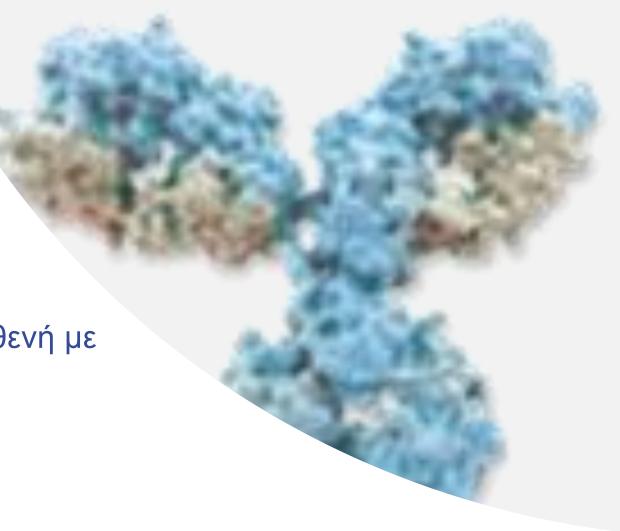
Διπλή αναστολή των IL17A και F:

Δεδομένα και κλινικό όφελος για τον ασθενή με μέτρια προς σοβαρή ψωρίαση

Βέργου Θεογνωσία Δερματολόγος – Αφροδισιολόγος Διδάκτωρ ΕΚΠΑ



Σύγκρουση Συμφερόντων

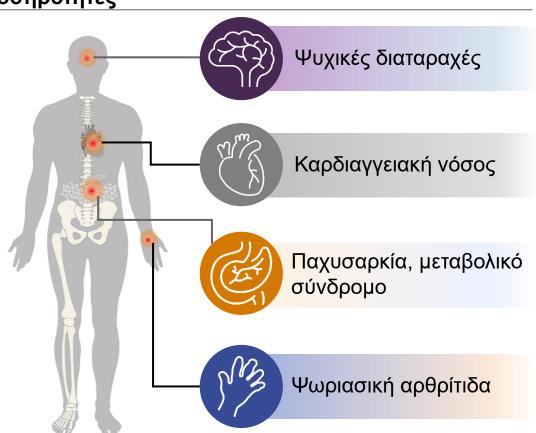
Έχω λάβει τιμητική αμοιβή στο παρελθόν από τις εταιρείες Abbvie, GSK, LEO, MSD, FARAN, Novartis, Pfizer, Roche, Jannsen-Cilag, Genesis-Pharma, UCB για τη συμμετοχή μου ως ομιλήτρια σε δορυφορικά συμπόσια ή εκπαιδευτικά σεμινάρια ή συμβουλευτικές επιτροπές

Συμμετείχα ή συμμετέχω ως ερευνήτρια σε κλινικές μελέτες των εταιρειών Abbvie, Amgen, Novartis, Pfizer, Jannsen, Genesis-Pharma, MSD, LEO

Έλαβα τιμητική αμοιβή για τη συγκεκριμένη παρουσίαση από την εταιρεία UCB

Η ψωρίαση είναι μια συστηματική νόσος που συνδέεται με πολλές συννοσηρότητες

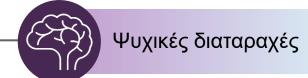
Συννοσηρότητες 1-3



Ο αντίκτυπος της ψωρίασης εκτείνεται πέρα από το δέρμα με ~75% των ασθενών να αναφέρουν τουλάχιστον μία συννοσηρότητα ¹⁻³

Η πανδημία COVID-19 επιδείνωσε τον αντίκτυπο της ψωριασικής νόσου στη ζωή και την ψυχική υγεία των ασθενών ^{1,2}

Συννοσηρότητα



PsOProtect¹

42.7% των ασθενών ανέφεραν επιδείνωση των συμπτωμάτων στη διάρκεια της πανδημίας COVID-19



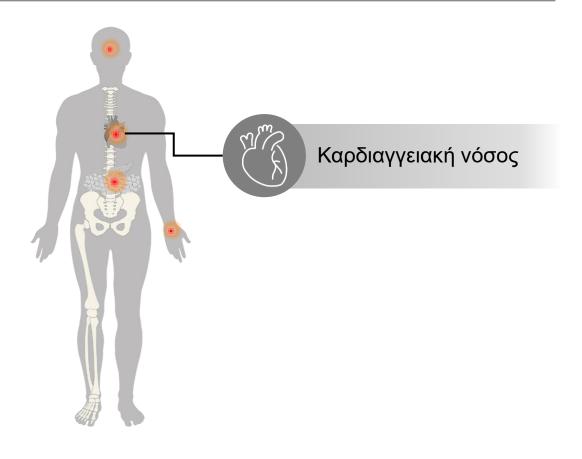


50.2% από αυτούς τους ασθενείς εμφάνισαν άγχος ή κατάθλιψη

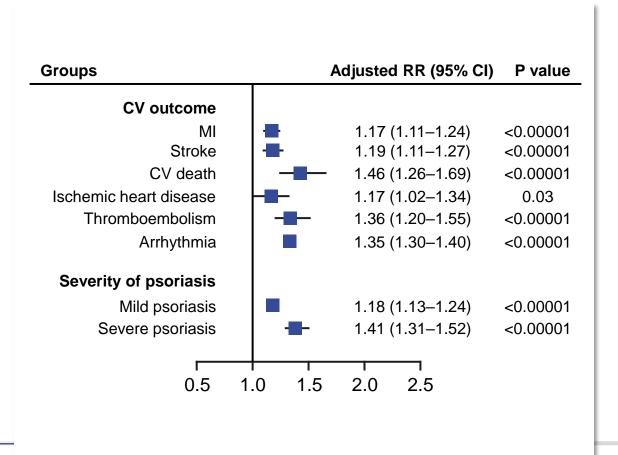
N=4043 people with psoriasis from 86 countries. Worsening psoriasis during the pandemic was reported by n=1728. N=3575 provided information on their mental health, of those reporting worsening psoriasis n=814/1621 had a positive mental health screen

Η ψωριασική νόσος σχετίζεται με αυξημένο κίνδυνο εμφάνισης καρδιαγγειακής νόσου

Συννοσηρότητα

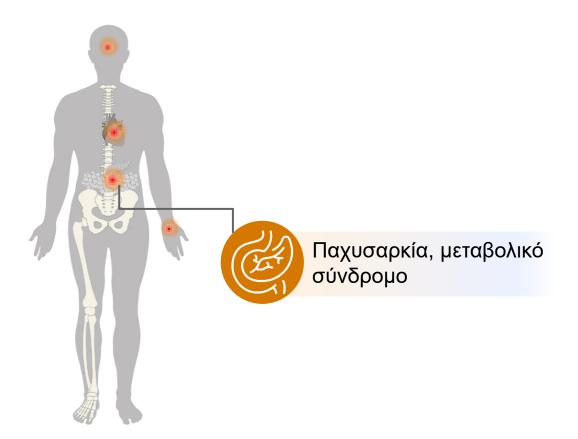


Network meta-analysis*



Το μεταβολικό σύνδρομο και οι τέσσερις συνιστώσες του εμφανίζονται πιο συχνά σε ασθενείς με ψωριασική νόσο σε σύγκριση με τον γενικό πληθυσμό ^{1,2}

Συννοσηρότητες



Ασθενείς με ψωρίαση έναντι υγιών μαρτύρων



Παχυσαρκία¹:

OR 2.23* 95% CI 1.63-3.05



Δυσλιπιδαιμία²:

OR 4.35[†] 95% CI 3.73–5.06



Υπέρταση 3:

OR 1.58[‡] 95% CI 1.42–1.76



Διαβήτης4:

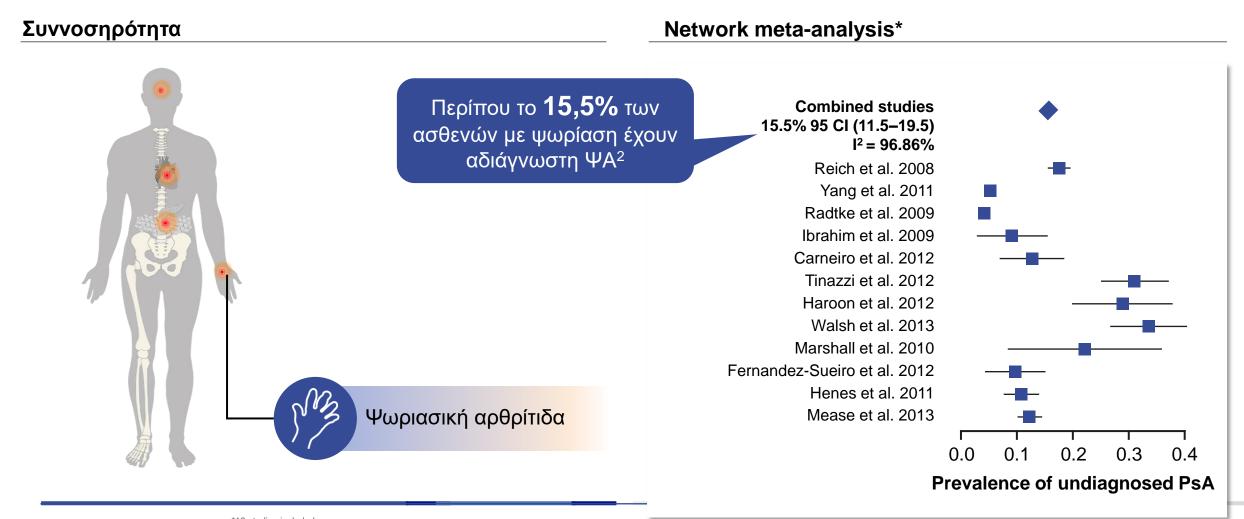
OR 1.59[§] 95% CI 1.38–1.83

^{*16} observational studies with a total of 2.1 million study participants fulfilling the inclusion criteria; †3236 patients with psoriasis vs 2500 control patients; ‡2.7 million study participants fulfilling the inclusion criteria; §22 studies included

CI, confidence interval; OR, odds ratio

^{1.} Armstrong AW, et al. Nutr Diabetes 2012;2:e54; 2. Elmets CA, et al. J Am Acad Dermatol 2019;80:1073—113; 3. Armstrong AW, et al. J Hypertens 2013;31:433–42; 4. Armstrong AW, et al. JAMA Dermatol 2013;149:84–91

Η ψωρίαση και η ψωριασική αρθρίτιδα συνδέονται στενά^{1,2}



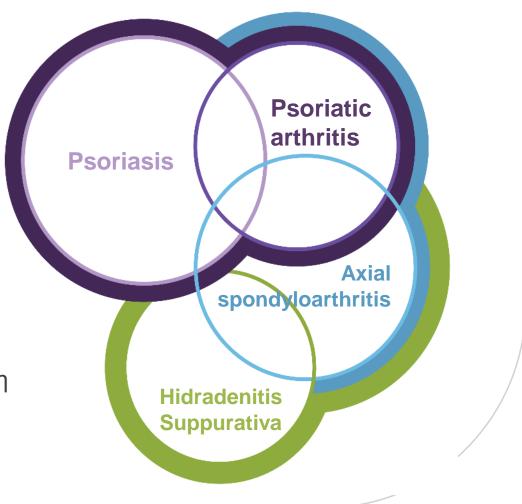
CI. confidence interval: PsA. psoriatic arthritis

