UCB VIRTUAL BRIEFING:

Bimekizumab in Moderate to Severe Plaque Psoriasis: Data Presented at the 31st EADV Congress

Bimekizumab is approved for moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy in the European Union and Great Britain. The label information may differ in other countries.

Please check local prescribing information.

Dosing of bimekizumab as per study design, may include off-label dosing. The recommended dose for adult patients with moderate-to-severe plaque psoriasis is 320 mg (given as 2 subcutaneous injections of 160 mg each) at week 0, 4, 8, 12, 16 and every 8 weeks thereafter. For some patients with a body weight ≥ 120 kg who did not achieve complete skin clearance at week 16, 320 mg every 4 weeks after week 16 may further improve treatment response

Inspired by **patients.**
Driven by **science.**

GL-N-BK-PSO-2200109 Date of preparation: September 2022.

Disclaimer and safe harbor

This presentation contains forward-looking statements, including, without limitation, statements containing the words "believes", "anticipates", "expects", "intends", "plans", "seeks", "estimates", "may", "will", "continue" and similar expressions. These forward-looking statements are based on current plans, estimates and beliefs of management. All statements, other than statements of historical facts, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial information, expected legal, arbitration, political, regulatory or clinical results or practices and other such estimates and results. By their nature, such forward-looking statements are not guaranteeing future performance and are subject to known and unknown risks, uncertainties, and assumptions which might cause the actual results, financial condition, performance or achievements of UCB, or industry results, to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements contained in this presentation.

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Introduction

Emmanuel Caeymaex

Executive Vice President
Immunology Solutions & Head of U.S.

Agenda

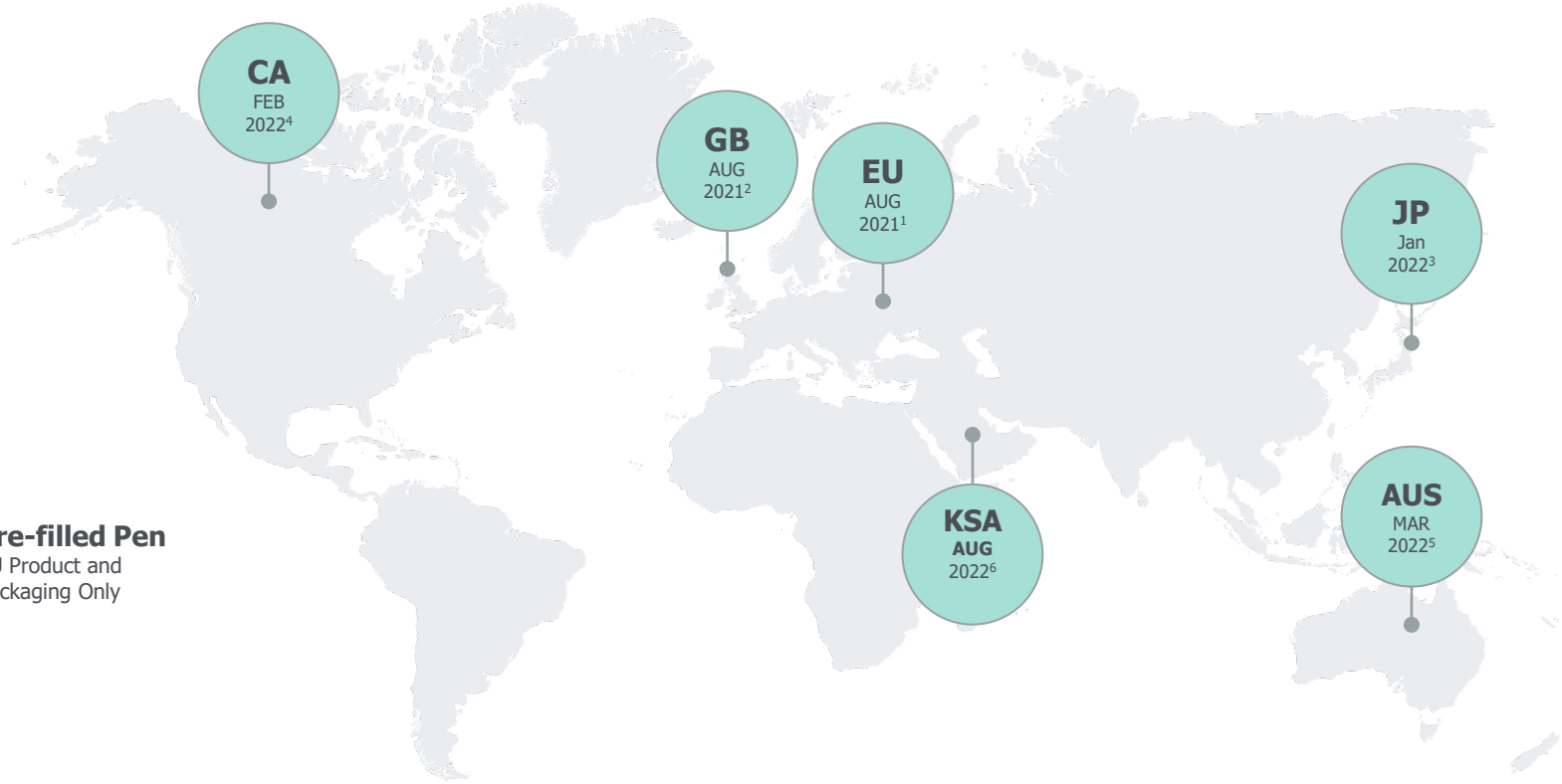
Antje Witte Head of Investor Relations, UCB	**WELCOME**
Emmanuel Caeymaex Executive Vice President Immunology Solutions & Head of U.S.	**INTRODUCTION**
Professor Bruce Strober Yale University, Connecticut, U.S.	**3-year responder analysis** from the **BE BRIGHT** open-label extension study **3-year analysis** from the **BE SURE** randomized control trial and **BE BRIGHT**
Professor Richard Warren Salford Royal NHS Foundation Trust and The University of Manchester, UK	**3-year** pooled **safety analysis** **2-year results** in high-impact areas in **patients who switched from adalimumab, ustekinumab, or secukinumab**
Emmanuel Caeymaex Executive Vice President Immunology Solutions & Head of U.S.	**SUMMARY**

Q & A Session Facilitated by Antje Witte

BIMZELX®▼(bimekizumab) is the first IL-17A and IL-17F inhibitor approved for the treatment of moderate to severe plaque psoriasis

Pre-filled Syringe
EU Product and
Packaging Only

Pre-filled Pen
EU Product and
Packaging Only



Bimekizumab is approved for moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy in the European Union and Great Britain. The label information may differ in other countries. Please check local prescribing information.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions

1. BIMZELX (bimekizumab) EU Summary of Product Characteristics https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf . Last accessed: August 2022; 2. BIMZELX (bimekizumab) GB Summary of Product Characteristics https://www.medicines.org.uk/emc/product/12834 ; https://www.medicines.org.uk/emc/product/12833. Last accessed: August 2022; 3. Pharmaceuticals and Medical Devices Agency https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html . Last accessed: August 2022; 4. BIMZELX (bimekizumab) Canada Product Monograph. Available at: https://pdf.hres.ca/dpd_pm/00064702.PDF 00064702.PDF (hres.ca) Last accessed: August 2022.; 5. BIMZELX (bimekizumab) Australia. Available at: https://www.tga.gov.au/apm-summary/bimzelx. Last accessed August 2022. 6. Saudi Food & Drug Information will be available at Information Lists | Saudi Food and Drug Authority (sfda.gov.sa) Last Accessed August 2022

In Phase 3 clinical studies bimekizumab demonstrated speed, depth and durability of response

Patients with moderate-to-severe plaque psoriasis place a high value on treatment which provides*[1]

- Clear skin
- Sustained response
- Rapid onset of action

Magnitude of response		
~6 out of **10** patients	achieved **PASI 100**	at **Week 16** [2,3,4]
Durability		
>6 out of **10** patients	achieved **PASI 100**	up to **one year**† [2,4]
Speed		
>7 out of **10** patients	achieved **PASI 75**	at **Week 4** after **1 dose** [2,3,4]

The most frequently reported treatment-emergent adverse events in bimekizumab-treated patients were **nasopharyngitis, oral candidiasis,** and **upper respiratory tract infection** [2,3,4,5]

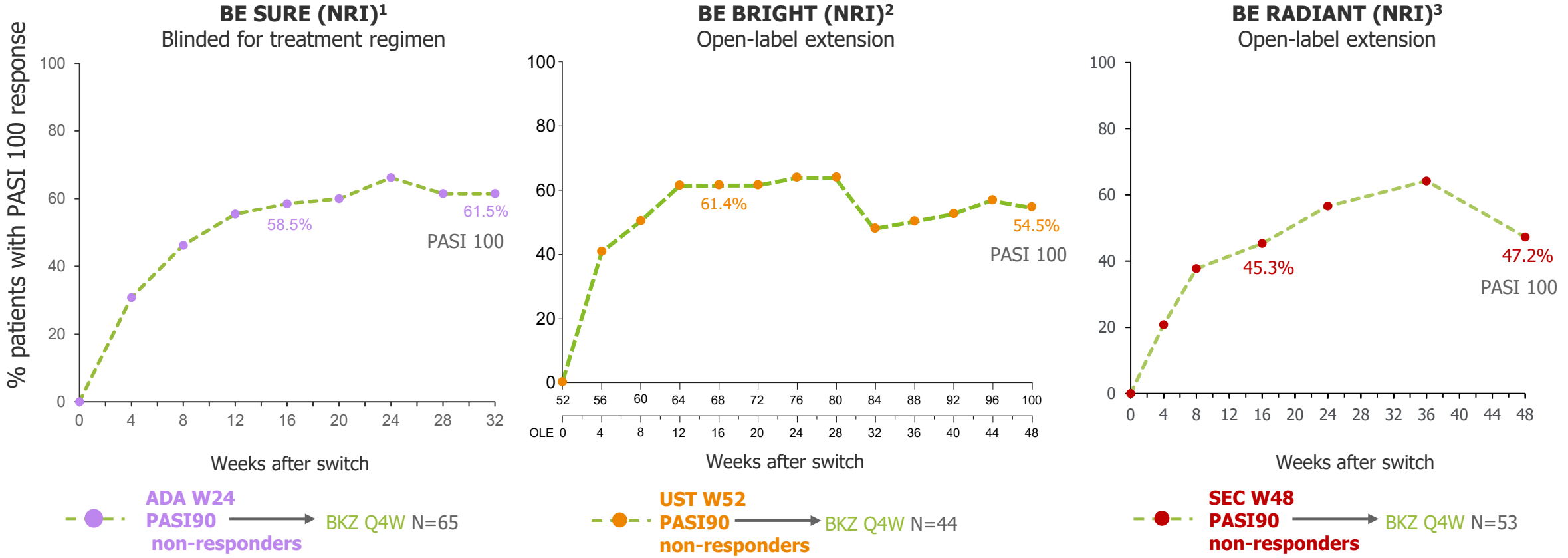
* U.S. Cross Sectional Patient Survey (N=500); Attributes are not exclusive
† 52-56 weeks

References: 1. Gorelick J, Shrom D, Sikand K, et al. Dermatol Ther (Heidelb). 2019; 9: 785-797; 2. Reich K, Papp KA, Blauvelt A, et al. Lancet. 2021;397(10273):487-498; 3. Gordon KB, Foley P, Krueger JG, et al. Lancet. 2021; 397(10273):475-486; 4. Warren RB, Blauvelt A, Bagel J, et al. N Engl J Med. 2021; 385(2):130-141; 5. BIMZELX EU Summary of Product Characteristics

The primary endpoints in the three Phase 3 studies were PASI 90 at week 16 and IGA 0/1 at week 16

Bimekizumab can achieve completely clear skin after an inadequate response to other treatments

PASI 100 with bimekizumab in patients with an inadequate response to secukinumab, ustekinumab or adalimumab PASI 90 (post hoc analyses)



Subgroup analyses for patients with an inadequate (PASI <90) response to initial treatment with adalimumab (at Week 24), secukinumab (at Week 48) or ustekinumab (at Week 52). Switch to BKZ was not related to response to initial treatment. ADA, adalimumab; BKZ, bimekizumab; NRI, non-responder imputation; OLE, open-label extension; PASI, psoriasis area and severity index; Q4W, every 4 weeks; Q8W, every 8 weeks; SEC, secukinumab; UST, ustekinumab. [1.] Strober et al. AAD VMX 2021; Poster: 27374. [2.] Leonardi et al. EADV 2021; Poster P1416. [3.] Lebwohl et al. AAD 2022; Poster P33817.

