UCB VIRTUAL BRIEFING

BIMZELX® (bimekizumab)

Four-Year Data in Moderate to Severe Plaque Psoriasis

Capital Market Call
12th March 2024

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

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Disclaimer & Safe harbor

This document contains forward-looking statements, including, without limitation, statements containing the words "potential", "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 document.

Important factors that could result in such differences include but are not limited to: global spread and impacts of wars and pandemics, changes in general economic, business and competitive conditions, the inability to obtain necessary regulatory approvals or to obtain them on acceptable terms or within expected timing, costs associated with research and development, changes in the prospects for products in the pipeline or under development by UCB, effects of future judicial decisions or governmental investigations, safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, product liability claims, challenges to patent protection for products or product candidates, competition from other products including biosimilars, changes in laws or regulations, exchange rate fluctuations, changes or uncertainties in tax laws or the administration of such laws, and hiring and retention of its employees. There is no guarantee that new product candidates will be discovered or identified in the pipeline, or that new indications for existing products will be developed and approved. Movement from concept to commercial product is uncertain; preclinical results do not guarantee safety and efficacy of product candidates in humans. So far, the complexity of the human body cannot be reproduced in computer models, cell culture systems or animal models. The length of the timing to complete clinical trials and to get regulatory approval for product marketing has varied in the past and UCB expects similar unpredictability going forward. Products or potential products which are the subject of partnerships, joint ventures or licensing collaborations may be subject to disputes between the partners or may prove to be not as safe, effective or commercially successful as UCB may have believed at the start of such partnership. UCB's efforts to acquire other products or companies and to integrate the operations of such acquired companies may not be as successful as UCB may have believed at the moment of acquisition. Also, UCB or others could discover safety, side effects or manufacturing problems with its products and/or devices after they are marketed. The discovery of significant problems with a product similar to one of UCB's products that implicate an entire class of products may have a material adverse effect on sales of the entire class of affected products. Moreover, sales may be impacted by international and domestic trends toward managed care and health care cost containment, including pricing pressure, political and public scrutiny, customer and prescriber patterns or practices, and the reimbursement policies imposed by third-party payers as well as legislation affecting biopharmaceutical pricing and reimbursement activities and outcomes. Finally, a breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of UCB's data and systems.

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About BIMZELX® in the United States (U.S.) and in the European Union (EU)

In the **U.S.**

BIMZLEX® (bimekizumab-bkzx) is approved for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.[1]

In the **EU**

Approved indications for BIMZELX ®▼ (bimekizumab) are:

Plaque Psoriasis	Bimekizumab is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.[2]
Psoriatic Arthritis	Bimekizumab, alone or in combination with methotrexate, is indicated for the treatment of active psoriatic arthritis in adults who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs (DMARDs).[2]
Axial Spondyloarthritis	Bimekizumab is indicated for the treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP), and/or magnetic resonance imaging (MRI) who have responded inadequately or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs), and for the treatment of adults with active ankylosing spondylitis who have responded inadequately or are intolerant to conventional therapy.[2]

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The label information may differ in other countries where approved. 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.

References: 1. BIMZELX® (bimekizumab-bkzx) U.S. PI. www.ucb-usa.com/bimzelx-prescribing-information.pdf. Accessed March 2024; 2. BIMZELX® (bimekizumab) EU SmPC. https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf. Accessed March 2024.

Introduction

Emmanuel Caeymaex

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

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Agenda

Antje Witte Head of Investor Relations, UCB	**WELCOME**
Emmanuel Caeymaex Executive Vice President Immunology Solutions & Head of U.S.	**INTRODUCTION**
Dr. Andrew Blauvelt Blauvelt Consulting, LLC Lake Oswego, OR, USA	**BIMZELX®** **Four-Year Data in Moderate to Severe Plaque Psoriasis**
Emmanuel Caeymaex Executive Vice President Immunology Solutions & Head of U.S.	**SUMMARY**

Q & A Session Facilitated by Antje Witte

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BIMZELX® is the first and only approved biologic to selectively target IL-17F in addition to IL-17A

Approvals in Moderate to Severe Plaque Psoriasis

12
REGULATORY AUTHORITIES

41
COUNTRIES

>20,000
PATIENTS ±

Approvals in Psoriatic Arthritis (PsA) and/or Axial Spondyloarthritis (axSpA) including non-radiographic axSpA (nr-axSpA) and Ankylosing Spondylitis (AS)

European Union[1]

Great Britain[2]

Japan[3]

United Arab Emirates[4]

Saudi Arabia[5]

Canada[6] **(PsA)**

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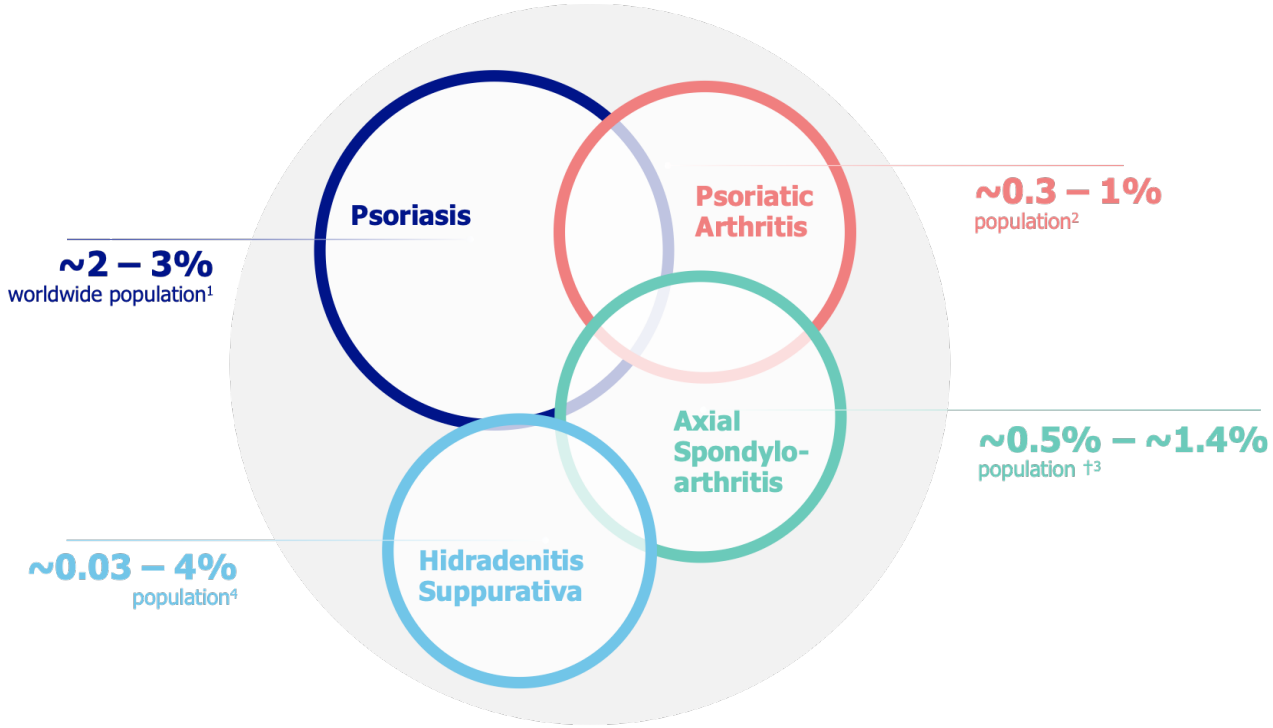
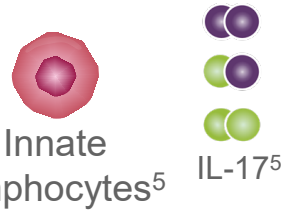
References: 1. BIMZELX® (bimekizumab) EU SmPC. https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf. Last Accessed March 2024; 2. BIMZELX GB Prescribing Information GB. https://www.medicines.org.uk/emc/product/12834/smpc https://www.medicines.org.uk/emc/product/12833/smpc Last accessed: March 2024; 3. BIMZELX Japan Prescribing Information - https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html. . Last accessed: March 2024; 4. https://mohap.gov.ae/en/services/registered-medical-product-directory. Last accessed: March 2024; 5. https://www.sfda.gov.sa/en Last accessed: March 2024; 6. BIMZELX Canada Prescribing Information https://pdf.hres.ca/dpd_pm/00064702.PDF. Last accessed: March 2024.;

GL-BK-2400026 | Date of preparation: March 2024

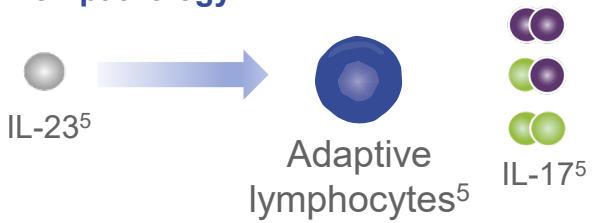
IL-17 plays a pivotal role in the pathogenesis of immune-mediated inflammatory diseases



Innate immunity driven pathology[5]



Adaptive immunity driven pathology[1]

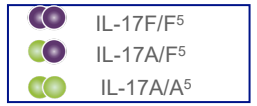


IL-17 production by innate lymphocytes can be independent of IL-23[6,7]

†U.S. prevalence.

References: 1. National Psoriasis Foundation. Statistics. Available at: https://www.psoriasis.org/content/statistics. Last accessed: March 2024; 2. Gladman DD, et al. Ann Rheum Dis. 2005; 64 (Suppl 2): ii14-7; 3. Reveille JD. AM J Med Sci. 2013; 345(6):431-36. 4. Calao M et al. PLoS ONE. 2018;13(7):e0200683. 5. Tsukazaki H, Kaito T. Int J Mol Sci. 2020;21(17):6401. 6. Cole S et al. Front Immunol. 2020;11:585134. 7. Łukasik Z, et al. Rheumatology (Oxford). 2021;60(Suppl 4):iv16-iv2

GL-BK-2400026 | Date of preparation: March 2024



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In Phase 3 clinical studies in moderate to severe plaque psoriasis bimekizumab demonstrated rapid, complete and maintained 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

Rapid	**>7 out of 10** patients	**achieved PASI 75**	**at Week 4 after 1 dose** [2,3,4]
Complete	**~6 out of 10** patients	**achieved PASI 100**	**at Week 16** [2,3,4]
Maintained	**>6 out of 10** patients	**achieved PASI 100**	**up to Year 1**[†2,4]

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

* U.S. Cross Sectional Patient Survey (N=500); Attributes are not exclusive

† 52-56 weeks

* Reported in more than 5% of bimekizumab-treated patients

References: 1. Gorelick J, et al. Dermatol Ther (Heidelb). 2019;9: 785-797. 2. Reich K, et al. Lancet. 2021;397(10273):487-498. 3. Gordon KB, et al. Lancet. 2021; 397(10273):475-486. 4. Warren RB, et al. N Engl J Med. 2021; 385(2):130-141.

