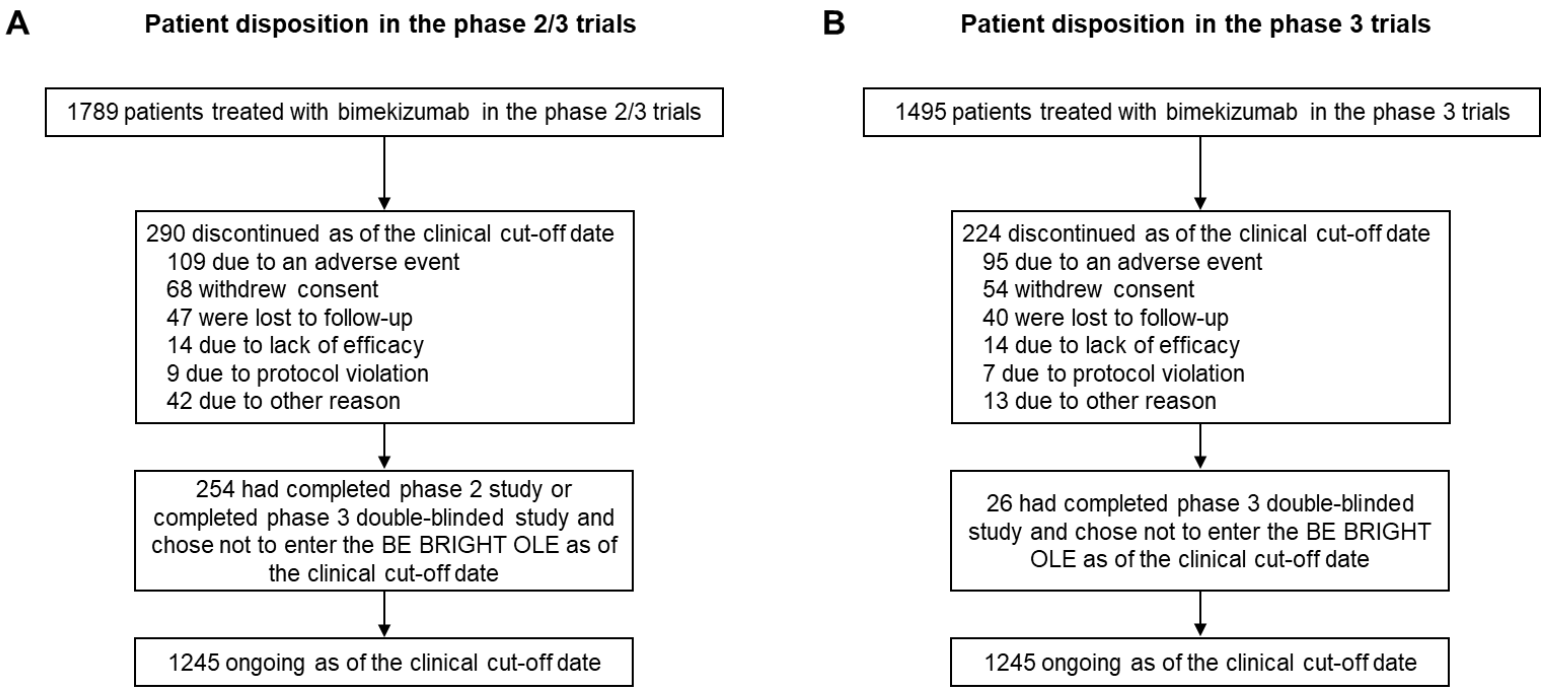
Supplementary Online Content

Gordon KB, Langley RG, Warren RB, et al. Bimekizumab safety in patients with moderate to severe plaque psoriasis: pooled results from phase 2 and phase 3 randomized clinical trials. *JAMA Dermatol*. Published online May 11, 2022. doi:10.1001/jamadermatol.2022.1185

This supplementary material has been provided by the authors to give readers additional information about their work.

eFigure. Patient disposition



A) Phase 2 trials included: BE ABLE 1 and the BE ABLE 2 OLE, and PS0016 and the PS0018 OLE study. Phase 3 trials included: BE VIVID, BE READY, BE SURE, and the BE BRIGHT OLE; B) Phase 3 trials included: BE VIVID, BE READY, BE SURE, and the BE BRIGHT OLE. For patients who participated in a feeder study and corresponding extension, the disposition is reported for the extension study. For patients who participated in a feeder study only, the disposition is reported for the feeder study. The clinical cut-off date for the ongoing BE BRIGHT trial was 9 November 2020. OLE: open-label extension.