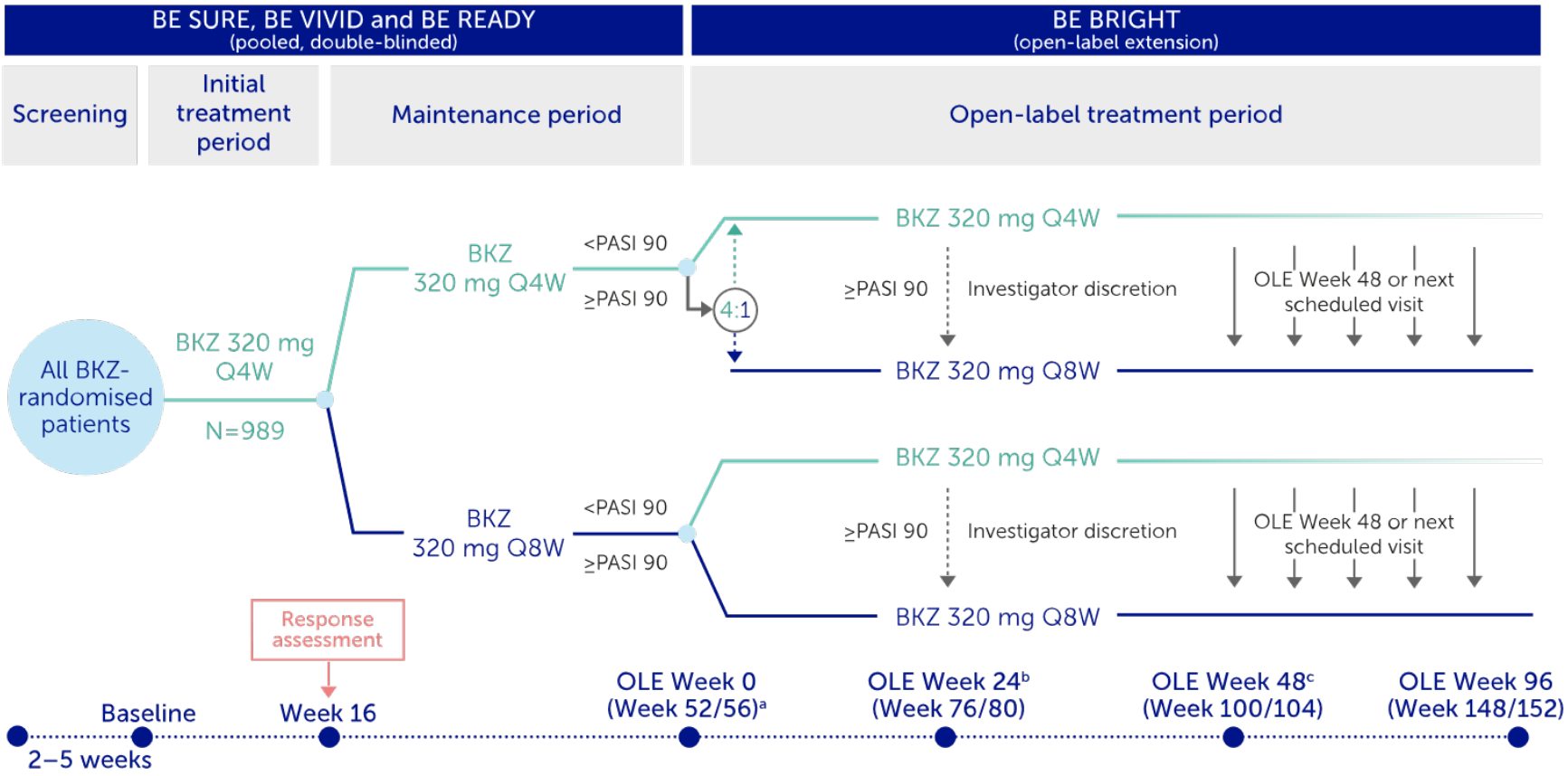
P1491

Bimekizumab maintenance of response through three years in patients with moderate to severe plaque psoriasis who responded at Week 16: Results from the BE BRIGHT open-label extension

Bruce Strober, Yayoi Tada, Ulrich Mrowietz, Mark Lebwohl, Peter Foley, Richard G. Langley, Jonathan Barker, Maggie Wang, Veerle Vanvoorden, Balint Szilagyi, Valerie Ciaravino, Carle Paul

Study design and presentation objective

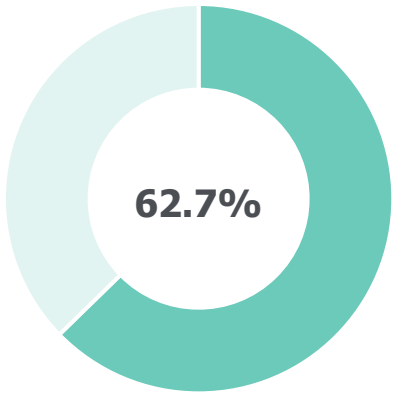
Presentation Objective:
To evaluate maintenance of response over three years among patients with moderate to severe plaque psoriasis who had an initial efficacy response after 16 weeks' BKZ treatment and entered the BE BRIGHT OLE



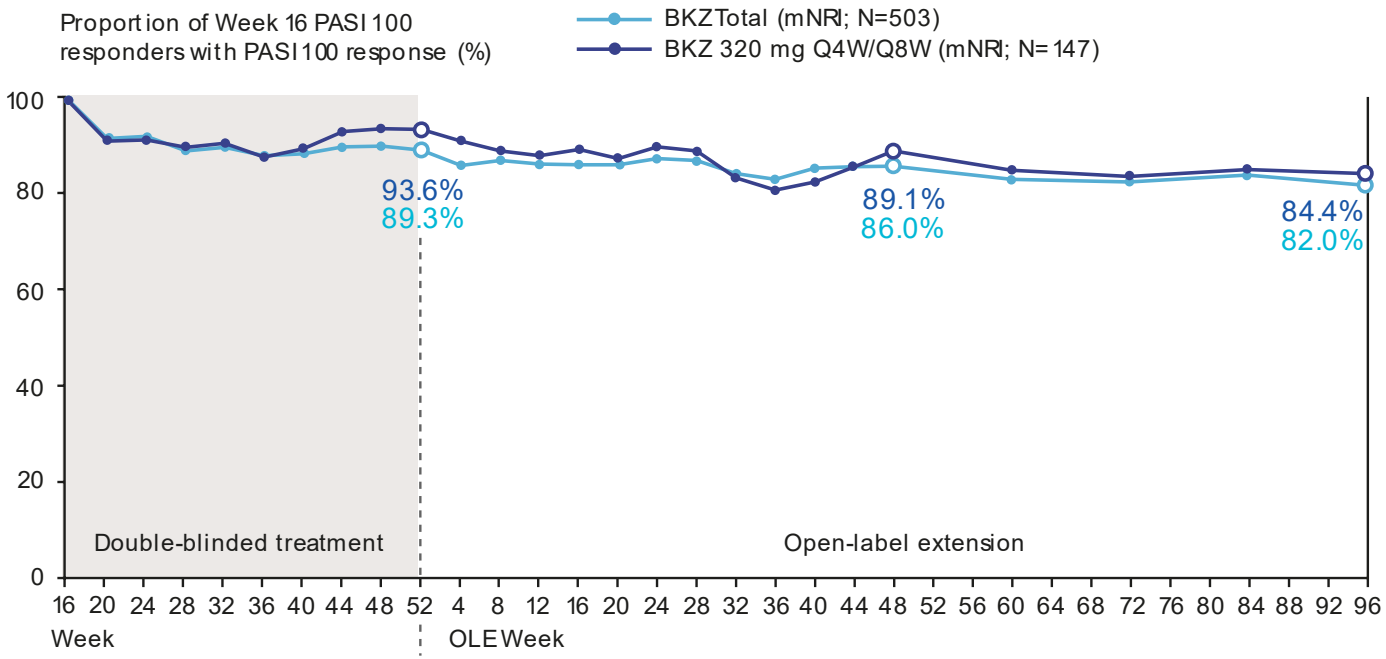
a. BE SURE and BE READY had a duration of 56 weeks and BE VIVID had a duration of 52 weeks; b. At OLE Week 24, patients receiving BKZ Q4W who achieved PASI 90 could switch to receive BKZ Q8W at the discretion of the investigator; c. At OLE Week 48, or at the next scheduled clinic visit, all patients were re-assigned to BKZ Q8W, following protocol amendment. BKZ: bimekizumab; OLE: open-label extension; PASI: Psoriasis Area and Severity Index; Q4W: every 4 weeks; Q8W: every 8 weeks. All content on this slide is from Strober et al. EADV 2022;Poster P1491.

Over 8 out of 10 BKZ-treated patients who achieved PASI 100 at week 16 maintained response through 3 years

Week 16 PASI 100 response rate in BKZ-randomised patients
(N=989)



BKZ 320 mg Q4W (NRI; Initial treatment period)

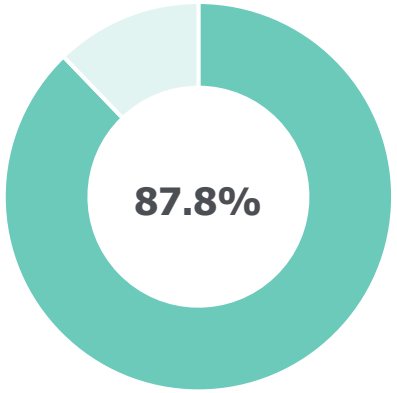


- 62.7% of the 989 patients randomized to BKZ Q4W at the start of the feeder studies achieved PASI 100 at Week 16 (NRI)
- 82.0% of BKZ-treated patients who achieved PASI 100 at Week 16 maintained their response at Year 3 (OLE Week 96; mNRI)

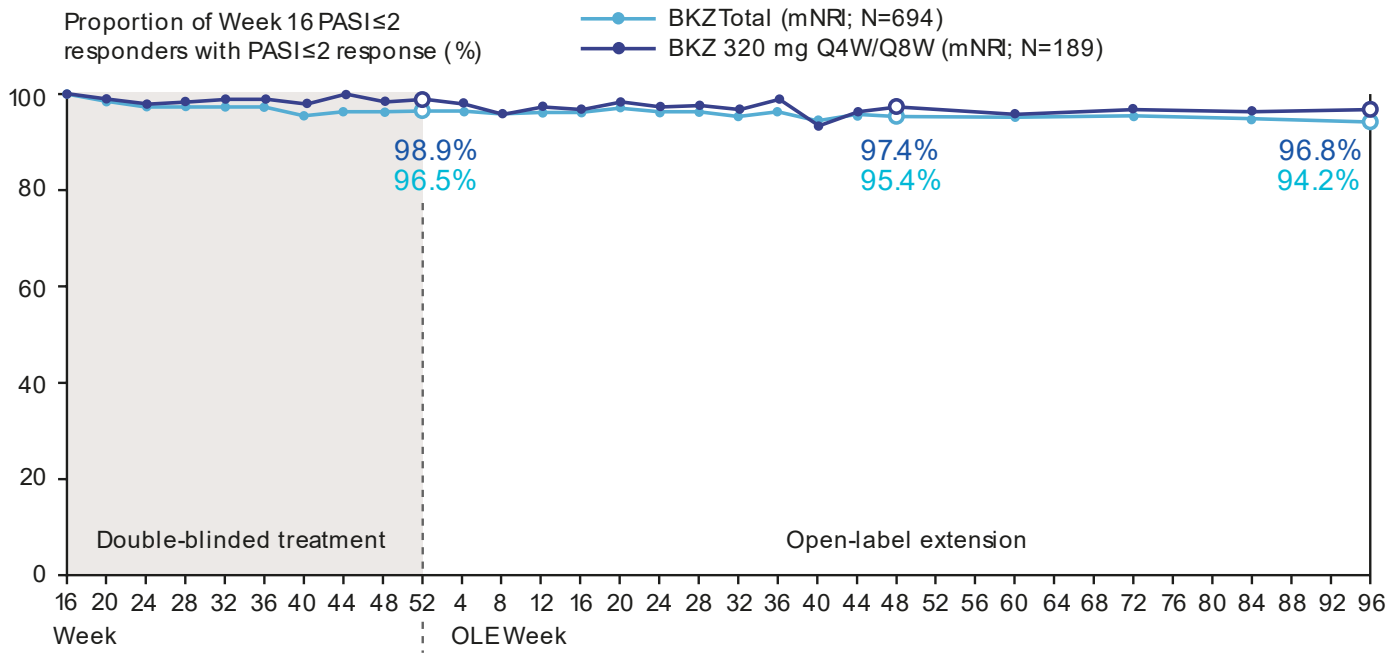
Week 16 responses are shown for all patients randomised to BKZ 320 mg Q4W in the initial treatment period. Due to the differing lengths of feeder studies, Week 56 data for PASI 100 response in BE SURE and BE READY are not presented in these pooled analyses. BKZ, bimekizumab; mNRI, modified non-responder imputation; NRI, Non-responder imputation; OLE, open-label extension; PASI, Psoriasis Area and Severity Index; Q4W, every 4 weeks; Q8W, every 8 weeks. All content on this slide is from Strober et al. EADV 2022;Poster P1491.