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

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In post-hoc analyses bimekizumab demonstrated high levels of skin clearance in patients with an inadequate response to other therapies

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

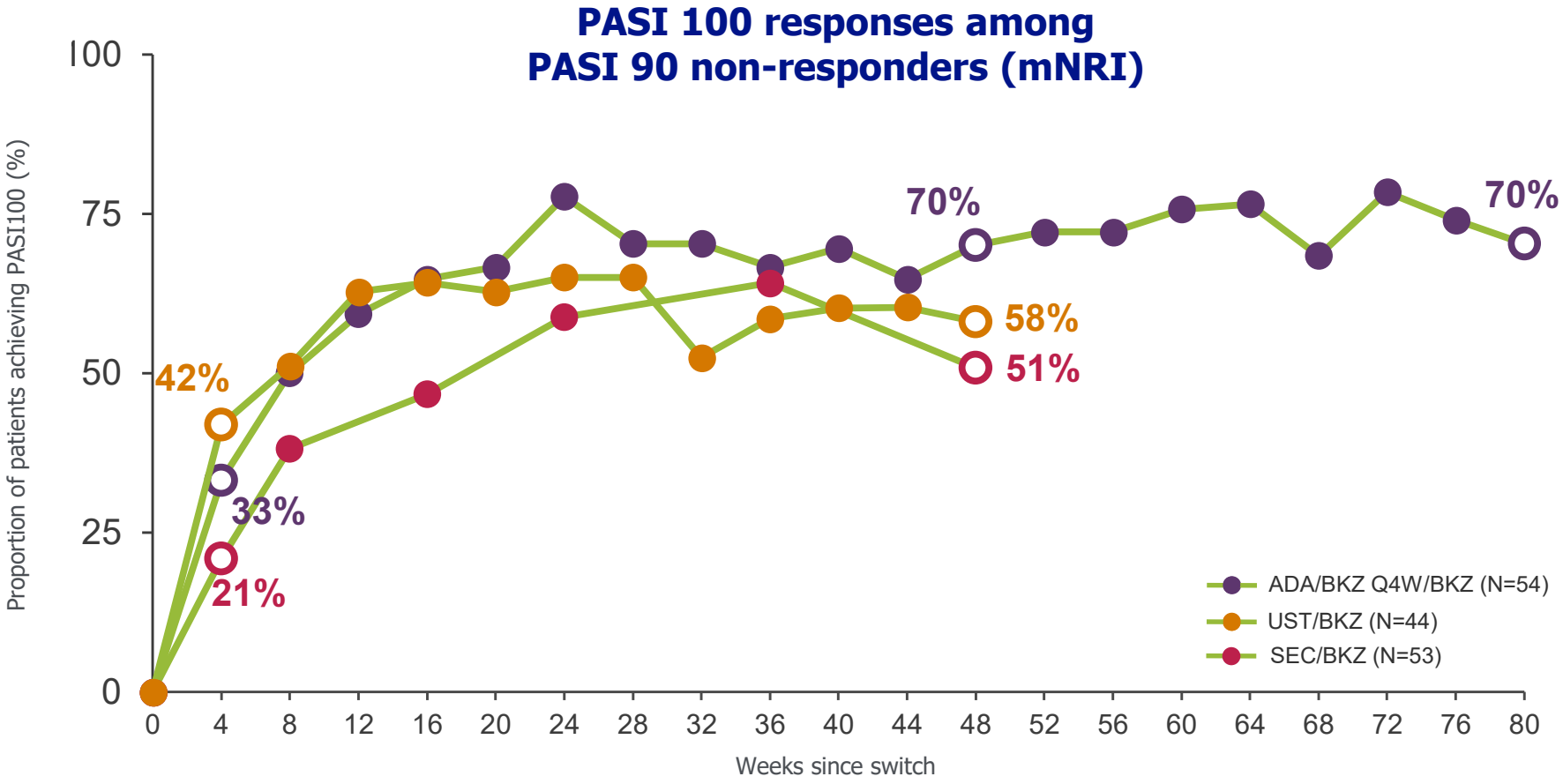

Figure adapted from reference 1. Clinical responses in PASI 90 non-responders initially treated with ADA, UST or SEC who switched to BKZ (mNRI). In BE SURE, patients switched from ADA to BKZ at Week 24. In BE VIVID, patients switched from UST to BKZ upon entry to the BE BRIGHT OLE at Week 52. In BE RADIANT, patients switched from SEC to BKZ upon entry to the BE RADIANT OLE at Week 48. On entering the OLEs, PASI 90 non-responders received BKZ 320 mg Q4W and could switch to Q8W during the OLE according to study designs. For mNRI, patients with missing data following treatment discontinuation due to lack of efficacy were considered non-responders, whereas all other missing data were imputed using multiple imputation.; ADA, adalimumab; BKZ, bimekizumab; mNRI, modified 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. Kokolakis G, et al. Br J Dermatol. 2023;188(3):330–40.

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Dr. Andrew Blauvelt
Blauvelt Consulting, LLC
Lake Oswego, OR, USA

BIMZELX®

Four-Year Data in Moderate to Severe Plaque Psoriasis

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Disclosures

Speaker received honoraria for Eli Lilly & Company, Pfizer, and UCB Pharma; served as a scientific adviser (received honoraria) for AbbVie, Abcentra, Aclaris, Affibody, Aligos, Almirall, Alumis, Amgen, AnaptysBio, Apogee, Arcutis, Arena, Aslan, Athenex, Bluefin Biomedicine, Boehringer Ingelheim, Bristol Myers Squibb, Cara Therapeutics, CTI BioPharma, Dermavant, EcoR1, Eli Lilly & Company, Escient, Evelo, Evommune, Forte, Galderma, HighlightII Pharma, Incyte, InnoventBio, Janssen, Landos, LEO Pharma, Lipidio, Microbion, Merck, Monte Rosa Therapeutics, Nektar, Novartis, Overtone Therapeutics, Paragon, Pfizer, Q32 Bio, Rani Therapeutics, RAPT Therapeutics, Regeneron, Sanofi-Genzyme, Spherix Global Insights, Sun Pharma, Takeda, TLL Pharmaceutical, TrialSpark, UCB Pharma, Union, Ventyx, Vibliome, and Xencor; has acted as a clinical study investigator (institution has received clinical study funds) for AbbVie, Acelyrin, Allakos, Almirall, Alumis, Amgen, Arcutis, Athenex, Boehringer Ingelheim, Bristol Myers Squibb, Concert, Dermavant, DermBiont, Eli Lilly & Company, Evelo, Evommune, Galderma, Incyte, Janssen, LEO Pharma, Merck, Novartis, Pfizer, Regeneron, Sanofi, Sun Pharma, Takeda, UCB Pharma, and Ventyx.

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Bimekizumab 4-year data

01

Bimekizumab efficacy from treatment initiation through 4 years in patients with moderate to severe plaque psoriasis:

A comprehensive, long-term, pooled analysis from BE BRIGHT[1]

02

Bimekizumab 4-year maintenance of responses in Week 16 responders with moderate to severe plaque psoriasis:

Results from the BE BRIGHT open-label extension phase 3 trial[2]

03

Bimekizumab safety and tolerability in moderate to severe plaque psoriasis:

Pooled analysis from up to 4 years of treatment in 5 phase 3/3b clinical trials[3]

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References: 1. Strober B. 2024 AAD. Oral Presentation. 2. Blauvelt A, et al. Bimekizumab 4-year maintenance of responses in Week 16 responders with moderate to severe plaque psoriasis: Results from the BE BRIGHT open label extension phase 3 trial. Abstract at the 2024 American Academy of Dermatology Annual Meeting, San Diego, CA, U.S., March 8–12, 2024. 3. Gordon KB, et al. Bimekizumab safety and tolerability in moderate to severe plaque psoriasis: Pooled analysis from up to 4 years of treatment in 5 phase 3/3b clinical trials. Abstract at the 2024 American Academy of Dermatology Annual Meeting, San Diego, CA, U.S., March 8–12, 2024.

01

OBJECTIVES:

- First disclosure of efficacy responses from BKZ treatment initiation through 4 years
- Report clinical and health-related quality of life outcomes, using the largest available 4-year pool

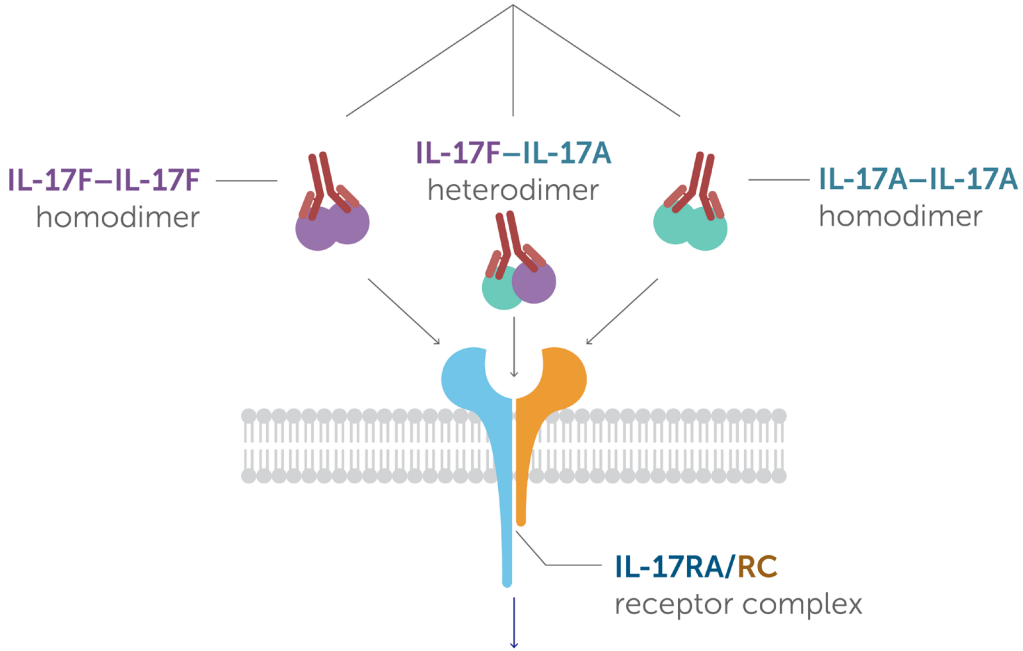
Background

- Psoriasis is a chronic disease; assessing long-term treatment efficacy is imperative[1]
- Bimekizumab (BKZ) is a monoclonal IgG1 antibody that selectively inhibits both interleukin (IL)-17A and IL-17F[2,3]
- BKZ has demonstrated rapid and superior efficacy in the treatment of moderate to severe plaque psoriasis versus ustekinumab, adalimumab, and secukinumab, with established long-term durability of response[4–8]

[a] Adapted from: Patel D et al. Ann Rheum Dis. 2013;72(Suppl 2):ii116–23. **1.** Mrowietz U. J Eur Acad Dermatol Venereol 2012;26 (Suppl 2):12–20; **2.** Adams R et al. Front Immunol 2020;11:1894; **3.** Glatt S et al. Ann Rheum D 2018;77:523–32; **4.** Reich K et al. Lancet 2021;397:487–98, NCT03370133; **5.** Gordon K et al. Lancet 2021;397:475–86, NCT03410992; **6.** Warren R et al. N Engl J Med 2021;385:130–41, NCT03412747; **7.** Reich K et al. N Engl J Med 2021;385:142–52, NCT03536884. **8.** Strober B et al. Br J Dermatol 2023;188:749–59. BKZ: bimekizumab; IL: interleukin.

