## SUPPLEMENTARY MATERIAL

# Single-injection options for administering a 320 mg dose of bimekizumab: 2 mL safety syringe and auto-injector

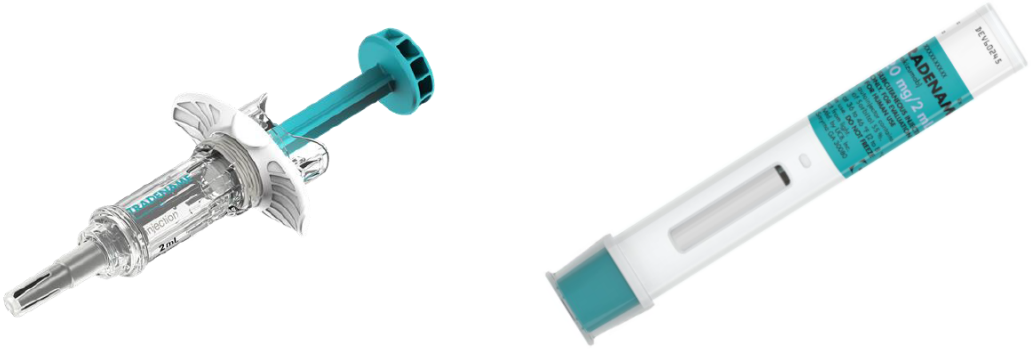
Michael Sebastian,[1] Jerry Bagel,[2, 3] Bengt Hoepken,[4] Bertram Knapp,[4] Ceyhun Bicer,[5] Merran MacPherson,[5] Richard G. Langley[6]

[1]Dermatology Practice, Mahlow, Germany; [2]Psoriasis Treatment Center of Central New Jersey, East Windsor, New Jersey, USA; [3]CorEvitas, LLC, Waltham, Massachusetts, USA; [4]UCB, Monheim am Rhein, Germany; [5]UCB, Brussels, Belgium; [6]Dalhousie University, Halifax, Canada

**Correspondence to:** Michael Sebastian, juliaseb@aol.com

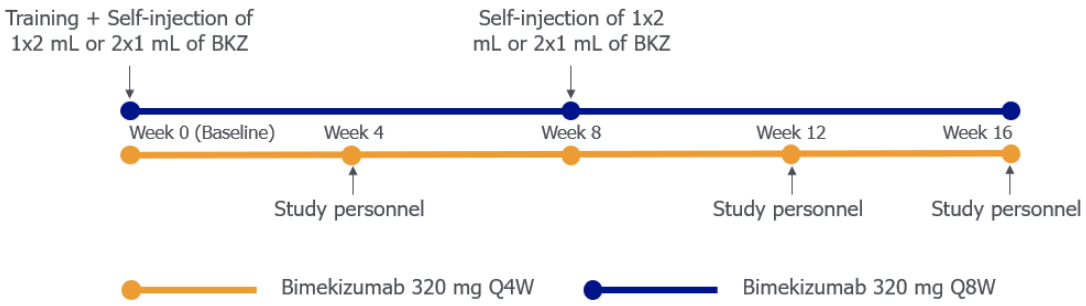
**Figure S1. The i) safety syringe (SSy) and ii) auto-injector (AI) self-injection devices assessed in DV0002 and DV0006**

i) ii)



**Abbreviations:** AI: auto-injector; SSy: safety syringe.

## Figure S2. DV0002/DV0006 study design




**Abbreviations:** 1x2 mL: a single self-injection; 2x1 mL: two self-injections; BKZ: bimekizumab; Q4W: every 4 weeks; Q8W: every 8 weeks.

**Table S1. Inclusion and exclusion criteria for DV0002 and DV0006**

| Inclusion criteria | Exclusion criteria |
|---|---|
| An Institutional Review Board approved written Informed Consent Form for DV0002/DV0006 was signed and dated by the study participant, study participant fulfilled all inclusion criteria for the PS0014 study, participant was considered reliable and capable of adhering to the DV0002/DV0006 study protocol (e.g. able to understand and complete questionnaires, able to use device presentation according to the instructions for use (IFU), and able to adhere to the visit schedule) according to the judgment of the Investigator, and willing to self-inject. | Study participants were not permitted to enrol in DV0002 if any of the PS0014 study exclusion criteria were met. Study participants who participated in the 1 mL device presentation cohort of DV0002 were not eligible to enrol in the 2 mL device presentation cohort. |

