Bimekizumab 4-year maintenance of responses in Week 16 responders with moderate to severe plaque psoriasis: Results from the BE BRIGHT open-label extension phase 3 trial

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OBJECTIVE:

- To evaluate maintenance of clinical responses over 4 years among patients with psoriasis who achieved complete or near-complete skin clearance after 16 weeks of bimekizumab (BKZ) treatment.

Background:

- Psoriasis is a chronic disease where loss of response to biologic therapies over time is commonly observed;[1] studying long-term efficacy of new treatments is important.
- Maintenance of high responses to BKZ have been reported previously through 3 years in patients with moderate to severe plaque psoriasis.[2]

Methods:

- Data were pooled from the 52-week BE VIVID and 56-week BE SURE and BE READY phase 3 trials, and their open-label extension BE BRIGHT.[2–5]
- Maintenance of **PASI 90**, **PASI 100**, and **BSA ≤1%** to Year 4 was assessed in respective Week 16 responders. **DLQI 0/1** was also assessed for patients who were PASI 100 responders at Week 16.
- Maintenance of responses are reported using modified non-responder imputation (mNRI):[a] patients who discontinued due to lack of efficacy/treatment-related adverse events were considered non-responders; multiple imputation was used for other missing data. Observed case results are also presented.

[a] Patients who entered the BE READY escape arm were considered as non-responders from the date of escape until the end of BE READY, after which they were considered in the same way as all other non-escape patients during the BE BRIGHT OLE.[5] **1.** Warren RB et al. J Invest Dermatol 2015;135:2632–40; **2.** Strober B et al. Br J Dermatol 2023;188:749–59, NCT03598790; **3.** Reich K et al. Lancet 2021;397:487–98, NCT03370133; **4.** Warren B et al. N Engl J Med 2021;385:130–41, NCT03412747; **5.** Gordon KB et al. Lancet 2021;397:475–86, NCT03410992. BKZ: bimekizumab; BSA: body surface area; DLQI: Dermatology Life Quality Index; mNRI: modified non-responder imputation; OLE: open-label extension; PASI: Psoriasis Area and Severity Assessment; PASI 90/100: ≥90%/100% improvement from baseline in Psoriasis Area and Severity Index.

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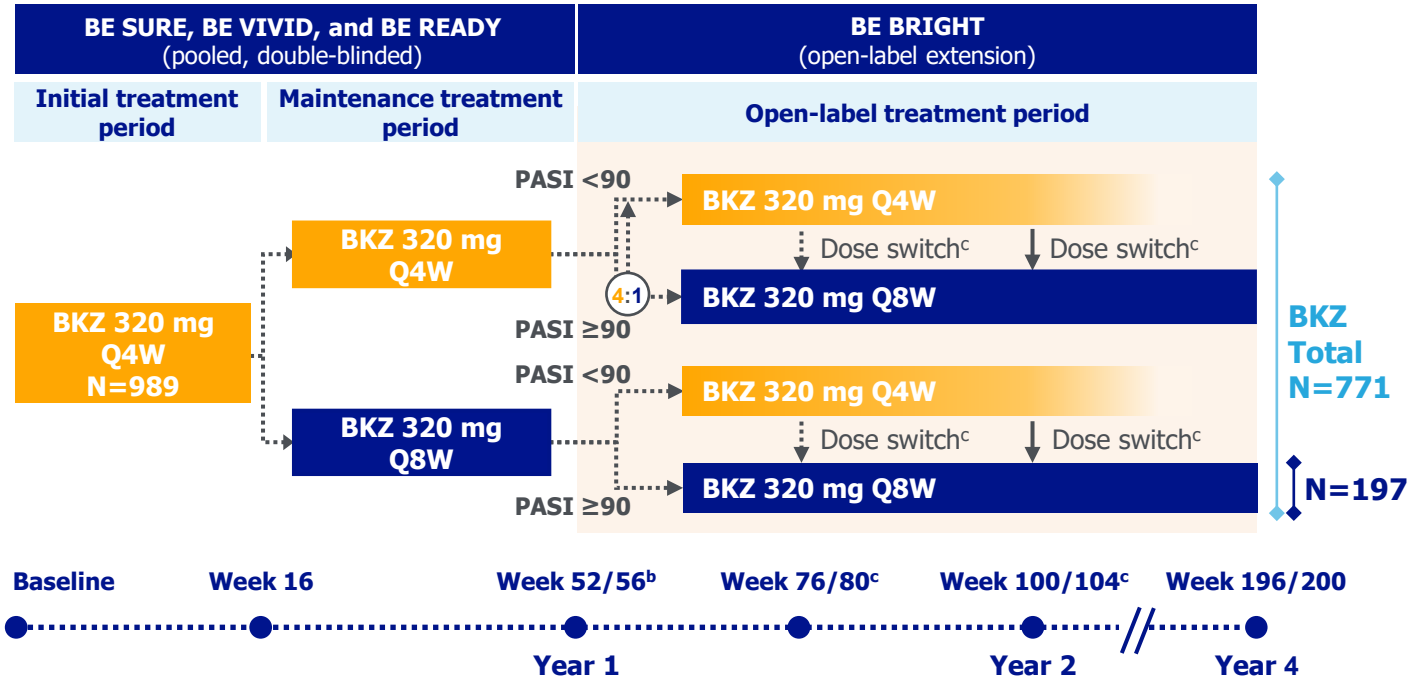
Study Design[a]



