Comparative Effectiveness of Bimekizumab in Patients with Psoriatic Arthritis: Results from a Systematic Literature Review and Network Meta-analysis

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Objectives

To establish the relative clinical efficacy and safety of bimekizumab vs approved biological or targeted synthetic disease-modifying antirheumatic drug (b/tsDMARDs) for psoriatic arthritis (PsA) using network meta-analysis (NMA).

Background

- PsA is a chronic, systemic, heterogeneous, inflammatory disease in which patients experience musculoskeletal symptoms alongside psoriasis-associated skin inflammation.[1]
- Bimekizumab is a monoclonal immunoglobulin G1 (IgG1) antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A.
- Bimekizumab has demonstrated clinically meaningful and significant joint and skin efficacy responses at Week 16 versus placebo in patients with PsA in phase 3 studies, BE OPTIMAL (bDMARD-naïve) and BE COMPLETE (prior tumor necrosis factor inhibitor [TNFi]-inadequate responders).[2,3]

Methods

- A systematic literature review (SLR) was conducted following Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines to identify randomized controlled trials (RCTs) of approved b/tsDMARDs in PsA published from January 1991 through 2 May 2022 **(Table 1)**.
- Bayesian binomial NMAs were conducted to compare the efficacy outcomes, American College of Rheumatology (ACR) 20/50/70, Psoriasis Area and Severity Index (PASI) 90/100, minimal disease activity (MDA), and safety for bimekizumab 160 mg with b/tsDMARDs at regulatory-approved doses in patients who were b/tsDMARD-naïve (bio-n) and TNFi-experienced (TNFi-exp).[4-6]
- Studies reporting data at Week 16 were included in the NMA. In the absence of 16-week data, data available at Weeks 12, 14, or 24 were included.
- Serious adverse events (SAEs) were analyzed using Week 12 to 24 data in a mixed population.
- Four NMA models (fixed-effect [FE] unadjusted, FE baseline risk-adjusted, random-effects [RE] unadjusted, and RE baseline risk-adjusted) were assessed for best fit using deviance, effective number of parameters, deviance information criterion, estimation of RE dispersion (for RE models only), and estimation of the baseline risk adjustments and the respective 95% credible interval (CrI)(beta placebo) for the adjusted model only.
- Analyses in bio-n patients were adjusted for variation in baseline risk across RCTs.
- Odds ratios (ORs) and differences of mean change with the associated 95% CrI were calculated for the best-fitting models.
- The probability of bimekizumab 160 mg being better than other treatments was calculated using surface under the cumulative ranking curve (SUCRA) to determine relative rank.

Results

- There were 41 studies that met the inclusion criteria of the NMA.
- The networks of evidence for ACR50 in bio-n and TNFi-exp patients are shown in **Figure 1.**
- The results for the NMA on efficacy outcomes are presented in **Figures 2 to 5**, and **Tables 2 and 3.**
- MDA: Bimekizumab 160 mg ranked 1st among 13 treatments in bio-n patients and 2nd among 11 treatments in TNFi-exp patients.
- **Joint outcomes**: Bimekizumab 160 mg ranked 6th for ACR20, 5th for ACR50 **(Figure 2)**, and 3rd for ACR70 among 21 treatments in bio-n patients, and 1st among 16 treatments for ACR20, 2nd among 15 treatments for ACR50 **(Figure 3)**, and 1st among 16 treatments for ACR70 in TNFi-exp patients.
- **Skin outcomes**: Bimekizumab 160 mg ranked 2nd among 15 treatments for PASI90 and 1st among 11 treatments for PASI100 **(Figure 4)** in bio-n patients, and 1st among 10 treatments for PASI90 and 2nd among 7 treatments for PASI100 in TNFi-exp patients **(Figure 5)**.
- **Safety**: In the mixed population including 24 treatments, bimekizumab 160 mg was comparable to other b/tsDMARDs for SAEs due to no significant pairwise comparison observed between active treatments.

Table 1 Inclusion criteria

Item	Inclusion criteria
Population	Adult patients with PsA
Intervention	BKZ 160 mg Q4W (IL-17A/17Fi)
Comparators	All regulatory approved treatments for PsA including IL-17Ai, IL-23i, IL-12/23i, TNFi, JAKi, CTLA-4i, and PDE-4i
Outcomes	At 12, 16, and 24 weeks (± 2 weeks): ACR20, ACR50, ACR70, PASI90, PASI100, MDA, SAE
Study design	RCTs: Phase 2, 2/3, and 3 and 4

