-injection, however the patient was reported to have safely and effectively self-injected. The other was determined to have no device issues after a thorough in-house engineering evaluation.

FIGURE 6. Safe and effective self-injection at Baseline. [a]Two patients in the bimekizumab auto-injector arm for DV0002 were administered one of the bimekizumab injections by study personnel at Baseline in error. Safe and effective self-injection was defined by the absence of any residual bimekizumab left in the device, which was assessed by visual inspection, and the absence of any adverse device effects leading to discontinuation.



DV0006

In DV0006, 100% of evaluable patients who used the safety syringe (n=43) and the auto-injector (n=43) were able to safely and effectively self-inject bimekizumab at Week 8 (Figure 5). At Baseline, 100% of evaluable patients who used the safety syringe (n=45) and the auto-injector (n=43) were also able to safely and effectively self-inject bimekizumab immediately after training (Figure 6).

Only one injection site reaction in the bimekizumab safety syringe group was reported which was assessed as mild, not device related and did not lead to discontinuation (Table 4).

Among the 176 safety syringes and 172 auto-injectors used, none were reported to show any signs of impaired structural integrity, product quality, or functional compromise.

Pain VAS Scores

DV0002

In DV0002, the median pain VAS scores associated with self-injection using the safety syringe were 9.0 (range: 0–100) at Baseline and 9.0 (range: 0–100) at Week 8. The median VAS scores associated with self-injection using the auto-injector were 16.0 (range: 0–84) at Baseline and 16.5 (range: 0–97) at Week 8 (Figure 7a).

TABLE 3.

DV0002 Injection Site Reactions

DV0002 (N=133)	Bimekizumab Safety Syringe			Bimekizumab Auto-Injector		
	Q8W (N=20)	Q4W (N=45)	Total (N=65)	Q8W (N=21)	Q4W (N=47)	Total (N=68)
Injection site reactions, n (%)	1 (5.0)	2 (4.4)	3 (4.6)	2 (9.5)[a]	1 (2.1)	3 (4.4)
Mild injection site reactions, n (%)	1 (5.0)	2 (4.4)	3 (4.6)	2 (9.5)	1 (2.1)	3 (4.4)
Bruising, n (%)	0	1 (2.2)	1 (1.5)	0	1 (4.3)	1 (1.5)
Pain, n (%)	0	1 (2.2)[b]	1 (1.5)	1 (4.8)	0	1 (1.5)
Induration at injection site, n (%)	1 (5.0)	0	1 (1.5)	0	0	0
Injection site reaction, n (%)	0	0	0	1 (4.8)	0	0
Moderate injection site reactions, n (%)	0	0	0	1 (4.8)	0	0
Pain, n (%)	0	0	0	1 (4.8)	0	0
Related to device, n (%)	0	0	0	0	0	0
Led to dropout, n (%)	0	0	0	0	0	0

[a]One patient in the bimekizumab auto-injector arm had one mild injection site reaction and one occurrence of moderate injection site pain.
[b]One patient in the bimekizumab safety syringe Q4W arm had two separate occurrences of mild injection site pain. Q4W: every 4 weeks; Q8W: every 8 weeks.

TABLE 4.

DV0006 Injection Site Reactions						
DV0006 (N=88)	Bimekizumab Safety Syringe			Bimekizumab Auto-Injector		
	Q8W (N=9)	Q4W (N=36)	Total (N=45)	Q8W (N=11)	Q4W (N=32)	Total (N=43)
Injection site reactions, n (%)	0	1 (2.8)	1 (2.2)	0	0	0
Mild injection site reactions, n (%)	0	1 (2.8)	1 (2.2)	0	0	0
Bruising, n (%)	0	1 (2.8)	1 (2.2)	0	0	0
Related to device, n (%)	0	0	0	0	0	0
Led to dropout, n (%)	0	0	0	0	0	0

Q4W: every 4 weeks; Q8W: every 8 weeks.

FIGURE 7. Patient pain VAS scores. (a) DV0002. (b) DV0006. Patient pain VAS scores were collected within 15 minutes of completing self-injections. Max: maximum; min: minimum; VAS: visual analog scale.