Over 9 out of 10 BKZ-treated patients who achieved PASI≤2 at week 16 maintained response through 3 years

Week 16 PASI ≤2 response rate in BKZ-randomised patients
(N=989)



BKZ 320 mg Q4W (NRI; Initial treatment period)

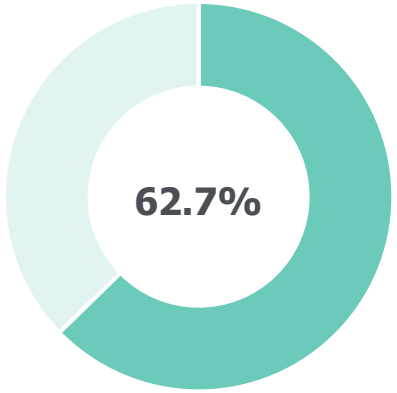


- 87.8% of the 989 patients randomized to BKZ Q4W at the start of the feeder studies achieved PASI ≤2 at Week 16 (NRI)
- 94.2% of BKZ-treated patients who achieved PASI ≤2 at Week 16 maintained their response at Year 3 (OLE Week 96; mNRI)

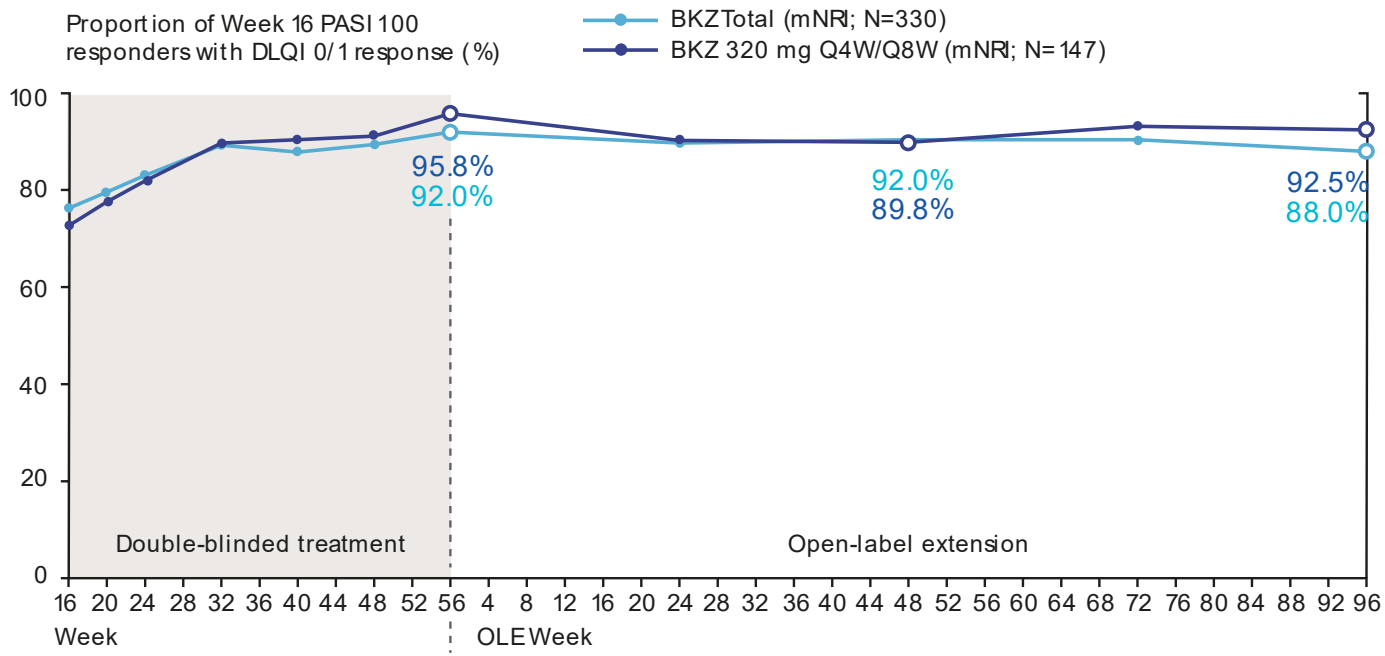
Week 16 responses are shown for all patients randomised to BKZ 320 mg Q4W in the initial treatment period. Due to the differing lengths of feeder studies, Week 56 data for PASI ≤2 response in BE SURE and BE READY are not presented in these pooled analyses. BKZ, bimekizumab; mNRI, modified non-responder imputation; NRI, Non-responder imputation; OLE, open-label extension; PASI, Psoriasis Area and Severity Index; Q4W, every 4 weeks; Q8W, every 8 weeks. All content on this slide is from Strober et al. EADV 2022;Poster P1491.

Over 8 out of 10 BKZ-treated patients who achieved PASI 100 at week 16 achieved DLQI 0/1 through 3 years

Week 16 PASI 100 response rate in BKZ-randomised patients
(N=989)



BKZ 320 mg Q4W (NRI; Initial treatment period)

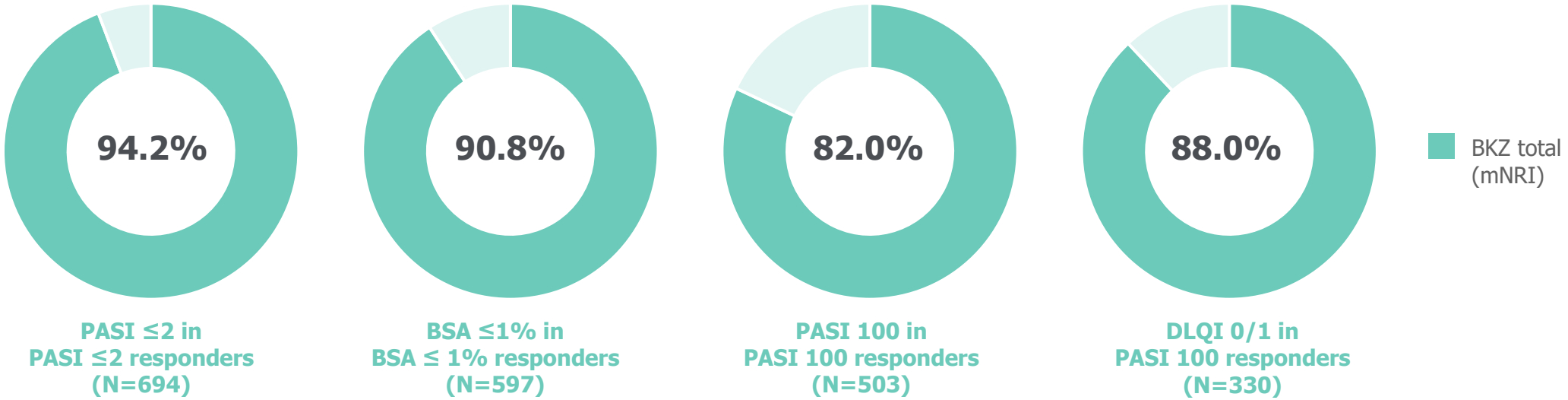


- DLQI 0/1 response rates in all BKZ-treated Week 16 PASI 100 responders increased through the first year of BKZ treatment, and were maintained through to the end of Year 3 (OLE Week 96) in 88.0% of patients

Week 16 responses are shown for all patients randomised to BKZ 320 mg Q4W in the initial treatment period. DLQI was measured on a different schedule in BE VIVID compared with BE SURE and BE READY; DLQI 0/1 data for patients enrolled in BE VIVID are therefore not included beyond Week 16, due to the lack of common visits at which DLQI was recorded. BKZ: bimekizumab; DLQI: Dermatology Life Quality Index; mNRI: modified non-responder imputation; OLE: open-label extension; PASI: Psoriasis Area and Severity Index; Q4W: every 4 weeks; Q8W: every 8 weeks. All content on this slide is from Strober et al. EADV 2022;Poster P1491.

Conclusions

Maintenance of Week 16 responses at Year 3 (OLE Week 96)



Among Week 16 responders, efficacy and health-related quality of life response rates were maintained through to three years of BKZ treatment, including among those who received BKZ 320 mg Q4W/Q8W

BKZ: bimekizumab; BSA: body surface area; DLQI: Dermatology Life Quality Index; mNRI: modified non-responder imputation; OLE: open-label extension; PASI: Psoriasis Area and Severity Index; PASI 100: 100% improvement from baseline in PASI.
All content on this slide is from Strober et al. EADV 2022;Poster P1491.

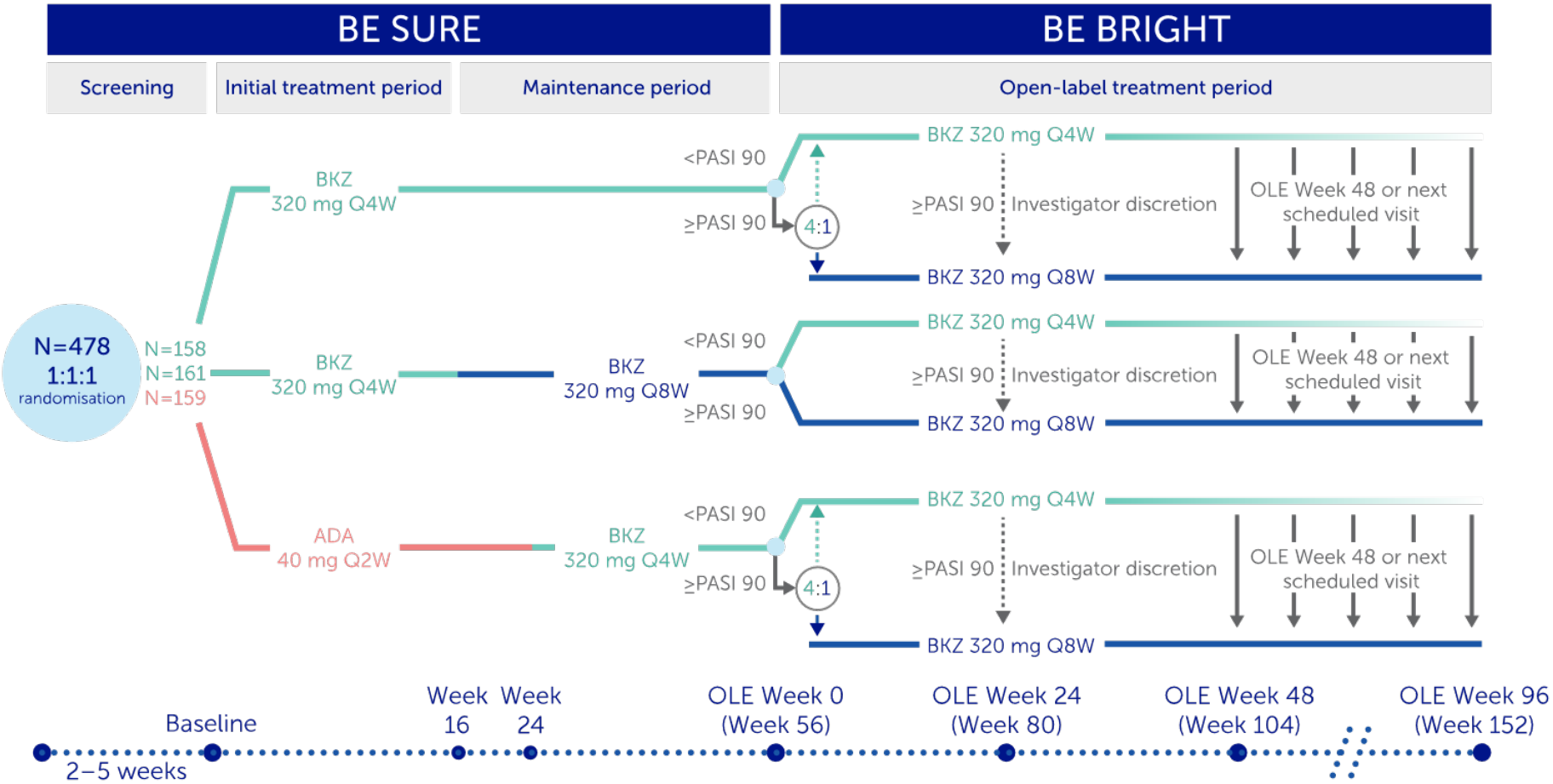
P1572

Bimekizumab efficacy and safety through three years in patients with moderate to severe plaque psoriasis: Long-term results from the BE SURE randomised controlled trial and the BE BRIGHT open-label extension

Diamant Thaçi, Ron Vender, Menno de Rie, Curdin Conrad, Jennifer Soung, Bruce Strober, Maggie Wang, Nancy Cross, Delphine Deherder, Natalie Nunez Gomez, Alice B. Gottlieb