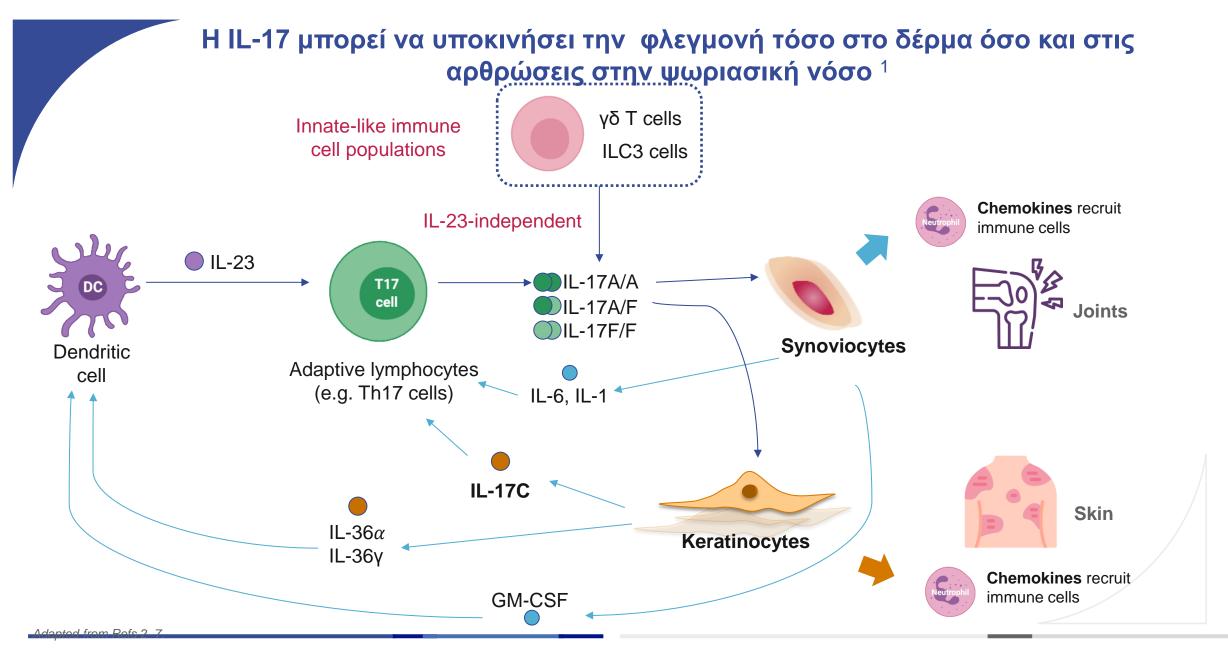
Παθοφυσιολογία Ψωρίασης:

Ποια είναι η γνώση μας σήμερα

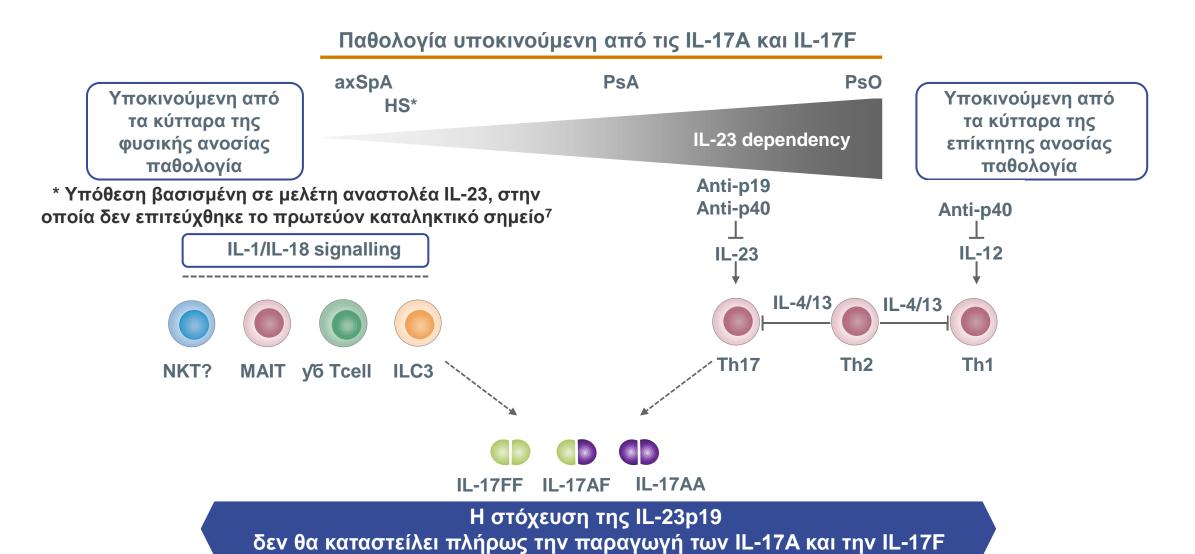
Η IL-17 εμπλέκεται στην παθογένεση πολλαπλών παθήσεων ¹

- Αυτές οι τέσσερις διαφορετικές φλεγμονώδεις καταστάσεις, από κοινού παρουσιάζουν μια παθογόνο αύξηση της συγκέντρωσης των κυτοκινών της οικογένειας των IL-17¹
- Οι θεραπείες που στοχεύουν την οικογένεια των IL-17 έχουν διερευνηθεί και διερευνώνται σε καθεμία από τις ενδείξεις που απεικονίζονται ^{2,3}
- Η εξαρτώμενη από την IL-23 αλλά και ανεξάρτητη παραγωγή IL-17A και IL-17F φαίνεται να συμβάλλει στη φλεγμονή αυτών των νόσων, συμπεριλαμβανομένης της ψωριασικής νόσου⁴



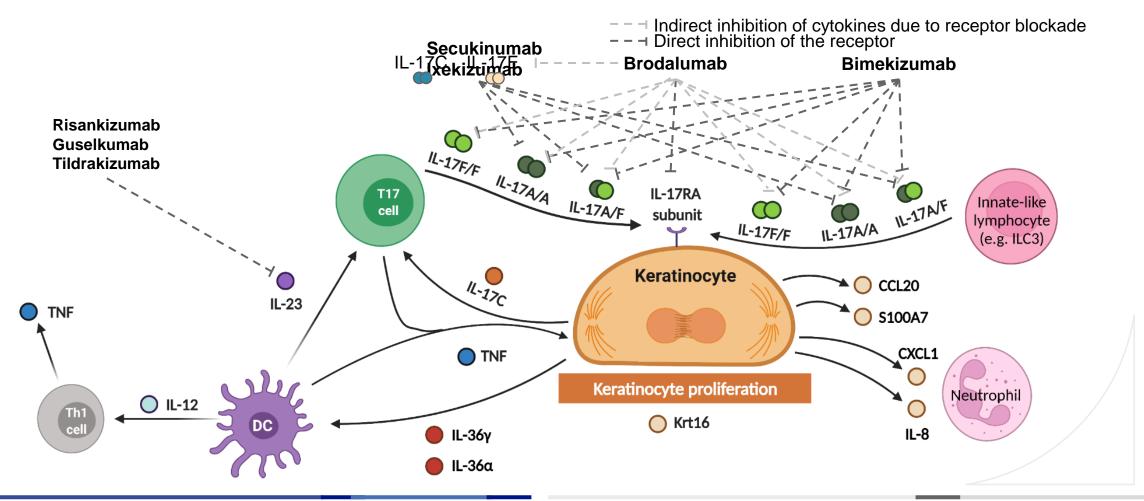


Ο άξονας IL-17/IL-23: μια μη γραμμική σχέση¹⁻⁶



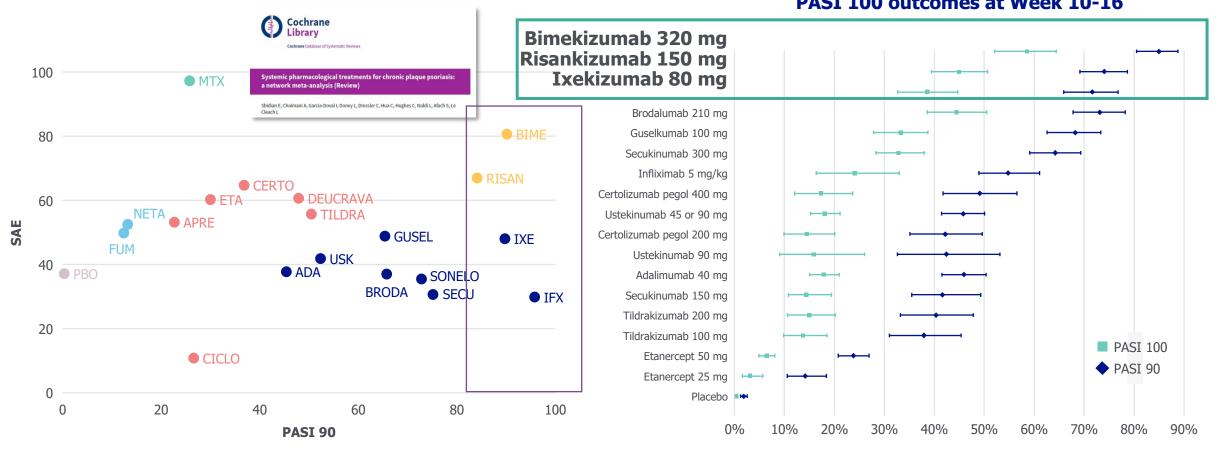
^{1.} Patel and Kuchroo. Immunity. 2015;43:1040–51. 2. Appel et al. Arthritis Res Ther. 2011;13:R95. 3. Sieper et al. Nat Rev Rheumatol. 2019;15:747–757. 4. Al-Mossawi et al. Ann Rheum Dis. 2015;74:A1.1. 5. Gracey et al. Ann Rheum Dis. 2016;75:2124–32. 6. Cole et al. Front Immunol. 2020;11:585134. 7. Janssen MD. [TREMFYA (guselkumab) (janssenmd.com)] [accessed 09 Nov 2022]. 8. Arakelyan et al. PLoS One. 2017;12:e0187572.

Η κατανόηση της παθογένειας της ψωρίασης έχει εξελιχθεί, προσφέροντας νέους θεραπευτικούς στόχους



Ψωρίαση: Το σύγχρονο θεραπευτικό τοπίο

Probabilities of achieving PASI 90 and PASI 100 outcomes at Week 10-16



Higher disease targets (PASI 90 and 100) we should be aiming for our patients

Figures adapted from Sbidian E, et al. 2022.

The different colours on the left figure represent different groups of interventions considering their performance on both outcomes simultaneously. Interventions belonging to the same group are assumed having a similar performance when the two primary outcomes are considered jointly.

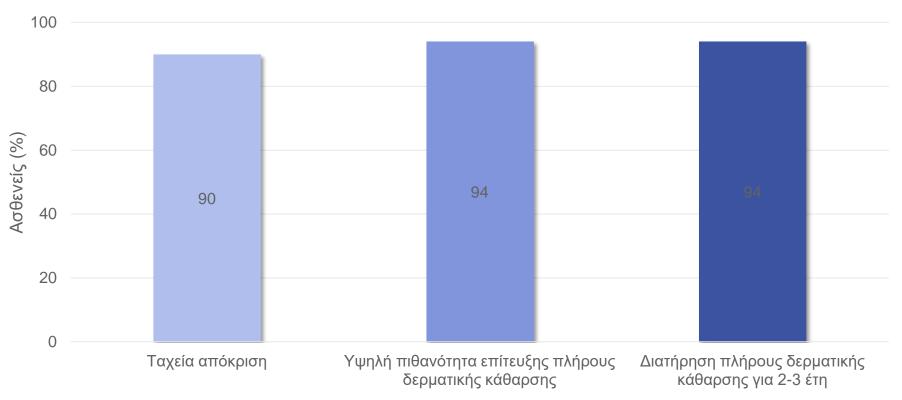
ADA, adalimumab; APRE, apremilast; BIME, bimekizumab; BRODA, brodalumab; CERTO, certolizumab; CICLO, cyclosporine; DEUCRAVA, deucravacitinib; ETA, etanercept; FUM, fumaric acid; GUSEL, guselkumab; IFX, infliximab; IXE, ixekizumab; MTX, methotrexate; NETA, netakimab; PASI, Psoriasis Area and Severity Index; PBO, placebo; RISAN, risankizumab; SAE, serious adverse event; SECU, secukinumab; SONELO, sonelokimab; TILDRA, tildrakizumab; USK, ustekinumab.

Sbidian E, et al. Cochrane Database Syst Rev. 2022;5(5):CD011535.

