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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OBJECTIVES

- To explore achievement of super response, according to a previously published definition, among bimekizumab (BKZ)-treated patients with moderate to severe plaque psoriasis.
- To investigate whether achievement of super responder (SR) status is associated with patients' baseline demographics and disease characteristics.

Achievement of super response was analyzed for patient subgroups based on baseline characteristics:

Background

- The increasing efficacy of biologics used to treat psoriasis has led to the proposal of a patient group termed SRs.[1,2] This patient group is thought to be more likely to achieve short- and long-term complete skin clearance (PASI 100),[3] and is hypothesized 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 randomized controlled trial in psoriasis.[4,6,7] Identifying predictors for durable skin clearance is key to refining therapeutic approaches.[1]

1. Thomas SE et al. Br J Dermatol 2023;189:621–2; **2.** Mastorino L et al. Exp Dermatol 2023;32:2187–8; **3.** Loft N et al. J Eur Acad Dermatol Venereol 2022;36:1284–91; **4.** Schäkel K et al. J Eur Acad Dermatol Venereol 2023;37:2016–27; **5.** Asadullah K et al. J Am Acad Dermatol 2024;91;AB222; **6.** Reich K et al. J Eur Acad Dermatol Venereol 2022;36:2393–400; **7.** Eyerich K et al. BMJ Open 2021;11:e049822. BKZ: bimekizumab; PASI 100: 100% improvement from baseline in Psoriasis Area and Severity Index; SR: super responder.

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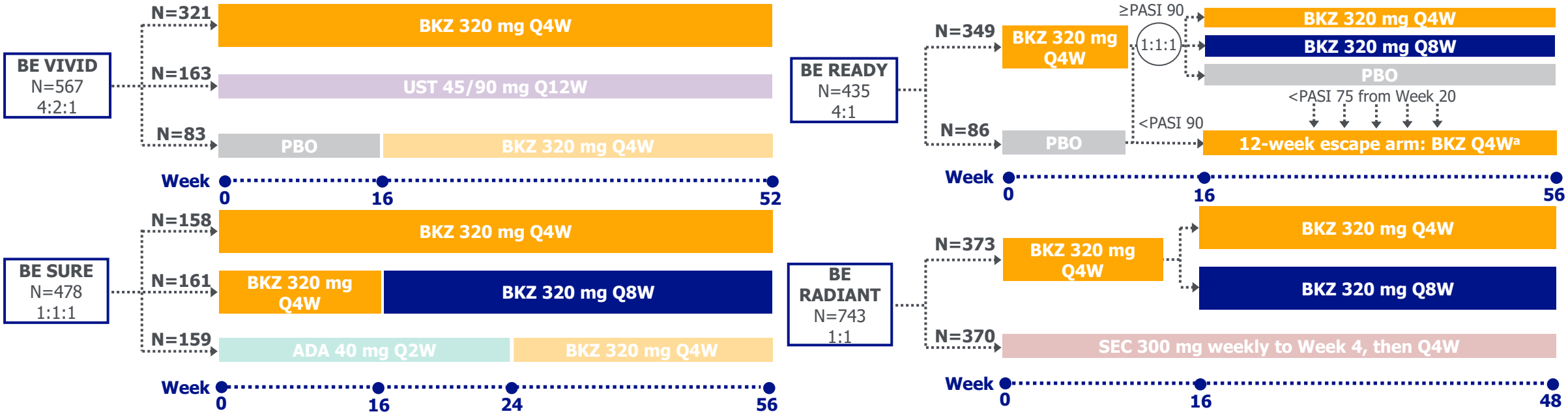
Methods and Study Designs



- Data were pooled from **BKZ-randomized patients** in the phase 3/3b trials BE VIVID,[1] BE SURE,[2] BE READY,[3] and BE RADIANT;[4] patients re-randomized to placebo at Week 16 in BE READY were excluded.
- Achievement of SR status, according to the definition published previously (PASI 100 at Weeks 20 and 28),[5,6] was analyzed post-hoc among subgroups based on baseline demographics (age/sex/weight) and 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.[7]
- 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).