**Abbreviations:** IFU: instructions for use.

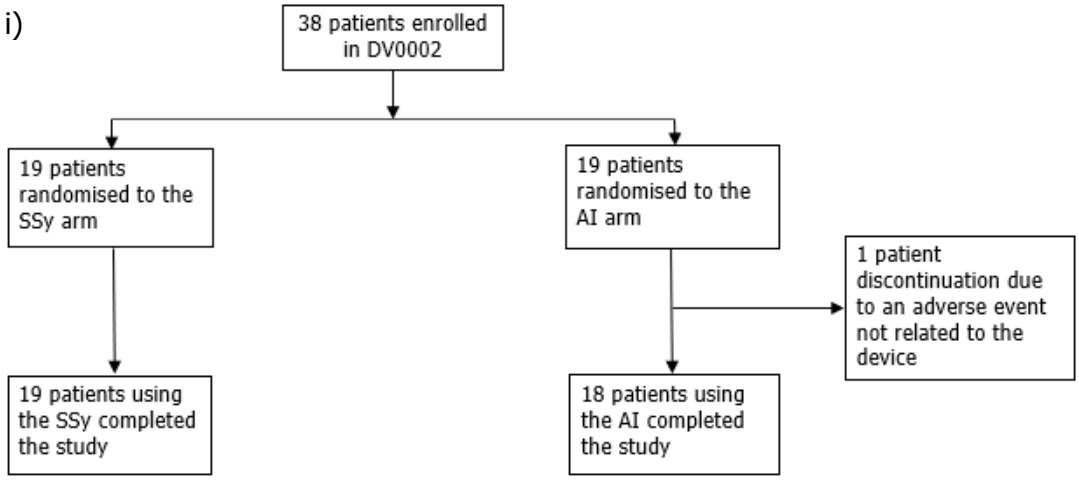
**Table S2. Inclusion and exclusion criteria for UP0068, and UP0119**

| Inclusion criteria | Exclusion criteria |
|---|---|
| To be eligible to participate in this study, male or female study participants were aged ≥18 years and ≤65 years of age, inclusive, at the time of signing the informed consent; were overtly healthy as determined by medical evaluation, including medical history, physical examination, vital signs, 12-lead ECG, and laboratory tests, at the Screening Visit and on admission; had a tympanic body temperature between 35.0°C and 37.5°C, inclusive, at the Screening Visit and on admission; and had a body weight minimum of 50 kg if male and 45 kg if female with a maximum of 100 kg, and body mass index (BMI) within the range 18 to 32 kg/$m^2$, inclusive, at the Screening Visit. | A study participant was not permitted to enrol in the study if he or she had an active infection (except common cold), a serious infection, or a history of opportunistic, recurrent, or chronic infections; had a history of a positive tuberculosis test or evidence of possible tuberculosis or latent tuberculosis infection at the Screening Visit; had concurrent acute or chronic viral hepatitis B or C or human immunodeficiency virus infection; was a female study participant who was pregnant, or planned to become pregnant during the study, or was lactating, or sexually active with childbearing potential and was not using a medically accepted birth control method; received any live (including attenuated) vaccination within the 8 weeks prior to the Screening Visit; had any medical or psychiatric condition that, in the opinion of the Investigator, could have jeopardised or would have compromised the study participant's ability to participate in this study; had active neoplastic disease or history of neoplastic disease within 5 years of the Screening Visit (except for basal or squamous cell carcinoma of the skin or carcinoma in situ that had been definitively treated with standard of care); had a positive test result for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2); had clinical signs and symptoms consistent with coronavirus disease 2019 (COVID-19) within the previous 14 days prior to the Screening Visit or on admission; or had severe course of COVID-19. |

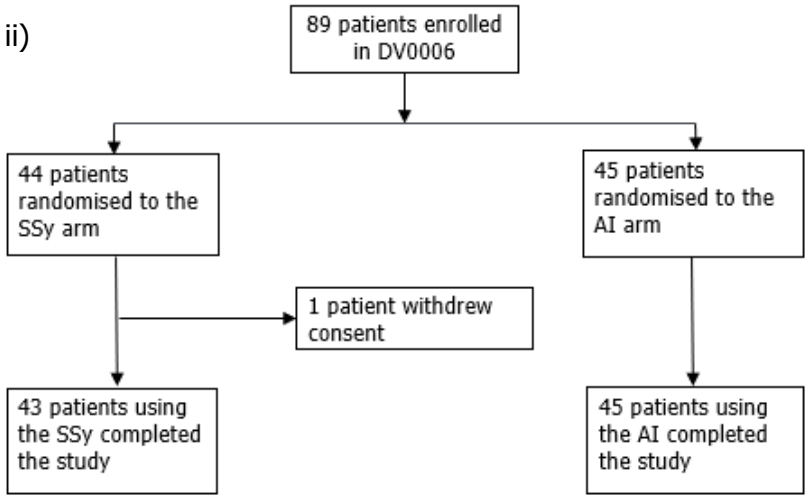
**Abbreviations:** BMI: body mass index; COVID-19: coronavirus disease 2019; ECG: electrocardiogram; SARS-CoV-2: severe acute respiratory syndrome coronavirus 2.