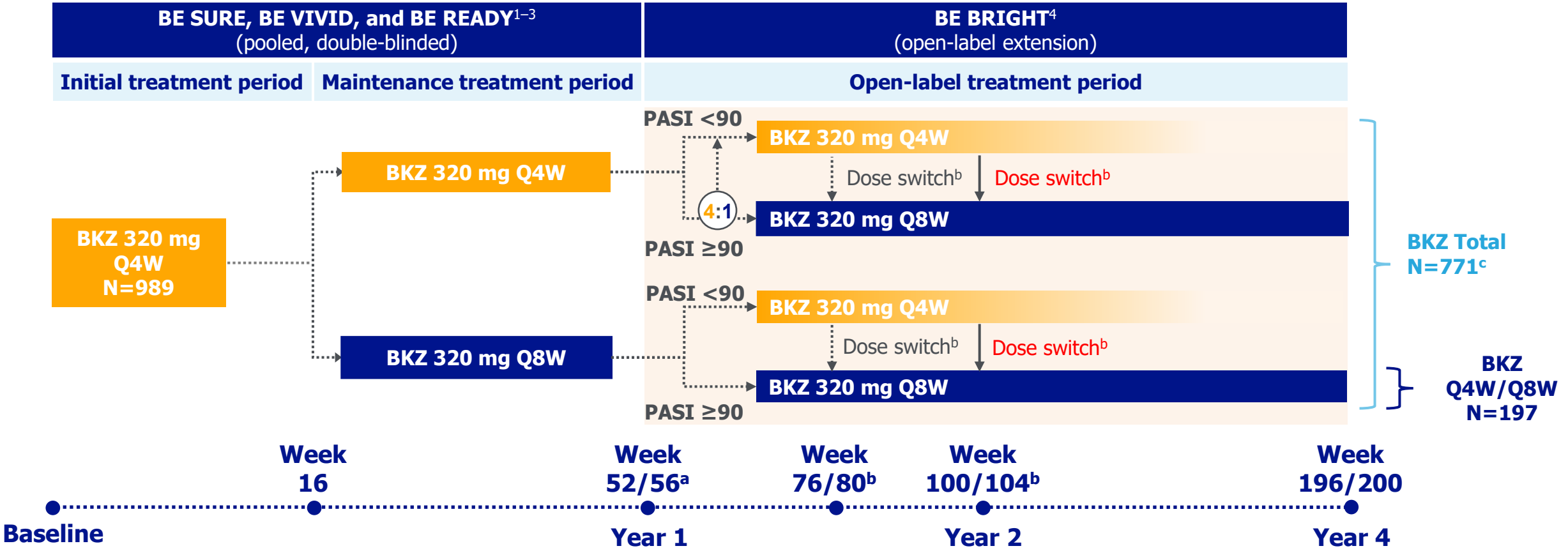
Reference: Adapted from Strober B. 2024 AAD. Oral Presentation.

Inhibition of IL-17 with BKZ[a]



Immune-mediated inflammatory disease[a]

Study design overview



- Proportions of patients achieving **PASI 90**, **PASI 100**, **PASI ≤2**, **BSA ≤1%**, and **DLQI 0/1** endpoints are reported from baseline through Year 4

Missing data were imputed using modified non-responder imputation (mNRI): patients who discontinued due to lack of efficacy/treatment-related adverse events were considered non-responders at subsequent timepoints; multiple imputation was used for other missing data. **[a]** BE VIVID lasted 52 weeks, BE SURE and BE READY lasted 56 weeks; **[b]** At Week 76/80 (OLE Week 24), patients achieving ≥PASI 90 could switch to Q8W at the investigator's discretion; all patients were re-assigned to BKZ Q8W at Week 100/104 (OLE Week 48) or the next scheduled visit via protocol amendment; **[c]** All patients who were randomized to BKZ 320 mg Q4W to Week 16, received BKZ Q4W or Q8W thereafter, and entered the OLE. **1.** Reich K et al. Lancet 2021;397:487–98, NCT03370133; **2.** Warren R et al. N Engl J Med2021;385:130–41, NCT03412747**; 3.** Gordon K et al. Lancet 2021;397:475–86, NCT03410992; **4.** Strober B et al. Br J Dermatol 2023;188:749–59, NCT03598790. BKZ: bimekizumab; BSA: body surface area; DLQI: Dermatology Life Quality Index; OLE: open-label extension; PASI 90/100: ≥90/100% improvement from baseline in Psoriasis Area and Severity Index; Q4W: every 4 weeks; Q8W: every 8 weeks. Reference: Adapted from Strober B. 2024 AAD. Oral Presentation.

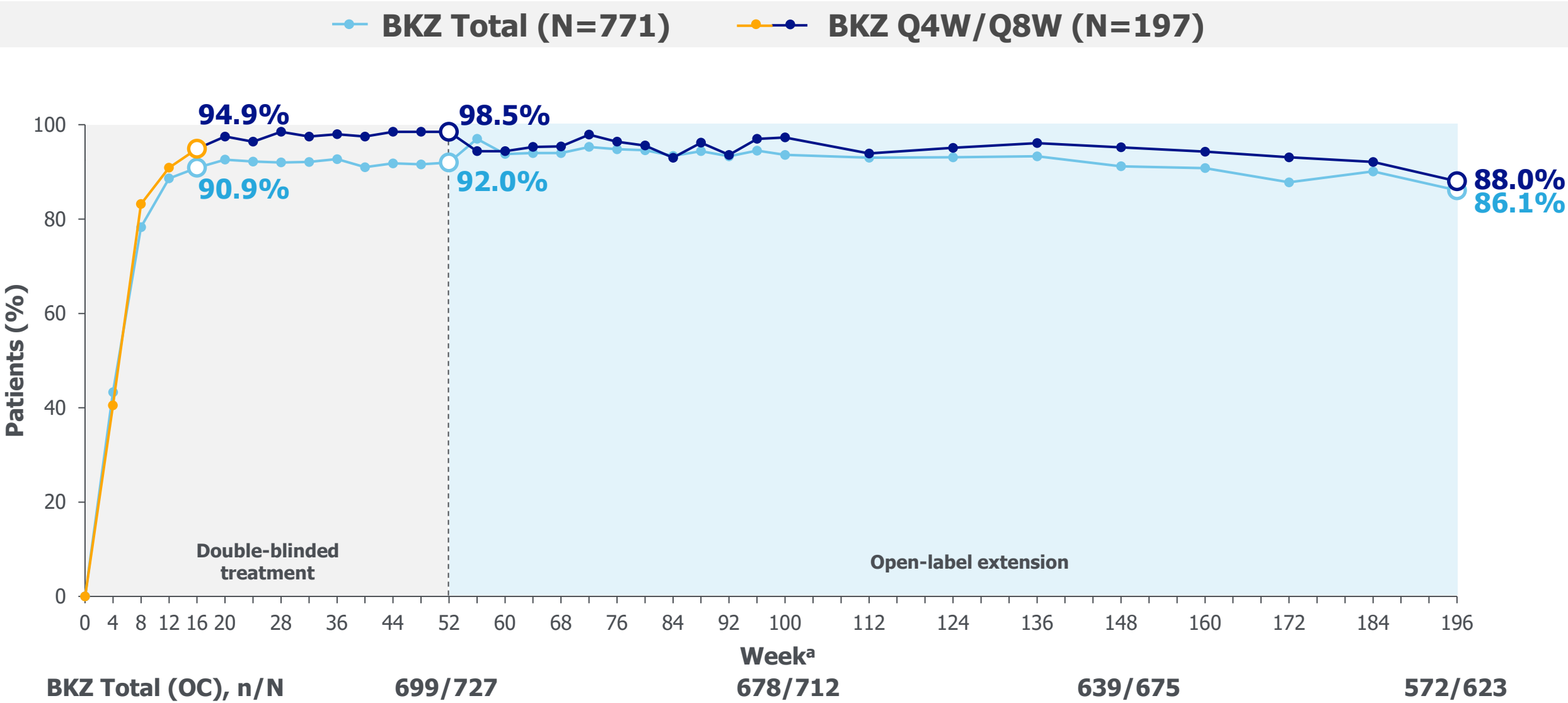
Baseline characteristics

	BKZ Total N=771[a]	BKZ Q4W/Q8W N=197
Age (years), mean ± SD	45.4 ± 13.5	45.0 ± 14.1
Male, n (%)	550 (71.3)	141 (71.6)
White, n (%)	656 (85.1)	185 (93.9)
Weight (kg), mean ± SD	89.7 ± 21.2	88.5 ± 20.8
BMI, (kg/m^2), mean ± SD	29.9 ± 6.6	29.3 ± 6.2
Duration of psoriasis (years), mean ± SD	18.6 ± 12.7	18.9 ± 12.0
PASI, mean ± SD	21.1 ± 7.6	20.4 ± 6.9
BSA (%), mean ± SD	27.0 ± 15.6	24.5 ± 12.2
IGA, n (%)		
3: moderate	508 (65.9)	142 (72.1)
4: severe	262 (34.0)	55 (27.9)
DLQI total score, mean ± SD	10.5 ± 6.3	10.8 ± 6.0
Any prior systemic therapy, n (%)	618 (80.2)	154 (78.2)
Any prior biologic therapy, n (%)	309 (40.1)	73 (37.1)
anti-TNF	113 (14.7)	19 (9.6)
anti-IL-17	193 (25.0)	48 (24.4)
anti-IL-23	37 (4.8)	13 (6.6)
anti-IL-12/23	43 (5.6)	13 (6.6)

[a] Baseline characteristics shown for all patients who were randomized to BKZ 320 mg Q4W to Week 16, received BKZ Q4W or Q8W thereafter and entered the OLE. BKZ: bimekizumab; BMI: body mass index; BSA: body surface area; DLQI: Dermatology Life Quality Index; IGA: Investigator's Global Assessment; IL: interleukin; OLE: open-label extension; PASI: Psoriasis Area and Severity Index; Q4W: every 4 weeks; Q8W: every 8 weeks; SD: standard deviation; TNF: tumor necrosis factor.