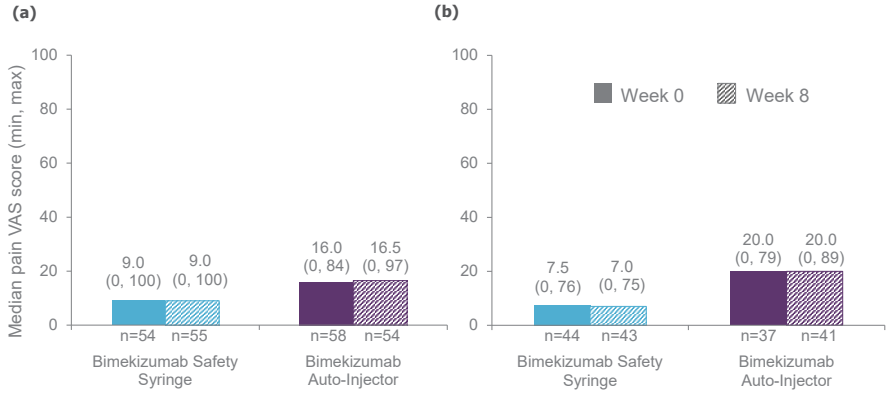


FIGURE 8. Pre-injection SIAQ domain score. (a) DV0002. (b) DV0006. Observed case. The pre-injection SIAQ consisted of 7 items which were grouped into 3 domains. Items were rated on a scale of 1–5 and these individual item scores were converted to a 10-point scale. SIAQ domain scores were only calculated if ≥50% of the items in the domain had been answered and were calculated as a mean of the item scores in that domain. Max: maximum; min: minimum; SIAQ: Self-Injection Assessment Questionnaire.

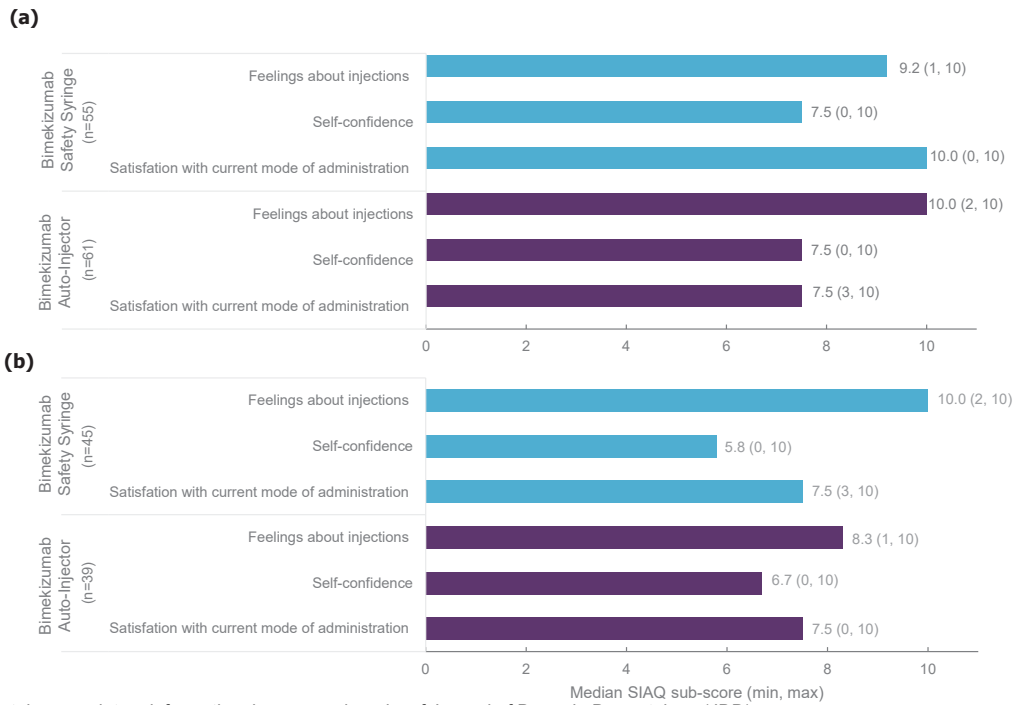


FIGURE 9. DV0002 post-injection SIAQ scores. Observed case. Higher scores indicate higher levels of confidence, satisfaction, less concerns with self-injection and an absence of injection site reactions. SIAQ domain scores were only calculated if ≥50% of the items in the domain had been answered and were calculated as a mean of the item scores in that domain. Max: maximum; min: minimum; SIAQ: Self-Injection Assessment Questionnaire; wk: week.