Summary of bimekizumab 160 mg results

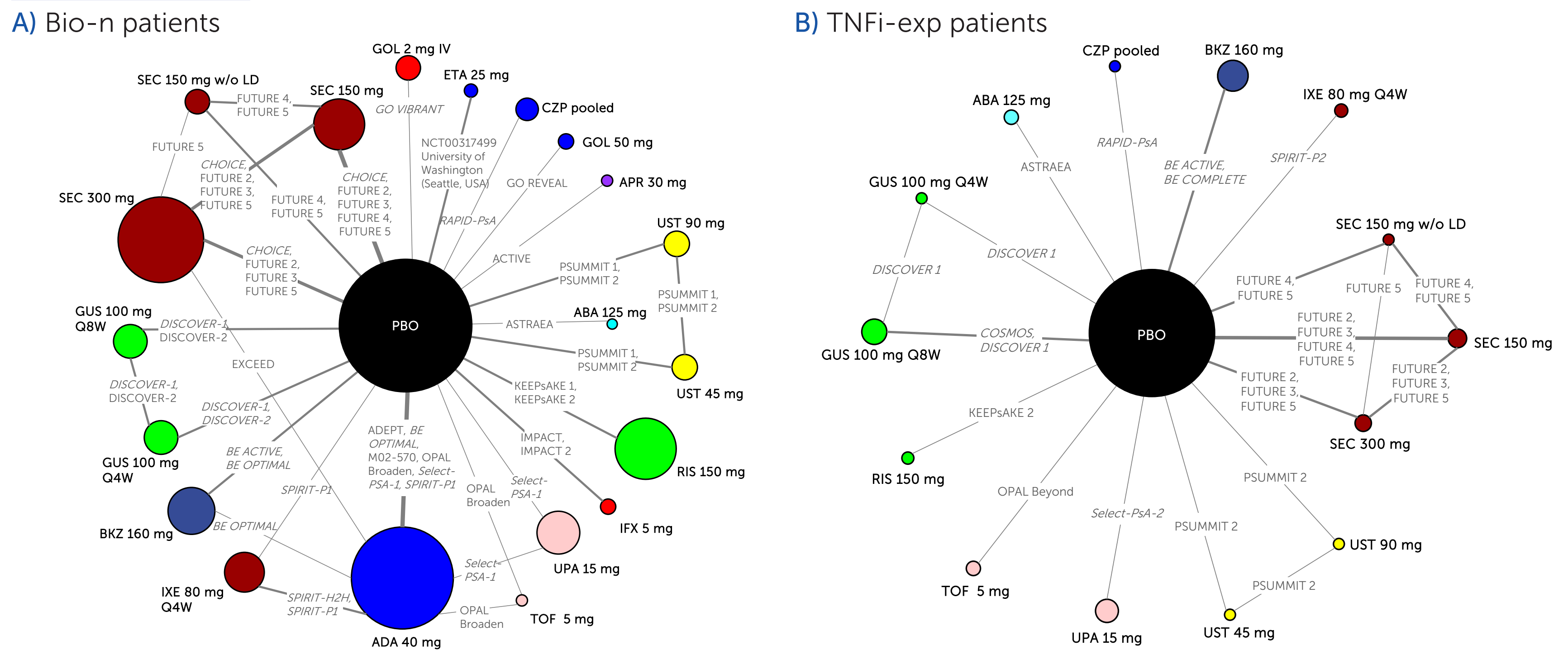
According to SUCRA values, bimekizumab 160 mg ranked:

Outcome	Bio-n patients	TNFi-exp patients
MDA	1st among 13 treatments	2nd among 11 treatments
ACR20	6th among 21 treatments	1st among 16 treatments
ACR50	5th among 21 treatments	2nd among 15 treatments
ACR70	3rd among 21 treatments	1st among 16 treatments
PASI90	2nd among 15 treatments	1st among 10 treatments
PASI100	1st among 11 treatments	2nd among 7 treatments

Conclusion

Bimekizumab 160 mg ranked highly for clinically meaningful stringent outcome measures including ACR response, PASI, and MDA when compared with other b/tsDMARDs in patients with PsA who are bio-n or TNFi-exp. Safety outcomes with bimekizumab were comparable with other b/tsDMARDs.