BE SURE/BE BRIGHT study design and presentation objective

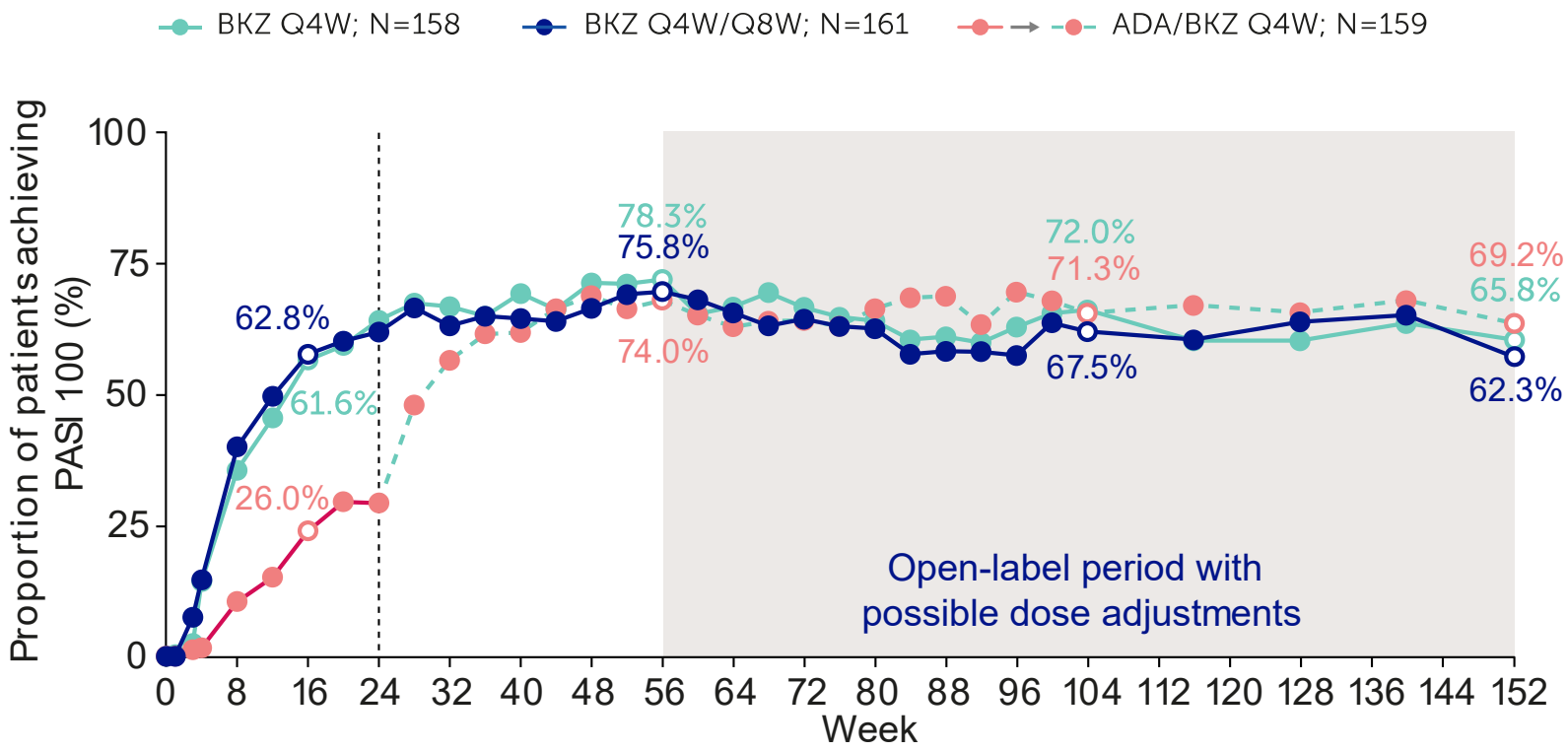
Presentation Objective:
To evaluate the long-term efficacy and safety of BKZ over three years in patients with moderate to severe plaque psoriasis who enrolled in the BE SURE phase 3 trial and entered the BE BRIGHT OLE



In BE SURE, patients were randomised 1:1:1 to: BKZ 320 mg Q4W for 56 weeks; BKZ 320 mg Q4W for 16 weeks then Q8W through Weeks 16–56; or ADA 40 mg Q2W for 24 weeks followed by BKZ 320 mg Q4W to Week 56. At Week 56, dose adjustments (to BKZ 320 mg Q4W or Q8W) could occur based on whether patients achieved PASI 90. Patients receiving BKZ 320 mg Q4W at Week 56 who achieved PASI 90 were randomised 4:1 to BKZ 320 mg Q4W or Q8W. At Week 24 of BE BRIGHT, for patients receiving BKZ 320 mg Q4W, if PASI 90 was achieved, the investigator could change the patient's dosing interval from 320 mg Q4W to 320 mg Q8W. All patients were switched to BKZ 320 mg Q8W at the next scheduled clinic visit on or after the Week 104 visit (OLE Week 48) following protocol amendment.

ADA, adalimumab; BKZ, bimekizumab; OLE, open-label extension; PASI, Psoriasis Area and Severity Index; Q4W, every 4 weeks; Q8W, every 8 weeks. All content on this slide is from Thaçi et al. EADV 2022;Poster P1572.

Over 6 out of 10 BKZ-treated patients achieved PASI 100 up to 152 weeks (mNRI)

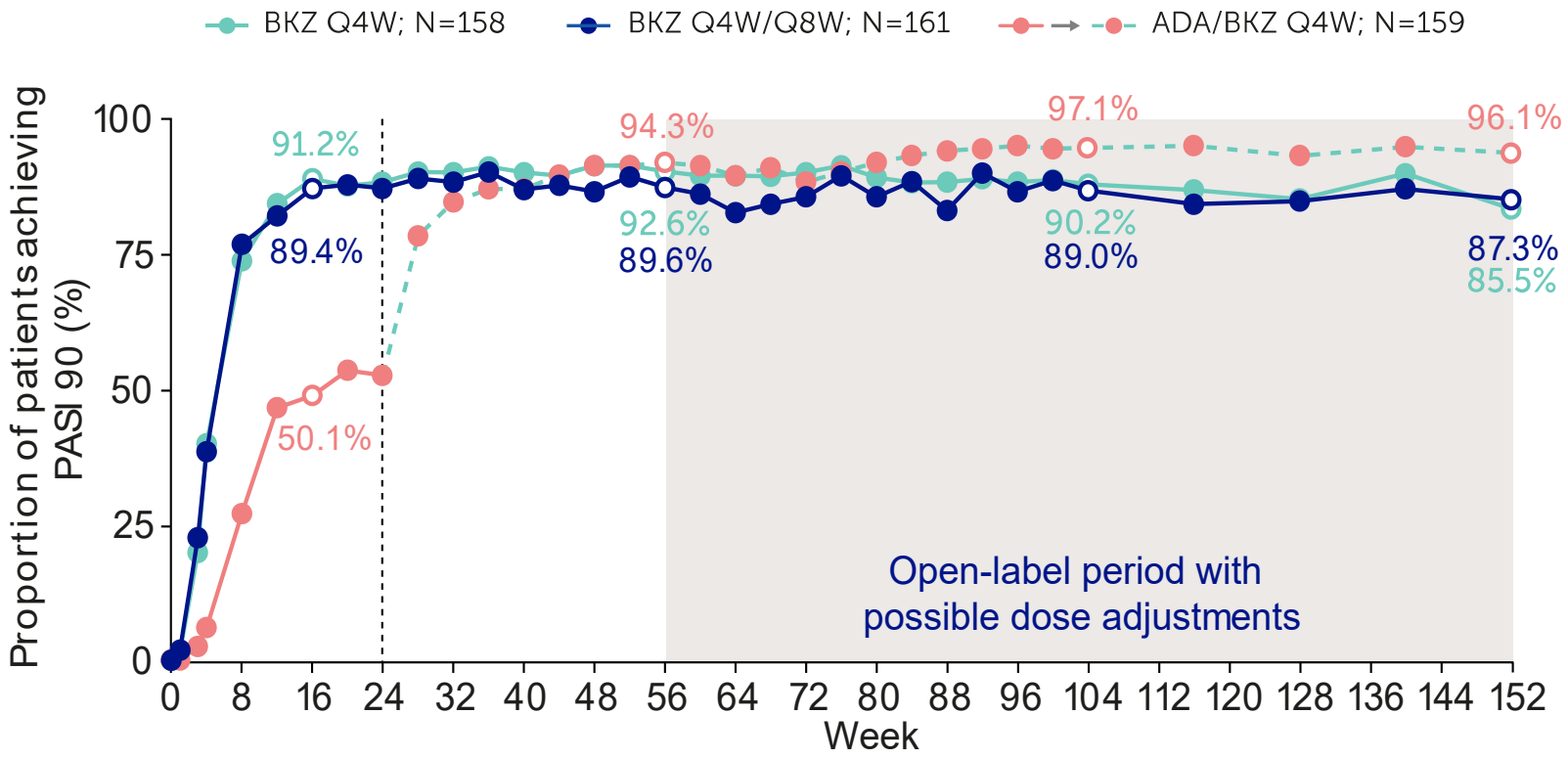


Among ADA-randomised patients, the rapid increases seen in PASI 100 response after the Week 24 ADA to BKZ switch were durable to Week 152, reaching similar levels compared to BKZ-randomised patients

Data are presented for the ITT population by initial randomisation group. The vertical line at Week 24 indicates when patients randomised to ADA switched to BKZ Q4W. Week 104 corresponds to OLE Week 48, and Week 152 to OLE Week 96

ADA. Adalimumab; BKZ, bimekizumab; ITT, intention-to-treat; mNRI, modified non-responder imputation; OLE, open-label extension; PASI, Psoriasis Area and Severity Index; Q4W, every 4 weeks; Q8W, every 8 weeks.
All content on this slide is from Thaçi et al. EADV 2022;Poster P1572.

Over 8 of 10 BKZ-treated patients achieved PASI 90 up to 152 weeks (mNRI)

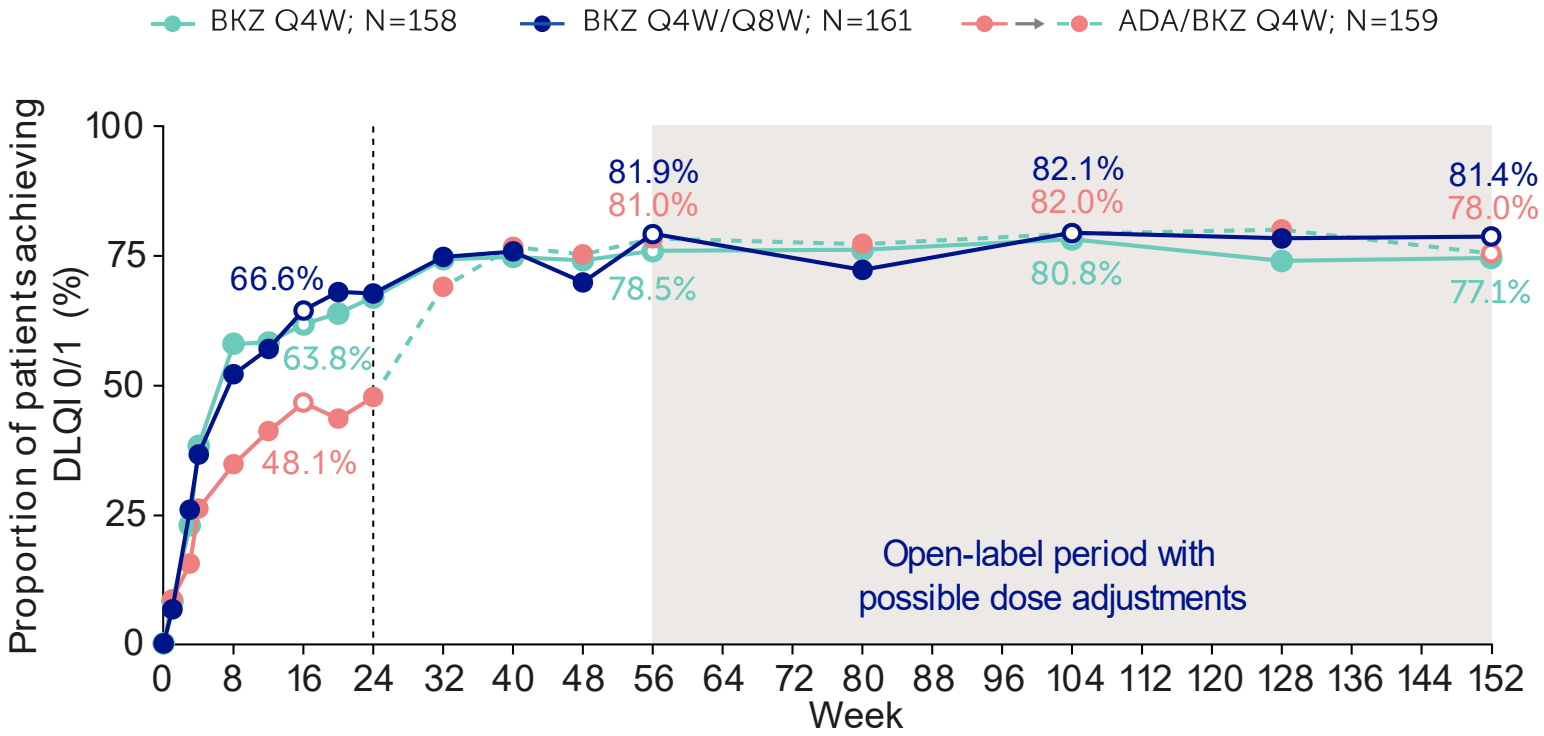


Among ADA-randomised patients, the rapid increases seen in PASI 90 response after the Week 24 ADA to BKZ switch were durable to Week 152, reaching similar levels compared to BKZ-randomised patients

Data are presented for the ITT population by initial randomisation group. The vertical line at Week 24 indicates when patients randomised to ADA switched to BKZ Q4W. Week 104 corresponds to OLE Week 48, and Week 152 to OLE Week 96

ADA. Adalimumab; BKZ, bimekizumab; ITT, intention-to-treat; mNRI, modified non-responder imputation; OLE, open-label extension; PASI, Psoriasis Area and Severity Index; Q4W, every 4 weeks; Q8W, every 8 weeks.
All content on this slide is from Thaçi et al. EADV 2022;Poster P1572.