[a] BKZ-randomized patients who entered the 12-week BKZ Q4W escape arm at Week 16 in BE READY were considered non-responders in this analysis. **1.** Reich K et al. Lancet 2021;397:487–98 (NCT03370133); **2.** Warren RB et al. N Engl J Med 2021;385:130–41 (NCT03412747); **3.** Gordon KB et al. Lancet 2021;397:475–86 (NCT03410992); **4.** Reich K et al. N Engl J Med 2021;385:142–52 (NCT03536884); **5.** Schäkel K et al. J Eur Acad Dermatol Venereol 2023;37:2016–27; **6.** Reich K et al. J Eur Acad Dermatol Venereol 2022;36:2393–400; **7.** European Medicines Agency, Summary of Product Characteristics, 2021. Available at: https://www.ema.europa.eu/en/medicines/human/EPAR/bimzelx [Accessed January 2025]. ADA: adalimumab; BKZ: bimekizumab; 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; Q2W: every 2 weeks; Q4W: every 4 weeks; Q8W: every 8 weeks; Q12W: every 12 weeks; SEC: secukinumab; SR: super responder; UST: ustekinumab.

Achievement of Super Response with BKZ

- 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 (271/664) and 34.4% in the GUIDE study (303/880), the only published analyses investigating achievement of super response in phase 3 randomized controlled trials.[1,2,a]
  - 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.

Baseline Characteristics

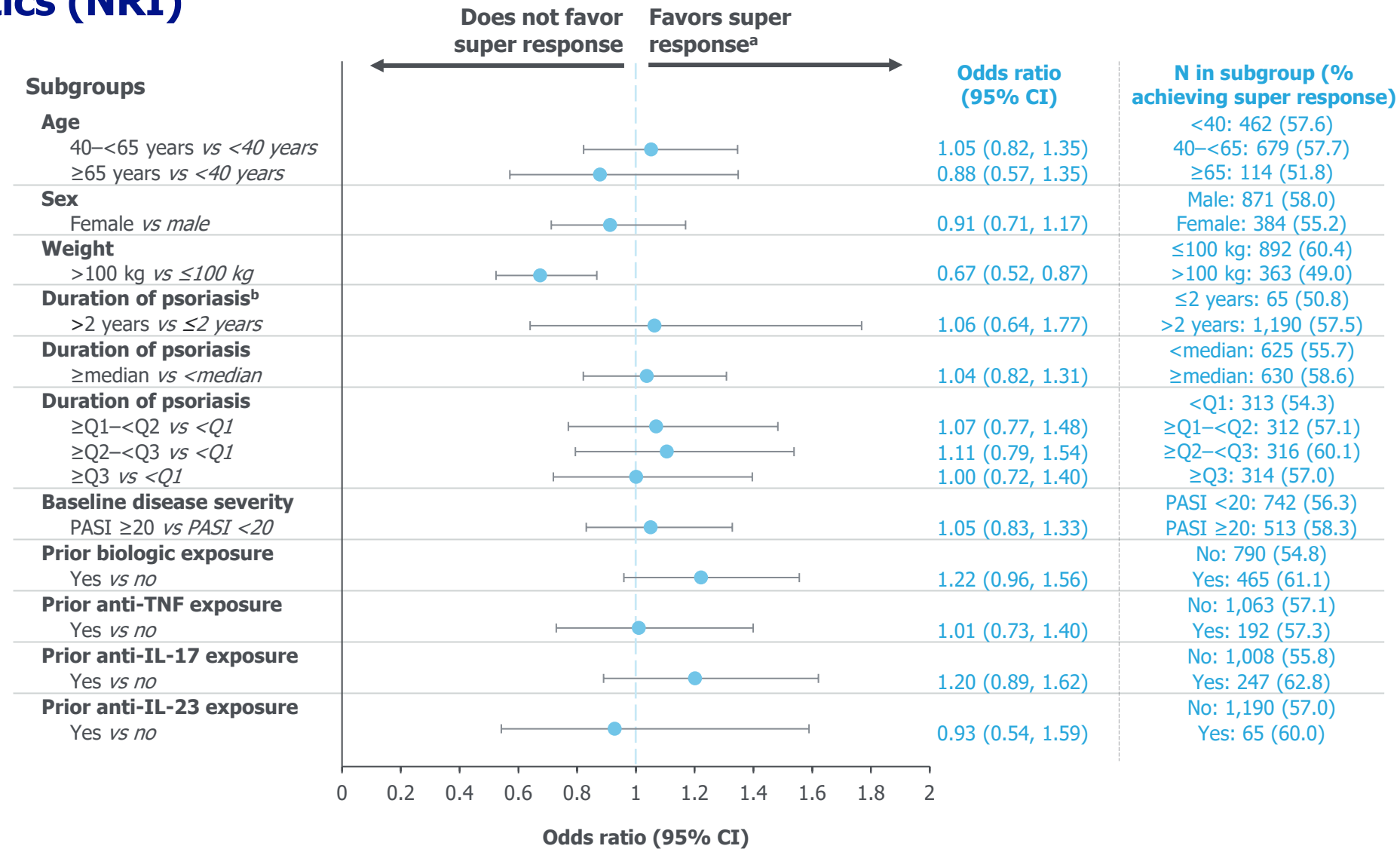
	SRs BKZ Total N=717	Non-SRs BKZ Total N=538
Age, n (%)		
<40 years	266 (37.1)	196 (36.4)
40–<65 years	392 (54.7)	287 (53.3)
≥65 years	59 (8.2)	55 (10.2)
Sex, male, n (%)	505 (70.4)	366 (68.0)
Racial group, white, n (%)	641 (89.4)	450 (83.6)
Weight (kg), mean (SD)	87.2 (19.9)	93.4 (24.2)
Weight, n (%)		
≤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, 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)