Figure 1 Network diagrams

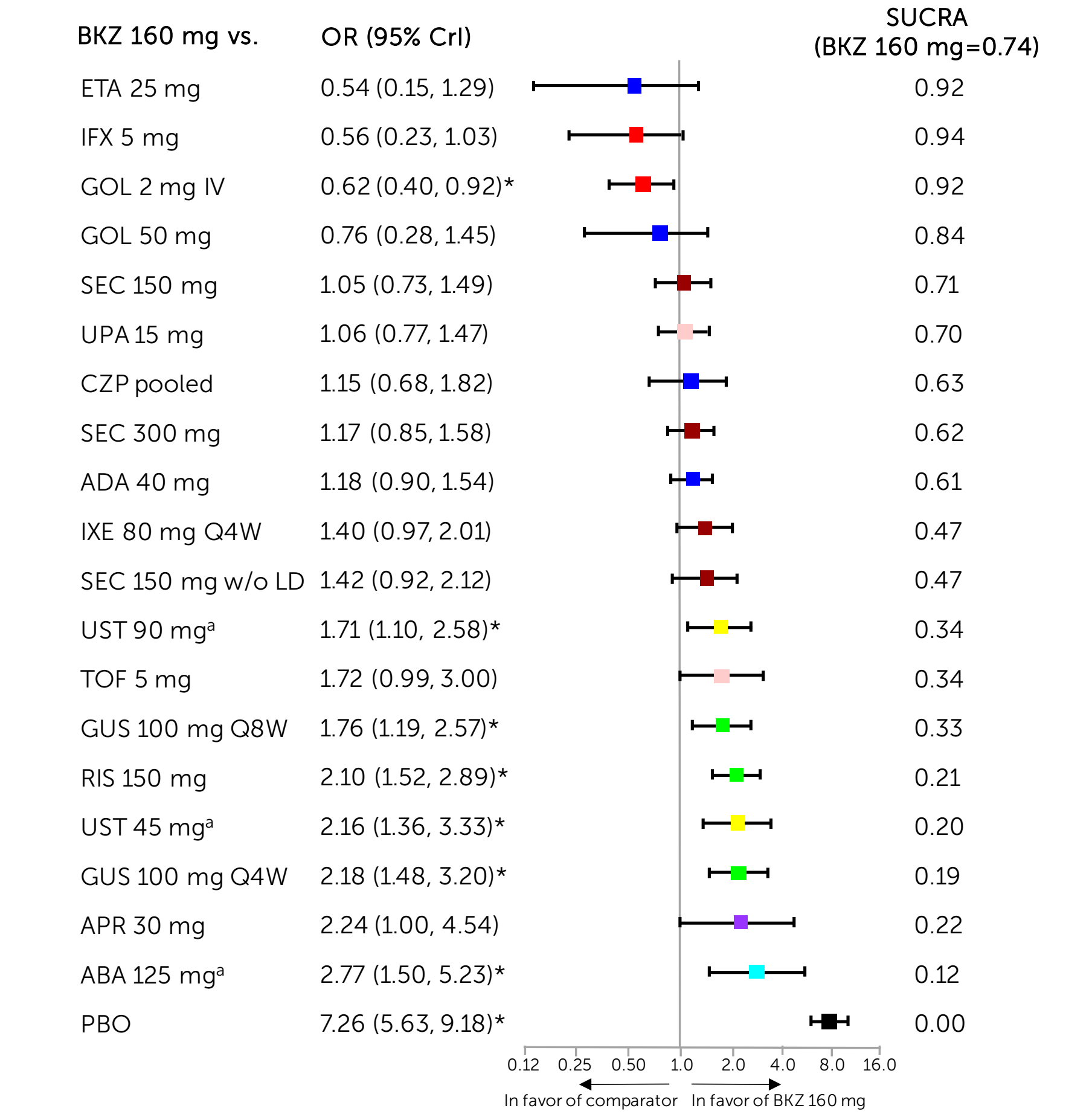


Figures 1A and 1B represent the networks for ACR50; *italicized* studies within the ACR50 network diagrams represent those included in the networks for PASI100. The number of patients analyzed for each intervention is not represented for PASI100. The size of the circle representing each intervention is proportional to the number of patients included in the analysis. Interventions with >1000 patients or <100 patients were capped to a maximum and minimum size, respectively. The line width is proportional to the number of studies connecting the intervention.

Legend: ■ IL-17A/17Fi ■ IL-17Ai 🟩 IL-23i 🟨 IL-12/23i 🟦 TNFi SC 🟥 TNFi IV ■ JAKi 🟪 PDE-4i ■ CTLA-4i ■ PBO