Reference: Adapted from Strober B. 2024 AAD. Oral Presentation.

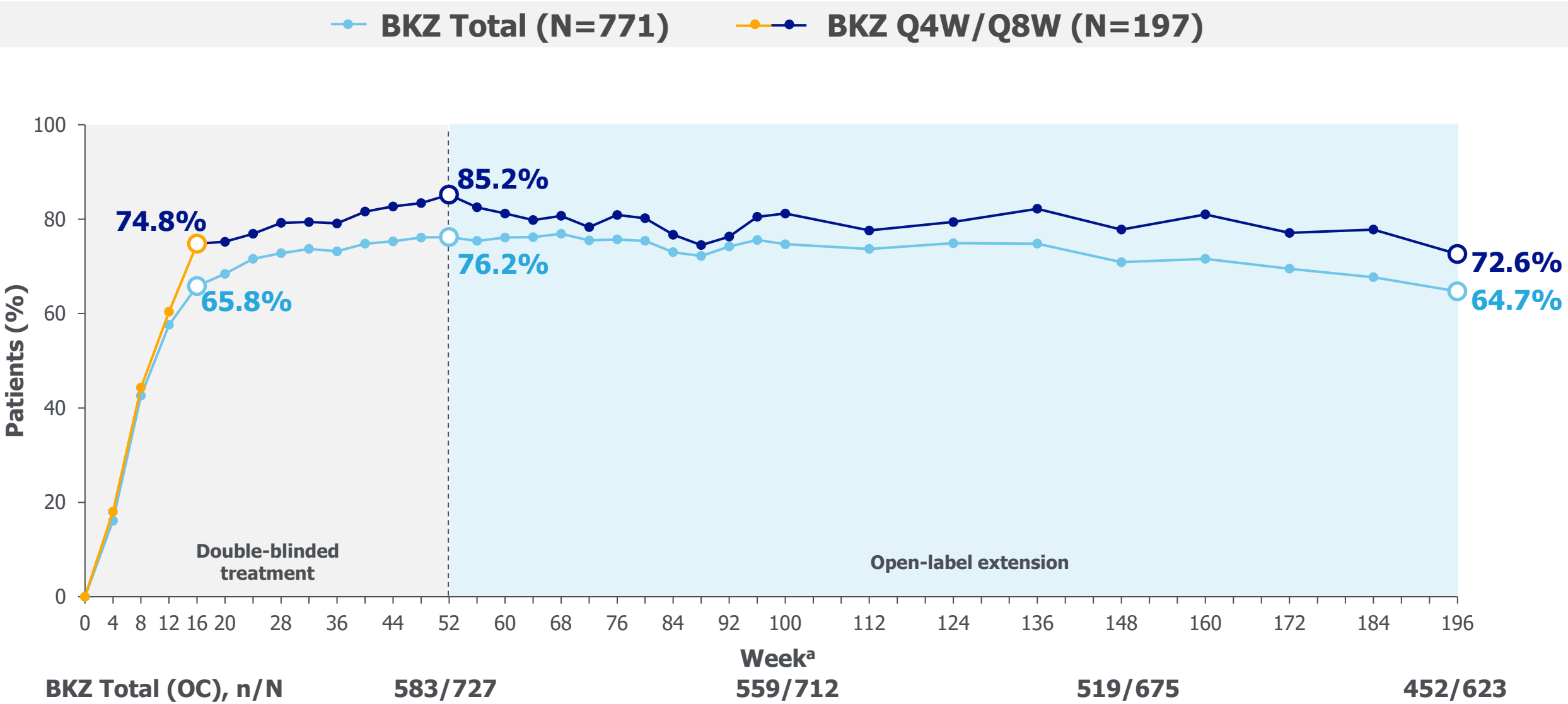
PASI 90 responses over 4 years (mNRI)



Gold line coloring signifies BKZ Q4W dosing. Missing data were imputed using modified non-responder imputation (mNRI): patients who discontinued due to lack of efficacy/treatment-related adverse events were considered non-responders at subsequent timepoints; multiple imputation was used for other missing data. For OC, data from the point of escape and through Week 56 of BE READY for these subjects are considered as missing, and from the point of entry into BE BRIGHT their data are presented as observed. **[a]** BE VIVID lasted 52 weeks and BE SURE and BE READY lasted 56 weeks; to pool data across studies, Week 56 data were not included. In this figure, the period after Week 52 corresponds to the BE BRIGHT OLE. BKZ: bimekizumab; mNRI: modified non-responder imputation; OC: observed cases; OLE: open-label extension; PASI 90: ≥90% improvement from baseline in Psoriasis Area and Severity Index; Q4W: every 4 weeks; Q8W: every 8 weeks.

Reference: Adapted from Strober B. 2024 AAD. Oral Presentation.

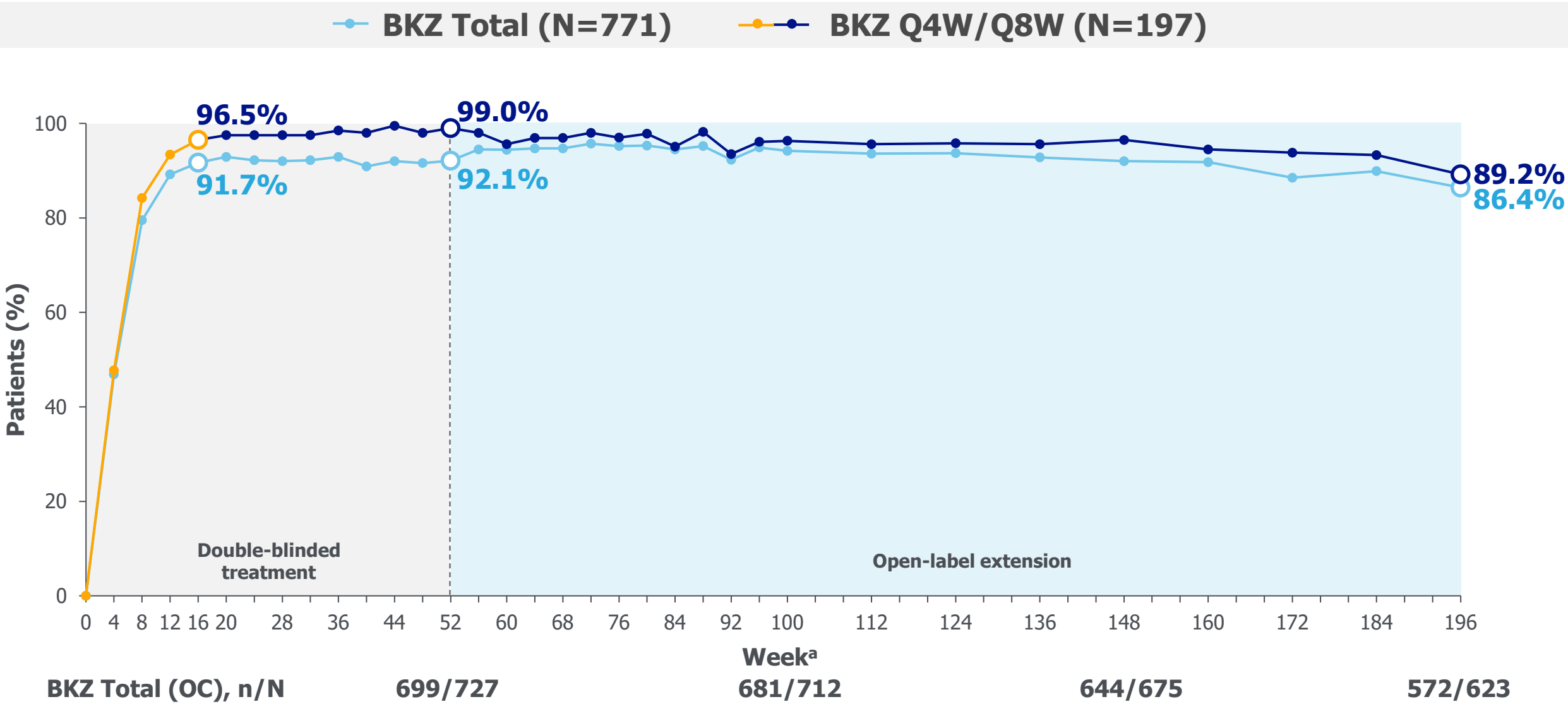
PASI 100 responses over 4 years (mNRI)



Gold line coloring signifies BKZ Q4W dosing. Missing data were imputed using modified non-responder imputation (mNRI): patients who discontinued due to lack of efficacy/treatment-related adverse events were considered non-responders at subsequent timepoints; multiple imputation was used for other missing data. For OC, data from the point of escape and through Week 56 of BE READY for these subjects are considered as missing, and from the point of entry into BE BRIGHT their data are presented as observed. **[a]** BE VIVID lasted 52 weeks and BE SURE and BE READY lasted 56 weeks; to pool data across studies, Week 56 data were not included. In this figure, the period after Week 52 corresponds to the BE BRIGHT OLE. BKZ: bimekizumab; mNRI: modified non-responder imputation; OC: observed cases; OLE: open-label extension; PASI 100: 100% improvement from baseline in Psoriasis Area and Severity Index; Q4W: every 4 weeks; Q8W: every 8 weeks.

Reference: Adapted from Strober B. 2024 AAD. Oral Presentation.