eTable 1. Overview of trials included in these analyses

Trial	Trial summary	Duration	Treatment
Phase 2			
BE ABLE 1 (NCT02905006)	Multicenter, randomized, double-blinded, placebo-controlled, parallel group, dose-ranging trial	12 weeks	Bimekizumab Q4W dosed 64 mg, 160 mg, 160 mg (with 320 mg loading dose at baseline), 320 mg, 480 mg, or placebo
BE ABLE 2 (NCT03010527)	Multicenter, randomized, double-blinded, placebo-controlled extension trial; patients who completed BE ABLE 1 were eligible	48 weeks	Bimekizumab Q4W dosed 64 mg 160 mg, 320 mg or placebo; dependent on treatment received in BE ABLE 1 and PASI 90 response at Week 12 of BE ABLE 1
PS0016 (NCT03025542)	Multicenter, randomized, double-blinded trial	28 weeks	Bimekizumab 320 mg at baseline and Week 4 followed by placebo at Week 16, or bimekizumab 320 mg at baseline, Week 4, and Week 16
PS0018 (NCT03230292)	Multicenter, open-label extension trial; patients who participated in PS0016 were eligible	48 weeks	Bimekizumab Q4W dosed 160 mg; option to increase dose to 320 mg Q4W based on PASI response and the investigator's discretion
Phase 3			
BE VIVID (NCT03370133)	Multicenter, randomized, double-blinded, active comparator- and placebo-controlled trial	52 weeks	Bimekizumab 320 mg Q4W, ustekinumab 45 mg or 90 mg at baseline and Week 4 then Q12W,[a] or placebo Q4W to Week 16 followed by bimekizumab 320 mg Q4W to Week 52
BE READY (NCT03410992)	Multicenter, randomized, double-blinded, placebo-controlled, randomized withdrawal trial	56 weeks	Bimekizumab 320 mg Q4W or placebo to Week 16. In the randomized withdrawal period, Week 16 PASI 90 responders were re-randomized to placebo, bimekizumab 320 mg Q4W or bimekizumab 320 mg Q8W to Week 56. Re-randomized patients who did not achieve PASI 75 at Week 20 or later entered a 12-week escape arm and received bimekizumab 320 mg Q4W. Patients who did not achieve PASI 90 at Week 16 also entered the 12-week escape arm

BE SURE (NCT03412747)	Multicenter, randomized, double-blinded, active comparator-controlled trial	56 weeks	Bimekizumab 320 mg Q4W, bimekizumab 320 mg Q4W to Week 16 followed by Q8W to Week 56, or adalimumab 80 mg at baseline, 40 mg at Week 1, then Q2W to Week 24 followed by bimekizumab 320 mg Q4W to Week 56
BE BRIGHT (NCT03598790)	Multicenter, open-label extension trial; patients who completed BE VIVID, BE READY, or BE SURE were eligible	144 weeks (currently ongoing)	Bimekizumab 320 mg Q4W or bimekizumab 320 mg Q8W, depending on PASI response and prior treatment in the BE VIVID, BE READY, and BE SURE feeder studies

[a]Ustekinumab was dosed based on patient weight at baseline; 45 mg for patients ≤100 kg and 90 mg for patients >100 kg. PASI 75/90: ≥75%/90% reduction from baseline in Psoriasis Area and Severity Index; Q2W: every 2 weeks; Q4W: every 4 weeks; Q8W: every 8 weeks; Q12W: every 12 weeks

eTable 2. Scheduled assessments for tuberculosis during the trials

Trial	TB Assessments
BE ABLE 1 (NCT02905006)	Chest X-ray: Screening IGRA TB test: Screening; Week 8 TB questionnaire: Screening; baseline; Week 12 or after discontinuation
BE ABLE 2 (NCT03010527)	Chest X-ray: Only when required to confirm or exclude TB IGRA TB test: Week 48 or after discontinuation TB questionnaire: Baseline; Week 12; Week 24; Week 36; Week 48 or after discontinuation
PS0016 (NCT03025542)	Chest X-ray: Screening IGRA TB test: Screening; safety follow-up TB questionnaire: Screening; baseline; Week 20; safety follow-up
PS0018 (NCT03230292)	Chest X-ray: Only when required to confirm or exclude TB IGRA TB test: Baseline; Week 48 or after discontinuation; safety follow-up TB questionnaire: Baseline; Week 12; Week 24; Week 36; Week 48 or after discontinuation
BE VIVID (NCT03370133)	Chest X-ray: Screening IGRA TB test: Screening; Week 48 TB questionnaire: Screening; baseline; Week 12; Week 24; Week 36; Week 52 or after discontinuation; safety follow-up
BE READY (NCT03410992)	Chest X-ray: Screening IGRA TB test:[a] Screening; Week 52 TB questionnaire:[a] Screening; baseline; Week 12; Week 24; Week 36; Week 48; Week 56 or after discontinuation; safety follow-up
BE SURE (NCT03412747)	Chest X-ray: Screening IGRA TB test: Screening; Week 52 TB questionnaire: Screening; baseline; Week 12; Week 24; Week 36; Week 48; Week 56; safety follow-up
BE BRIGHT (NCT03598790)	IGRA TB test: Week 48 TB questionnaire: Week 12; Week 24; Week 36; Week 48