Figure 2 ACR50: bio-n patients at Week 16[a], FE baseline-adjusted

A) Forest plot



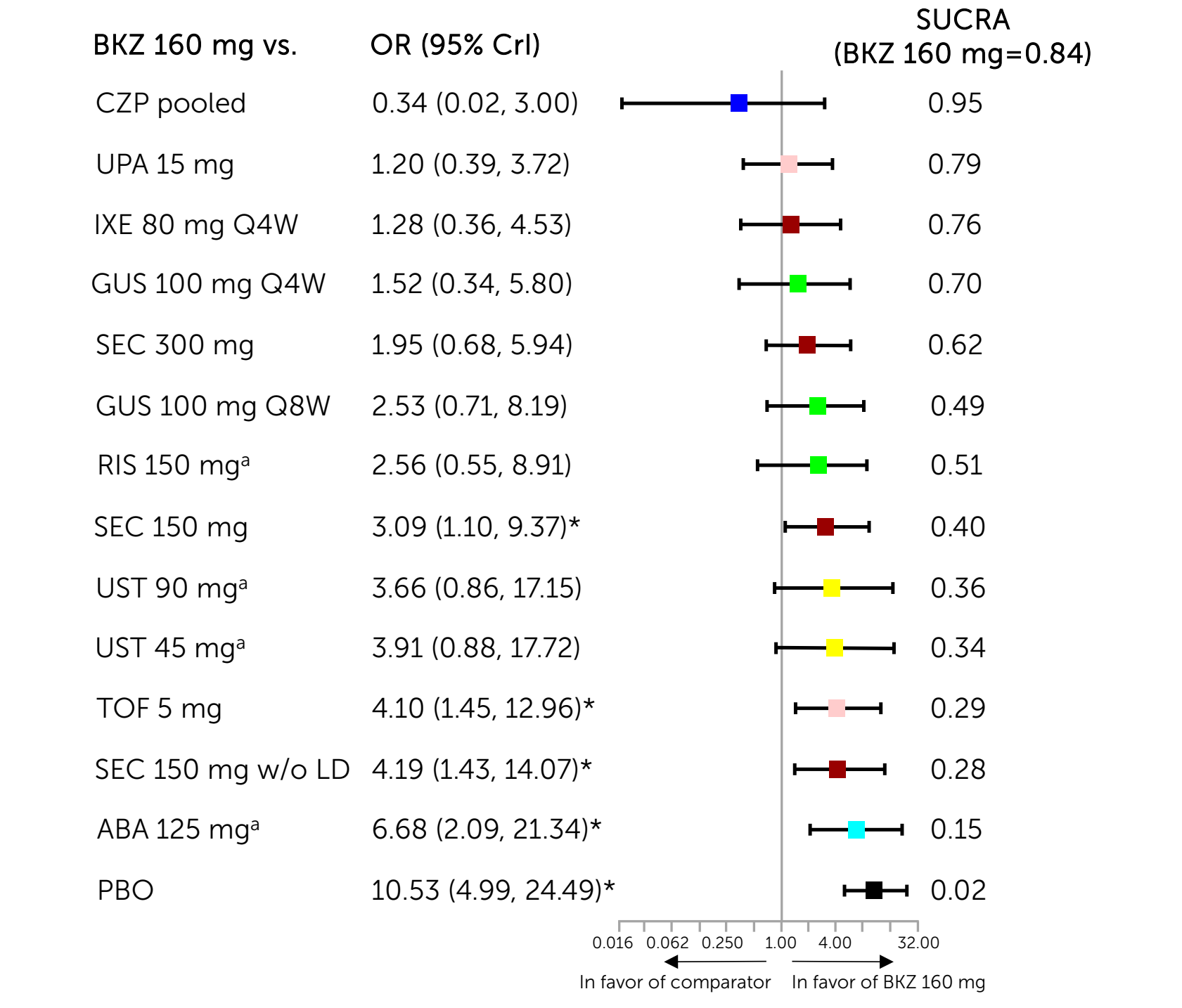
BKZ 160 mg vs.	OR (95% CrI)	SUCRA (BKZ 160 mg=0.74)
ETA 25 mg	0.54 (0.15, 1.29)	0.92
IFX 5 mg	0.56 (0.23, 1.03)	0.94
GOL 2 mg IV	0.62 (0.40, 0.92)*	0.92
GOL 50 mg	0.76 (0.28, 1.45)	0.84
SEC 150 mg	1.05 (0.73, 1.49)	0.71
UPA 15 mg	1.06 (0.77, 1.47)	0.70
CZP pooled	1.15 (0.68, 1.82)	0.63
SEC 300 mg	1.17 (0.85, 1.58)	0.62
ADA 40 mg	1.18 (0.90, 1.54)	0.61
IXE 80 mg Q4W	1.40 (0.97, 2.01)	0.47
SEC 150 mg w/o LD	1.42 (0.92, 2.12)	0.47
UST 90 mg[a]	1.71 (1.10, 2.58)*	0.34
TOF 5 mg	1.72 (0.99, 3.00)	0.34
GUS 100 mg Q8W	1.76 (1.19, 2.57)*	0.33
RIS 150 mg	2.10 (1.52, 2.89)*	0.21
UST 45 mg[a]	2.16 (1.36, 3.33)*	0.20
GUS 100 mg Q4W	2.18 (1.48, 3.20)*	0.19
APR 30 mg	2.24 (1.00, 4.54)	0.22
ABA 125 mg[a]	2.77 (1.50, 5.23)*	0.12
PBO	7.26 (5.63, 9.18)*	0.00

B) Model fit statistics: ACR50, bio-n patients

Model	Iterations	Deviance	pD	DIC	SD (95% CrI)	beta	Patients	Treatments	Studies
FE Adjusted	**30000**	**415.37**	**54.22**	**469.59**		**-0.55 (-0.72, -0.30)**	**11323**	**21**	**29**
RE Adjusted	30000	406.99	68.92	475.91	0.20 (0.02, 0.36)	-0.64 (-0.90, -0.37)	11323	21	29
FE Unadjusted	30000	412.12	470.01	882.13			11323	21	29
RE Unadjusted	30000	403.38	64.14	467.53	0.22 (0.03, 0.38)		11323	21	29