Ασθενείς με Ψωρίαση: ποιες είναι οι προσδοκίες τους

Η επίτευξη γρήγορης, πλήρους και με διάρκεια απόκρισης αποτελούν τα πιο σημαντικά στοιχεία για τους ασθενείς

Ποσοστό ασθενών που θεωρούν το συγκεκριμένο στοιχείο ως υψηλής σημαντικότητας * N=500



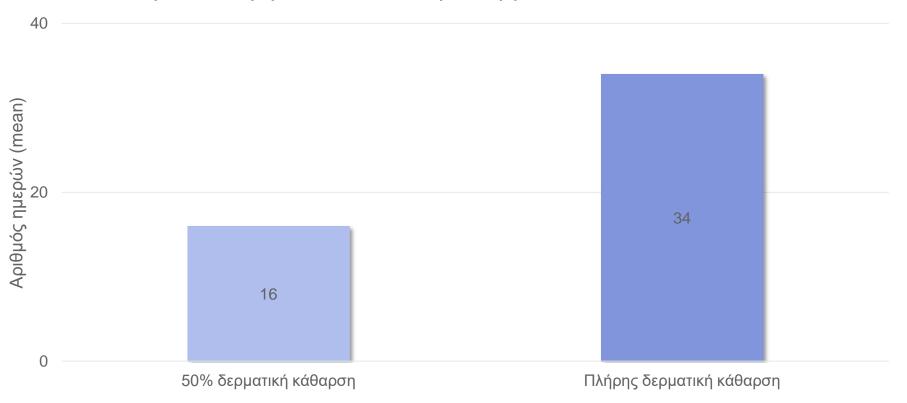
Σχεδόν όλοι οι ασθενείς υπέδειξαν ότι η επίτευξη και διατήρηση καθαρού δέρματος με ταχεία απόκριση είναι υψίστης σημασίας

^{*}Not an exhaustive list of treatment attributes in the survey. Patients scored treatment attributes for importance on a scale of 0–10; a score of 7 or above was considered to denote a high preference for the given attribute.

Gorelick et al. Dermatol Ther. 2019;9:785–97.

Πόσο γρήγορα αναμένουν την κλινική ανταπόκριση οι ασθενείς με μέτρια-σοβαρή ψωρίαση;

Πόσο χρόνο προσδοκούν να περιμένουν προκειμένου να επιτύχουν 50% βελτίωση ή απόλυτα καθαρό δέρμα?



των ασθενών με ψωρίαση αξιολογούν την ταχεία κλινική ανταπόκριση ως μία σημαντική παράμετρο και προσδοκούν την επίτευξη της απόλυτης δερματικής κάθαρσης σε ~30 μέρες¹

Διπλή αναστολή των IL17A και F με Bimekizumab: Ένας νέος μηχανισμός δράσης

Βασικά σημεία μελετών

Bimekizumab (BKZ): Μηχανισμός δράσης



είναι ένα εξανθρωποποιημένο μονοκλωνικό IgG1 αντίσωμα ¹

Εκτιμώμενος χρόνος ημίσειας ζωής: ~23 ημέρες.¹ IgG, Immunoglobulin G.



Καινοτόμος σχεδιασμός

Διπλή Αναστολή των IL-17A και IL-17F²



Υψηλή συγγένεια

Υψηλή δεσμευτική ικανότητα για IL-17A και IL-17F³



Στοχεύει σε 3 διμερή

Συνδέεται σε **IL-17Α/A**, **IL-17Α/F** και **IL-17F/F**³

Μελέτες Φάσης 3 του Bimekizumab σε Ψωρίαση, Ψωριασική Αρθρίτιδα, Αξονική Σπονδυλαρθρίτιδα και Διαπυητική Ιδρωταδενίτιδα



Psoriasis



BE VIVID (PS0009)¹

Double-blind, placebo and ustekinumab-controlled study in moderate to severe **plaque PSO**

BE READY (PS0013)²

Double-blind, placebo-controlled study with randomised withdrawal period in moderate to severe **plaque PSO**

BE SURE (PS0008)³

Double-blind, adalimumab-controlled, dose-blind study in moderate to severe **plaque PSO**

Hidradenitis suppurativa (HS)



BE BRIGHT (PS0014)⁴

Open-label extension study (from PS0009, PS0013, PS0008) in moderate to severe **plaque PSO**

BE RADIANT (PS0015)⁵

Double-blind, secukinumab-controlled study in moderate to severe **plaque PSO**, and open-label extension

BE HEARD (HS0003/4)^{6,7}

Double-blind, placebo-controlled study in patients with moderate to severe **HS**

Psoriatic arthritis (PsA)



BE OPTIMAL (PA0010)⁸

Double-blind, placebo-controlled study in active **PsA in TNFi-naïve** patients with an active reference arm (adalimumab)

BE COMPLETE (PA0011)⁹

Double-blind, placebo-controlled study in active **PsA** patients with **inadequate response to TNFi**

BE VITAL (PA0012)¹⁰

Open-label extension study (from PA0010 and PA0011) in active **PsA**

Axial spondyloarthritis (axSpA)



BE MOBILE 1 (AS0010)¹¹

Double-blind, placebo-controlled study in patients with active **nr-axSpA**

BE MOBILE 2 (AS0011)¹²

Double-blind, placebo-controlled study in patients with active **AS**

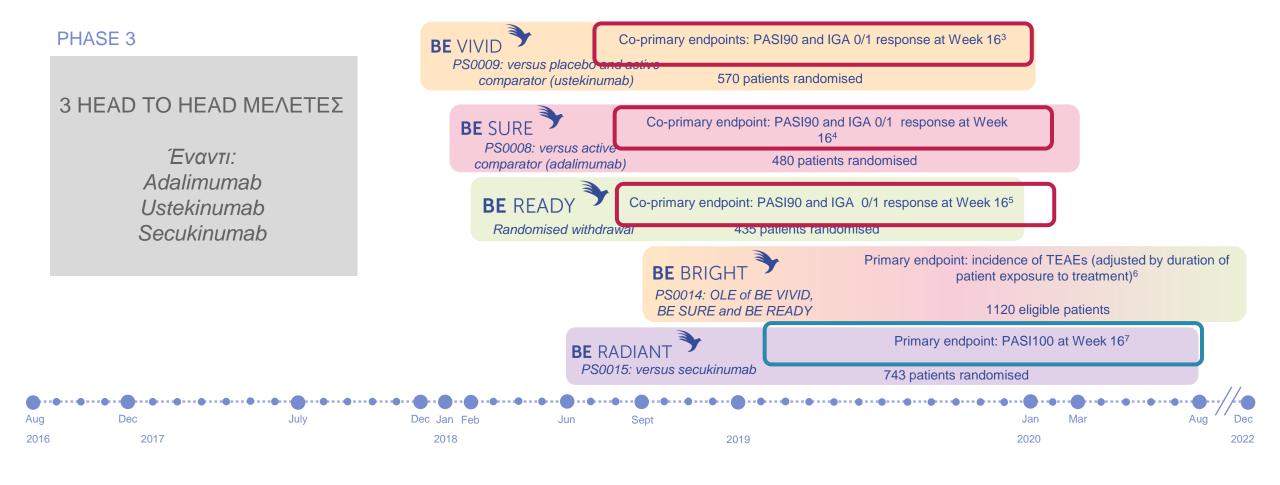
BE MOVING (AS0014)¹³

Open-label extension study (from AS0010 and AS0011) in **active axSpA**

^{7.} HS0004, https://clinicaltrials.gov/ct2/show/NCT04242498. Accessed January 2024. 8. PA0010, https://clinicaltrials.gov/ct2/show/NCT03895203. Accessed January 2024. 9. PA0011, https://clinicaltrials.gov/ct2/show/NCT03896581. Accessed January 2024. 10. PA0012, https://clinicaltrials.gov/ct2/show/NCT03928704. Accessed January 2024. 12. AS0011, https://clinicaltrials.gov/ct2/show/NCT03928743. Accessed January 2024. 12. AS0011, https://clinicaltrials.gov/ct2/show/NCT03928743. Accessed January 2024. 13. Accessed January 2024. 14. AS0011, https://clinicaltrials.gov/ct2/show/NCT03928743. Accessed January 2024. 15. AS

^{13.} AS0014, https://clinicaltrials.gov/ct2/show/NCT04436640. Accessed January 202

Bimekizumab: Μελέτες φάσης 3 στην Ψωρίαση

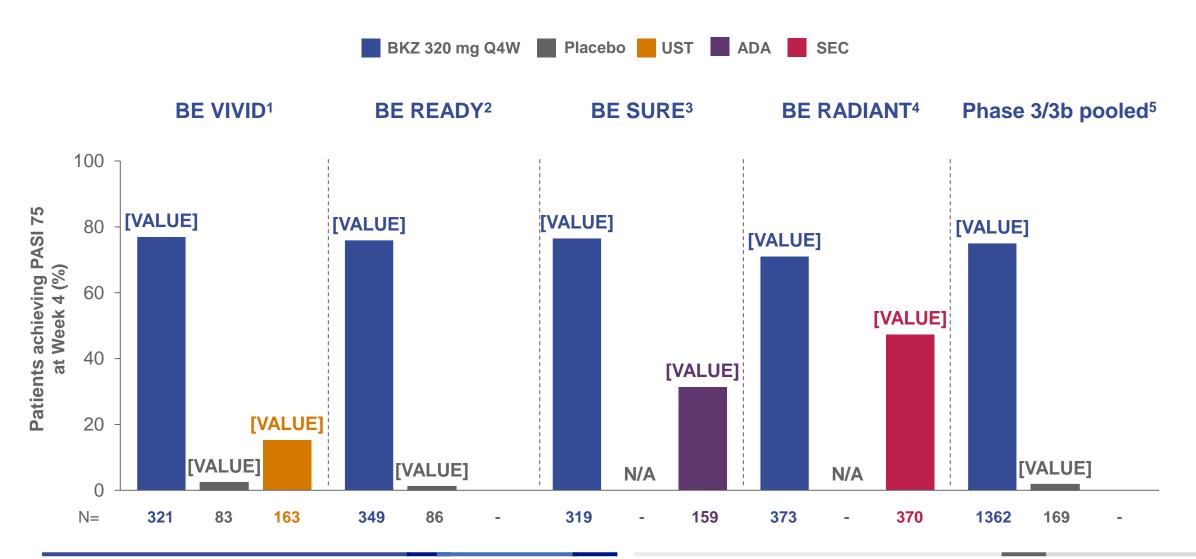


^{1.} Papp et al, J Am Acad Dermatol 2018; 79:277-86; 2. PS0011, https://clinicaltrials.gov/ct2/show/NCT03010527,[accessed: Nov 19]; 3.PS0009, https://clinicaltrials.gov/ct2/show/NCT03370133, [accessed: Nov 19];

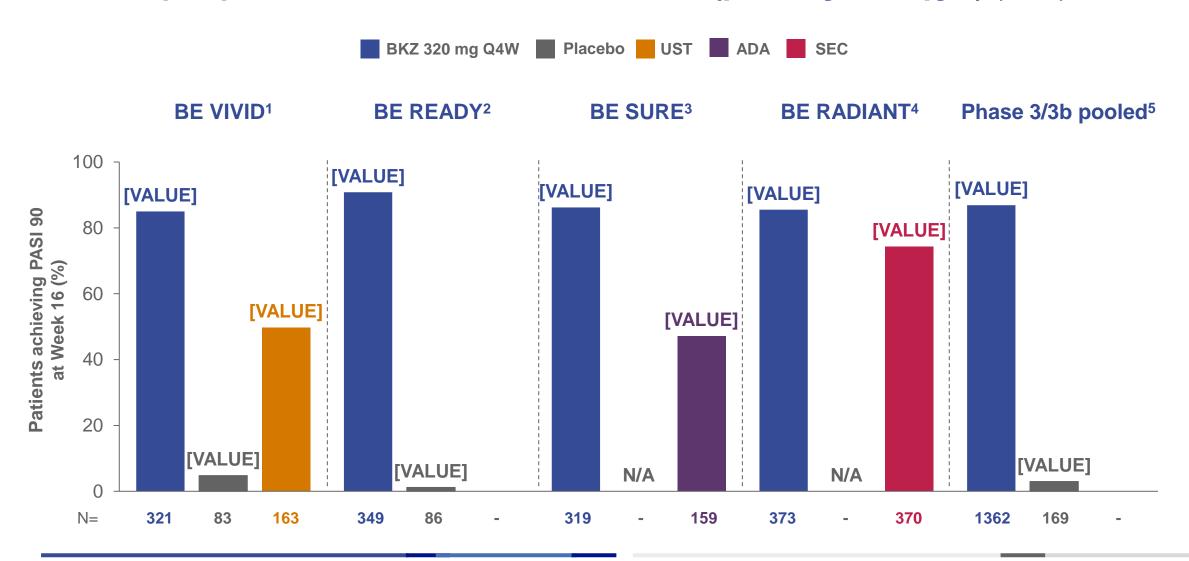
 $^{4. \} PS0008, \\ \underline{\text{https://clinicaltrials.gov/ct2/show/record/NCT03412747}}, \\ [accessed: Nov 19]; \\ 5. \ PS0013, \\ \underline{\text{https://clinicaltrials.gov/ct2/show/record/NCT03410992}}, \\ [accessed: Nov 19]; \\ [accessed: Nov 1$