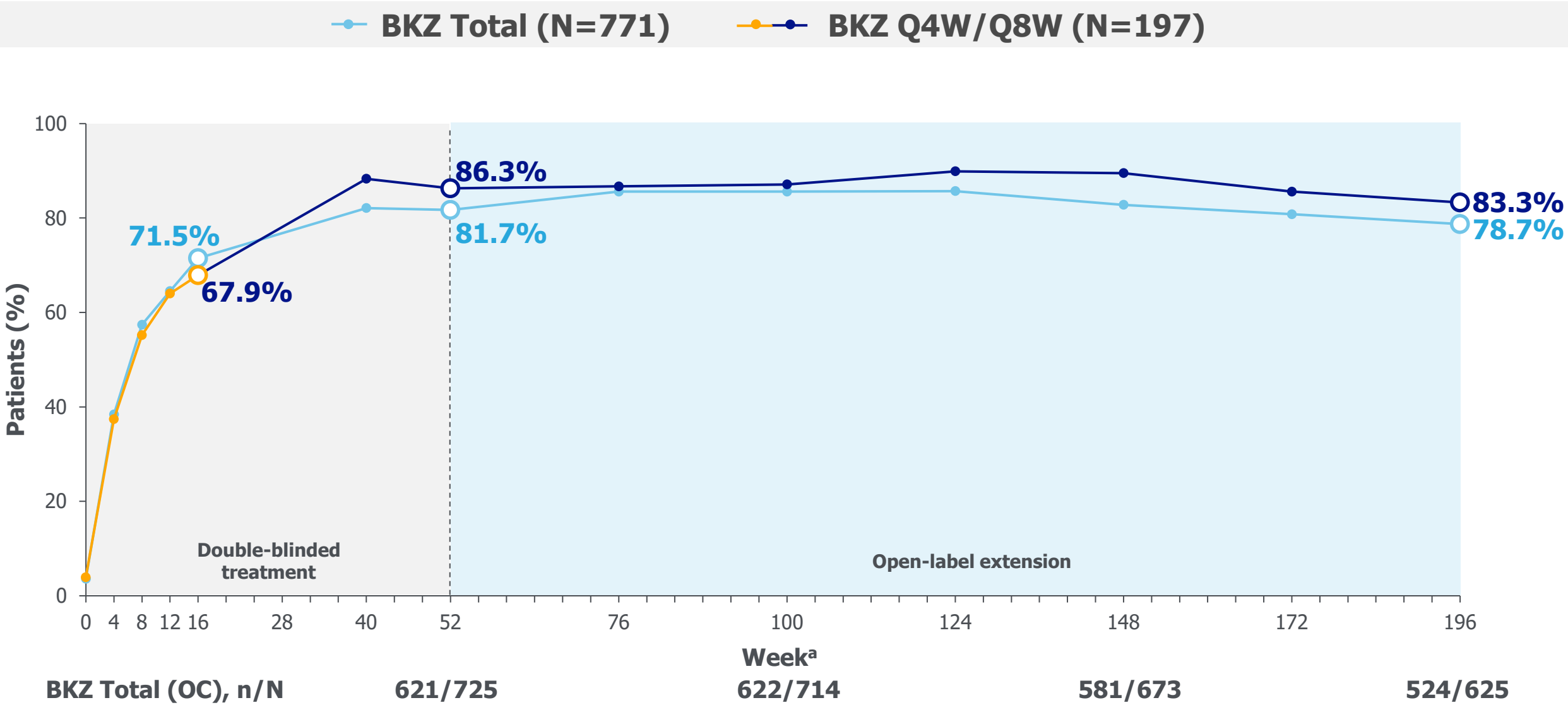
PASI ≤2 responses over 4 years (mNRI)



Gold line coloring signifies BKZ Q4W dosing. Missing data were imputed using modified non-responder imputation (mNRI): patients who discontinued due to lack of efficacy/treatment-related adverse events were considered non-responders at subsequent timepoints; multiple imputation was used for other missing data. For OC, data from the point of escape and through Week 56 of BE READY for these subjects are considered as missing, and from the point of entry into BE BRIGHT their data are presented as observed. **[a]** BE VIVID lasted 52 weeks and BE SURE and BE READY lasted 56 weeks; to pool data across studies, Week 56 data were not included. In this figure, the period after Week 52 corresponds to the BE BRIGHT OLE. BKZ: bimekizumab; mNRI: modified non-responder imputation; OC: observed cases; OLE: open-label extension; PASI: Psoriasis Area and Severity Assessment Index; Q4W: every 4 weeks; Q8W: every 8 weeks.

Reference: Adapted from Strober B. 2024 AAD. Oral Presentation.

DLQI 0/1 responses over 4 years (mNRI)



Gold line coloring signifies BKZ Q4W dosing. Missing data were imputed using modified non-responder imputation (mNRI): patients who discontinued due to lack of efficacy/treatment-related adverse events were considered non-responders at subsequent timepoints; multiple imputation was used for other missing data. For OC, data from the point of escape and through Week 56 of BE READY for these subjects are considered as missing, and from the point of entry into BE BRIGHT their data are presented as observed. **[a]** BE VIVID lasted 52 weeks and BE SURE and BE READY lasted 56 weeks; to pool data across studies, Week 56 data were not included. In this figure, the period after Week 52 corresponds to the BE BRIGHT OLE. Here, Week 52 corresponds to the Week 48 assessment for BE SURE and BE READY, and Week 52 for BE VIVID, due to DLQI being assessed on a different schedule in these studies. BKZ: bimekizumab; DLQI: Dermatology Life Quality Index; mNRI: modified non-responder imputation; OC: observed cases; OLE: open-label extension; Q4W: every 4 weeks; Q8W: every 8 weeks.

Reference: Adapted from Strober B. 2024 AAD. Oral Presentation.

02

OBJECTIVE:

To evaluate maintenance of clinical responses over 4 years among patients with psoriasis who achieved complete or near-complete skin clearance after 16 weeks of bimekizumab (BKZ) treatment

Background

- Maintenance of high responses to BKZ has been reported previously through 3 years in patients with moderate to severe plaque psoriasis[1]

Methods

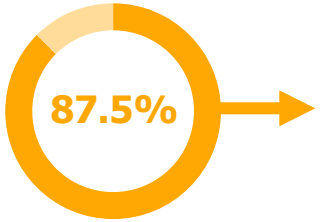
- Data were pooled from the 52-week BE VIVID and 56-week BE SURE and BE READY phase 3 trials, and their open-label extension BE BRIGHT[1–4]
- Maintenance of **PASI 90**, **PASI 100**, and **BSA ≤1%** to Year 4 was assessed in respective Week 16 responders. **DLQI 0/1** was also assessed for patients who were PASI 100 responders at Week 16
- Maintenance of responses are reported using modified non-responder imputation (mNRI):[a] patients who discontinued due to lack of efficacy/treatment-related adverse events were considered non-responders; multiple imputation was used for other missing data. Observed case results are also presented

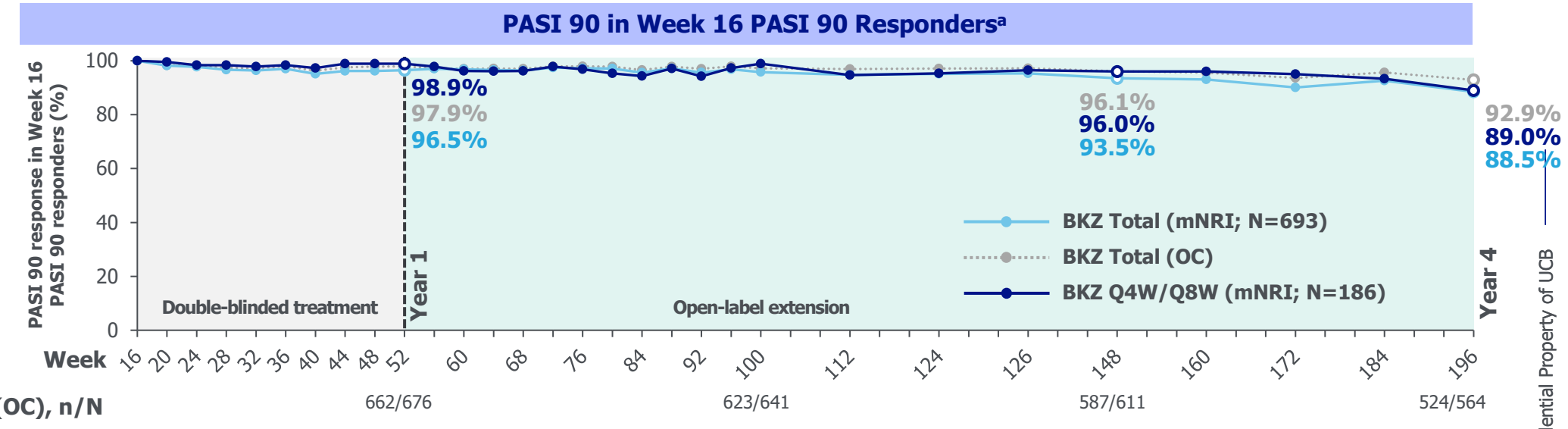
[a] Patients who entered the BE READY escape arm were considered as non-responders from the date of escape until the end of BE READY, after which they were considered in the same way as all other non-escape patients during the BE BRIGHT OLE.[5] **1.** Strober B et al. Br J Dermatol 2023;188:749–59, NCT03598790; **2.** Reich K et al. Lancet 2021;397:487–98, NCT03370133; **3.** Warren B et al. N Engl J Med 2021;385:130–41, NCT03412747; **4.** Gordon KB et al. Lancet 2021;397:475–86, NCT03410992. 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 Assessment; PASI 90/100: ≥90%/100% improvement from baseline in Psoriasis Area and Severity Index.

Reference:. Adapted from Blauvelt A, et al. Bimekizumab 4-year maintenance of responses in Week 16 responders with moderate to severe plaque psoriasis: Results from the BE BRIGHT open label extension phase 3 trial. Abstract at the 2024 American Academy of Dermatology Annual Meeting, San Diego, CA, U.S., March 8–12, 2024

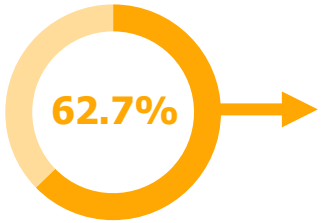
PASI 90 and 100 response maintenance in patients who entered the OLE

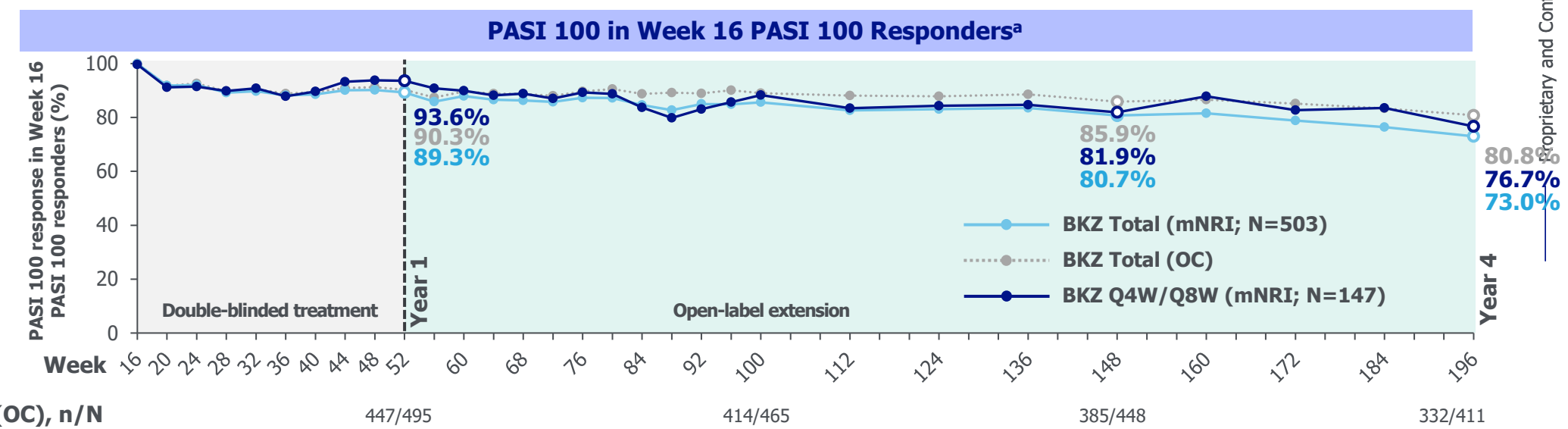
Week 16 PASI 90 response rate in BKZ-randomized patients (N=989; NRI)