Figure 3 ACR50: TNFi-exp at Week 16[a], RE unadjusted

A) Forest plot



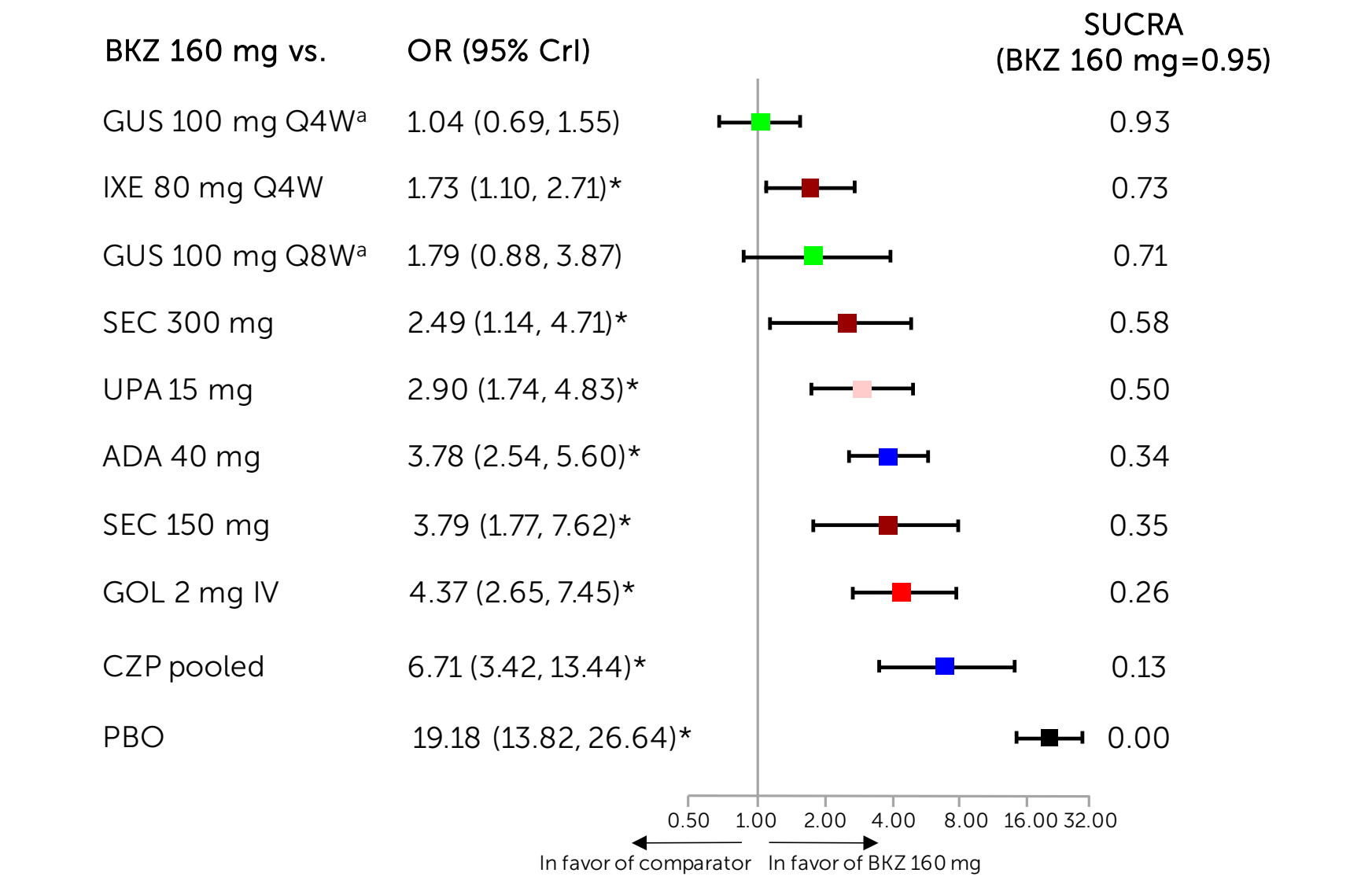
BKZ 160 mg vs.	OR (95% CrI)	SUCRA (BKZ 160 mg=0.84)
CZP pooled	0.34 (0.02, 3.00)	0.95
UPA 15 mg	1.20 (0.39, 3.72)	0.79
IXE 80 mg Q4W	1.28 (0.36, 4.53)	0.76
GUS 100 mg Q4W	1.52 (0.34, 5.80)	0.70
SEC 300 mg	1.95 (0.68, 5.94)	0.62
GUS 100 mg Q8W	2.53 (0.71, 8.19)	0.49
RIS 150 mg[a]	2.56 (0.55, 8.91)	0.51
SEC 150 mg	3.09 (1.10, 9.37)*	0.40
UST 90 mg[a]	3.66 (0.86, 17.15)	0.36
UST 45 mg[a]	3.91 (0.88, 17.72)	0.34
TOF 5 mg	4.10 (1.45, 12.96)*	0.29
SEC 150 mg w/o LD	4.19 (1.43, 14.07)*	0.28
ABA 125 mg[a]	6.68 (2.09, 21.34)*	0.15
PBO	10.53 (4.99, 24.49)*	0.02

B) Model fit statistics: ACR50, TNFi-exp patients

Model	Iterations	Deviance	pD	DIC	SD (95% CrI)	beta	Patients	Treatments	Studies
FE Adjusted	30000	176.73	36.83	213.56		-1.40 (-3.63, 1.78)	3083	15	15
RE Adjusted	30000	175.04	32.21	207.25	0.17 (0.01, 0.39)	-1.76 (-3.95, 0.43)	3083	15	15
FE Unadjusted	30000	175.21	86.78	261.98			3083	15	15
RE Unadjusted	**30000**	**175.11**	**30.21**	**205.33**	**0.16 (0.01, 0.38)**		**3083**	**15**	**15**