[a]For patients who entered the 12-week bimekizumab escape arm, assessments were performed at Week 12, or after discontinuation of treatment. IGRA: interferon gamma release assay; TB: tuberculosis.

eTable 3. Pooled baseline demographics and characteristics for bimekizumab-treated patients in the phase 2 and phase 3 trials

	Phase 3			Phase 2/3
Patient Characteristic	**Bimekizumab 320 mg Q4W (N=1456)**	**Bimekizumab 320 mg Q8W (N=930)**	**Bimekizumab Total (N=1495)**	**Bimekizumab Total (N=1789)**
Age, years, mean ± SD	45.4 ± 13.5	45.2 ± 13.2	45.4 ± 13.4	45.2 ± 13.5
Male, n (%)	1042 (71.6)	675 (72.6)	1067 (71.4)	1252 (70.0)
Caucasian, n (%)	1173 (80.6)	777 (83.5)	1208 (80.8)	1468 (82.1)
Region, n (%)				
North America	534 (36.7)	278 (29.9)	542 (36.3)	635 (35.5)
Central/Eastern Europe	535 (36.7)	402 (43.2)	558 (37.3)	728 (40.7)
Western Europe	164 (11.3)	121 (13.0)	168 (11.2)	168 (9.4)
Asia/Australia	223 (15.3)	129 (13.9)	227 (15.2)	258 (14.4)
Weight (kg), mean ± SD	89.1 ± 22.3	88.2 ± 21.9	89.1 ± 22.3	89.0 ± 22.0
Disease duration (years), mean ± SD	17.8 ± 12.3	18.1 ± 12.0	17.9 ± 12.3	17.7 ± 12.3
Prior biologic therapy, n (%)	559 (38.4)	341 (36.7)	576 (38.5)	636 (35.6)
anti-TNF	200 (13.7)	117 (12.6)	207 (13.8)	240 (13.4)
anti-IL-17	331 (22.7)	214 (23.0)	343 (22.9)	343 (19.2)
Prior systemic therapy, n (%)	1135 (78.0)	721 (77.5)	1166 (78.0)	1360 (76.0)

Patients who received both bimekizumab 320 mg Q4W and Q8W at different times in the trials are included in the total population count of each treatment group, but only once in each bimekizumab total group. Therefore, the total number of patients in both the Q4W and Q8W groups exceeds the total number of patients in the bimekizumab total groups. IL: interleukin; Q4W: every 4 weeks; Q8W: every 8 weeks; SD: standard deviation; TNF: tumor necrosis factor.

eTable 4. Most common TEAEs (preferred terms reported with an EAIR of >5.0/100 Person-Years in bimekizumab-treated patients in the phase 2/3 trials)

	Phase 3						Phase 2/3	
Preferred Term	**Bimekizumab 320 mg Q4W (N=1456)**		**Bimekizumab 320 mg Q8W (N=930)**		**Bimekizumab Total (N=1495)**		**Bimekizumab Total (N=1789)**	
	n (%)	**EAIR/100 PY (95% CI)**	**n (%)**	**EAIR/100 PY (95% CI)**	**n (%)**	**EAIR/100 PY (95% CI)**	**n (%)**	**EAIR/100 PY (95% CI)**
Nasopharyngitis	331 (22.7)	21.7 (19.4, 24.2)	129 (13.9)	17.2 (14.3, 20.4)	420 (28.1)	19.3 (17.5, 21.2)	475 (26.6)	19.1 (17.4, 20.9)
Oral candidiasis	264 (18.1)	16.4 (14.5, 18.5)	78 (8.4)	9.6 (7.6, 12.0)	301 (20.1)	12.9 (11.5, 14.4)	337 (18.8)	12.6 (11.3, 14.0)
Upper respiratory tract infection	156 (10.7)	9.1 (7.8, 10.7)	68 (7.3)	8.3 (6.5, 10.5)	207 (13.8)	8.4 (7.3, 9.6)	249 (13.9)	8.9 (7.8, 10.1)

Data are reported to two years of treatment. For patients who received both Q4W and Q8W bimekizumab doses during the trials, TEAEs were assigned to the dose most recently received prior to the date of onset of the TEAE. Patients who received both bimekizumab 320 mg Q4W and Q8W at different times in the trials are included in the population count of both treatment groups, but only once in each bimekizumab total group. Therefore, the total number of patients in each group exceeds the total number of patients in the bimekizumab total groups. CI: confidence interval; EAIR: exposure-adjusted incidence rate; PY: patient-years; Q4W: every 4 weeks; Q8W: every 8 weeks; TEAE: treatment-emergent adverse event.