^{6.} PS0014, https://clinicaltrials.gov/ct2/show/record/NCT03598790, [accessed: Nov 19]; 7. PS0015, https://clinicaltrials.gov/ct2/show/record/NCT03536884, [accessed: Nov 19]

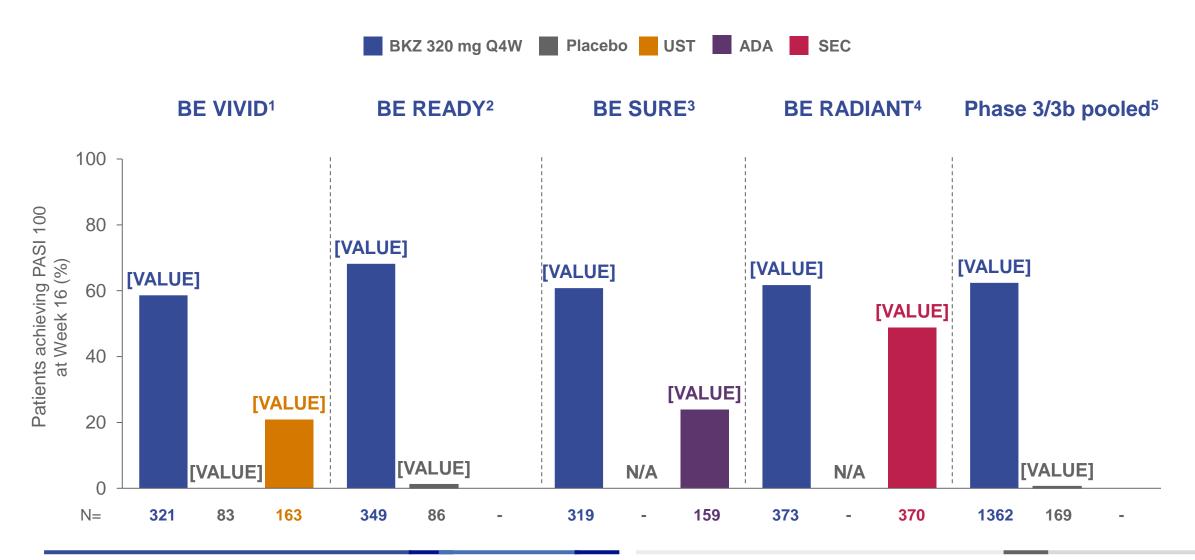
Ταχύτητα επίτευξης θεραπευτικού αποτελέσματος Εβδομάδα 4, PASI 75: Bimekizumab (μελέτες Φάσης 3) (NRI)



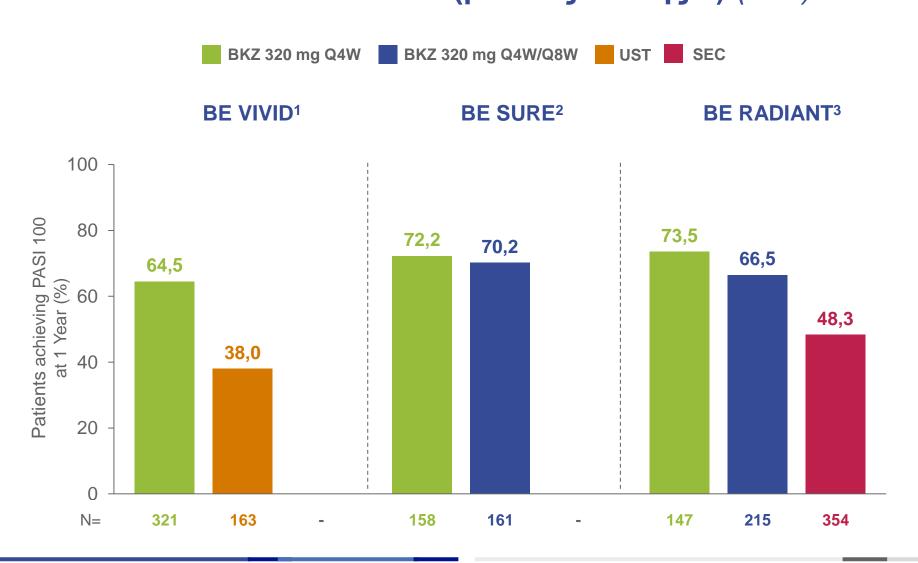
Αξιολόγηση θεραπευτικού αποτελέσματος Εβδομάδα 16, PASI 90: Bimekizumab (μελέτες Φάσης 3) (NRI)



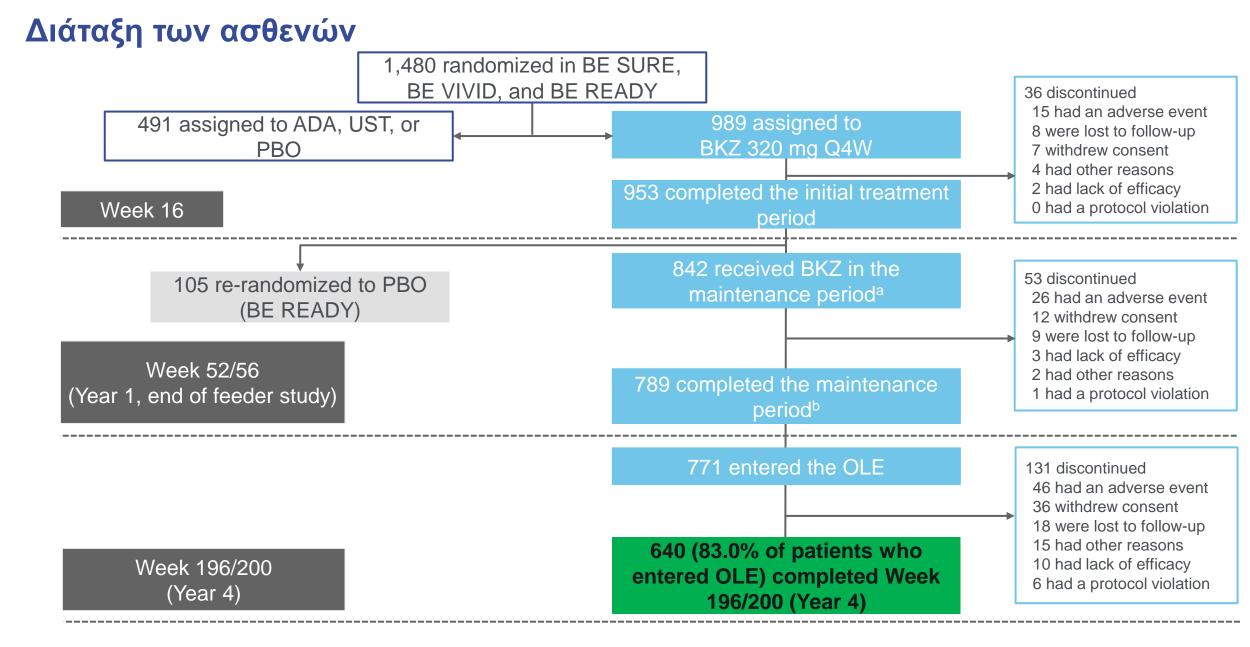
Επίτευξη του απόλυτου θεραπευτικού αποτελέσματος Εβδομάδα 16, PASI 100: Bimekizumab (μελέτες Φάσης 3) (NRI)



Αξιολόγηση θεραπευτικού αποτελέσματος στο έτος PASI 100: Bimekizumab (μελέτες Φάσης 3) (NRI)



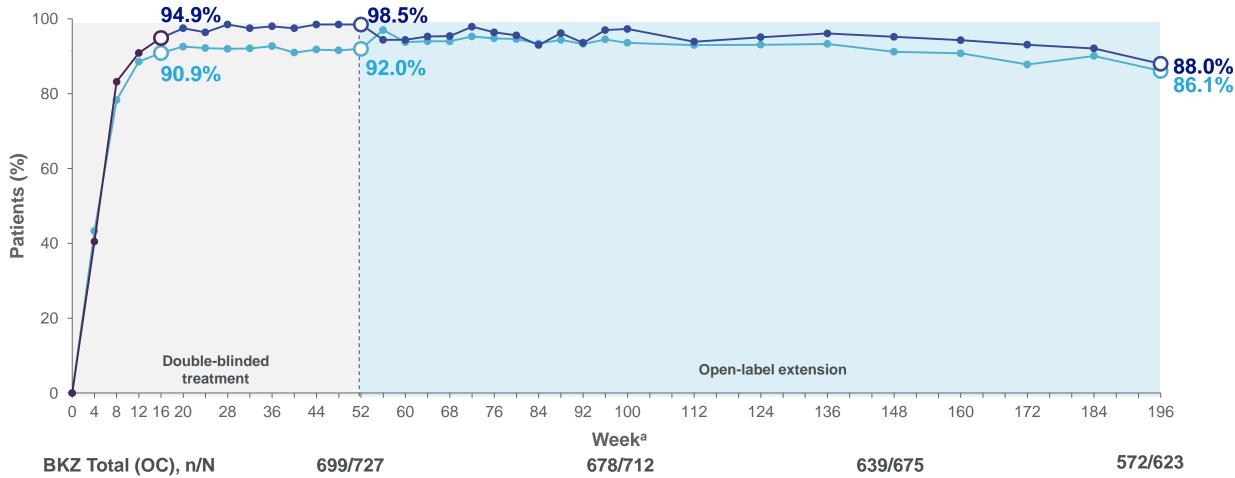
Μακροχρόνια αποτελεσματικότητα (4 έτη) Εβδομάδα 196/200



[a] Of these patients, 34 entered the escape treatment period (23 who did not achieve PASI 90 at Week 16, and 11 who did, were re-randomized to BKZ, and relapsed). [b] Includes patients who completed the escape treatment period. ADA: adalimumab; BKZ: Bimekizumab; OLE: open-label extension; PBO: placebo; Q4W: every 4 weeks; UST: Ustekinumab. All content on this slide is from Strober B, et al. AAD 2024. Presentation 061013.