Week 16 PASI 100 response rate in BKZ-randomized patients (N=989; NRI)





Results differ slightly from the accepted abstract due to updated mNRI methodology. **[a]** BE VIVID lasted 52 weeks and BE SURE and BE READY lasted 56 weeks; to pool data across studies, Week 56 data were not included. In these figures, the period after Week 52 corresponds to the BE BRIGHT OLE. BKZ: bimekizumab; mNRI: modified non-responder imputation; NRI: non-responder imputation; OC: observed case; OLE: open-label extension; PASI: Psoriasis Area and Severity Index; PASI 90/100: ≥90/100% improvement from baseline in PASI; Q4W: every 4 weeks; Q8W: every 8 weeks.

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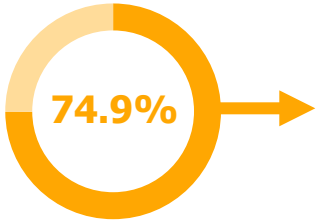
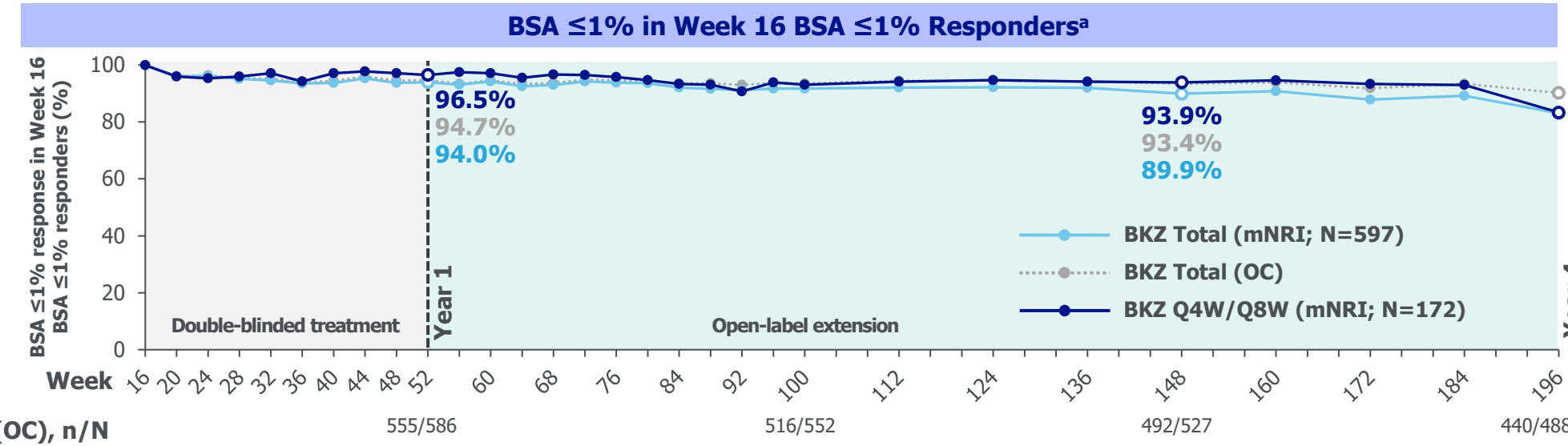
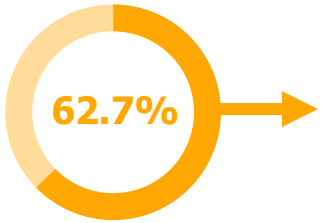
BSA ≤1% and DLQI 0/1 response maintenance in patients who entered the OLE

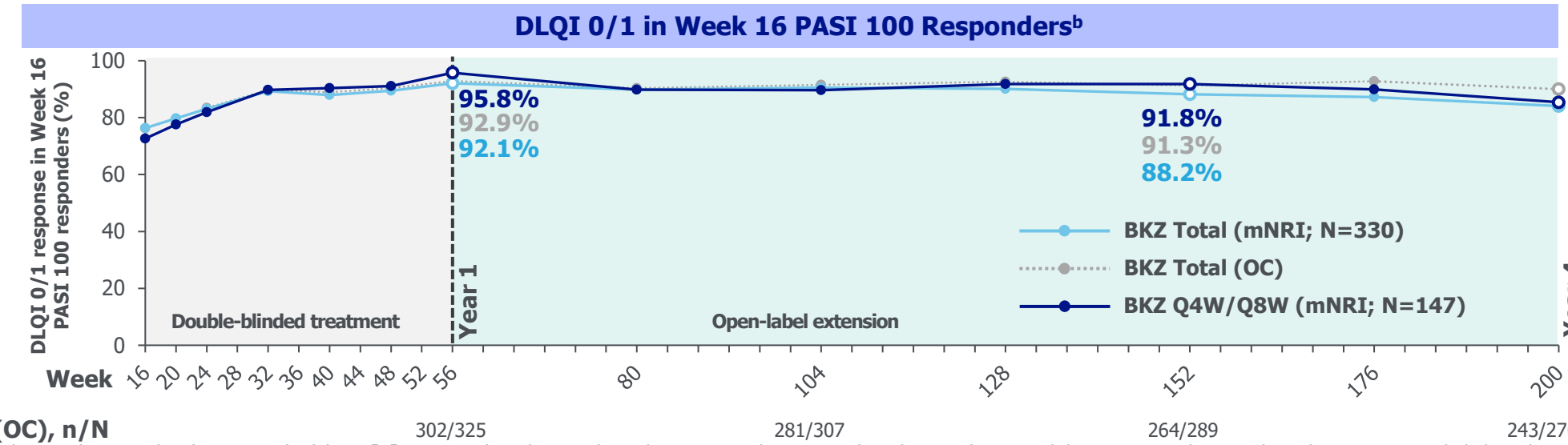
Week 16 BSA ≤1% response rate in BKZ-randomized patients (N=989; NRI)





Week 16 PASI 100 response rate in BKZ-randomized patients (N=989; NRI)





Results differ slightly from the accepted abstract due to updated mNRI methodology. **[a]** BE VIVID lasted 52 weeks and BE SURE and BE READY lasted 56 weeks; to pool data across studies, Week 56 data were not included. In this figure, the period after Week 52 corresponds to the BE BRIGHT OLE; **[b]** DLQI 0/1 responses were performed on a different schedule to BE SURE and BE READY in BE VIVID; BE VIVID data are therefore not included in this analysis and Week 56 was used as the last common timepoint when pooling the studies. BKZ: bimekizumab; BSA: body surface area; DLQI: Dermatology Life Quality Index; mNRI: modified non-responder imputation; NRI: non-responder imputation; OC: observed case; OLE: open-label extension; PASI: Psoriasis Area and Severity Index; PASI 100: 100% improvement from baseline in Psoriasis Area and Severity Index; Q4W: every 4 weeks; Q8W: every 8 weeks.

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03

OBJECTIVE:

To evaluate bimekizumab (BKZ) safety data up to 4 years in patients with moderate to severe plaque psoriasis, using the largest pool of phase 3/3b safety data

Background

- Psoriasis is a chronic condition requiring long-term management, so evaluating **long-term safety** of treatments is essential to informing decision-making for clinicians while managing risk for patients.[1]

Methods

- Data were pooled from the BE SURE, BE VIVID, and BE READY phase 3 trials, their open-label extension (OLE) BE BRIGHT, and the BE RADIANT phase 3b trial.[2–6]
- Included patients received BKZ 320 mg every 4 weeks (Q4W) or every 8 weeks (Q8W); all received Q8W from Week 64 (BE RADIANT) / OLE Week 48 (BE BRIGHT) or the next scheduled clinic visit
- Patients switching from adalimumab, ustekinumab, or secukinumab to BKZ in BE SURE, BE VIVID, and BE RADIANT, respectively, are also included following switch to BKZ
- **Treatment-emergent adverse events (TEAEs)** are reported here **over 4 years** using exposure-adjusted incidence rates (EAIRs) per 100 patient-years (PY)
- TEAEs were also evaluated **separately for Years 1**, **2**, **3**, and **4** (Weeks 0–52, 52–104, 104–156, and 156–208) of BKZ treatment.

1. Al-Janabi A & Yiu ZZN Psoriasis (Auckl) 2022;12:1–14; **2.** Warren RB et al. N Engl J Med 2021;385:130–41, NCT03412747; **3.** Reich K et al. Lancet 2021;397:487–98, NCT03370133; **4.** Gordon KB et al. Lancet 2021;397:475–86, NCT03410992; **5.** Gordon KB et al. JAMA Dermatol 2022;158:735–44, NCT03598790; **6.** Reich K et al. N Engl J Med 2021;385:142–52, NCT03536884. BKZ: bimekizumab; EAIRs: exposure-adjusted incidence rates; OLE: open-label extension; PY: patient-years; Q4W: every 4 weeks; Q8W: every 8 weeks; TEAEs: treatment-emergent adverse events.

Reference: Adapted from Gordon KB, et al. Bimekizumab safety and tolerability in moderate to severe plaque psoriasis: Pooled analysis from up to 4 years of treatment in 5 phase 3/3b clinical trials. Abstract at the 2024 American Academy of Dermatology Annual Meeting, San Diego, CA, U.S., March 8–12, 2024.