Over 7 out of 10 BKZ-treated patients achieved DLQI 0/1 up to 152 weeks (mNRI)



Data are presented for the ITT population by initial randomisation group. The vertical line at Week 24 indicates when patients randomised to ADA switched to BKZ Q4W. Week 104 corresponds to OLE Week 48, and Week 152 to OLE Week 96

ADA. Adalimumab; BKZ, bimekizumab; DLQI, Dermatology Life Quality Index; ITT, intention-to-treat; mNRI, modified non-responder imputation; OLE, open-label extension; Q4W, every 4 weeks; Q8W, every 8 weeks.
All content on this slide is from Thaçi et al. EADV 2022;Poster P1572.

Overview of adverse events during BKZ treatment in patients from BE SURE who entered BE BRIGHT, Weeks 104–152

EAIR/100 PY (95% CI)	BKZ Total N=380	BKZ Q4W/Q4W N=132	BKZ Q4W/Q8W N=124	ADA/BKZ Q4W N=124
Any TEAE	101.7 (88.7, 116.0)	108.8 (85.5, 134.6)	99.4 (77.6, 125.4)	97.6 (76.2, 123.1)
Serious TEAEs	6.2 (3.9, 9.5)	5.1 (1.9, 11.1)	8.2 (3.7, 15.5)	5.5 (2.0, 11.9)
Discontinuation due to TEAEs	2.9 (1.4, 5.4)	2.5 (0.5, 7.4)	3.5 (1.0, 9.1)	2.7 (0.6, 7.9)
Severe TEAEs	5.0 (2.9, 8.0)	3.4 (0.9, 8.7)	8.2 (3.7, 15.5)	3.6 (1.0, 9.2)
Deaths	1.2 (0.3, 3.0)	1.7 (0.2, 6.1)	0.9 (0.0, 4.9)	0.9 (0.0, 5.0)
Most common TEAEs[a]				
Coronavirus infection	**6.6 (4.1, 10.0)**	**5.2 (1.9, 11.3)**	**8.3 (3.8, 15.8)**	**6.4 (2.6, 13.3)**
Nasopharyngitis	**4.8 (2.7, 7.7)**	**4.3 (1.4, 10.1)**	2.7 (0.6, 7.8)	**7.4 (3.2, 14.6)**
Oral candidiasis	**6.3 (3.9, 9.7)**	**6.1 (2.5, 12.6)**	**7.3 (3.2, 14.4)**	**5.6 (2.0, 12.1)**
Urinary tract infection	3.5 (1.8, 6.2)	3.4 (0.9, 8.8)	**5.4 (2.0, 11.7)**	1.8 (0.2, 6.6)

Two-year safety data have been reported previously (Weeks 0–104).[1,2] Data are presented as EAIRs of new cases per 100 patient-years from Weeks 104–152 for all patients who received ≥1 BKZ dose in the Week 104–152 period (data cut-off: 23 Oct 2021), both by initial randomisation group regardless of BKZ OLE dosing regimen, and for all patients pooled (BKZ Total). All patients received BKZ Q8W from Week 104 (OLE Week 96; or next visit).

- [1]Thaçi D et al. Presented at EADV 2021, P1324; [2] Warren RB et al. N Engl J Med 2021;385:130–41. [a] Values in bold are the three most common TEAEs for the treatment group.
  ADA, adalimumab, BKZ, bimekizumab; CI, confidence interval; EAIR, exposure-adjusted incidence rates; OLE, open-label extension; PY patient-years; Q4W, every 4 weeks; Q8W, every 8 weeks; TEAEs, treatment-emergent adverse events.
  All content on this slide is from Thaçi et al. EADV 2022;Poster P1572.

Conclusions

Clinical and health-related quality of life responses observed during the first two years of treatment were sustained to three years of treatment, regardless of BKZ maintenance dose frequency prior to the third year

Additionally, responses were sustained in the third year with all patients switching to BKZ every 8 weeks

Increases in responses after the ADA to BKZ switch were also sustained to Week 152

BKZ was well-tolerated over three years, with no unexpected safety findings

ADA, adalimumab; BKZ, bimekizumab; Q4W, every 4 weeks; Q8W, every 8 weeks.

P1569

Bimekizumab safety in patients with moderate to severe plaque psoriasis: Analysis of pooled data from up to three years of treatment in phase 2 and 3 clinical trials

Kenneth B. Gordon, Richard G. Langley, Richard B. Warren, Yukari Okubo, David Rosmarin, Mark Lebwohl, Luke Peterson, Cynthia Madden, Dirk de Cuyper, Natalie Nunez Gomez, Diamant Thaçi

Introduction and presentation objective

Objective:

To report long-term safety data, pooled to include three years of treatment, in patients with moderate to severe plaque psoriasis treated with BKZ across four phase 2 and four phase 3 clinical trials.

Background:

- Given the chronic nature of psoriasis, it is important to consider long-term safety of treatments[1]
- Data pooled over two years have indicated that BKZ is generally well-tolerated[2]

Methods:

- Long-term safety data were evaluated for all patients who received ≥1 dose of BKZ in four phase 3 trials (BE SURE, BE VIVID, BE READY, and their ongoing open-label extension BE BRIGHT [data cut-off: 23 Oct 2021]) and four phase 2 trials (BE ABLE 1, BE ABLE 2, PS0016, and PS0018)

[1.] Warren et al. J Invest Dermatol 2015;135:2632–40; [2.] Gordon et al. JAMA Dermatol 2022;158(7):735–744.
BKZ, bimekizumab; All content on this slide is from Gordon et al. EADV 2022;Poster P1569.

Baseline characteristics

Baseline demographics were similar between BKZ dose groups

	Phase 2 and 3		Phase 3	
	BKZ Total[a] N=1,789	**BKZ 320 mg Q4W** N=1,456	**BKZ 320 mg Q8W** N=1,289	**BKZ total**[a] N=1,495
Age (years), mean ± SD	45.2 ± 13.5	45.4 ± 13.5	45.5 ± 13.3	45.4 ± 13.4
Male, n (%)	1,252 (70.0)	1,042 (71.6)	934 (72.5)	1,067 (71.4)
Caucasian, n (%)	1,468 (82.1)	1,173 (80.6)	1,057 (82.0)	1,208 (80.8)
Region, n (%)				
North America	635 (35.5)	534 (36.7)	432 (33.5)	542 (36.3)
Central/Eastern Europe	728 (40.7)	535 (36.7)	528 (41.0)	558 (37.3)
Western Europe	168 (9.4)	164 (11.3)	144 (11.2)	168 (11.2)
Asia/Australia	258 (14.4)	223 (15.3)	185 (14.4)	227 (15.2)
Weight (kg), mean ± SD	89.0 ± 22.0	89.1 ± 22.3	89.0 ± 21.7	89.1 ± 22.3
Disease duration (years), mean ± SD	17.7 ± 12.3	17.8 ± 12.3	18.3 ± 12.4	17.9 ± 12.3
Prior biologic therapy, n (%)	636 (35.6)	559 (38.4)	508 (39.4)	576 (38.5)
Anti-TNF	240 (13.4)	200 (13.7)	180 (14.0)	207 (13.8)
Anti-IL-17	343 (19.2)	331 (22.7)	312 (24.2)	343 (22.9)
Prior systemic therapy, n (%)	1,360 (76.0)	1,135 (78.0)	1,019 (79.1)	1,166 (78.0)

[a] Patients who received both BKZ 320 mg Q4W and Q8W are included in the population count of both treatment groups, but only once in each BKZ Total group.

BKZ, bimekizumab; IL, interleukin; Q4W, every 4 weeks; Q8W, every 8 weeks; SD, standard deviation; TNF, tumour necrosis factor.
All content on this slide is from Gordon et al. EADV 2022;Poster P1569.

Summary of treatment exposure, summary of TEAEs and most common TEAEs in BKZ-treated patients in the Phase 2 and 3 trials

	TEAEs over 2 years	TEAEs over 3 years	TEAEs over 3 years		
	Phase 2 and 3	Phase 2 and 3	Phase 3		
	BKZ Total[a] N=1,789	BKZ total[a] N=1,789	BKZ 320 mg Q4W N=1,456	BKZ 320 mg Q8W N=1,289	BKZ total[a] N=1,495
Summary of treatment exposure					
Total exposure, PY	3,109.7	4,245.3	1,965.6	1,914.5	3,876.4
Mean exposure ± SD, (days)	608.5 ± 232.6	837.0 ± 365.7	476.2 ± 284.4	536.5 ± 290.8	932.4 ± 317.7
Median exposure (range), (days)	673.0 (1–1,037)	995.0 (1–1,326)	504.0 (23–1,093)	448.0 (1–1,214)	1,058.0 (23–1,326)
Summary of TEAEs, EAIR/100 PY (95% CI)					
Any TEAE	202.4 (192, 212.6)	186.1 (177.2, 195.3)	217.9 (205.8, 230.5)	115.6 (108.2, 123.3)	175.5 (166.4, 185.0)
Severe TEAEs	5.4 (4.6, 6.3)	4.9 (4.3, 5.6)	5.3 (4.3, 6.4)	4.2 (3.3, 5.2)	4.5 (3.9, 5.3)
TEAEs leading to discontinuation	3.8 (3.1, 4.6)	3.5 (3.0, 4.1)	3.8 (2.9, 4.7)	2.5 (1.9, 3.3)	3.2 (2.6, 3.8)
Treatment-related TEAEs	35.4 (32.9, 38.0)	29.4 (27.4, 31.5)	42.3 (38.8, 45.9)	21.1 (18.8, 23.5)	28.9 (26.8, 31.1)
Serious TEAEs	5.9 (5.1, 6.9)	5.6 (4.9, 6.4)	6.2 (5.1, 7.4)	5.4 (4.4, 6.5)	5.5 (4.8, 6.4)
TEAEs leading to death	0.4 (0.2, 0.6)	0.4 (0.3, 0.7)	0.4 (0.2, 0.8)	0.4 (0.2, 0.8)	0.4 (0.2, 0.7)
Three most common TEAEs, EAIR/100 PY (95% CI)					
Nasopharyngitis	19.1 (17.4, 20.9)	15.3 (13.9,16.7)	21.1 (18.9, 23.5)	10.0 (8.5, 11.6)	15.0 (13.6, 16.5)
Oral candidiasis	12.6 (11.3, 14.0)	10.2 (9.1, 11.3)	15.9 (14.1, 17.9)	7.1 (5.9, 8.5)	10.1 (9.1, 11.3)
Upper respiratory tract infection	8.9 (7.8, 10.1)	7.1 (6.2, 8.0)	8.9 (7.6, 10.4)	4.9 (3.9, 6.1)	6.5 (5.7, 7.4)

- **Safety data observed over three years were consistent with those observed over two years of BKZ treatment;[1] EAIRs did not increase with longer BKZ exposure, and were generally lower in Q8W- vs Q4W-treated patients**
- **The three most common TEAEs in the phase 2/3 trials with BKZ were nasopharyngitis, oral candidiasis, and upper respiratory tract infection**

Data are shown as of the data cut-off (two years: 9 Nov 2020; three years: 23 Oct 2021). [a] Patients are included in the relevant BKZ dose group based on the dose most recently received prior to the date of the adverse event or assessment. Patients who received both BKZ 320 mg Q4W and Q8W are included in the population count of both treatment groups, but only once in each BKZ Total group. [1] Gordon et al Jama Dermatol 2022; 158 (7) ; 735-744. BKZ, bimekizumab; CI, confidence interval; EAIR, exposure-adjusted incidence rates; Q4W, every 4 weeks; Q8W, every 8 weeks; PY, patient years; SD, standard deviation; TEAE, treatment-emergent adverse event.
All content on this slide is from Gordon et al. EADV 2022;Poster P1569.

