Bimekizumab achievement of 'super response' using a previously published definition in moderate to severe plaque psoriasis: Results from four phase 3/3b trials

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Objective

To explore achievement of super response, according to a previously published definition, among bimekizumab (BKZ)-treated patients with moderate to severe plaque psoriasis.

We also investigate whether achievement of super response is associated with patients' baseline demographics and disease characteristics.

Background

- The increasing efficacy of biologics used to treat psoriasis has led to the proposal of a patient group termed super responders (SRs).[1,2] This patient group is thought to be more likely to achieve short- and long-term complete skin clearance (100% improvement from baseline in Psoriasis Area and Severity Index; PASI 100)[3] and is hypothesised to maintain response for a long period upon treatment withdrawal.[4,5]
- There is no established consensus on a SR definition;[1,2] however, achievement of complete skin clearance (PASI 100) at Weeks 20 and 28 has been proposed in the design of a phase 3 randomised controlled trial in psoriasis.[4,6,7] Identifying predictors for durable skin clearance is key to refining therapeutic approaches.[1]

Methods

- Data were pooled from BKZ-randomised patients in the phase 3/3b trials BE VIVID,[8] BE SURE,[9] BE READY[10] and BE RADIANT;[11] patients re-randomised to placebo at Week 16 in BE READY were excluded (**Figure 1**).
- Achievement of SR status, according to the definition published previously (PASI 100 at Weeks 20 and 28),[4,6] was analysed post-hoc among subgroups based on:
  - Baseline demographics: age, sex, weight
  - Disease characteristics: disease duration, disease severity, prior biologic therapies
- An alternative definition (PASI 100 at Weeks 16 and 24) was also explored to account for differences between drugs in when steady-state trough serum concentration levels are achieved.[12]
- Associations between subgroups and SR achievement are presented using odds ratios (ORs), calculated using the stratified Cochran–Mantel–Haenszel test on non-responder imputation (NRI) data (with study/region as stratification variables).

Results

- Overall, 57.1% (N=717/1,255) of BKZ-treated patients were SRs according to the previously published definition (PASI 100 at Weeks 20 and 28).
  - Proportions of SRs published previously with guselkumab were 40.8% in the VOYAGE-1 and VOYAGE-2 studies (N=271/664) and 34.4% in the GUIDE study (N=303/880), the only published analyses investigating achievement of super response in phase 3 randomised controlled trials.[4,6]
  - These data originate from different clinical studies with differing trial designs, patient populations, and methodologies; therefore, any comparisons between BKZ and guselkumab data should be interpreted with caution.
  - When the alternative SR definition was applied (PASI 100 at Weeks 16 and 24), the proportion of BKZ-treated patients identified as SRs was similar (55.1%; N=692/1,255).
- Most baseline characteristics were generally similar between SRs and non-SRs with BKZ (**Table**).
- SR rates were not observed to be associated with the analysed subgroups based on baseline characteristics, except for weight (**Figure 2**):
  - Patients ≤100 kg at baseline had higher SR rates (60.4%) vs patients >100 kg (49.0%).
- In a previously published analysis using this SR definition (PASI 100 at Weeks 20 and 28), age, weight and disease severity (PASI and Investigator's Global Assessment [IGA]) were significant predictors of super response.[6]

Conclusions

High proportions of bimekizumab-treated patients were super responders, according to a previously published definition, and proportions of super responders remained high when an alternative definition was explored.

Super responder rates in bimekizumab-treated patients were high across the analysed subgroups based on baseline characteristics.

Summary

Achievement of super response was analysed, according to a previously published definition (complete skin clearance at Weeks 20 and 28), for patient subgroups based on baseline characteristics:

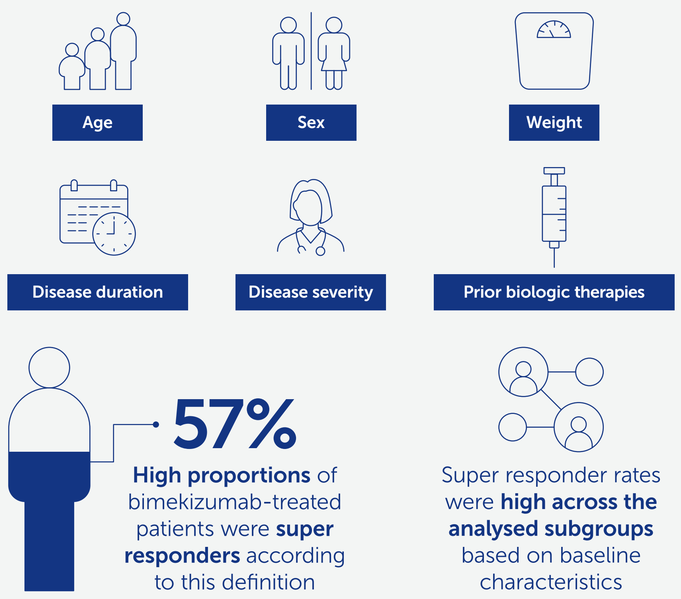
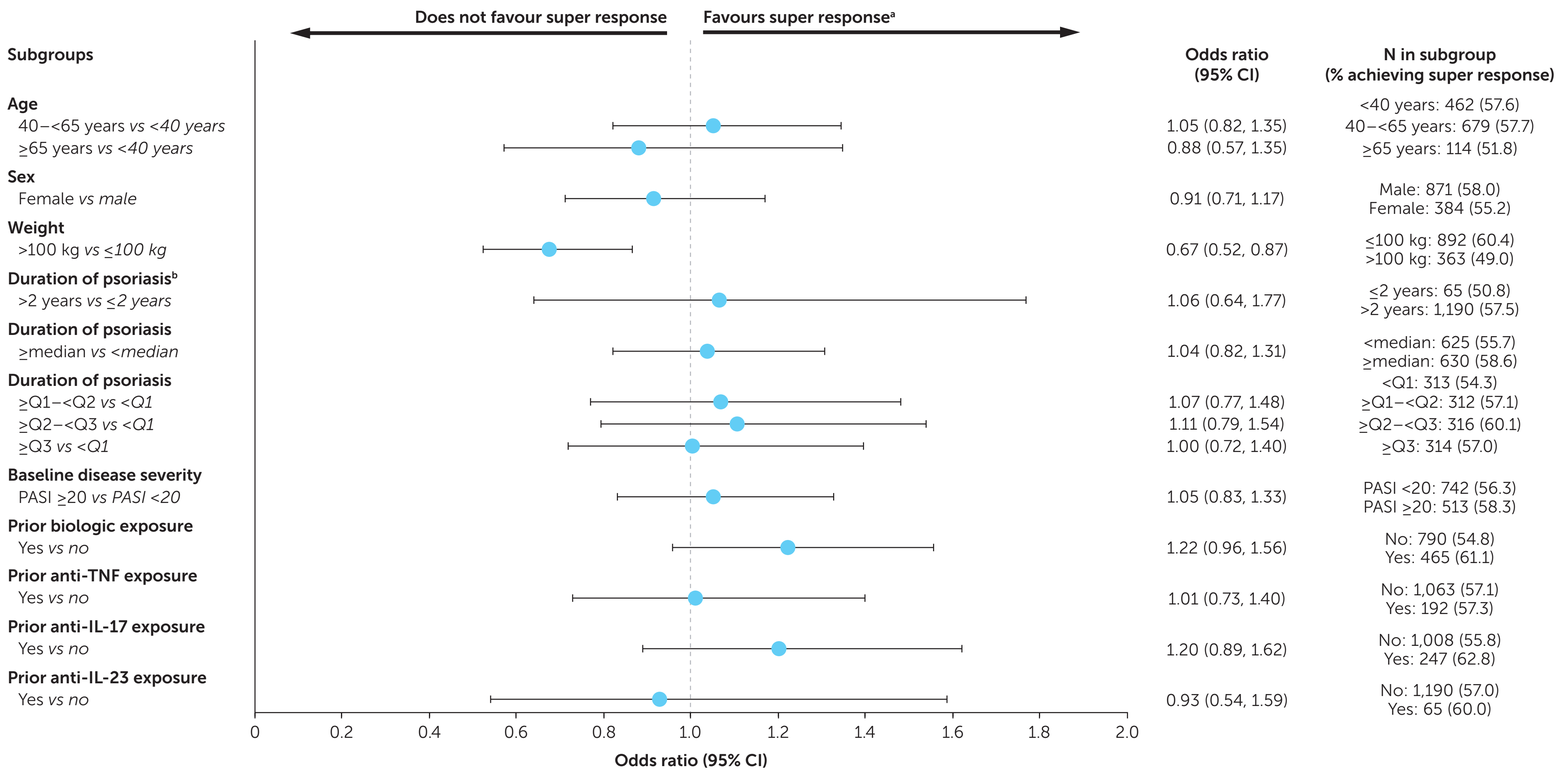