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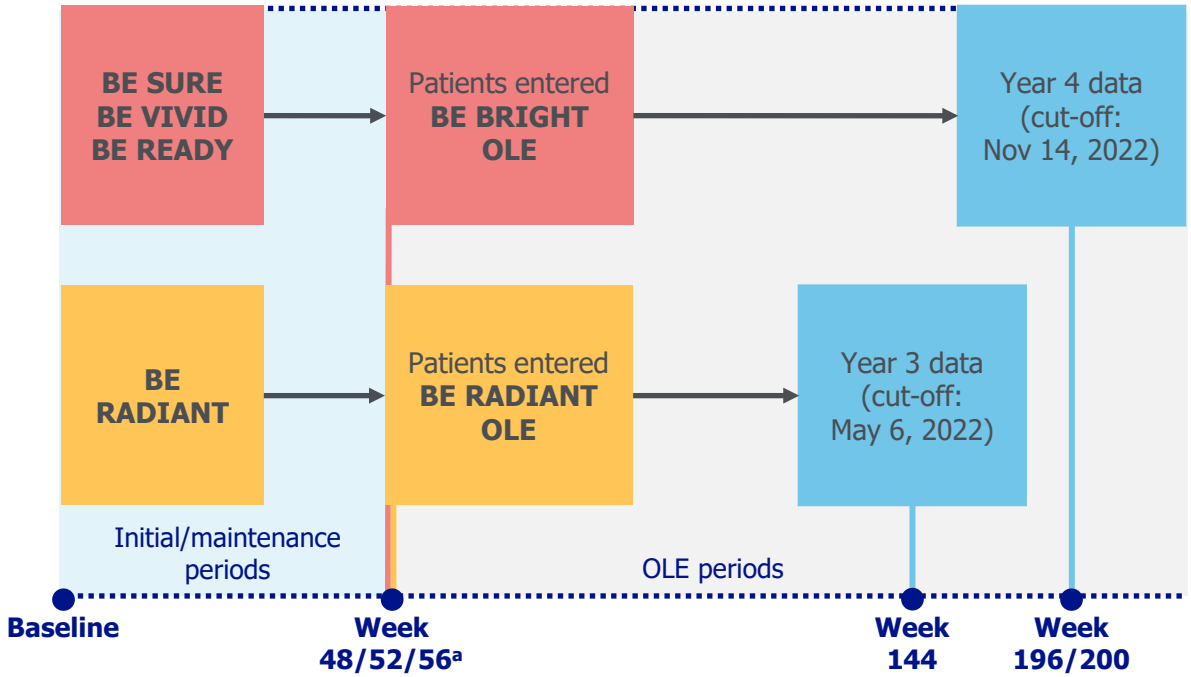
Included studies

- Data were pooled for all patients who received ≥1 BKZ dose in the studies below (**BKZ Total**).



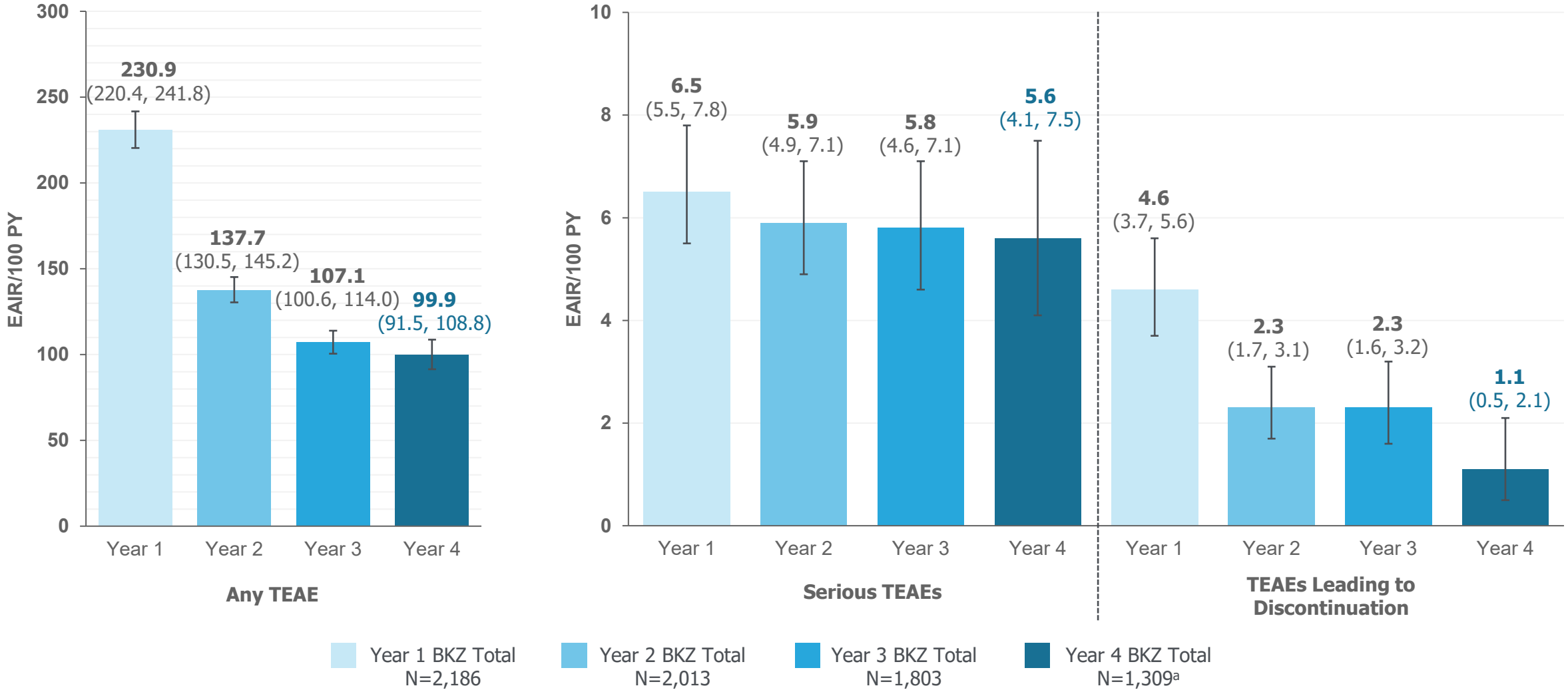
- The BE RADIANT trial ran for 3 years; therefore, the overall total pooled exposure only includes BE RADIANT data to Year 3, in addition to BE BRIGHT data to Year 4.

Summary of exposure and TEAEs

	BKZ Total				
	Year 1 N=2,186	Year 2 N=2,013	Year 3 N=1,803	Year 4 N=1,309	Overall N=2,186
Weeks	0–52	52–104[b]	104–156[b]	156–208	All[c]
Total exposure, PY	2,053.3	1,904.3	1,521.1	819.5	6,324.3[d]
Mean exposure ± SD, days	345.7 ± 63.4	340.9 ± 62.2	328.5 ± 58.8	237.0 ± 94.0	988.4 ± 388.5
Median exposure (range), days	364 (23–364)	364 (1–364)	364 (7–364)	281 (1–364)	1,013 (23–1,569)
TEAE Summary, EAIR/100 PY (95% CI)					
Any TEAE	230.9 (220.4, 241.8)	137.7 (130.5, 145.2)	107.1 (100.6, 114.0)	99.9 (91.5, 108.8)	170.5[e] (163.2, 178.1)
Serious TEAEs	6.5 (5.5, 7.8)	5.9 (4.9, 7.1)	5.8 (4.6, 7.1)	5.6 (4.1, 7.5)	5.5[f] (4.9, 6.2)
TEAEs leading to discontinuation	4.6 (3.7, 5.6)	2.3 (1.7, 3.1)	2.3 (1.6, 3.2)	1.1 (0.5, 2.1)	2.9 (2.5, 3.3)
Severe TEAEs	6.0 (5.0, 7.2)	5.0 (4.1, 6.2)	4.8 (3.7, 6.0)	5.1 (3.7, 6.9)	4.8 (4.3, 5.4)
TEAEs leading to death	0.3 (0.1, 0.6)	0.3 (0.1, 0.7)	0.5 (0.2, 0.9)	0.2 (0.0, 0.9)	0.3 (0.2, 0.5)

Data and any adjudication are shown as of the data cut-offs (BE RADIANT: May 6, 2022; BE BRIGHT: Nov 14, 2022). **[a]** Patients entered the BE BRIGHT OLE at Week 52 if they were enrolled in BE VIVID and Week 56 if they were enrolled in BE SURE or BE READY; patients in BE RADIANT entered the BE RADIANT OLE period at Week 48; **[b]** All patients were switched to BKZ 320 mg Q8W at the next scheduled clinic visit on or after the Week 64/Week 104 visit (BE RADIANT/BE BRIGHT) following protocol amendment; **[c]** Entire pooled study period; **[d]** Total BKZ exposure over 4 years is greater than the sum of BKZ exposure in individual years, as data beyond Week 208 are included due to the use of a cut-off date; **[e]** The EAIR of TEAEs over 4 years was numerically lower in patients receiving BKZ Q8W vs Q4W (115.4/100 PY vs 224.4/100 PY); **[f]** The rate of serious TEAEs over 4 years is lower than the rate in any individual year due to time not accounted for in the individual year summaries. BKZ: bimekizumab; CI: confidence interval; EAIR: exposure-adjusted incidence rate; SD: standard deviation; OLE: open-label extension; PY: patient-years; TEAE: treatment-emergent adverse event.

Incidence rates of TEAEs: *Any, Serious, and Discontinuations Over Time (BKZ Total)*



Overall, the EAIR of TEAEs **decreased with longer BKZ exposure** over 4 years

Data are reported as EAIRs; error bars represent 95% CI. Data are presented for the BKZ Total for the full pooled trial period, and separately for Years 1 (Weeks 0–52), 2 (Weeks 52–104), 3 (Weeks 104–156), and 4 (Weeks 156–208). Data were pooled for all patients who received ≥1 BKZ dose in each of the periods examined (BKZ Total). **[a]** BE RADIANT patients are not included after Year 3. BKZ: bimekizumab; CI: confidence intervals; EAIR: exposure-adjusted incidence rate; PY: patient-years; TEAE: treatment-emergent adverse event.