TEAEs of interest in BKZ-treated patients in the Phase 2 and 3 trials

	TEAEs over 2 years	TEAEs over 3 years	TEAEs over 3 years		
	Phase 2 and 3	Phase 2 and 3	Phase 3		
	BKZ Total[a] N=1,789	BKZ total[a] N=1,789	BKZ 320 mg Q4W N=1,456	BKZ 320 mg Q8W N=1,289	BKZ total[a] N=1,495
TEAEs of interest, EAIR/100 PY (95% CI)					
Serious infections	1.0 (0.7, 1.4)	1,2 (0.9, 1.5)	1.4 (0.9, 2.0)	1.1 (0.7, 1.7)	1.2 (0.9, 1.6)
Active tuberculosis	0.0	0.0	0.0	0.0	0.0
Fungal infections	20.1 (18.4, 22.0)	16.6 (15.3, 18.1)	25.0 (22.6, 27.6)	12.6 (10.9, 14.4)	16.7 (15.3, 18.3)
Oral candidiasis	12.6 (11.3, 14.0)	10.2 (9.1, 11.3)	15.9 (14.1, 17.9)	7.1 (5.9, 8.5)	10.1 (9.1, 11.3)
Inflammatory bowel disease	0.1 (0.0, 0.3)	0.1 (0.0, 0.3)	0.2 (0.0, 0.4)	0.1 (0.0, 0.4)	0.1 (0.0, 0.3)
Adjudicated MACE	0.5 (0.3, 0.8)	0.6 (0.4, 0.8)	0.7 (0.4, 1.1)	0.5 (0.2, 0.9)	0.6 (0.4, 0.9)
Malignancies	0.8 (0.5, 1.2)	0.9 (0.6, 1.2)	0.6 (0.3, 1.1)	1.2 (0.7, 1.8)	0.9 (0.6, 1.2)
NMSC	0.3 (0.2, 0.6)	0.3 (0.2, 0.6)	0.3 (0.1, 0.7)	0.3 (0.1, 0.7)	0.3 (0.2, 0.5)
Adjudicated SIB	0.0 (0.0, 0.2)	0.1 (0.0, 0.2)	0.1 (0.0, 0.4)	0.1 (0.0, 0.3)	0.1 (0.0, 0.2)
Neutropenia events	0.8 (0.6, 1.2)	0.6 (0.4, 0.9)	0.8 (0.4, 1.3)	0.2 (0.0, 0.5)	0.4 (0.3, 0.7)
Hepatic events	4.3 (3.6, 5.2)	4.0 (3.4, 4.7)	3.7 (2.9, 4.7)	3.2 (2.5, 4.1)	3.2 (2.7, 3.8)
AST or ALT elevations[b]					
>3x ULN	2.4 (1.9, 3.0)	2.2 (1.7, 2.7)	2.8 (2.1, 3.6)	1.9 (1.3, 2.6)	2.1 (1.7, 2.6)
>5x ULN[d]	0.8 (0.5, 1.2)	0.6 (0.4, 0.9)	0.7 (0.4, 1.2)	0.5 (0.2, 0.9)	0.6 (0.4, 0.9)
Serious hypersensitivity reactions[c]	0.2 (0.1, 0.4)	0.1 (0.0, 0.3)	0.2 (0.0, 0.4)	0.1 (0.0, 0.3)	0.1 (0.0, 0.3)
Injection site reactions	2.3 (1.8, 2.9)	1.9 (1.5, 2.3)	2.7 (2.0, 3.5)	1.2 (0.8, 1.8)	1.8 (1.4, 2.3)

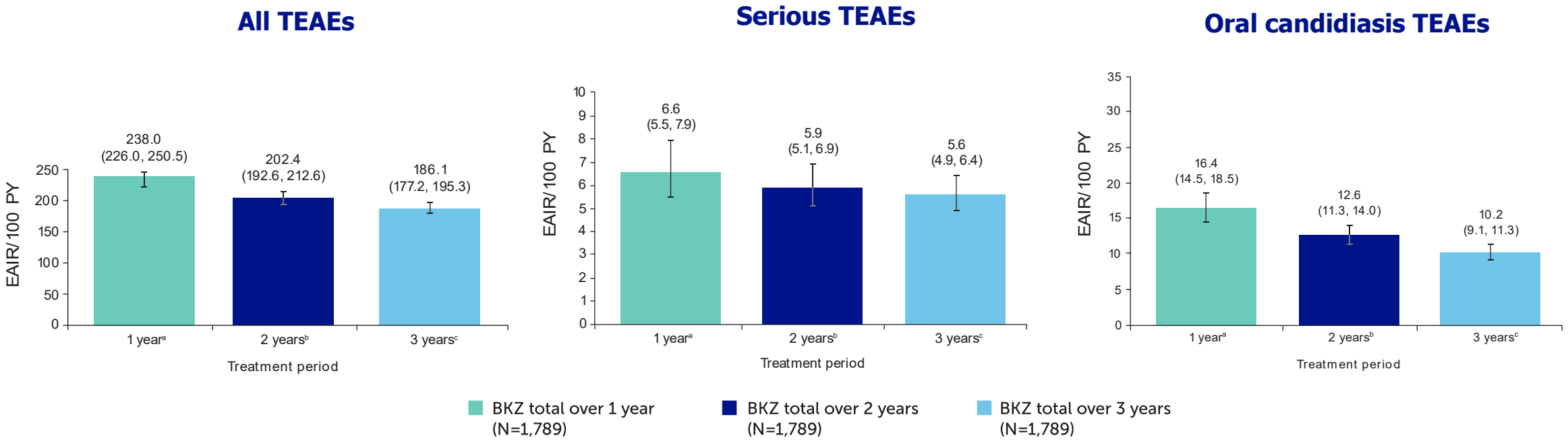
- **The rates of TEAEs of interest remained low, and were comparable to two-year data.[1] There were no cases of active tuberculosis.**
- **Rates of oral candidiasis did not increase with longer duration of bimekizumab exposure. No serious oral candidiasis events occurred; and were generally lower in Q8W- vs Q4W-treated patients**

Data are shown as of the data cut-off (two years: 9 Nov 2020; three years: 23 Oct 2021). [a] Patients are included in the relevant BKZ dose group based on the dose most recently received prior to the date of the adverse event or assessment. Patients who received both BKZ 320 mg Q4W and Q8W are included in the population count of both treatment groups, but only once in each BKZ Total group; [b] Not all hepatic laboratory parameter elevations were reported as adverse events; [c] >3x and >5x elevations are evaluated independently, hence patients with >5x elevations are also included in the >3x data; [d] No anaphylactic reactions associated with BKZ were reported

1. Gordon KB et al. JAMA Dermatol 2022;158(7):735–744.

BKZ, bimekizumab; CI, confidence interval; EAIR, exposure-adjusted incidence rates; Q4W, every 4 weeks; Q8W, every 8 weeks; NMSC, non-melanoma skin cancer; MACE, major adverse cardiac event; PY, patient years; SIB, suicidal ideation and behaviour; TEAE, treatment-emergent adverse event; ULN, upper limit of normal.
All content on this slide is from Gordon et al. EADV 2022;Poster P1569.

Exposure adjusted incidence rates of TEAEs did not increase compared with data from 2 years of treatment



Conclusions: BKZ was well-tolerated over three years of treatment; no safety signals were identified.

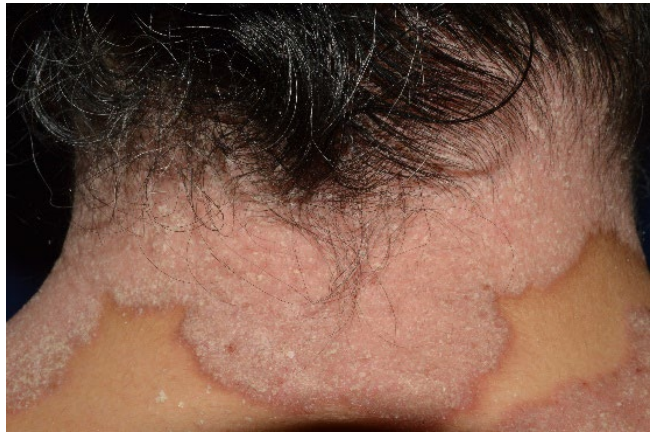
Error bars represent 95% CI. Data are pooled from four phase 2 and four phase 3 trials. Phase 2 data were not collected beyond 2 years. Data are reported as of the relevant data cut-offs: [a] 1 Nov 2019; [b] 9 Nov 2020; [c] 23 Oct 2021
BKZ, bimekizumab; EAIR, exposure-adjusted incidence rates; PY, patient years; TEAEs, treatment-emergent adverse events.
All content on this slide is from Gordon et al. EADV 2022;Poster P1569.

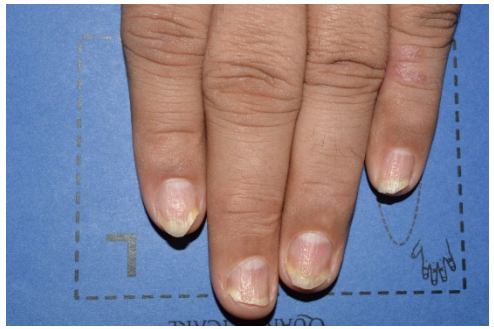
P1478

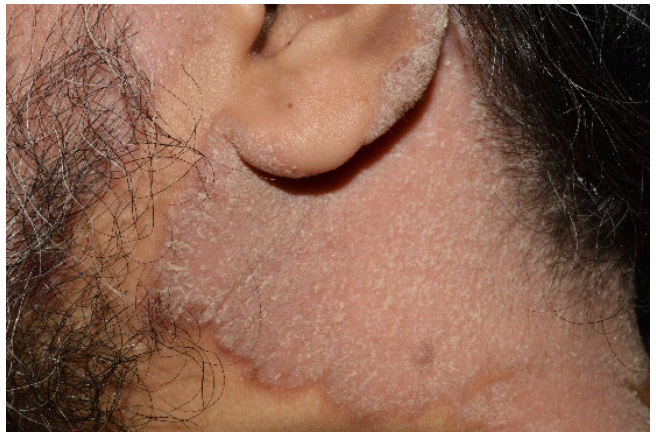
Bimekizumab efficacy over two years in patients with moderate to severe plaque psoriasis with scalp and nail involvement who switched from adalimumab, ustekinumab, or secukinumab: Results from the BE SURE, BE VIVID, BE BRIGHT, and BE RADIANT phase 3/3b trials

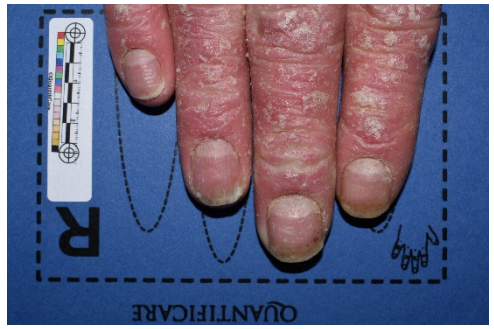
Richard B. Warren, Bruce Strober, Andreas Pinter, Andrew Blauvelt, Michael Sebastian, Leah Davis, Veerle Vanvoorden, Susanne Wiegratz, Melinda Gooderham

Psoriatic lesions in highly visible areas, such as the scalp and nails, disproportionally impact patients' health-related quality of life[1]