Figure 4 PASI100: bio-n patients at Week 16[a], FE baseline-adjusted

A) Forest plot



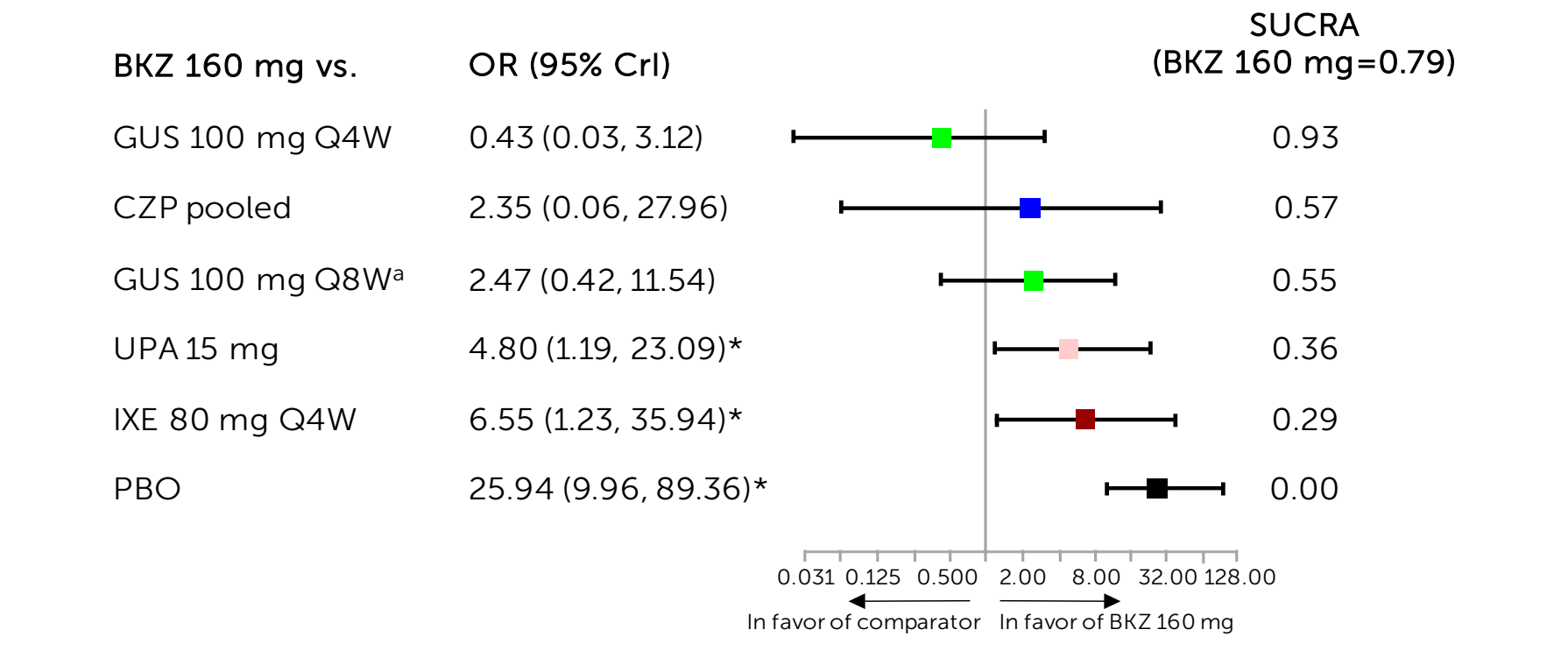
BKZ 160 mg vs.	OR (95% CrI)	SUCRA (BKZ 160 mg=0.95)
GUS 100 mg Q4W[a]	1.04 (0.69, 1.55)	0.93
IXE 80 mg Q4W	1.73 (1.10, 2.71)*	0.73
GUS 100 mg Q8W[a]	1.79 (0.88, 3.87)	0.71
SEC 300 mg	2.49 (1.14, 4.71)*	0.58
UPA 15 mg	2.90 (1.74, 4.83)*	0.50
ADA 40 mg	3.78 (2.54, 5.60)*	0.34
SEC 150 mg	3.79 (1.77, 7.62)*	0.35
GOL 2 mg IV	4.37 (2.65, 7.45)*	0.26
CZP pooled	6.71 (3.42, 13.44)*	0.13
PBO	19.18 (13.82, 26.64)*	0.00

B) Model fit statistics: PASI100, bio-n patients

Model	Iterations	Deviance	pD	DIC	SD (95% CrI)	beta	Patients	Treatments	Studies
FE Adjusted	**30000**	**129.20**	**21.06**	**150.27**		**-0.95 (-1.23, -0.63)**	**3205**	**11**	**10**
RE Adjusted	30000	129.00	21.30	150.30	0.14 (0.01, 0.38)	-0.94 (-1.30, -0.42)	3205	11	10
FE Unadjusted	30000	135.32	65.94	201.26			3205	11	10
RE Unadjusted	30000	132.87	20.14	153.01	0.23 (0.02, 0.39)		3205	11	10

Figure 5 PASI100: TNFi-exp at Week 16[a], RE unadjusted

A) Forest plot



BKZ 160 mg vs.	OR (95% CrI)	SUCRA (BKZ 160 mg=0.79)
GUS 100 mg Q4W	0.43 (0.03, 3.12)	0.93
CZP pooled	2.35 (0.06, 27.96)	0.57
GUS 100 mg Q8W[a]	2.47 (0.42, 11.54)	0.55
UPA 15 mg	4.80 (1.19, 23.09)*	0.36
IXE 80 mg Q4W	6.55 (1.23, 35.94)*	0.29
PBO	25.94 (9.96, 89.36)*	0.00

B) Model fit statistics: PASI100, TNFi-exp patients

Model	Iterations	Deviance	pD	DIC	SD (95% CrI)	beta	Patients	Treatments	Studies
FE Adjusted	30000	65.84	14.05	79.90		-0.74 (-0.98, 0.88)	1102	7	7
RE Adjusted	30000	65.56	13.80	79.35	0.20 (0.01, 0.39)	-0.84 (-1.17, 3.04)	1102	7	7
FE Unadjusted	30000	66.32	21.18	87.50			1102	7	7
RE Unadjusted	**30000**	**66.56**	**15.20**	**81.76**	**0.20 (0.01, 0.39)**		**1102**	**7**	**7**

Forest plots: *The 95% CrI does not include 1; bimekizumab 160 mg is considered either superior or inferior depending on the direction of the effect. [a]If Week 16 data not available, Week 24 data was used.
Model fit statistics: The best fit model is in **bold**.