PASI 90, 4 έτη θεραπείας (mNRI)

→ BKZ Total (N=771)
→ BKZ Q4W/Q8W/Q8W (N=197)

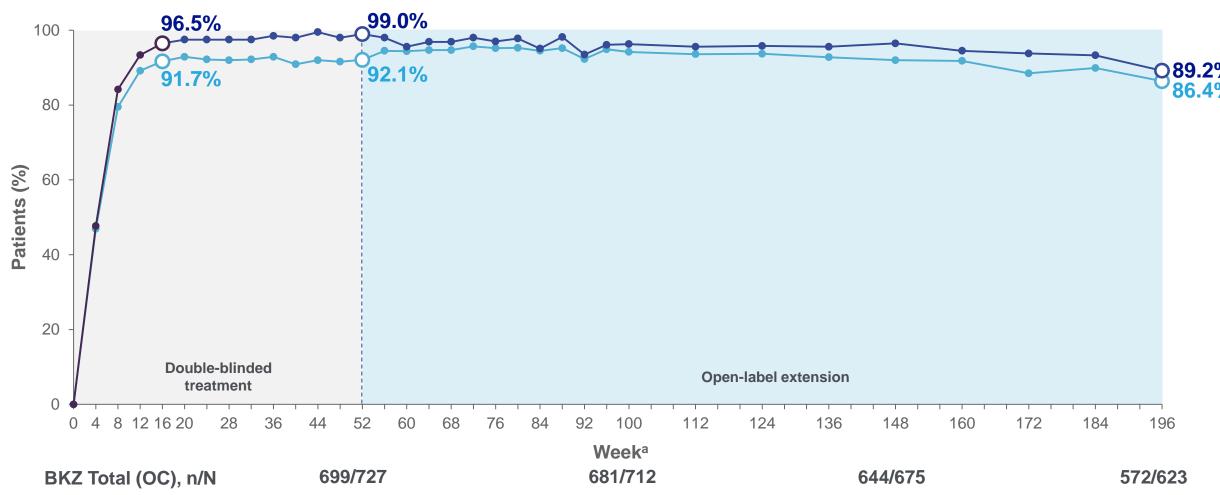


Gold line coloring signifies BKZ Q4W dosing. Missing data were imputed using modified non-responder imputation (mNRI): patients who discontinued due to lack of efficacy/treatment-related adverse events were considered non-responders at subsequent timepoints; multiple imputation was used for other missing 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. All content on this slide is from Strober B, et al. AAD 2024. Presentation 061013.

Date of preparation: March 2024 | GL-BK-2400014

PASI ≤2, 4 έτη θεραπείας (mNRI)

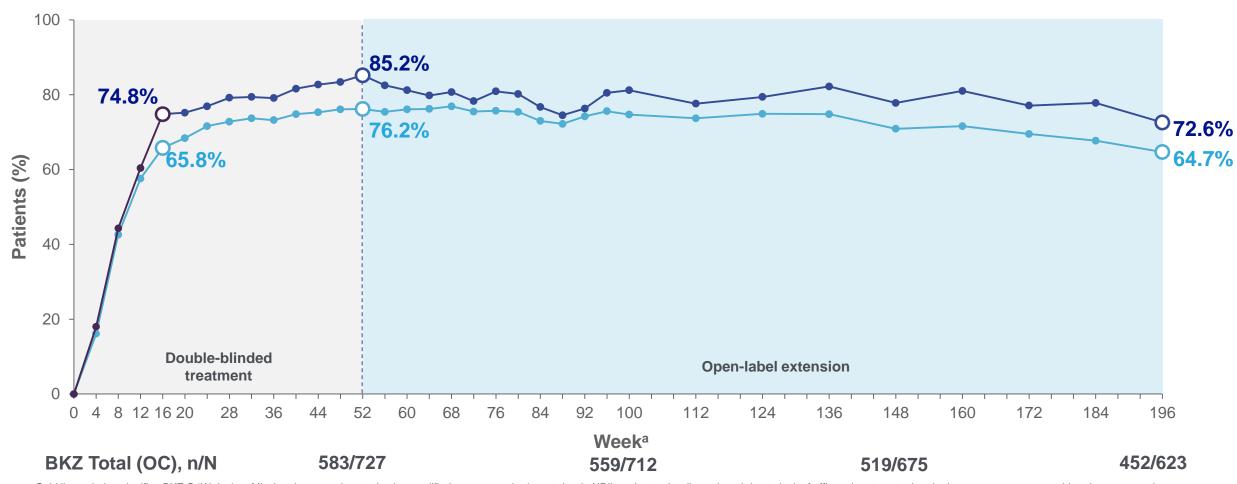
→ BKZ Total (N=771)
→ BKZ Q4W/Q8W/Q8W (N=197)



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. All content on this slide is from Strober B, et al. AAD 2024. Presentation 06 parts of preparation: March 2024 | GL-BK-2400014

PASI 100, 4 έτη θεραπείας (mNRI)

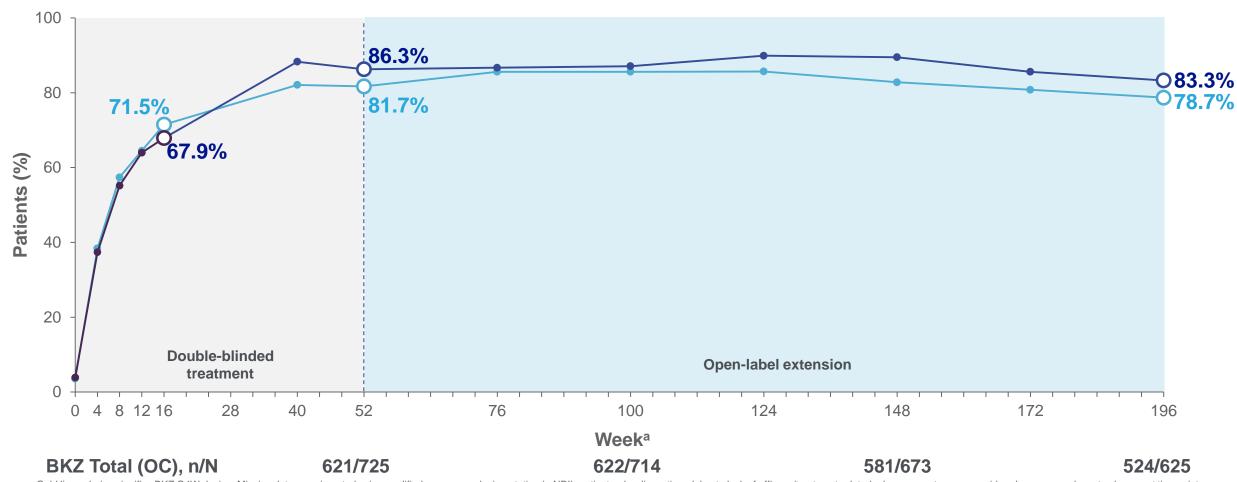
→ BKZ Total (N=771)
→ BKZ Q4W/Q8W/Q8W (N=197)



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. All content on this slide is from Strober B, et al. AAD 2024. Presentation 061 part of preparation: March 2024 | GL-BK-2400014

DLQI 0/1, 4 έτη θεραπείας (mNRI)

→ BKZ Total (N=771)
→ BKZ Q4W/Q8W/Q8W (N=197)

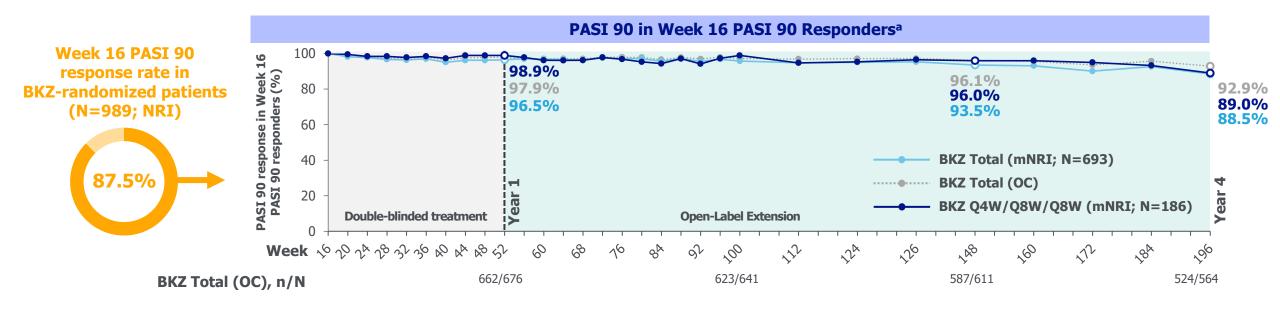


Gold line coloring signifies BKZ Q4W dosing. Missing data were imputed using modified non-responder imputation (mNRI): patients who discontinued due to lack of efficacy/treatment-related adverse events were considered non-responders at subsequent timepoints; multiple imputation was used for other missing 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. All content on this slide is from Strober B, et al. AAD 2024. Presentation 061013.

Date of preparation: March 2024 | GL-BK-2400014

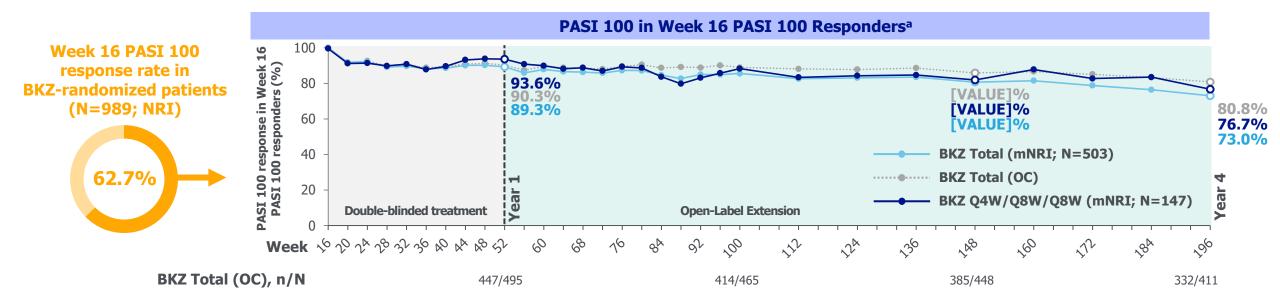
Διατήρηση της αποτελεσματικότητας Εβδομάδα 196/200 σε ασθενείς που επέτυχαν ανταπόκριση

Διατήρηση του PASI 90 στους ασθενείς που είχαν επιτύχει ανταπόκριση την Εβδομάδα 16



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. 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: ≥90% improvement from baseline in PASI; Q4W: every 8 weeks. All content on this slide is from Blauvelt A et al. AAD 2024. Presentation 52661.

Διατήρηση του PASI 100 στους ασθενείς που είχαν επιτύχει ανταπόκριση την Εβδομάδα 16



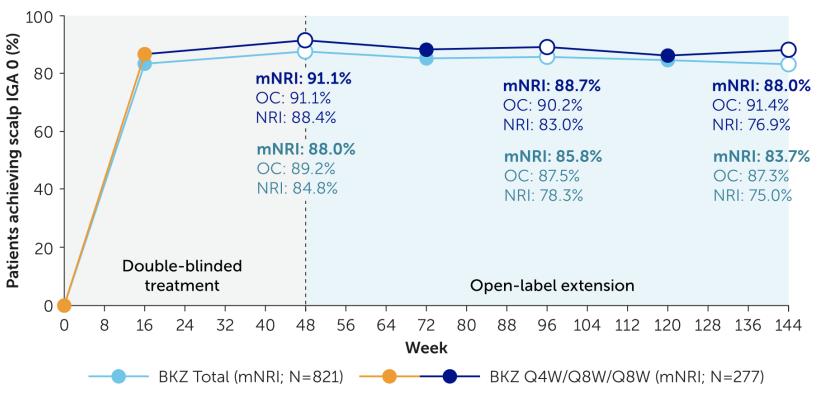
Results differ slightly from the accepted abstract due to updated mNRI methodology. [a] BE VIVID lasted 52 weeks and BE SURE and BE READY lasted 56 weeks; to pool data across studies, Week 56 data were not included. In this figure, the period after Week 52 corresponds to the BE BRIGHT OLE. BKZ: bimekizumab; mNRI: modified non-responder imputation; NRI: non-responder imputation; OC: observed case; OLE: open-label extension; PASI: Psoriasis Area and Severity Index; PASI 100: ≥100% improvement from baseline in PASI; Q4W: every 8 weeks. All content on this slide is from Blauvelt A et al. AAD 2024. Presentation 52661.