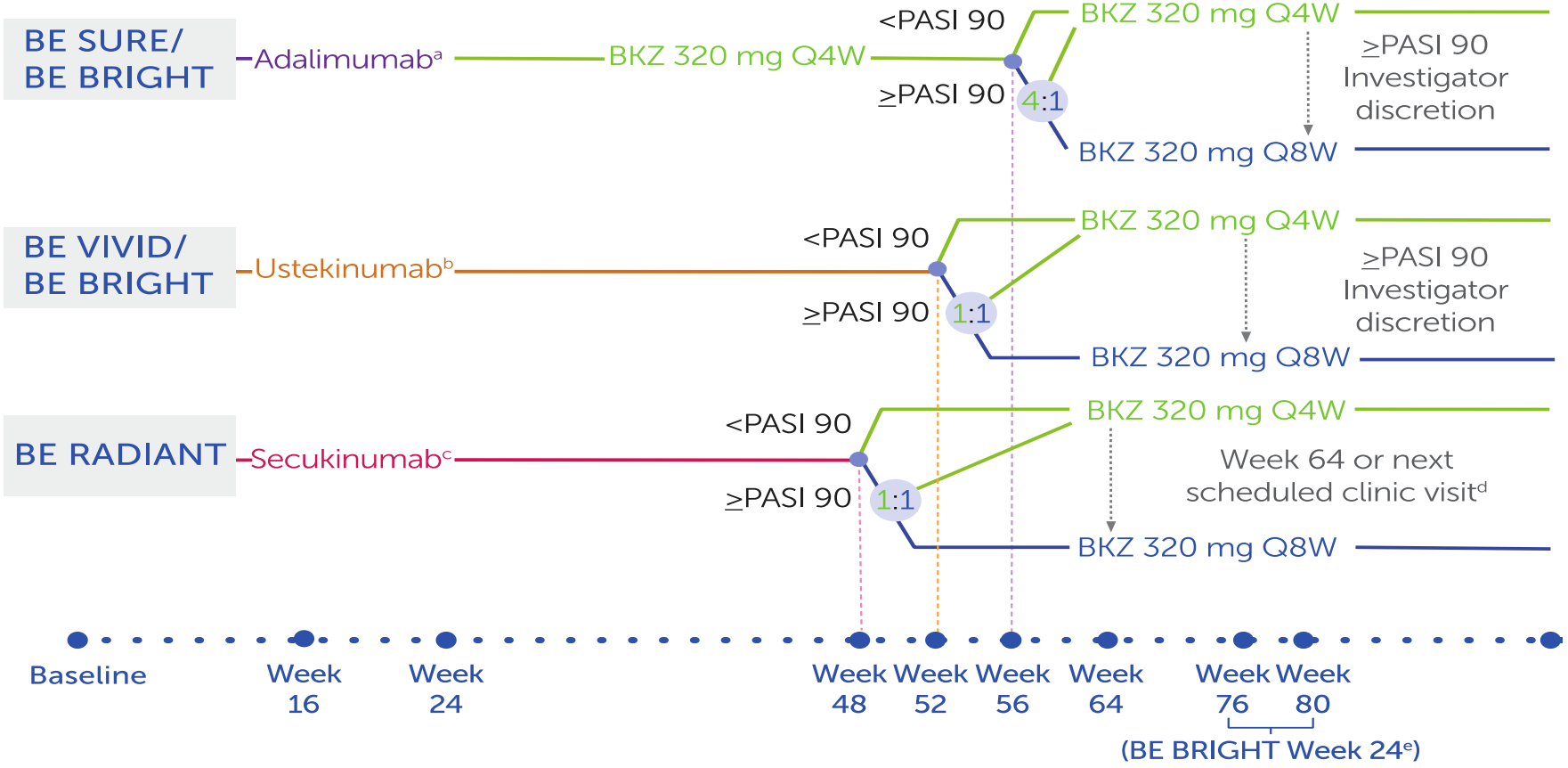




1. Augustin M et al. Br J Dermatol 2019;181:358–65.IGA.

Study design and presentation objective

Objective: To evaluate scalp and nail outcomes over two years in patients with moderate to severe plaque psoriasis who switched to BKZ from ADA, UST, or SEC.



Only active-comparator treatment groups in BE SURE, BE VIVID, and BE RADIANT are shown. Patients who completed BE SURE or BE VIVID could enrol in the BE BRIGHT OLE and received BKZ Q4W or Q8W, depending on PASI response on completion of the feeder trial. Patients who completed the 48-week double-blinded treatment period could enter the BE RADIANT OLE and received BKZ Q4W or Q8W, depending on Week 48 PASI response. In these analyses, BKZ Q4W and Q8W treatment arms for each trial are pooled

[a.] Dosed 80 mg at baseline, 40 mg at Week 1, then 40 mg Q2W; [b.] Dosing based on bodyweight at baseline: 45 mg for patients weighing ≤100 kg, and 90 mg patients weighing >100 kg, received at baseline, Week 4, then Q12W; [c.] Dosed 300 mg weekly to Week 4, then Q4W; [d.] At Week 64, or the next scheduled clinic visit, patients switched from BKZ 320 mg Q4W to Q8W after the implementation of a protocol amendment; [e.] At BE BRIGHT Week 24 patients receiving BKZ 320 mg Q4W who achieved PASI 90 could switch to Q8W, at the investigator's discretion. ADA, adalimumab; BKZ, bimekizumab; mNAPSI, modified Nail Psoriasis Severity Index, Q4W, every 4 weeks; Q8W, every 8 weeks; SEC, secukinumab; UST, ustekinumab.
All content on this slide is from Warren RB, et al. EADV 2022; Poster P1478.

Patient disposition

Baseline:
Patients with moderate to severe scalp or nail involvement

Comparator treatment period:
Patients who did not achieve complete nail or scalp clearance

Proportion of patients who had not achieved complete nail or scalp clearance at switch to BKZ (OC):

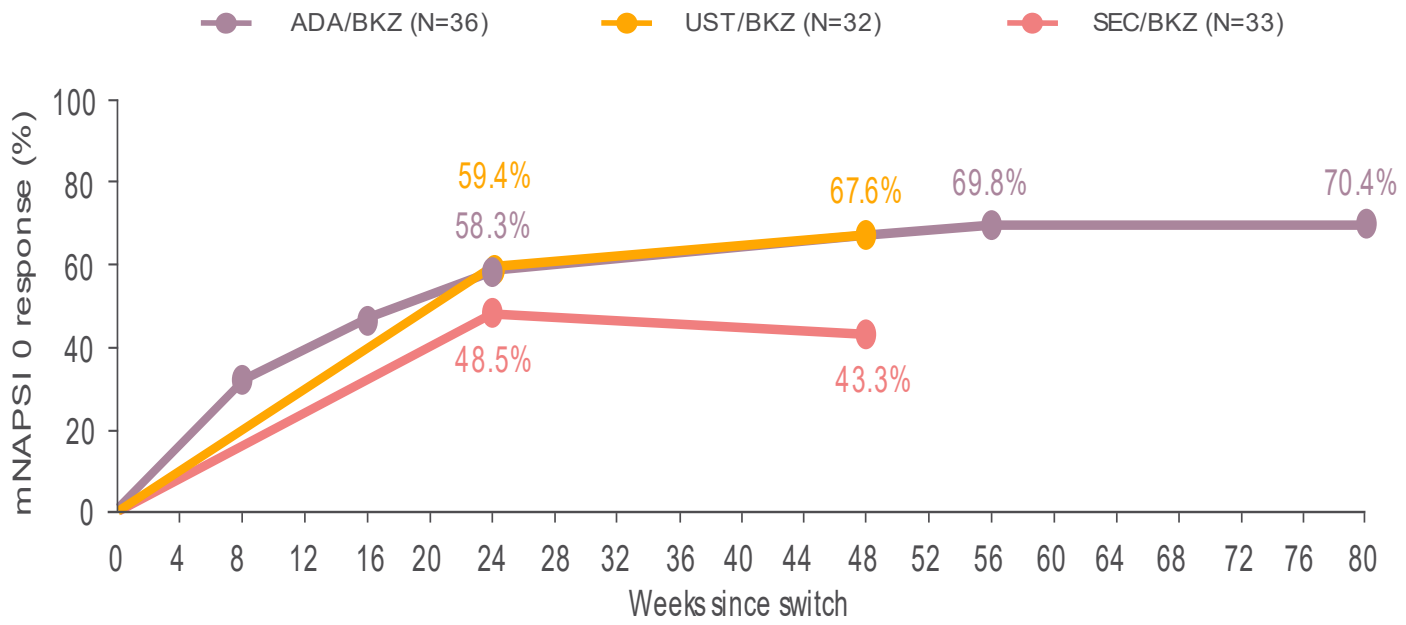
	Baseline	Comparator treatment period	Nail	Scalp
Adalimumab	mNAPSI >10 (N=48) Scalp IGA ≥3 (N=91)	After 24 weeks of adalimumab mNAPSI >0 (N=36) Scalp IGA >0 (N=33)	36/48 75.0%	33/91 36.3%
Ustekinumab	mNAPSI >10 (N=49) Scalp IGA ≥3 (N=79)	After 52 weeks of ustekinumab mNAPSI >0 (N=32) Scalp IGA >0 (N=31)	32/49 65.3%	31/79 39.2%
Secukinumab	mNAPSI >10 (N=81) Scalp IGA ≥3 (N=215)	After 48 weeks of secukinumab mNAPSI >0 (N=33) Scalp IGA >0 (N=42)	33/81 40.7%	42/215 19.5%

Switched to bimekizumab

IGA, Investigator's Global Assessment; mNAPSI, modified Nail Psoriasis Severity Index. All content on this slide is from Warren RB, et al. EADV 2022; Poster P1478. Data reported for patients with baseline mNAPSI >10 or scalp IGA ≥3 (moderate to severe regional involvement) who had not achieved mNAPSI 0 or scalp IGA 0 at time of switch to BKZ. Due to differences in scheduling, assessments were performed at different timepoints after switch from ADA, UST, and SEC to BKZ. Long-term data up to 80 weeks after switch from UST and SEC to BKZ are still pending.

A high proportion of patients who did not achieve mNAPSI 0 with ADA, UST or SEC achieved complete clearance 24 weeks after switch to BKZ

Proportion of mNAPSI 0 non-responders who achieved mNAPSI 0 after switch to BKZ (mNRI)

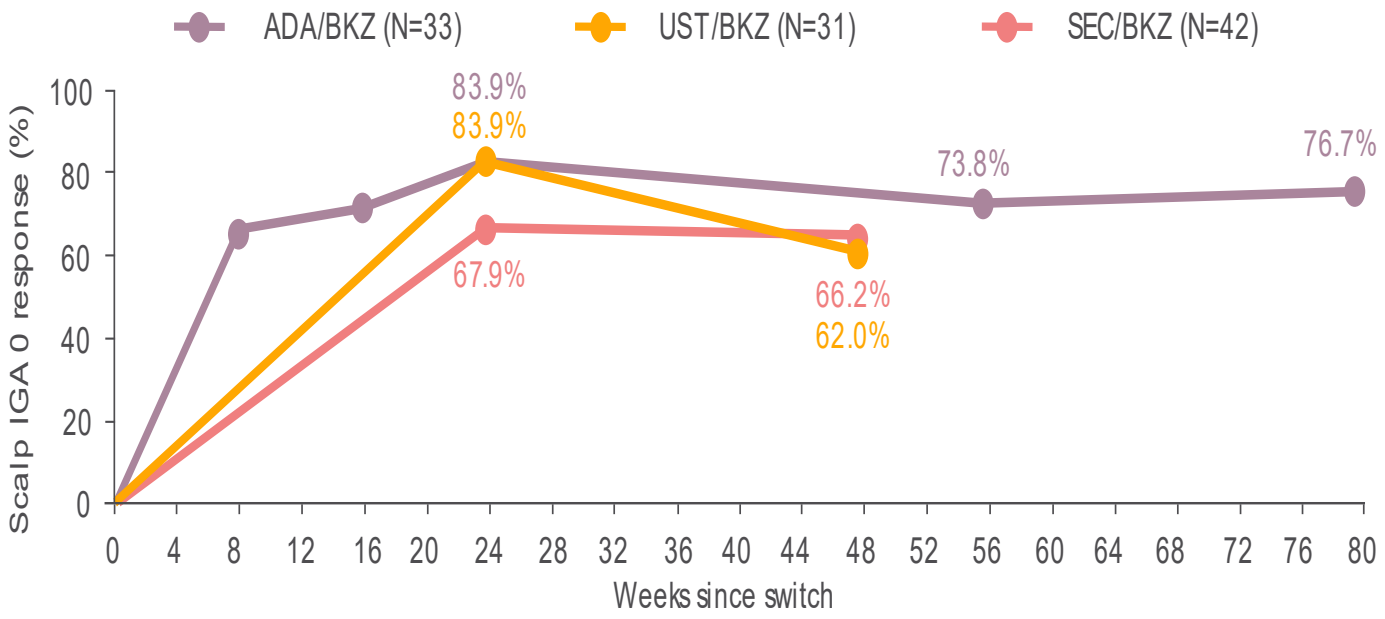


- At switch, mean (range) mNAPSI in non-responders was 10.6 (1.0-45.0), 12.6 (2.0-35.0), and 10.0 (1.0-40.0)

Data reported for patients with baseline mNAPSI >10 (moderate to severe regional involvement) who had not achieved mNAPSI 0 at time of switch to BKZ. Due to differences in scheduling, assessments were performed at different timepoints after switch from ADA, UST, and SEC to BKZ. Long-term data up to 80 weeks after switch from UST and SEC to BKZ are still pending. ADA, adalimumab; BKZ, bimekizumab; mNAPSI, modified Nail Psoriasis Severity Index; mNRI, modified non-responder imputation; OC, observed case; SEC, secukinumab; UST, ustekinumab.
All content on this slide is from Warren RB, et al. EADV 2022; Poster P1478.