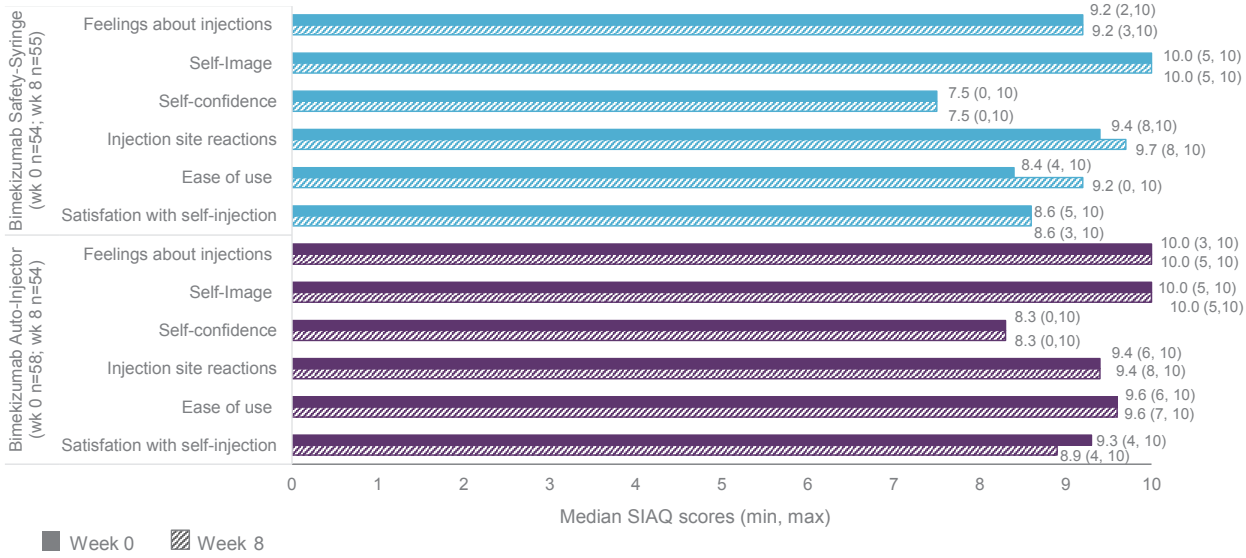
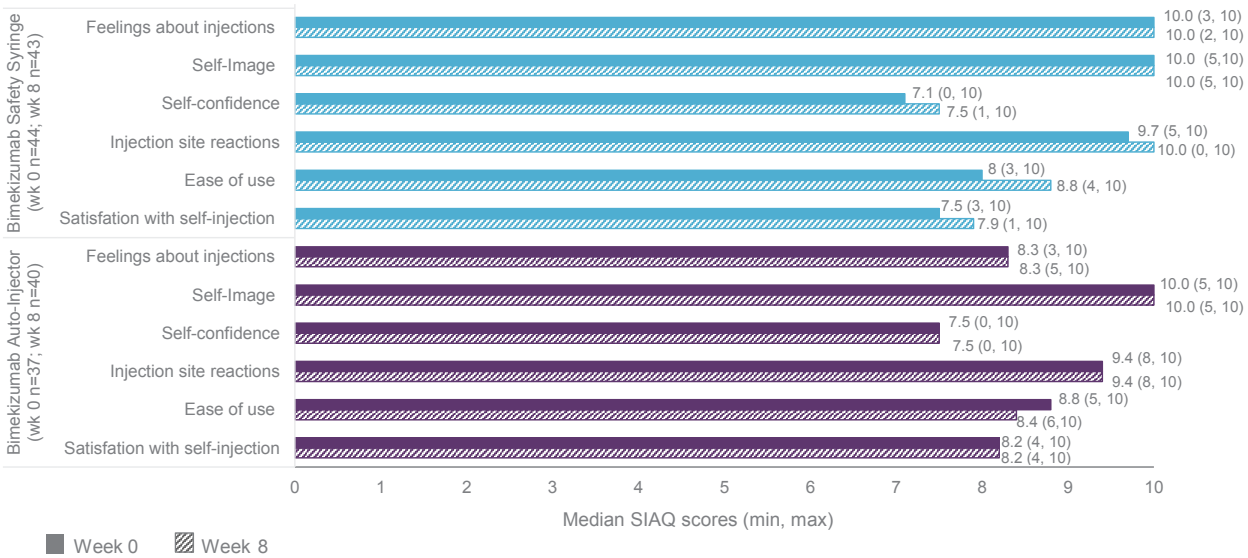


FIGURE 10. DV0006 post-injection SIAQ scores. Observed case. Higher scores indicate higher levels of confidence, satisfaction, less concerns with self-injection and an absence of injection site reactions. SIAQ domain scores were only calculated if ≥50% of the items in the domain had been answered and were calculated as a mean of the item scores in that domain. Max: maximum; min: minimum; SIAQ: Self-Injection Assessment Questionnaire; wk: week.



DV0006

Similarly, in DV0006, median painVAS scores associated with self-injection using the safety syringe were 7.5 (range: 0–76) at Baseline and 7.0 (range: 0–75) at Week 8. The median VAS scores associated with self-injection using the auto-injector were 20.0 (range: 0–79) at Baseline and 20.0 (range: 0–89) at Week 8 (Figure 7b).