Ειδικές Εντοπίσεις- Αποτελεσματικότητα στα 3 έτη



Ποσοστό επίτευξης πλήρους κάθαρσης ψωρίασης του τριχωτού της κεφαλής στα 3 έτη (mNRI, NRI, OC)

Scalp IGA 0 in patients with baseline scalp IGA ≥3

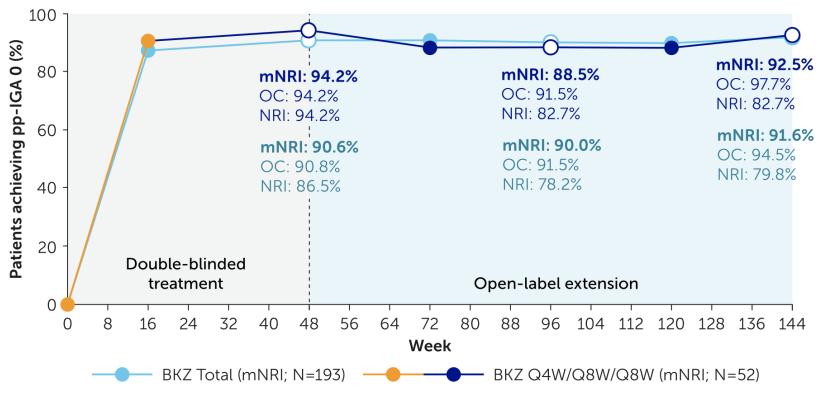


 Among patients with scalp IGA ≥3 at baseline, high levels of complete clearance were attained after 16 weeks and sustained through 3 years

[•] BKZ Total patients were randomised to receive BKZ 320 mg Q4W to Week 16, then received BKZ either Q4W or Q8W in the maintenance period and OLE. BKZ Q4W/Q8W/Q8W patients received BKZ 320 mg Q4W to Week 16, then BKZ Q8W throughout the maintenance period and on OLE entry. Due to differences in assessment schedules, no scalp, palmoplantar, or nail outcomes were collected at Week 48 in BE VIVID; therefore, Week 52 data from BE VIVID were included at the Week 48 timepoint. The BE READY and BE SURE feeder studies had a duration of 56 weeks, BE VIVID had a duration of 52 weeks, and BE RADIANT had a duration of 48 weeks; to pool the data across all four studies, Week 52/56 data from the feeder studies were otherwise not included. Therefore, timepoints after Week 48 in this figure are from the BE BRIGHT/BE RADIANT OLEs. BKZ, bimekizumab; IGA, Investigator's Global Assessment; mNRI, modified non-responder imputation; N, number of patients; NRI, non-responder imputation; OC, observed case; OLE, open-label extension; Q4W, every 4 weeks; Q8W, every 8 weeks. All content on this slide is from Merola J.F. et al. EADV 2023; Poster 2547.

Ποσοστό επίτευξης πλήρους κάθαρσης ψωρίασης παλαμών πελμάτων στα 3 έτη (mNRI, NRI, OC)

pp-IGA 0 in patients with baseline pp-IGA ≥3

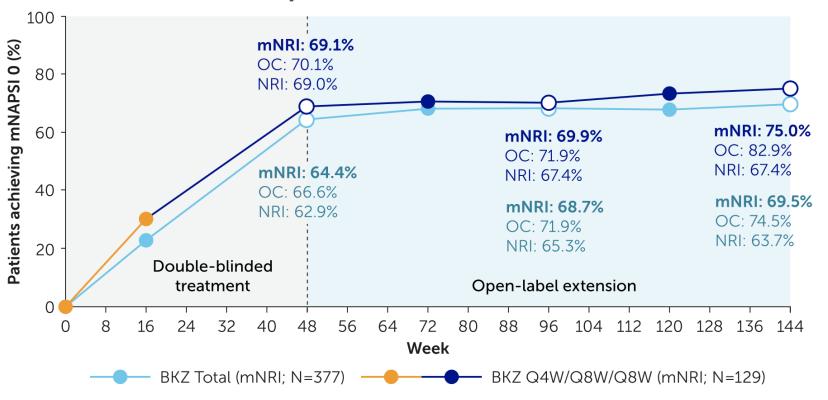


 Among patients with pp-IGA ≥3 at baseline, high levels of complete clearance were attained after 16 weeks and sustained through 3 years

[•] BKZ Total patients were randomised to receive BKZ 320 mg Q4W to Week 16, then received BKZ either Q4W or Q8W in the maintenance period and OLE. BKZ Q4W/Q8W/Q8W patients received BKZ 320 mg Q4W to Week 16, then BKZ Q8W throughout the maintenance period and on OLE entry. Due to differences in assessment schedules, no scalp, palmoplantar, or nail outcomes were collected at Week 48 in BE VIVID; therefore, Week 52 data from BE VIVID were included at the Week 48 timepoint. The BE READY and BE SURE feeder studies had a duration of 56 weeks, BE VIVID had a duration of 52 weeks, and BE RADIANT had a duration of 48 weeks; to pool the data across all four studies, Week 52/56 data from the feeder studies were otherwise not included. Therefore, timepoints after Week 48 in this figure are from the BE BRIGHT/BE RADIANT OLEs. BKZ, bimekizumab; IGA, Investigator's Global Assessment; mNRI, modified non-responder imputation; N, number of patients; NRI, non-responder imputation; OC, observed case; OLE, open-label extension; pp, palmoplantar; Q4W, every 4 weeks; Q8W, every 8 weeks. All content on this slide is from Merola J.F. et al. EADV 2023; Poster 2547.

Ποσοστό επίτευξης πλήρους κάθαρσης ψωριασικής ονυχίας στα 3 έτη (mNRI, NRI, OC)

mNAPSI 0 in patients with baseline mNAPSI >10

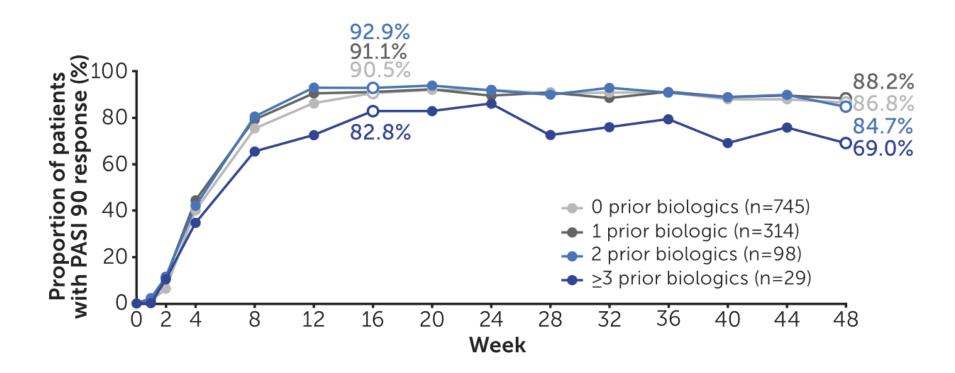


• Among patients with mNAPSI >10 at baseline, levels of complete clearance increased through Year 1 and were sustained to Year 3; rates of clearance were reflective of the longer timescale required for nail growth and repair

[•] BKZ Total patients were randomised to receive BKZ 320 mg Q4W to Week 16, then received BKZ either Q4W or Q8W in the maintenance period and OLE. BKZ Q4W/Q8W/Q8W patients received BKZ 320 mg Q4W to Week 16, then BKZ Q8W throughout the maintenance period and on OLE entry. Due to differences in assessment schedules, no scalp, palmoplantar, or nail outcomes were collected at Week 48 in BE VIVID; therefore, Week 52 data from BE VIVID were included at the Week 48 timepoint. The BE READY and BE SURE feeder studies had a duration of 56 weeks, BE VIVID had a duration of 52 weeks, and BE RADIANT had a duration of 48 weeks; to pool the data across all four studies, Week 52/56 data from the feeder studies were otherwise not included. Therefore, timepoints after Week 48 in this figure are from the BE BRIGHT/BE RADIANT OLEs. BKZ, bimekizumab; IGA, Investigator's Global Assessment; mNRI, modified non-responder imputation; N, number of patients; NRI, non-responder imputation; OC, observed case; OLE, open-label extension; pp, palmoplantar; Q4W, every 4 weeks; Q8W, every 8 weeks. All content on this slide is from Merola J.F. et al. EADV 2023: Poster 2547.

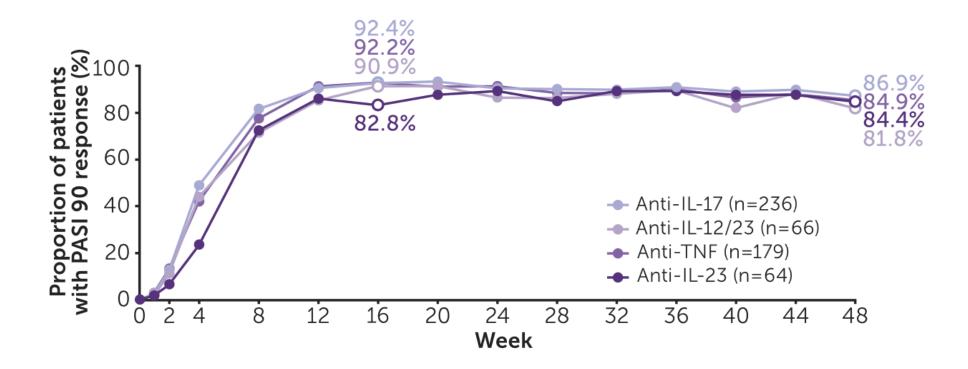
Ειδικοί πληθυσμοί, Εβδομάδα 48/52 (προηγηθείσα έκθεση σε βιολογικούς)

PASI 90, Εβδομάδα 48, *με βάση τον αριθμό* προηγουμένων βιολογικών θεραπειών (NRI)



- At Week 16 and Week 48, PASI 90 responses were consistently high in biologic-naïve patients, as well as in those who had received 1 or 2 prior biologics
- Responses were numerically lower in the subgroup of patients who had received ≥3 prior biologics

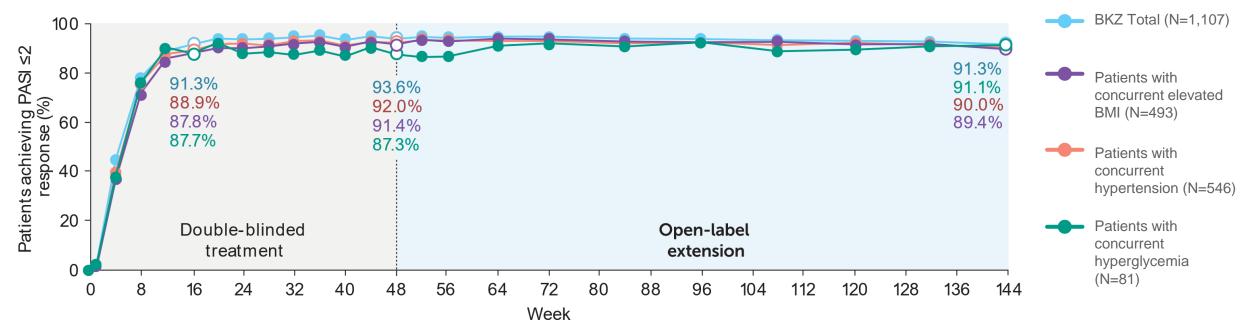
PASI 90, Εβδομάδα 48, *με βάση την κατηγορία* προηγουμένων βιολογικών θεραπειών (NRI)



In biologic-experienced patients, high levels of PASI 90 responses were observed across all subgroups by type of prior biologic

Ειδικοί πληθυσμοί-Συννοσηρότητες (Εβδομάδα 144)

Εβδομάδα 144, PASI ≤2 με BKZ σε ασθενείς με συννυπάρχουσα αρτηριακή υπέρταση, αυξημένο BMI, και υπεργλυκαιμία στην αρχική επίσκεψη (mNRI)



- High PASI ≤2 response rates were observed at Week 16 in those with hypertension, elevated BMI, or hyperglycemia, and were sustained to Year 3
 - Response rates were consistent with the overall response rate among all BKZ-treated patients

Data are pooled from BE SURE, BE VIVID, BE READY, their OLE BE BRIGHT, and BE RADIANT phase 3 trials through 3 years. The feeder studies ran for different lengths of time (BE RADIANT: 48 weeks; BE VIVID: 52 weeks; BE SURE and BE READY: 56 weeks); to pool the data across all studies, Week 52/56 data from the feeder studies were not included. Therefore, timepoints after Week 48 in this figure are from the BE BRIGHT and BE RADIANT OLEs. BKZ Total includes all patients who received continuous BKZ treatment in the initial and maintenance periods, and entered the OLE. Hypertension group includes patients with baseline systolic blood pressure >130 mmHg or diastolic blood pressure >85 mmHg. Elevated BMI group includes patients with baseline BMI >30 kg/m². Hyperglycemia group includes patients with baseline blood glucose ≥140 mg/dL or ≥7.8 mmol/L. Definitions for comorbidities were based on the criteria for metabolic syndrome where possible and aligned to other similar studies in the field.¹

1. Cornier MA et al. Endocr Rev. 2008;29:777–822. BKZ, bimekizumab; BMI, body mass index; mNRI, modified non-responder imputation; OLE, open-label extension; PASI, Psoriasis Area and Severity Index. All content on this slide is from Armstrong A. et al. at Fall Clinical Dermatology Conference 2023; Poster FC23_2.