Table 2 Odds ratios and SUCRA for ACR20, ACR70, PASI90, and MDA: bio-n patients at Week 16[a]

Treatment	ACR20		ACR70		PASI90		MDA	
	OR (95% CrI)	SUCRA	OR (95% CrI)	SUCRA	OR (95% CrI)	SUCRA	OR (95% CrI)	SUCRA
BKZ 160 mg	REF	0.75	REF	0.81	REF	0.89	REF	0.87
GOL 2 mg IV	0.42 (0.28, 0.63)*	0.99	0.67 (0.39, 1.06)	0.97	2.46 (1.63, 3.79)*	0.46	1.08 (0.50, 1.89)	0.78
IFX 5 mg	0.63 (0.35, 1.04)	0.92	0.78 (0.32, 1.45)	0.91	1.87 (0.98, 3.24)	0.60	-	-
ETA 25 mg	0.73 (0.42, 1.20)	0.88	2.83 (0.88, 7.55)	0.19	24.26 (8.86, 88.77)*	0.03	-	-
GOL 50mg	0.87 (0.44, 1.49)	0.80	1.68 (0.74, 3.32)	0.42	4.78 (2.21, 8.85)*	0.20	-	-
UPA 15 mg	0.98 (0.70, 1.36)	0.77	1.03 (0.69, 1.47)	0.79	2.72 (1.76, 4.25)*	0.40	1.32 (0.88, 1.89)	0.58
ADA 40 mg	1.09 (0.85, 1.41)	0.68	1.10 (0.80, 1.49)	0.73	2.91 (2.09, 4.11)*	0.35	1.35 (0.95, 1.85)	0.54
SEC 300 mg	1.13 (0.85, 1.50)	0.64	1.04 (0.66, 1.58)	0.77	1.41 (0.94, 2.15)	0.72	1.29 (0.85, 1.90)	0.61
SEC 150 mg w/o LD	1.14 (0.79, 1.64)	0.63	1.52 (0.88, 2.64)	0.47	-	-	-	-
IXE 80 mg Q4W	1.24 (0.86, 1.75)	0.56	1.62 (1.03, 2.47)*	0.42	1.14 (0.73, 1.76)	0.82	1.09 (0.67, 1.74)	0.78
SEC 150 mg	1.33 (0.98, 1.77)	0.48	1.13 (0.72, 1.72)	0.71	2.78 (1.69, 4.68)*	0.39	1.36 (0.78, 2.30)	0.54
CZP pooled	1.45 (0.95, 2.20)	0.41	1.19 (0.69, 1.91)	0.67	4.62 (2.68, 7.70)*	0.19	1.27 (0.49, 2.41)	0.63
GUS 100 mg Q4W	1.45 (1.03, 2.03)*	0.41	1.88 (1.11, 3.06)*	0.32	1.01 (0.66, 1.57)[a]	0.88	2.03 (1.26, 3.12)*[a]	0.17
RIS 150 mg	1.55 (1.16, 2.09)*	0.35	1.94 (1.31, 2.80)*	0.29	1.99 (1.37, 2.96)*	0.58	1.99 (1.39, 2.76)*[a]	0.18
GUS 100 mg Q8W	1.65 (1.18, 2.33)*	0.30	1.40 (0.85, 2.18)	0.54	0.89 (0.58, 1.39)[a]	0.95	1.73 (1.09, 2.64)*[a]	0.30
TOF 5 mg	1.76 (1.08, 2.87)*	0.27	1.49 (0.81, 2.80)	0.49	-	-	1.40 (0.74, 2.59)	0.52
ABA 125 mg	1.93 (1.11, 3.30)*	0.23	2.77 (1.36, 6.46)*[a]	0.16	-	-	-	-
UST 90 mg	1.93 (1.27, 2.82)*	0.21	1.69 (1.00, 2.74)[a]	0.39	-	-	-	-
APR 30 mg	2.27 (1.65, 3.10)*	0.12	2.62 (0.80, 7.64)	0.22	-	-	-	-
UST 45 mg	2.52 (1.68, 3.70)*	0.09	2.08 (1.21, 3.51)*[a]	0.26	-	-	-	-
PBO	4.91 (3.93, 6.15)*	0.00	8.99 (6.75, 11.53)*	0.00	21.09 (15.77, 28.73)*	0.04	6.30 (4.59, 8.19)*	0.00

REF=reference treatment for all comparisons. Interventions are ordered from highest to lowest SUCRA for ACR20. *As the 95% CrI does not include 1, bimekizumab 160 mg is superior if the OR >1 (shaded dark green) or inferior if the OR<1 (shaded red). For OR>1.1 bimekizumab 160 mg has a numerical advantage without significance (comparable, shaded light green), for OR 1±0.1 there is no meaningful difference (shaded peach), and for OR<0.9 bimekizumab 160 mg has a numerical disadvantage without significance (comparable, shaded light red). [a]If Week 16 data not available, Week 24 data was used.