**Figure S3. Patient disposition in i) DV0002 and ii) DV0006**

i)



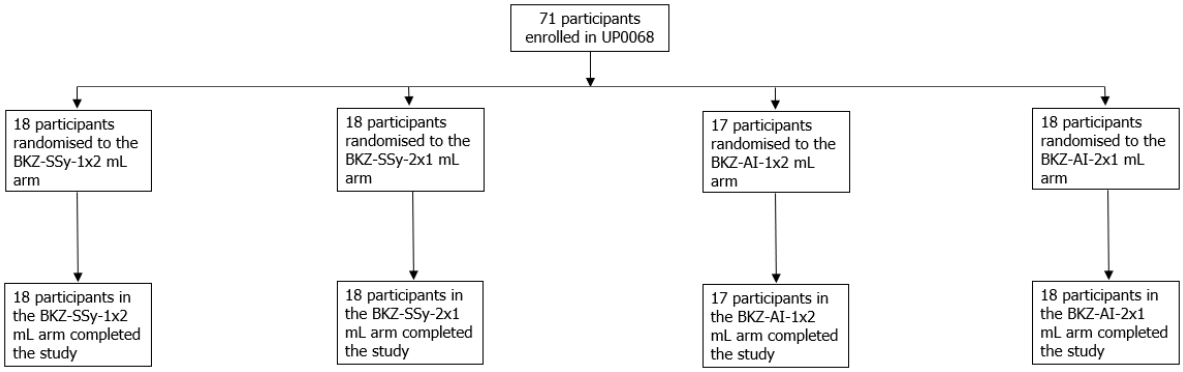

ii)



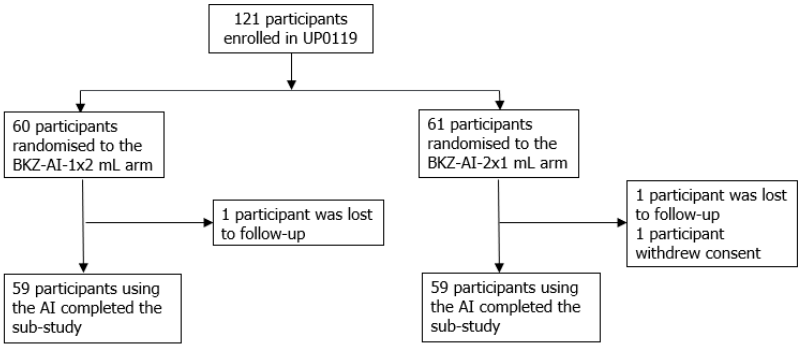

**Abbreviations:** AI: auto-injector; SSy: safety syringe.

**Figure S4. Participant disposition in i) UP0068 and ii) UP0119**

i)




ii)




**Abbreviations:** 1x2 mL: a single 2 mL injection; 2x1 mL: two 1 mL injections; AI: auto-injector; BKZ: bimekizumab; SSy: safety syringe.

## Table S3. Safety outcomes for UP0068 and UP0119

| | UP0068 | | | | UP0119 | |
|---|---|---|---|---|---|---|
| **Safety Outcome, n (%)** | BKZ-SSy-1x2 mL, n=18 | BKZ-SSy-2x1 mL, n=18 | BKZ-AI-1x2 mL, n=17 | BKZ-AI-2x1 mL, n=18 | BKZ-AI-1x2 mL, n=60 | BKZ-AI-2x1 mL, n=61 |
| Any TEAEs | 12 (66.7) | 8 (44.4) | 12 (70.6) | 7 (38.9) | 26 (43.3) | 30 (49.2) |
| Serious TEAEs | 0 | 0 | 0 | 0 | 0 | 0 |
| Severe TEAEs | 0 | 0 | 0 | 0 | 0 | 0 |
| Drug-related TEAEs | 6 (33.3) | 1 (5.6) | 4 (23.5) | 3 (16.7) | 12 (20.0) | 15 (24.6) |
| Discontinuations due to TEAEs | 0 | 0 | 0 | 0 | 0 | 0 |
| All deaths (AEs leading to death) | 0 | 0 | 0 | 0 | 0 | 0 |
| ADE | 1 (5.6) | 0 | 1 (5.9) | 3 (16.7) | 1 (1.7) | 0 |
| Serious ADEs | 0 | 0 | 0 | 0 | 0 | 0 |

**Abbreviations:** 1x2 mL: a single 2 mL injection; 2x1 mL: two 1 mL injections; ADE: adverse device effect; AE: adverse events; AI: auto-injector; BKZ: bimekizumab; SAEs: serious adverse events; SSy; safety syringe; TEAE: treatment-emergent adverse event.