Q1 refers to 8.52 years
Q2 refers to 15.66 years
Q3 refers to 25.45 years

[a] 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. **1.** Reich K et al. J Eur Acad Dermatol Venereol 2022;36:2393–400; **2.** Schäkel K et al. J Eur Acad Dermatol Venereol 2023;37:2016–27. BKZ: bimekizumab; BMI: body mass index; NRI: non-responder imputation; PASI: Psoriasis Area and Severity Index; Q: quartile; Q4W: every 4 weeks; Q8W: every 8 weeks; SD: standard deviation; SR: super responder.

Analysis of Super Response Achievement between Patient Subgroups based on Baseline Characteristics (NRI)

- SR rates were not observed to be associated with the analyzed subgroups based on baseline characteristics, except for weight:
  - 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 IGA) were significant predictors of super response.[1]



[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. **1.** Reich K et al. J Eur Acad Dermatol Venereol 2022;36:2393–400. CI: confidence interval; IGA: Investigator's Global Assessment; IL: interleukin; NRI: non-responder imputation; PASI: Psoriasis Area and Severity Index; Q: quartile; SR: super responder; TNF: tumor necrosis factor.

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 analyzed subgroups based on baseline characteristics.

Author Contributions: Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **ML, RGL, BS, DT, AA, KBG, LPu, OD, LPe, LD, RBW**; Drafting of the publication, or reviewing it critically for important intellectual content: **ML, RGL, BS, DT, AA, KBG, LPu, OD, LPe, LD, RBW**; Final approval of the publication: **ML, RGL, BS, DT, AA, KBG, LPu, OD, LPe, LD, RBW**. **Disclosures: ML:** Employee of Mount Sinai and receives research funds from Abbvie, Amgen, Arcutis, Avotres, Boehringer Ingelheim, Cara Therapeutics, Dermavant, Eli Lilly and Company, Incyte, Inozyme, Janssen Research & Development, LLC, Ortho Dermatologics, Pfizer, Sanofi-Regeneron, and UCB; consultant for Almirall, AltruBio, AnaptysBio, Apogee, Arcutis, AstraZeneca, Atomwise, Avotres Therapeutics, Brickell Biotech, Boehringer-Ingelheim, Bristol Myers Squibb, Castle Biosciences, Celltrion, CorEvitas, Dermavant, EPI, Evommune, Facilitation of International Dermatology Education, Forte Biosciences, Foundation for Research and Education in Dermatology, Galderma, Genentech, Incyte, LEO Pharma, Meiji Seika Pharma, Mindera, Pfizer, Sanofi-Regeneron, Seanergy, Strata, Takeda, Trevi, and Verrica. **RGL:** Principal investigator for AbbVie, Amgen, Boehringer Ingelheim, Celgene, Eli Lilly and Company, LEO Pharma, Merck, Novartis, Pfizer, and UCB; served on scientific advisory boards for AbbVie, Amgen, Boehringer Ingelheim, Celgene, Eli Lilly and Company, LEO Pharma, Merck, Novartis, Pfizer, and