SIAQ Scores

DV0002

Median pre-injection SIAQ domain scores associated with self-injection using the safety syringe and auto-injector were 9.2 (range: 1–10) and 10.0 (range: 2–10) for 'feelings about injections', 7.5 (range: 0–10) and 7.5 (range: 0–10) for 'self-confidence', and

10.0 (range: 0–10) and 7.5 (range: 3–10) for 'satisfaction with current mode of administration' (Figure 8a).

Median post-injection SIAQ domain scores associated with self-injection using the safety syringe ranged from 7.5 (range: 0–10) to 10.0 (range: 5–10) at both Baseline and Week 8. Median post-injection SIAQ domain scores associated with self-injection using the auto-injector ranged from 8.3 (range: 0–10) to 10 (range: 3–10) at Baseline, and 8.3 (range: 0–10) to 10 (range: 5–10) at Week 8 (Figure 9).

DV0006

Median pre-injection SIAQ domain scores for patients randomized to the safety syringe and auto-injector arms were 10.0 (range: 2–10) and 8.3 (range: 1–10) for 'feelings about injections', 5.8 (range: 0–10) and 6.7 (range: 0–10) for 'self-confidence', and 7.5 (range: 3–10) and 7.5 (range: 0–10) for 'satisfaction with current mode of administration' (Figure 8b).

Median post-injection SIAQ domain scores for the bimekizumab safety syringe ranged from 7.1 (range: 0–10) to 10 (range: 3–10) at Baseline and 7.5 (range: 1–10) to 10 (range: 0–10) at Week 8. Median post-injection SIAQ domain scores for the bimekizumab auto-injector ranged from 7.5 (range: 0–10) to 10 (range: 5–10) at both Baseline and Week 8 (Figure 10).

DISCUSSION

Patients with psoriasis were able to effectively self-inject bimekizumab using both devices safely. There were no ADEs that would preclude further use, either immediately after training at Baseline or eight weeks later. Furthermore, of the 860 devices used across both sub-studies, only one auto-injector was determined to have a deficiency, suggesting both devices are structurally sound.

Injection site pain is a significant barrier to self-injection,[23] however, median VAS scores were low suggesting that self-injection of bimekizumab was tolerable and associated with low levels of injection site pain. Other barriers to self-injection include needle phobia and lack of confidence.[16,17] Nevertheless, the high pre-injection and post-injection SIAQ scores across all domains, indicate patient perceptions and experience of self-injection were positive, regardless of bimekizumab self-injection device.

Limitations

This study recruited a small number of patients who only received two bimekizumab self-injections. Therefore, results may not be generalizable to a larger population of patients using bimekizumab self-injection devices over a prolonged period.

CONCLUSION

The safety syringe and auto-injector provide patients with psoriasis two options for the self-administration of bimekizumab that are safe, effective and associated with an overall positive self-administration experience. By providing both options, patients have the choice to use the device that best suits their preferences on the level of control over the self-injection process. Moreover, evidence suggests that patients using their preferred method of self-injection may have improved treatment adherence and clinical outcomes.[24]

DISCLOSURES

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Ethics Approval

The study protocol, amendments, and patient informed consent were reviewed by a national, regional, or Independent Ethics Committee (IEC) or Institutional Review Board (IRB). This study was conducted in accordance with the current version of the applicable regulatory and International Conference on Harmonisation (ICH)-Good Clinical Practice (GCP) requirements, the ethical principles that have their origin in the principles of the Declaration of Helsinki, and the local laws of the countries involved.

Data Sharing

Underlying data from this manuscript may be requested by qualified researchers six months after product approval in the US and/or Europe, or global development is discontinued, and 18 months after trial completion. Investigators may request access to anonymised individual patient-level data and redacted trial documents, which may include: analysis-ready datasets, study protocol, annotated case report form, statistical analysis plan, dataset specifications, and clinical study report. Prior to use of the data, proposals need to be approved by an independent review panel at www.Vivli.org and a signed data sharing agreement will need to be executed. All documents are available in English only, for a pre-specified time, typically 12 months, on a password protected portal.

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Author's Contributions

Substantial contributions to study conception and design: JB, DT, SH, BK, CM, LP, MS; substantial contributions to analysis and interpretation of the data: JB, DT, SH, BK, CM, LP, MS; drafting of the article or revising it critically for important intellectual content JB, DT, SH, BK, CM, LP, MS; final approval of the version of the article to be published JB, DT, SH, BK, CM, LP, MS.

Consent for Publication

All the results presented in this article are in aggregate form, and no personally identifiable information was used for this study.

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AUTHOR CORRESPONDENCE

Daljit Tatla

E-mail:..... daljit.tatla@ucb.com