- Analyzed patients were randomized to **BKZ Q4W** to Week 16, then received **BKZ Q4W** or **Q8W** during the maintenance and OLE periods (**BKZ Total**).
- The subset of patients who received **BKZ Q4W/Q8W/Q8W** (initial/maintenance/OLE), the dosing regimen that is approved for most patients, were also analyzed.

Baseline Characteristics (Included Patients)

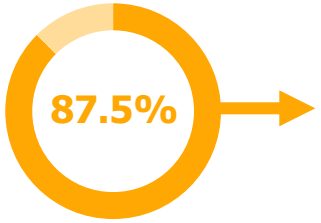
	BKZ Total[d]		
	Week 16 PASI 90 responders (N=693)	**Week 16 PASI 100 responders** (N=503)	**Week 16 BSA ≤1% responders** (N=597)
Age (years), mean ± SD	45.0 ± 13.3	44.8 ± 13.2	44.9 ± 13.3
Male, n (%)	494 (71.3)	352 (70.0)	420 (70.4)
White, n (%)	591 (85.3)	441 (87.7)	513 (85.9)
Weight (kg), mean ± SD	89.0 ± 20.9	87.8 ± 19.3	88.4 ± 20.3
Duration of psoriasis (years), mean ± SD	18.4 ± 12.5	18.0 ± 12.3	18.3 ± 12.6
PASI, mean ± SD	21.5 ± 7.7	21.3 ± 7.2	21.1 ± 7.4
BSA (%), mean ± SD	27.7 ± 15.9	26.7 ± 14.9	26.7 ± 15.2
IGA, n (%)			
3: moderate	456 (65.8)	331 (65.8)	400 (67.0)
4: severe	236 (34.1)	171 (34.0)	196 (32.8)
DLQI total score, mean ± SD	10.6 ± 6.3	10.9 ± 6.4	10.7 ± 6.3
Any prior systemic therapy, n (%)	557 (80.4)	415 (82.5)	486 (81.4)
Any prior biologic therapy, n (%)	281 (40.5)	210 (41.7)	245 (41.0)