Δυνατότητα ευέλικτου δοσολογικού σχήματατος 1-3

Ευέλικτα δασολογικά σχήματα για ενήλικες με μέτρια έως σοβαρή ψωρίαση

Bimekizumab: μπορεί να εξεταστεί το ενδεχόμενο συχνότερης δόσης σε ασθενείς με ΣΒ≥120 kg, που δεν έχουν επιτύχει την επιθυμητή κλινκή ανταπόκριση

	Δόση εφόδου	Σχήμα συντήρησης
Ασθενείς<120 kg : Κλασικό δοσολογικό		320 mg Q8W
Ασθενείς ≥120 kg, εἀν το δέρμα δεν είναι καθαρό την Εβδομάδα 16: Συχνότερο δοσολογικό	320 mg Q4W (Week 0-16)	320 mg Q4W



^{1.} Bimzelx ® EU SmPC. https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf [Accessed on May 2022].

Δεδομένα πραγματικού κόσμου από νοσοκομείο Συγγρός

Archives of Dermatological Research (2024) 316:133 https://doi.org/10.1007/s00403-024-02868-7

RESEARCH LETTER



Bimekizumab in psoriasis: a monocentric study evaluating short- and mid-term effectiveness and safety profile in a real-world setting

Natalia Rompoti¹ · Irene Stefanaki¹ · Pantelis Panagakis¹ · Charitomeni Vavouli¹ · Maria Politou¹ · Marina Papoutsaki¹ · Aggeliki Befon¹ · Fiori Koutsa¹ · Eleni Lazou¹ · Ioannis-Alexios Koumprentziotis¹ · Vasiliki Chasapi¹ · Alexander Stratigos¹ · Electra Nicolaidou¹

Received: 21 March 2024 / Revised: 21 March 2024 / Accepted: 7 April 2024 © The Author(s), under exclusive licence to Springer-Verlag GmbH Germany, part of Springer Nature 2024



Δημογραφικά χαρακτηριστικά

Dimethyl fumarate, n (%)	2/60	
Apremilast, n (%)	24/60	
anti-TNFa, n (%)	29/60	
IL 12/23 inhibitor, n (%)	11/60	
IL17 inhibitor, n (%)	23/60	
IL23 inhibitor, n (%)	7/60	
Systemic treatment directly prior to bimekizuma	ab initiation, n (%)	
None	7/61 (11.5)	
IL-17 inhibitor	21/61 (34.4)	
IL-23 inhibitor	7/61 (11.5)	



Αποτελεσματικότητα

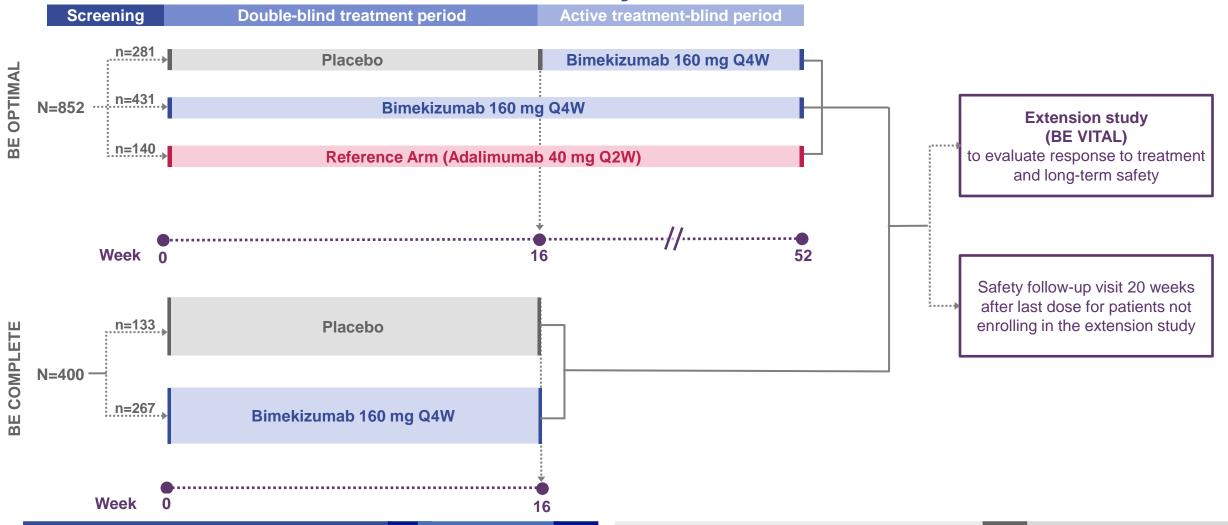
 Table 2 Clinical response to bimekizumab treatment

- canore = campron	ir response to o	1111011120111100	11 0 (11 11 11 11 11 11 11 11 11 11 11 11 11	
Clinical	Week 0	Week 4	Week 16	Week 24
response				
PASI score, mean (SD)	10.08 (7.7)	2.81(3.16)	0.78 (1.71)	1.16 (2.79)
PASI 75, %		65.7	92.3	89.5
PASI 90, %		45.7	76.9	78.9
PASI 100, %		32.4	66.7	70.0
$PASI \le 3$		63.2	92.9	95.0
$PASI \le 2$		42.1	85.7	80.0
PASI≤1		31.6	78.6	75.0



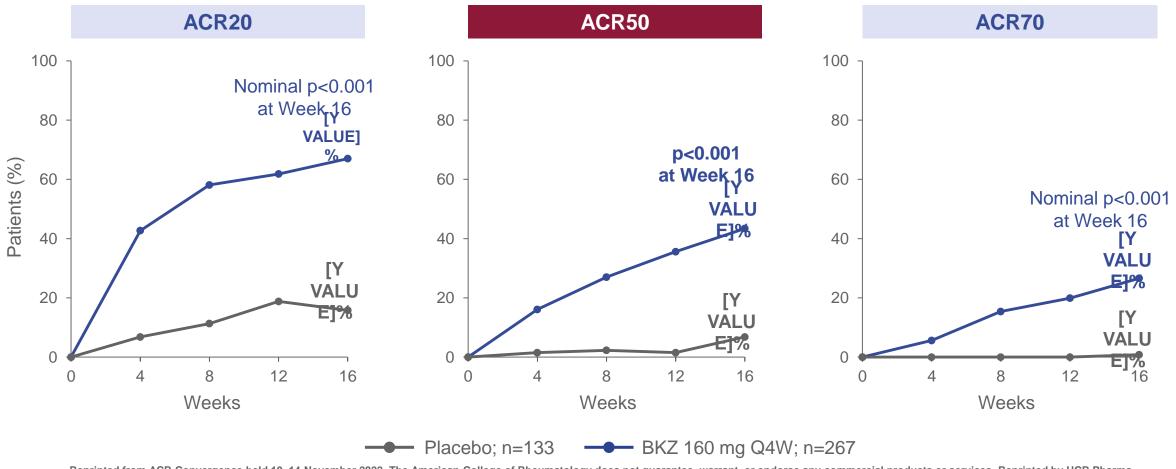
Αποτελεσματικότητα στην Ψωριασική Αρθρίτιδα

BE OPTIMAL – Μελέτη Φάσης 3 σε bionaive ασθενείς BE COMPLETE – Μελέτη Φάσης 3 σε ασθενείς που δεν έχουν ανταποκριθεί σε αναστολείς TNF



Ανταπόκριση ACR έως την Εβδομάδα 16 (NRI)

BKZ demonstrated improvements vs placebo in the achievement of all ACR response criteria at Week 16

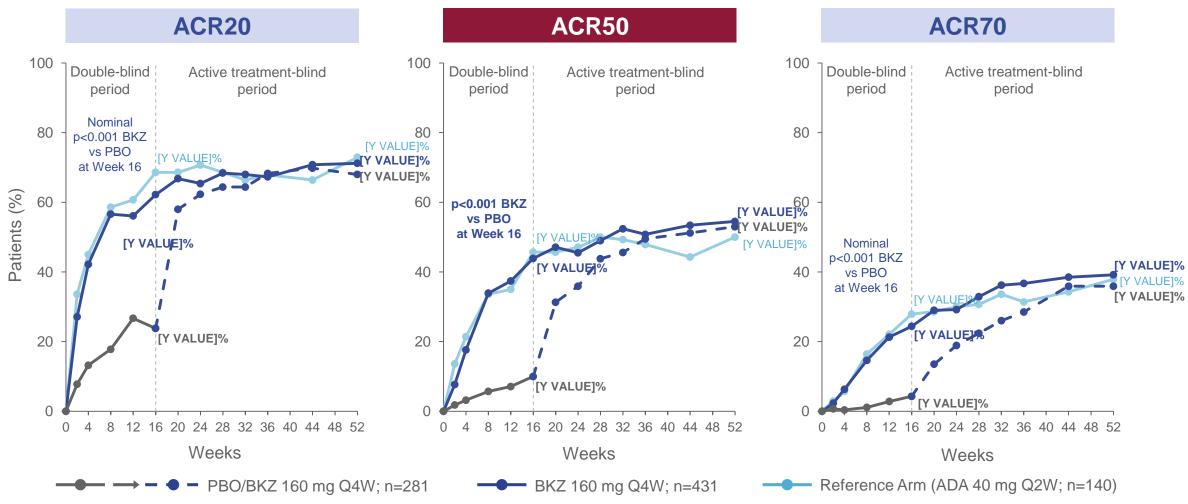


Reprinted from ACR Convergence held 10–14 November 2022. The American College of Rheumatology does not guarantee, warrant, or endorse any commercial products or services. Reprinted by UCB Pharma. Bimekizumab is currently in clinical development and is not authorised for use by any regulatory authority worldwide for PsA; therefore, this document discusses unlicensed indications and contains off-label information

Randomized set. p values were obtained from logistic regression with treatment, prior TNFi exposure, and region as factors. Nominal p values were not powered or adjusted for multiplicity and should not be used to assess statistical significance. ACR20/50/70: American College of Rheumatology criteria ≥20/50/70% response; BKZ: bimekizumab; NRI: non-responder imputation; Q4W: every 4 weeks; TNFi: tumor necrosis factor inhibitor.