Table Baseline characteristics

	SRs BKZ Total N=717	Non-SRs BKZ Total N=538
Age, n (%)		
<40 years	266 (37.1)	196 (36.4)
40–<65 years	392 (54.7)	287 (53.3)
≥65 years	59 (8.2)	55 (10.2)
Sex, **male**, n (%)	505 (70.4)	366 (68.0)
Racial group, **white**, n (%)	641 (89.4)	450 (83.6)
Weight (kg), mean (SD)	87.2 (19.9)	93.4 (24.2)
Weight, n (%)		
≤100 kg	539 (75.2)	353 (65.6)
>100 kg	178 (24.8)	185 (34.4)
BMI (kg/m²), mean (SD)	29.1 (6.2)	31.2 (7.5)
Duration of psoriasis (years), mean (SD)	18.4 (12.4)	17.9 (12.9)
Duration of psoriasis,[a] n (%)		
<Q1	170 (23.7)	143 (26.6)
≥Q1–<Q2	178 (24.8)	134 (24.9)
≥Q2–<Q3	190 (26.5)	126 (23.4)
≥Q3	179 (25.0)	135 (25.1)
≤2 years	33 (4.6)	32 (5.9)
PASI, mean (SD)	20.6 (7.1)	21.0 (8.3)
PASI, n (%)		
<20	418 (58.3)	324 (60.2)
≥20	299 (41.7)	214 (39.8)
Any prior systemic therapy, n (%)	564 (78.7)	396 (73.6)
Any prior biologic therapy, n (%)	284 (39.6)	181 (33.6)

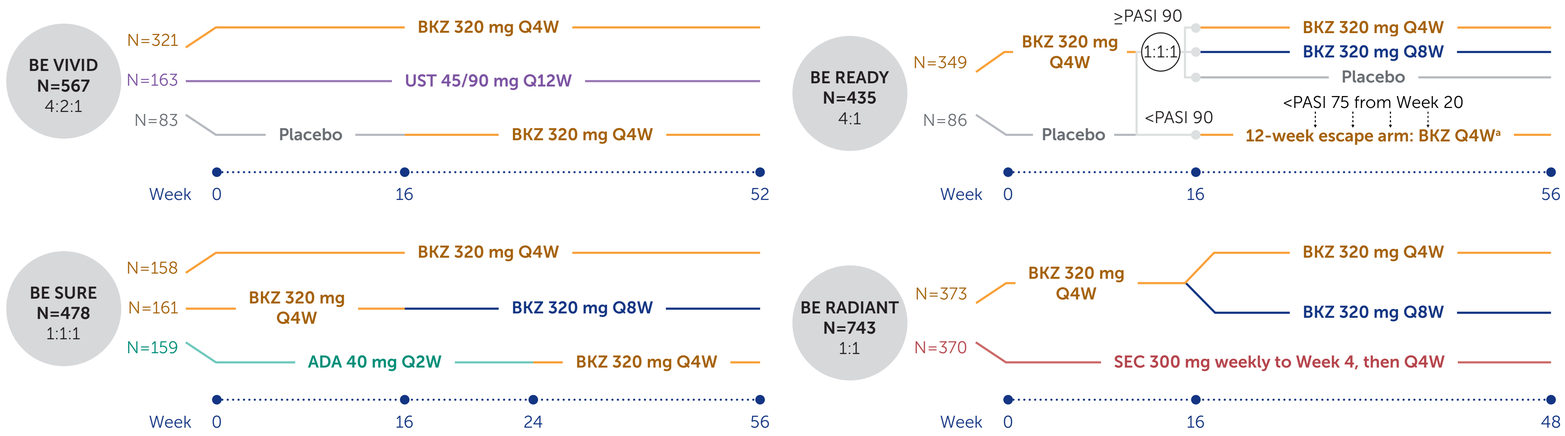
[a] Q1 refers to 8.52 years; Q2 refers to 15.66 years; Q3 refers to 25.45 years.

Figure 2 Super response achievement between patient subgroups based on baseline characteristics (NRI)



[a] An odds ratio >1 indicates that patients in the subgroup are more likely to achieve super response vs the reference subgroup (shown in italics). An association was considered significant if the 95% CI did not cross 1;
[b] Very few patients with short disease duration (≤2 years) were enrolled in the phase 3/3b BE VIVID, BE SURE, BE READY and BE RADIANT trials; further analysis in this population may be warranted.

Figure 1 Study designs



[a] BKZ-randomised patients who entered the 12-week BKZ Q4W escape arm at Week 16 in BE READY were considered non-responders in this analysis.

ADA: adalimumab; **BKZ:** bimekizumab; **BMI:** body mass index; **CI:** confidence interval; **IGA:** Investigator's Global Assessment; **IL:** interleukin; **NRI:** non-responder imputation; **OR:** odds ratio; **PASI 75/90/100:** ≥75%/≥90%/100% improvement from baseline in Psoriasis Area and Severity Index; **PBO:** placebo; **Q:** quartile; **Q2W:** every 2 weeks; **Q4W:** every 4 weeks; **Q8W:** every 8 weeks; **Q12W:** every 12 weeks; **SD:** standard deviation; **SEC:** secukinumab; **SR:** super responder; **TNF:** tumour necrosis factor; **UST:** ustekinumab.

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