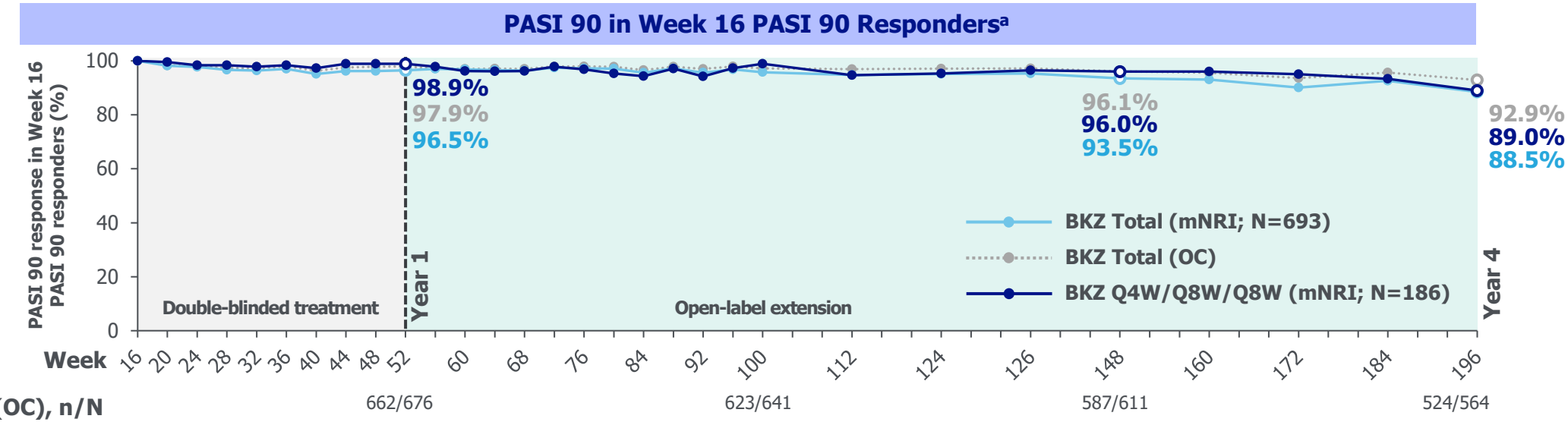
- In Week 16 responders (N=771),[e] **OLE study discontinuation** due to lack of efficacy (8 [1.0%]) or adverse events (42 [5.4%]) **was low**.

[a] Includes patients randomized to BKZ Q4W at baseline only; **[b]** BE VIVID lasted 52 weeks and BE SURE and BE READY lasted 56 weeks; **[c]** At Week 76/80 (OLE Week 24), patients achieving ≥PASI 90 could switch to Q8W at the investigator's discretion; all patients were re-assigned to BKZ Q8W at Week 100/104 (OLE Week 48) or the next scheduled visit via protocol amendment; **[d]** Baseline characteristics shown for all patients who were randomized to BKZ at the start of the feeder studies, entered the OLE and had been responders at Week 16 for the corresponding outcome; **[e]** Week 16 PASI 90, PASI 100, PASI ≤2, or BSA ≤1% responders.
BKZ: bimekizumab; BSA: body surface area; DLQI: Dermatology Life Quality Index; IGA: Investigator's Global Assessment; OLE: open-label extension; PASI: Psoriasis Area and Severity Index; PASI 90/100: ≥90/100% improvement from baseline in PASI; Q4W: every 4 weeks; Q8W: every 8 weeks; SD: standard deviation.

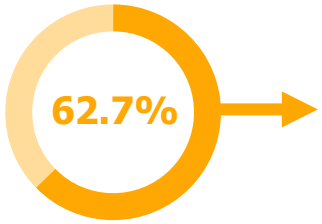
PASI 90 and 100 Response Maintenance in Patients that Entered the OLE