Ανταπόκριση ACR εως την Εβδομάδα 52 (NRI)

Bimekizumab treatment demonstrated sustained joint efficacy responses from Week 16 to Week 52 in patients with PsA

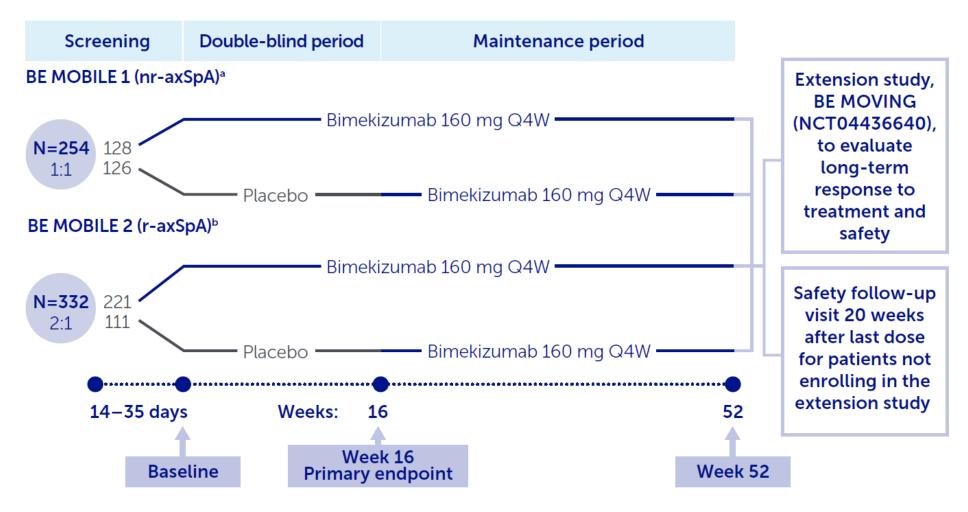


Reprinted from ACR Convergence held 10–14 November 2022. The American College of Rheumatology does not guarantee, warrant, or endorse any commercial products or services. Reprinted by UCB Pharma. Bimekizumab is currently in clinical development and is not authorised for use by any regulatory authority worldwide for PsA; therefore, this document discusses unlicensed indications and contains off-label information

Randomized set. p value was calculated using a logistic regression model with treatment, bone erosion at baseline, and region as stratification factors. Nominal p values are not powered or adjusted for multiplicity and should not be used to assess statistical significance. The study was not powered for statistical comparisons of ADA to BKZ or PBO. ACR20/50/70: American College of Rheumatology criteria ≥20/50/70% response; ADA: adalimumab; BKZ: bimekizumab; NRI: non-responder imputation; PBO: placebo; PsA: psoriatic arthritis; Q2W: every 2 weeks; Q4W: every 4 weeks.

Αποτελεσματικότητα στην Αξονική σπονδυλαρθρίτιδα

BE MOBILE 1 and 2 Study Designs

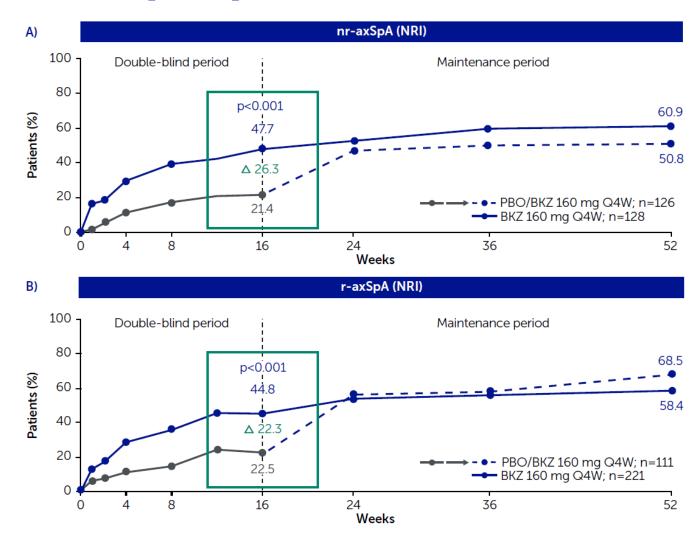


Baraliakos X et al. EULAR 2023. Presentation POS1103.

Patients were eligible to receive non-biologic rescue therapy from Week 20 at the discretion of the investigator, while continuing to receive BKZ. All patients had active nr-axSpA or r-axSpA at baseline (BASDAI ≥4 and spinal pain ≥4). aIncluded patients had adult-onset nr-axSpA fulfilling ASAS classification criteria and objective signs of inflammation (active sacrolilitis on MRI and/or elevated CRP [≥6 mg/L]); bIncluded patients had radiographic evidence of r-axSpA fulfilling Modified New York criteria. ASAS: Assessment of SpondyloArthritis international Society; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BKZ: bimekizumab; CRP: C-reactive protein; MRI: magnetic resonance imaging; nr-axSpA: non-radiographic axial spondyloarthritis; O4W: every four weeks: r-axSpA: radiographic axial spondyloarthritis.



ASAS40 to Week 52 (NRI)





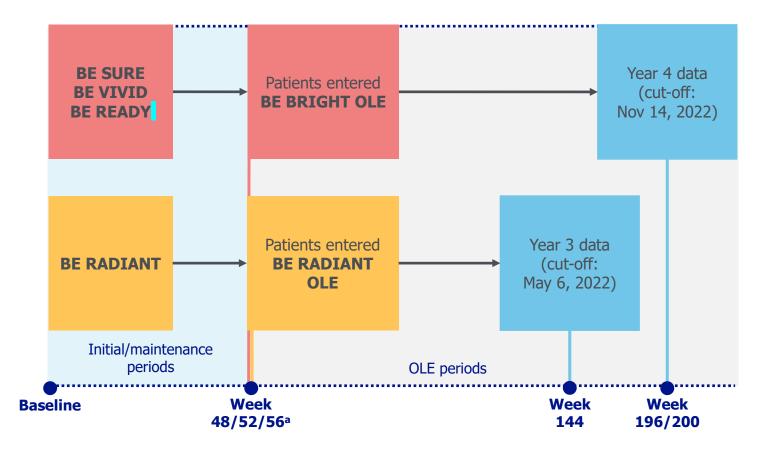
Randomised set. Missing data were imputed using NRI. p values were calculated using logistic regression with treatment, prior MRI/CRP status (BE MOBILE 1) or TNFi exposure (BE MOBILE 2), and region as factors. ASAS40: Assessment of SpondyloArthritis international Society 40% response; BKZ: bimekizumab; CRP: C-reactive protein; MRI: magnetic resonance imaging; nr-axSpA: non-radiographic axial spondyloarthritis; NRI: non-responder imputation; PBO: placebo; Q4W: every four weeks; r-axSpA: radiographic axial spondyloarthritis; TNFi: tumour necrosis factor inhibitor.



Ασφάλεια Εβδομάδα 196/200

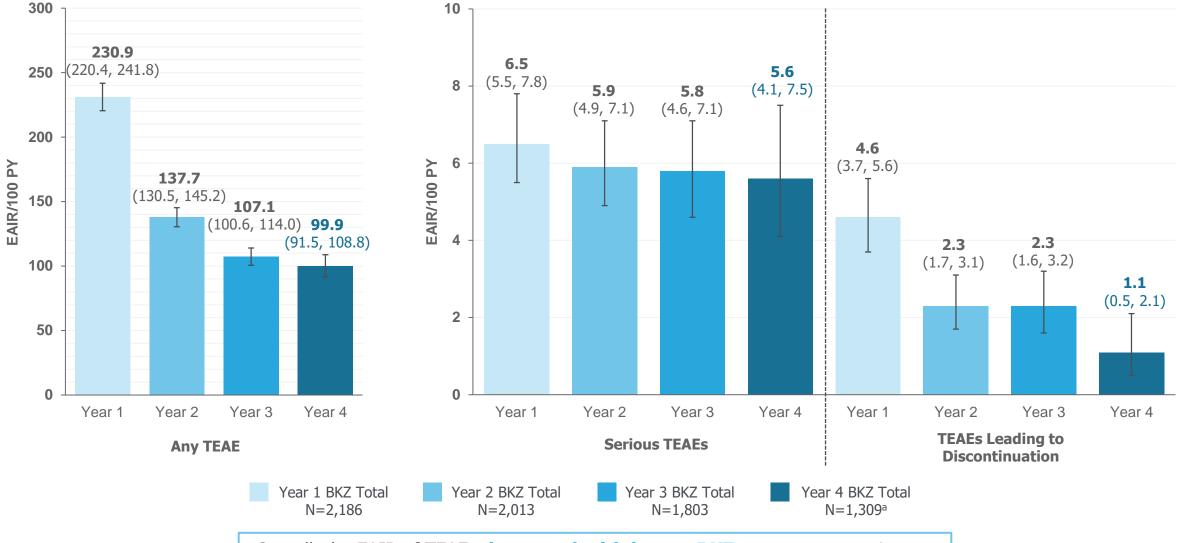
Ασθενείς που συμπεριελήφθησαν

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.

Ποσοστά επίπτωσης ΤΕΑΕ: Οποιεσδήποτε, Σοβαρές και Διακοπές με την πάροδο του χρόνου (Total BKZ)



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. All content on this slide is from Gordon KB et al. AAD 2024. Presentation 52671.

Σύνοψη των ΤΕΑΕ και των πιο κοινών ΤΕΑΕ σε ασθενείς που έλαβαν ΒΚΖ (BKZ Total)

					i
	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. All content on this slide is from Gordon KB et al. AAD 2024. Presentation 52671.

Σύνοψη των ΤΕΑΕ και των πιο κοινών ΤΕΑΕ σε ασθενείς που έλαβαν ΒΚΖ (BKZ Total)

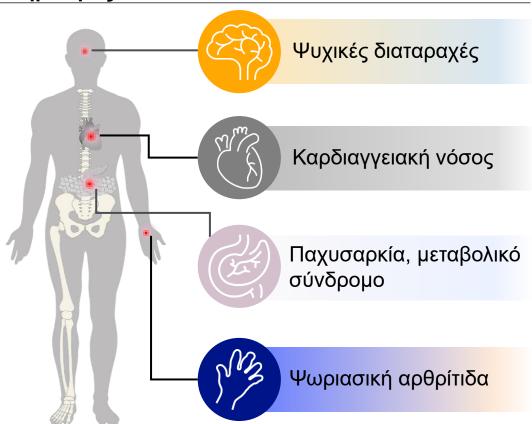
	Year 1 (N=2,186)	Year 2 (N=2,013)	Year 3 (N=1,803)a	Year 4 (N=1,309)a	Overall (N=2,186)
Most Common TEAEs, EAIR/100 PY (95% CI)					
Nasopharyngitis	25.8 (23.5, 28.3)	13.2 (11.6, 15.0)	5.4 (4.3, 6.7)	5.9 (4.4, 7.9)	12.7 (11.7, 13.8)
Oral candidiasis	18.9 (16.9, 21.0)	10.7 (9.2, 12.3)	6.8 (5.6, 8.3)	5.4 (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)

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. All content on this slide is from Gordon KB et al. AAD 2024. Presentation 52671.

Συμπερασματικά

Η χρησιμοποίηση μιας ευρείας διεπιστημονικής ομάδας θα βελτιώσει περαιτέρω τα αποτελέσματα για τους ασθενείς

Συννοσηρότητες



Συνεργασίες ως μέρος μιας διεπιστημονικής ομάδας^{1,2}

Συνεργασία με ψυχίατρο



Συνεργασία με καρδιολόγο



Συνεργασία με διαιτολόγο ή/και γαστρεντερολόγο



Συνεργασία με ρευματολόγο

 ^{1.} Queiro R & Coto P. Rheumatology 2017;56:1829–1831; 2. University of Rochester Medical Center. Dermatology: Psoriasis Center.
 Available at: <a href="https://www.urmc.rochester.edu/dermatology/specialty/psoriasis/multidisciplinary-approach.aspx#:~:text=%22Multidisciplinary%22%20means%20we%20bring%20a,a%20psychiatrist%20and%20a%20nutritionist. Accessed July 2015.

Οι προσδοκίες των ασθενών με μέτρια προς σοβαρή ψωρίαση κατά πλάκας



90% Γρήγορη ανταπόκριση



94% Καθαρό δέρμα



94% Μακροχρόνια αποτελεσματικότητα

Bimekizumab: Διπλή ανατολή των IL17A και F

Μοναδικός αναστολέας των IL17A και F

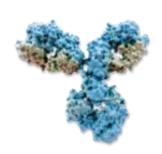
Εβδομάδα 16, 85.5% PASI 90, 61.7% PASI 100

Διατήρηση αποτελεσματικότητας στα 4 έτη θεραπείας

Υψηλή αποτελεσματικότητα σε ειδικές εντοπίσεις

Υψηλή αποτελεσματικότητα και σε ειδικές ομάδες ασθενών

Ένδειξη σε Ψωριασική αρθρίτδα και αξονική σπονδυλαρθρίτιδα



Εξανθρωποποιημένο μονοκλωνικό IgG1 αντίσωμα

Ευχαριστώ