Most common TEAEs and TEAEs of interest (BKZ Total)

	Year 1 (N=2,186)	Year 2 (N=2,013)	Year 3 (N=1,803)[a]	Year 4 (N=1,309)[a]	Overall (N=2,186)
Most Common TEAEs, EAIR/100 PY (95% CI)					
Nasopharyngitis	25.8 (23.5, 28.3)	13.2 (11.6, 15.0)	5.4 (4.3, 6.7)	5.9 (4.4, 7.9)	12.7 (11.7, 13.8)
Oral candidiasis	18.9 (16.9, 21.0)	10.7 (9.2, 12.3)	6.8 (5.6, 8.3)	5.4 (3.9, 7.3)	8.9 (8.1, 9.7)[b]
Upper respiratory tract infection	10.4 (9.0, 12.0)	5.7 (4.7, 6.9)	3.7 (2.8, 4.9)	3.9 (2.6, 5.5)	5.7 (5.1, 6.4)
TEAEs of Interest, EAIR/100 PY (95% CI)					
Serious infections	1.7 (1.2, 2.3)	0.8 (0.5, 1.4)	1.4 (0.9, 2.1)	1.1 (0.5, 2.1)	1.3 (1.0, 1.6)
Active tuberculosis	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
Fungal infections	30.6 (28.0, 33.3)	18.8 (16.8, 21.0)	11.9 (10.2, 13.8)	8.6 (6.6, 10.9)	15.7 (14.6, 16.9)
Candida infections	22.2 (20.1, 24.4)	12.8 (11.2, 14.6)	7.8 (6.5, 9.4)	5.7 (4.1, 7.6)	10.4 (9.5, 11.3)
Oral candidiasis	18.9 (16.9, 21.0)	10.7 (9.2, 12.3)	6.8 (5.6, 8.3)	5.4 (3.9, 7.3)	8.9 (8.1, 9.7)[b]
Adjudicated inflammatory bowel disease[c]	0.3 (0.1, 0.7)	0.2 (0.0, 0.5)	0.1 (0.0, 0.4)	0.1 (0.0, 0.7)	0.2 (0.1, 0.3)
Adjudicated major adverse cardiac event	0.5 (0.3, 1.0)	0.3 (0.1, 0.7)	0.6 (0.3, 1.1)	1.1 (0.5, 2.1)	0.6 (0.4, 0.8)
Malignancies	0.9 (0.6, 1.5)	1.1 (0.7, 1.7)	0.9 (0.5, 1.5)	1.0 (0.4, 1.9)	0.9 (0.6, 1.1)
Excluding non-melanoma skin cancer	0.4 (0.2, 0.8)	0.6 (0.3, 1.1)	0.7 (0.4, 1.3)	0.9 (0.3, 1.8)	0.6 (0.4, 0.8)
Adjudicated suicidal ideation and behavior	0.1 (0.0, 0.4)	0.2 (0.0, 0.5)	0.1 (0.0, 0.5)	0.0 (0.0, 0.0)	0.1 (0.1, 0.2)
Neutropenia events	0.8 (0.5, 1.3)	0.5 (0.3, 1.0)	0.1 (0.0, 0.5)	0.2 (0.0, 0.9)	0.5 (0.3, 0.7)
ALT or AST elevations					
>3x ULN	2.6 (1.9, 3.4)	2.4 (1.7, 3.2)	1.9 (1.3, 2.8)	1.8 (1.0, 3.0)	1.9 (1.6, 2.3)
>5x ULN[d]	0.8 (0.5, 1.3)	0.3 (0.1, 0.7)	0.5 (0.2, 1.0)	0.6 (0.2, 1.4)	0.5 (0.4, 0.7)
Serious hypersensitivity reactions[e]	0.1 (0.0, 0.4)	0.1 (0.0, 0.4)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.1 (0.0, 0.2)
Injection site reactions	3.3 (2.5, 4.2)	1.1 (0.6, 1.6)	1.2 (0.7, 1.9)	0.4 (0.1, 1.1)	1.7 (1.4, 2.0)

Data were pooled from the BE SURE, BE VIVID, and BE READY feeder trials, their OLE BE BRIGHT, and BE RADIANT. Data are presented for the BKZ Total for the full pooled trial period, and separately for Years 1 (Weeks 0–52), 2 (Weeks 52–104), 3 (Weeks 104–156), and 4 (Weeks 156-208). Data were pooled for all patients who received ≥1 BKZ dose in each of the periods examined (BKZ Total). **[a]** Confounding factors linked to the COVID-19 pandemic, including social isolation, mask-wearing, and lockdowns, may have impacted Year 3 and Year 4 data, particularly respiratory infection TEAEs such as nasopharyngitis; **[b]** The EAIR for oral candidiasis over 4 years was numerically lower in patients receiving BKZ Q8W vs Q4W (6.5/100 PY vs 16.7/100 PY); **[c]** Includes any TEAE adjudicated as definite or probable IBD; **[d]** Patients with elevations >5x ULN were a subset of patients with elevations >3x ULN; **[e]** No anaphylactic reactions associated with BKZ were reported. ALT: alanine aminotransferase; AST: aspartate aminotransferase; BKZ: bimekizumab; CI: confidence interval; EAIR: exposure-adjusted incidence rate; OLE: open-label extension; PY: patient-years; Q4W: every 4 weeks; Q8W: every 8 weeks; TEAE: treatment-emergent adverse event, ULN: upper limit of normal.

Conclusions

01

- In patients who received BKZ and enrolled in the OLE, high rates of clinical and health-related quality-of-life responses were achieved rapidly and were highly durable in the long-term through 4 years[1]

>6 out of 10

patients **achieved PASI 100 at year 4[1±]**

- PASI 90, PASI 100, PASI ≤2, BSA ≤1% and DLQI 0/1 response rates were consistent in the subset of patients enrolled in the OLE who received BKZ 320 mg Q4W to Week 16 then Q8W thereafter, the approved dosing regimen for the majority of patients with plaque psoriasis[1]

02

- Pooled data from three trials and their open-label extension found that, among Week 16 responders, high clinical responses were maintained through 4 years of bimekizumab 320 mg treatment[2]

~9 out of 10

patients who achieved **PASI90 at Week 16,** maintained **response to year 4[2±]**

>7 out of 10

patients who achieved **PASI100 at Week 16,** maintained **response to year 4[2±]**

03

- Bimekizumab demonstrated good tolerability and a consistent safety profile over 4 years in patients with moderate to severe plaque psoriasis[3]

- EAIRs of TEAEs remained consistent or decreased with longer bimekizumab exposure, with no new safety signals observed[3]

References: 1. Strober B. 2024 AAD. Oral Presentation. 2. Blauvelt A, et al. Bimekizumab 4-year maintenance of responses in Week 16 responders with moderate to severe plaque psoriasis: Results from the BE BRIGHT open label extension phase 3 trial. Abstract at the 2024 American Academy of Dermatology Annual Meeting, San Diego, CA, U.S., March 8–12, 2024. 3. Gordon KB, et al. Bimekizumab safety and tolerability in moderate to severe plaque psoriasis: Pooled analysis from up to 4 years of treatment in 5 phase 3/3b clinical trials. Abstract at the 2024 American Academy of Dermatology Annual Meeting, San Diego, CA, U.S., March 8–12, 2024.

± - modified non-responder imputation; BKZ Total

Summary

Emmanuel Caeymaex

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

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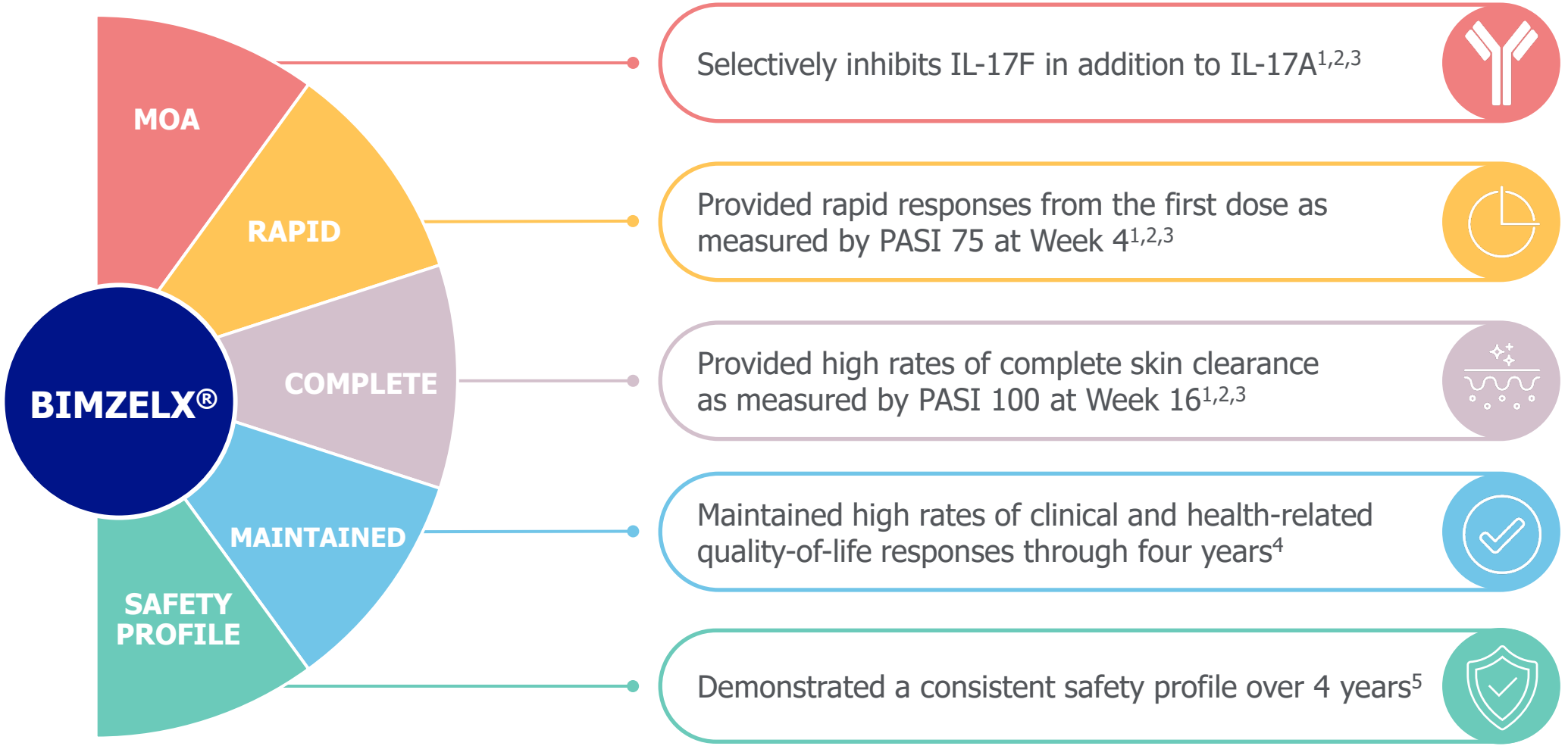
Summary | BIMZELX® in moderate to severe plaque psoriasis



References: 1. Reich K, et al. Lancet. 2021;397(10273):487-498; 2. Gordon KB, et al. Lancet. 2021; 397(10273):475-486; 3. Warren RB, et al. N Engl J Med. 2021; 385(2):130-141; 4. Strober B. 2024 AAD. Oral Presentation. 5. Gordon KB,, et al. Bimekizumab safety and tolerability in moderate to severe plaque psoriasis: Pooled analysis from up to 4 years of treatment in 5 phase 3/3b clinical trials. Abstract at the 2024 American Academy of Dermatology Annual Meeting, San Diego, CA, U.S., March 8–12, 2024.

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Q&A

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Thank you

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

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