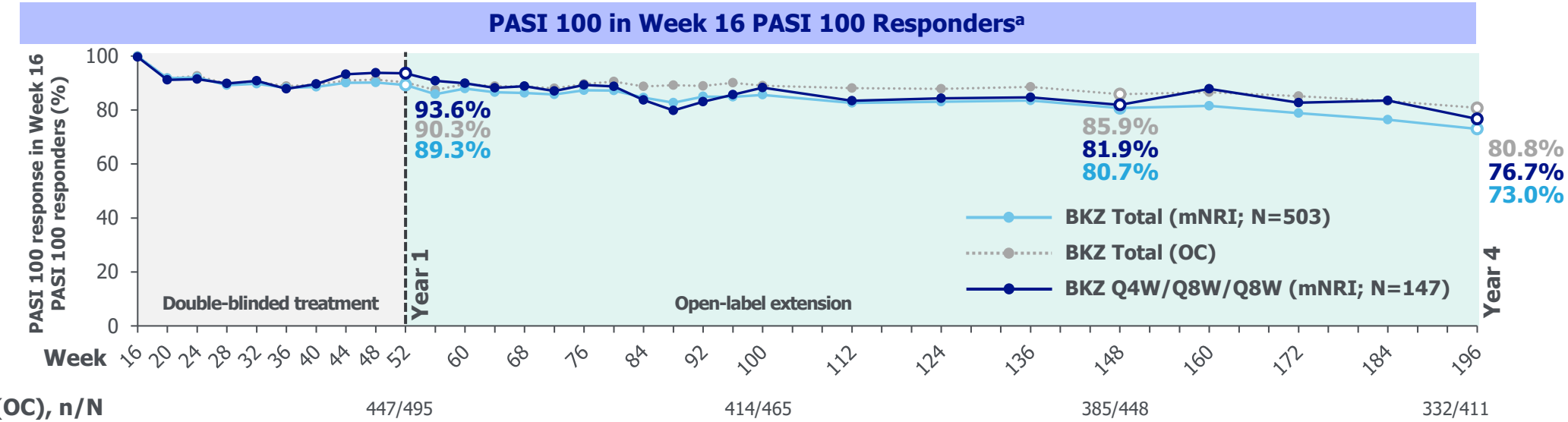
Week 16 PASI 90 response rate in BKZ-randomized patients (N=989; NRI)





Week 16 PASI 100 response rate in BKZ-randomized patients (N=989; NRI)

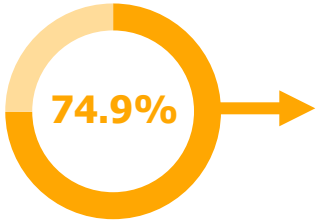




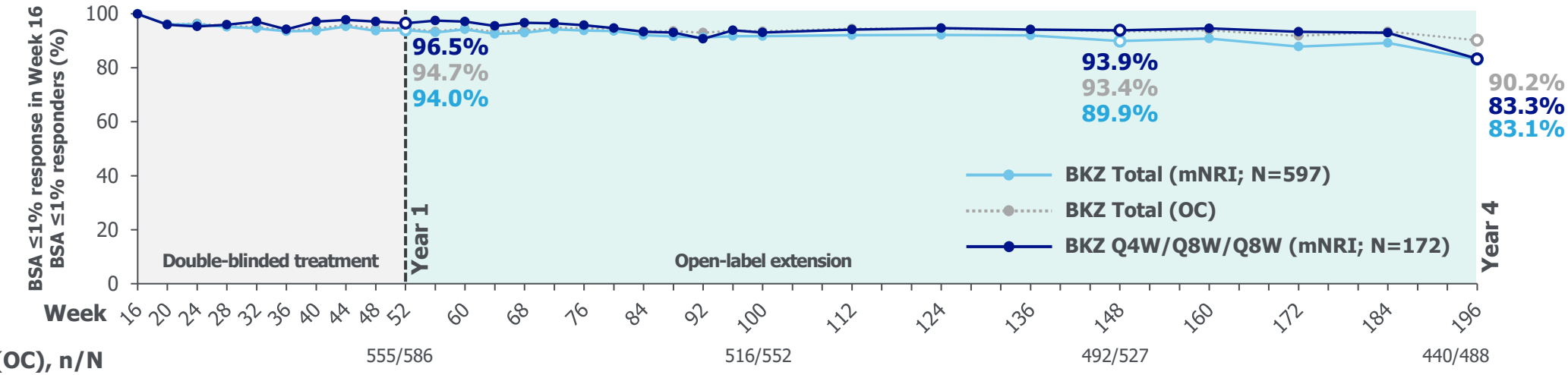
Results differ slightly from the accepted abstract due to updated mNRI methodology. **[a]** BE VIVID lasted 52 weeks and BE SURE and BE READY lasted 56 weeks; to pool data across studies, Week 56 data were not included. In these figures, the period after Week 52 corresponds to the BE BRIGHT OLE. BKZ: bimekizumab; mNRI: modified non-responder imputation; NRI: non-responder imputation; OC: observed case; OLE: open-label extension; PASI: Psoriasis Area and Severity Index; PASI 90/100: ≥90/100% improvement from baseline in PASI; Q4W: every 4 weeks; Q8W: every 8 weeks.