Table 3 Odds ratios and SUCRA for ACR20, ACR70, PASI90, and MDA: TNFi-exp patients at Week 16[a]

Treatment	ACR20		ACR70		PASI90		MDA	
	OR (95% CrI)	SUCRA	OR (95% CrI)	SUCRA	OR (95% CrI)	SUCRA	OR (95% CrI)	SUCRA
BKZ 160 mg	REF	0.96	REF	0.83	REF	0.85	REF	0.78
CZP pooled	1.07 (0.24, 4.19)	0.90	2.02 (0.12, 9.66)	0.59	1.44 (0.04, 12.35)	0.69	1.26 (0.05, 12.49)	0.66
GUS 100 mg Q4W	2.16 (0.73, 6.84)	0.71	1.12 (0.15, 4.19)	0.80	1.48 (0.31, 6.73)	0.72	0.89 (0.15, 5.42)	0.79
UPA 15 mg	2.39 (1.09, 6.01)*	0.68	2.11 (0.73, 10.88)	0.55	4.78 (1.60, 15.16)*	0.29	2.27 (0.65, 7.54)	0.49
SEC 300 mg	2.57 (1.22, 6.15)*	0.65	1.24 (0.08, 4.48)	0.82	3.32 (0.09, 40.65)[a]	0.50	1.42 (0.04, 15.09)	0.64
APR 30 mg	2.46 (0.91, 7.16)	0.64	-	-	-	-	-	-
GUS 100 mg Q8W	2.67 (1.18, 6.52)*	0.62	5.00 (1.21, 24.73)*[a]	0.25	2.32 (0.64, 8.10)[a]	0.55	1.69 (0.36, 7.75)[a]	0.58
IXE 80 mg Q4W	2.72 (1.13, 7.37)*	0.60	1.61 (0.22, 4.92)	0.69	2.69 (0.59, 10.86)	0.51	1.72 (0.43, 6.59)	0.59
TOF 5 mg	3.57 (1.38, 9.32)*	0.44	1.41 (0.04, 7.48)	0.75	-	-	6.47 (2.07, 20.46)*	0.16
SEC 150 mg	3.78 (1.83, 8.80)*	0.41	2.10 (0.12, 8.07)	0.57	6.62 (0.20, 69.73)[a]	0.31	3.30 (0.05, 40.52)	0.40
UST 45 mg	4.68 (1.24, 16.48)*	0.34	7.95 (1.25, 118.50)*[a]	0.16	-	-	-	-
UST 90 mg	4.98 (1.40, 17.81)*	0.31	7.23 (1.27, 90.04)*[a]	0.17	-	-	-	-
SEC 150 mg w/o LD	4.81 (1.86, 11.78)*	0.30	2.18 (0.14, 10.14)	0.55	-	-	-	-
RIS 150 mg	4.77 (1.94, 12.96)*	0.30	5.63 (0.58, 22.47)[a]	0.23	2.22 (0.54, 8.74)[a]	0.58	2.95 (0.74, 11.09)[a]	0.39
ABA 125 mg	7.29 (3.11, 19.63)*	0.13	3.02 (0.17, 12.75)[a]	0.43	-	-	-	-
PBO	11.43 (6.52, 22.65)*	0.01	8.87 (0.90, 23.82)	0.11	28.40 (13.02, 72.19)*	0.02	11.28 (4.99, 28.63)*	0.03

REF=reference treatment for all comparisons. Interventions are ordered from highest to lowest SUCRA for ACR20. *As the 95% CrI does not include 1, bimekizumab 160 mg is superior if the OR >1 (shaded dark green) or inferior if the OR<1 (shaded red). For OR>1.1 bimekizumab 160 mg has a numerical advantage without significance (comparable, shaded light green), for OR 1±0.1 there is no meaningful difference (shaded peach), and for OR<0.9 bimekizumab 160 mg has a numerical disadvantage without significance (comparable, shaded light red). [a]If Week 16 data not available, Week 24 data was used.

ABA: abatacept; **ACR:** American College of Rheumatology; **ADA:** adalimumab; **APR:** apremilast; **bio-n:** b/tsDMARD-naïve; **BKZ:** bimekizumab; **b/tsDMARDs:** biological or targeted synthetic disease-modifying antirheumatic drug; **CrI:** credible interval; **CTLA4-Ig:** cytotoxic T lymphocyte antigen 4-immunoglobulin; **CZP:** certolizumab pegol; **DIC:** deviance information criterion; **ETA:** etanercept; **FE:** fixed effects; **GOL:** golimumab; **GUS:** guselkumab; **IFX:** infliximab; **IgG1:** immunoglobulin G1; **IL:** interleukin; **IL-12/23i:** IL-12/23 inhibitor; **IL-17Ai:** IL-17A inhibitor; **IL-17A/17Fi:** IL-17A/17F inhibitor; **IL-23i:** IL-23 inhibitor; **IV:** intravenous; **IXE:** ixekizumab; **JAKi:** Janus kinase inhibitor; **MDA:** minimal disease activity; **NICE:** The National Institute for Health and Care Excellence; **NMA:** network meta-analysis; **OR:** odds ratio; **PASI:** Psoriasis Area and Severity Index; **PBO:** placebo; **pD:** posterior mean of the deviance; **PDE-4i:** phosphodiesterase-4 inhibitor; **PRISMA:** Preferred Reporting Items for Systematic Reviews and Meta-Analyses; **PsA:** psoriatic arthritis; **Q4W:** every 4 weeks; **Q8W:** every 8 weeks; **RCT:** randomized controlled trial; **RE:** random effects; **REF:** reference treatment; **RIS:** risankizumab; **SAE:** serious adverse event; **SD:** standard deviation; **SEC:** secukinumab; **SLR:** systematic literature review; **SUCRA:** surface under the cumulative rank; **TNFi:** tumor necrosis factor inhibitor; **TNFi-exp:** TNFi-experienced; **TOF:** tofacitinib; **UPA:** upadacitinib; **UST:** ustekinumab; **vs:** versus; **w/o LD:** without loading dose.

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