UCB; provided lectures for AbbVie, Amgen, Celgene, Eli Lilly and Company, LEO Pharma, Merck, Novartis, and Pfizer. **BS:** Consultant (honoraria) for AbbVie, Almirall, Alumis, Amgen, Arcutis, Boehringer Ingelheim, Bristol Myers Squibb, Capital One, CorEvitas, Dermavant, Eli Lilly and Company, Janssen, LEO Pharma, Maruho, Meiji Seika Pharma, Novartis, Oruka, Pfizer, Protagonist, Rapt, Regeneron, Sanofi Genzyme, Takeda, UCB, and Union Therapeutics; stock options from Connect Biopharma, Mindera Health; speaker for AbbVie, Arcutis, Dermavant, Eli Lilly and Company, Incyte, Janssen, Regeneron, and Sanofi Genzyme; Scientific Co-Director (consulting fee): CorEvitas Psoriasis Registry; investigator for CorEvitas Psoriasis Registry; editor-in-chief (honorarium): Journal of Psoriasis and Psoriatic Arthritis. **DT:** Investigator and/or consultant/advisor for AbbVie, Almirall, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celltrion, Eli Lilly and Company, Galderma, Johnson & Johnson, Kyowa Kirin, LEO Pharma, L'Oreal, New Bridge, Novartis, Pfizer, Regeneron, Samsung, Sanofi, Takeda, Target-RWE, UCB, and Vichy; received grants from AbbVie, LEO Pharma, and Novartis. **AA:** Has served as a research investigator and/or scientific advisor to AbbVie, Almirall, Arcutis, ASLAN, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Dermira, Eli Lilly and Company, EPI, Incyte, Janssen, LEO Pharma, Nimbus, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sun Pharma, Sanofi, and UCB. **KBG:** Received consulting fees from AbbVie, Almirall, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Dermira, Eli Lilly and Company, Janssen, Novartis, Pfizer, Sun Pharma, and UCB; research support from AbbVie, Bristol Myers Squibb, Celgene, Eli Lilly and Company, Janssen, Novartis, and UCB. **LPu:** Received consultancy/speaker's honoraria from and/or participated in trials sponsored by AbbVie, Almirall, Amgen, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly and Company, Fresenius Kabi, Horizon, Janssen, LEO Pharma, Novartis, Pfizer, Sandoz, STADA, Sun Pharma, and UCB. **OD, LPe, LD:** Employee and shareholder of UCB. **RBW:** Consulting fees from AbbVie, Almirall, Amgen, Arena, Astellas, Avillion, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, DICE Therapeutics, Eli Lilly and Company, GSK, Janssen, LEO Pharma, Meiji Pharma, Novartis, Pfizer, RAPT Therapeutics, Sanofi, Sun Pharma, UCB, and Union; research grants to his institution from AbbVie, Almirall, Amgen, Celgene, Eli Lilly and Company, Janssen, LEO Pharma, Novartis, Pfizer, and UCB; honoraria from AbbVie, Almirall, Bristol Myers Squibb, Eli Lilly and Company, Galderma, Janssen, and Novartis.

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