A high proportion of patients who did not achieve scalp IGA 0 with ADA, UST or SEC achieved complete clearance 24 weeks after switch to BKZ

Proportion of scalp IGA 0 non-responders who achieved scalp IGA 0 after switch to BKZ (mNRI)



- At switch, mean (range) scalp IGA in these non-responders was 1.9 (1.0-4.0), 1.7 (1.0-4.0), and 1.4 (1.0-3.0)

Data reported for patients with baseline scalp IGA ≥3 (moderate to severe regional involvement) who had not achieved scalp IGA 0 at time of switch to BKZ. Due to differences in scheduling, assessments were performed at different timepoints after switch from ADA, UST, and SEC to BKZ. Long-term data up to 80 weeks after switch from UST and SEC to BKZ are still pending. ADA, adalimumab; BKZ, bimekizumab; mNAPSI, modified Nail Psoriasis Severity Index; mNRI, modified non-responder imputation; OC, observed case; SEC, secukinumab; UST, ustekinumab.
All content on this slide is from Warren RB, et al. EADV 2022; Poster P1478.

Conclusions

High proportions of patients who did not achieve mNAPSI 0 or scalp IGA 0 with ADA, UST or SEC demonstrated substantial improvements in complete clearance 24 weeks after switching to BKZ

Results were generally maintained across a BKZ treatment period of up to 80 weeks

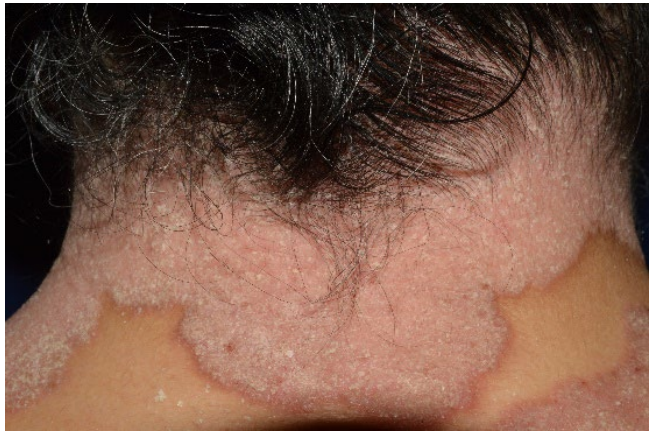
ADA, adalimumab; BKZ, bimekizumab; SEC, secukinumab

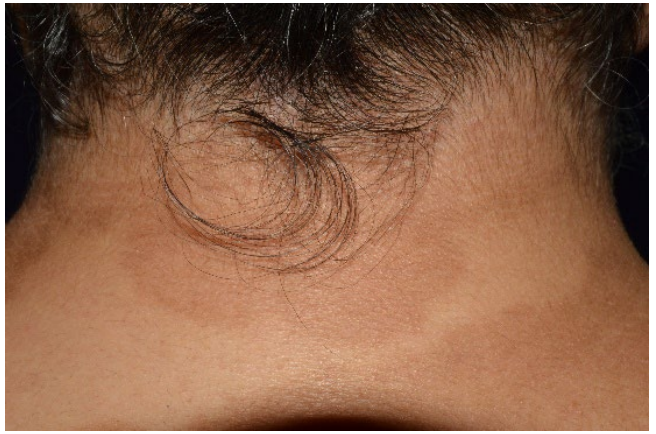
BE VIVID scalp IGA improvement over 52 weeks

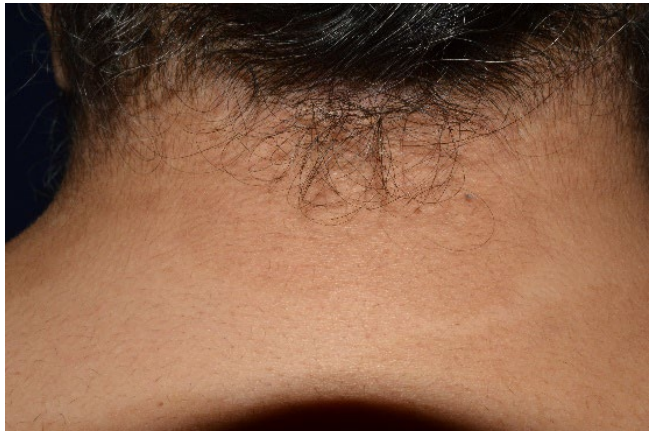
Week 0
sIGA = Moderate

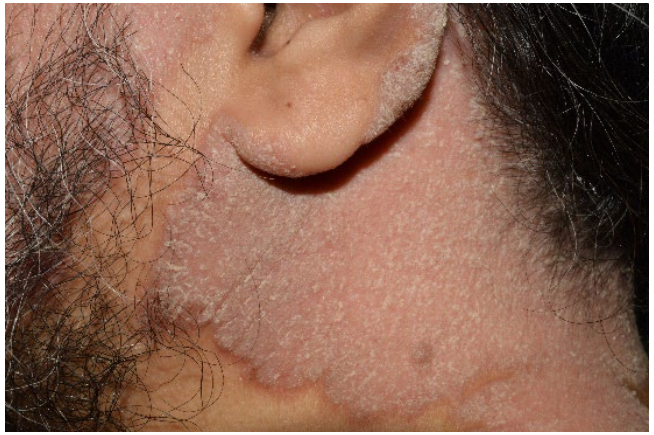
Week 16
sIGA = Clear (0)

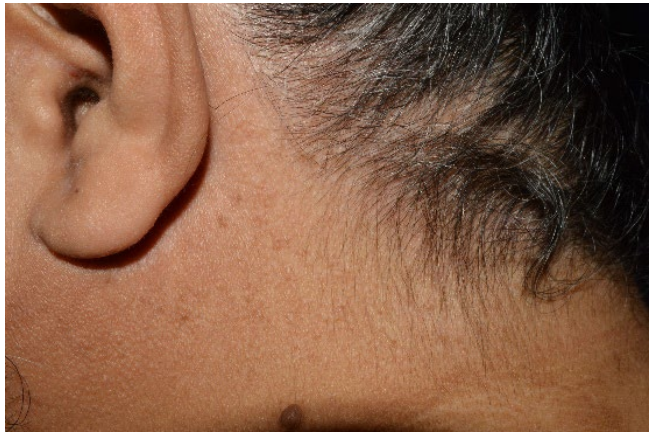
Week 52
sIGA = Clear (0)

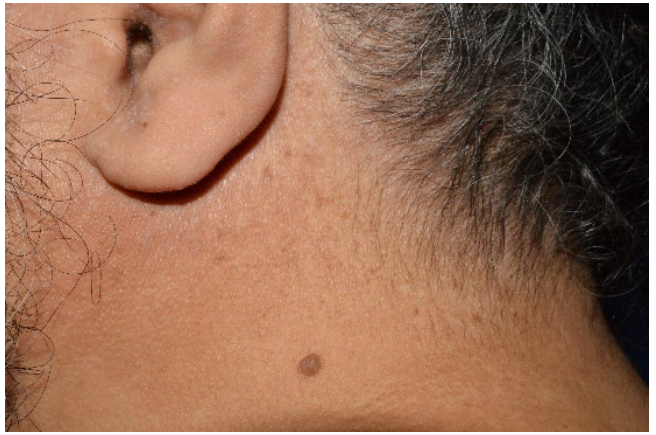








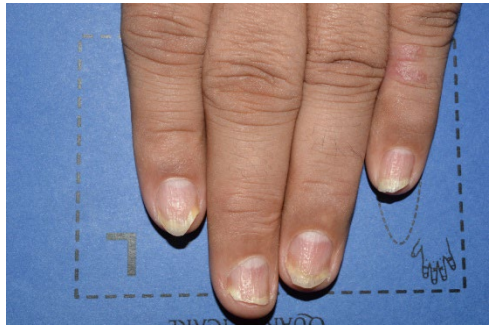




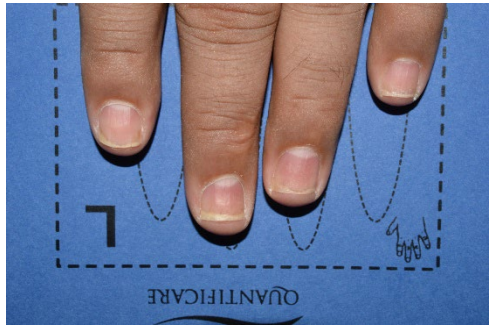
IGA: Investigator's Global Assessment

BE VIVID mNAPSI improvement over 52 weeks

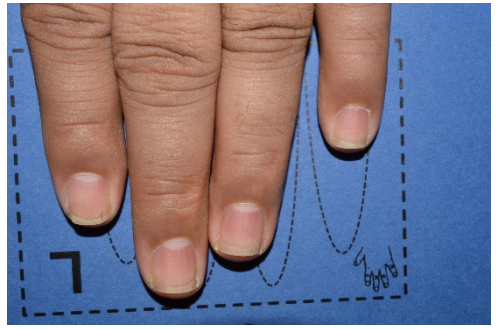
Week 0
mNAPSI = 22



Week 16
mNAPSI = 20

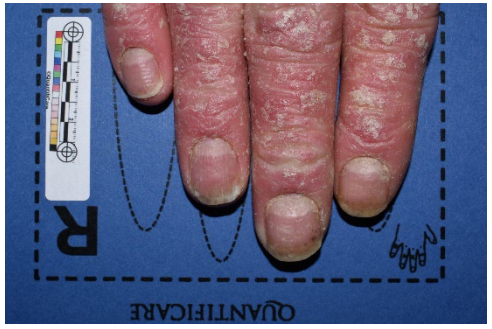


Week 52
mNAPSI = 0

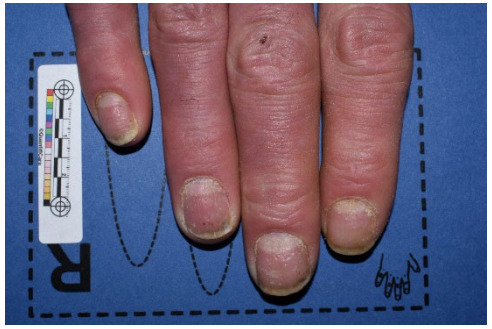


BE RADIANT mNAPSI improvement over 16 weeks

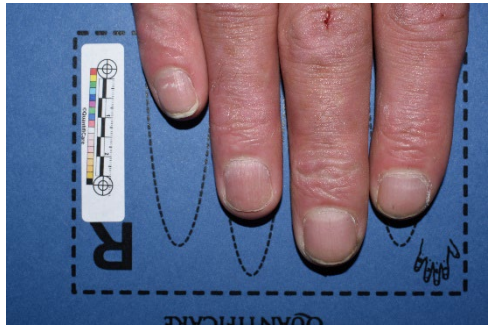
Week 0
mNAPSI = 21



Week 2
Not reported



Week 16
mNAPSI = 8



mNAPSI: modified Nail Psoriasis Severity Index; mNAPSI 0: an mNAPSI score of 0.

Summary

Emmanuel Caeymaex

Executive Vice President
Immunology Solutions & Head of U.S.

Summary

Patients place a high value on treatments which provide:

Speed, **depth and durability** of response[1]

3-year efficacy

Over **six out of 10 patients achieved PASI 100 up to three years**[2]

Over **eight out of 10 patients** who achieved **PASI 100 at week 16** maintained **PASI 100 responses and health-related quality of life through to three years**[3]

3-year safety

Bimekizumab was **well tolerated with no new safety signals identified** over three years[4]

High Impact Areas: Switch

A high proportion of adalimumab, ustekinumab, and secukinumab-randomised mNAPSI 0 and scalp IGA 0 non-responders **demonstrated substantial improvements in complete clearance 24 weeks after switch to bimekizumab**[5]

Bimekizumab has demonstrated depth and durability of response up to 3 years

References: 1. Gorelick J, Shrom D, Sikand K, et al. Dermatol Ther (Heidelb). 2019; 9: 785-797 2. Thaçi D, Vender R, de Rie M et al. Bimekizumab efficacy and safety through three years in patients with moderate to severe plaque psoriasis: Long-term results from the BE SURE randomised controlled trial and the BE BRIGHT open-label extension #P1572 Presented at the 31st EADV Congress 3. Strober B, Tada Y, Mrowietz U, Lebwohl M et al. Bimekizumab maintenance of response through three years in patients with moderate to severe plaque psoriasis who responded at Week 16: Results from the BE BRIGHT open-label extension #P1491 Presented at the 31st EADV Congress 4. Gordon, K.B., Langley R. G., Warren, R.B.et al. Bimekizumab safety in patients with moderate to severe plaque psoriasis: Analysis of pooled data from up to three years of treatment in Phase 2 and 3 clinical trials #P1569 Presented at the 31st EADV 5. Warren, R.B., Strober, B., Pinter, A. et al. Bimekizumab efficacy over two years in patients with moderate to severe plaque psoriasis with scalp and nail involvement who switched from adalimumab, ustekinumab, or secukinumab: Results from the BE SURE, BE VIVID, BE BRIGHT, and BE RADIANT Phase 3/3b trials #P1478, Presented at the 31st EADV Congress

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Q&A

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Yale University, Connecticut, U.S.

Professor Richard Warren
Salford Royal NHS Foundation Trust and The University of Manchester, UK

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Thank you

Inspired by **patients.**
Driven by **science.**