BSA ≤1% and DLQI 0/1 Response Maintenance in Patients that Entered the OLE

Week 16 BSA ≤1% response rate in BKZ-randomized patients (N=989; NRI)

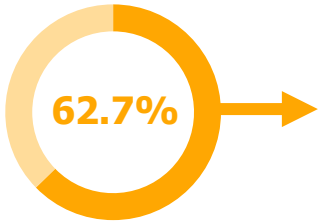


BSA ≤1% in Week 16 BSA ≤1% Responders[a]

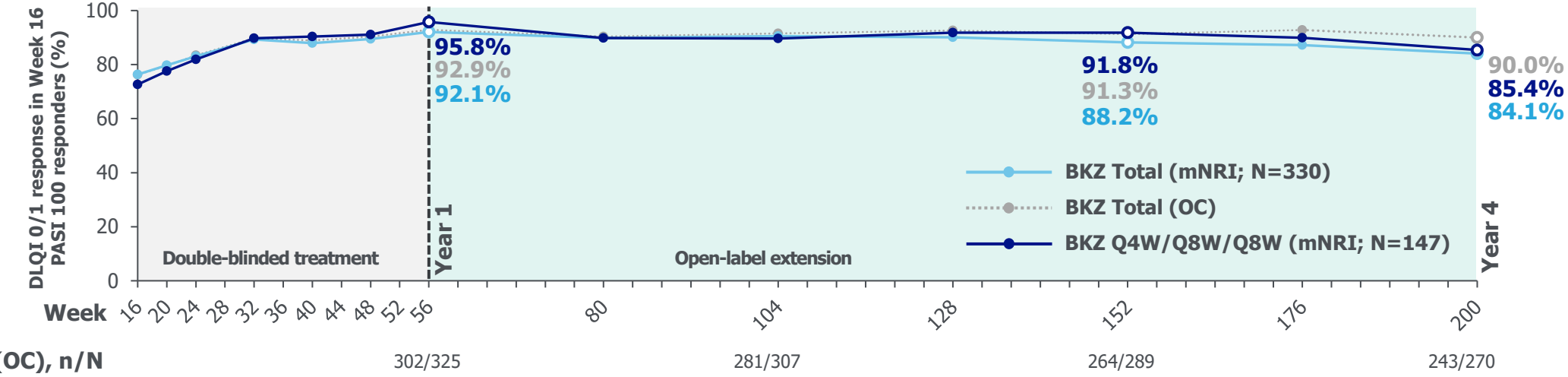


BKZ Total (OC), n/N	555/586	516/552	492/527	440/488

Week 16 PASI 100 response rate in BKZ-randomized patients (N=989; NRI)



DLQI 0/1 in Week 16 PASI 100 Responders[b]



BKZ Total (OC), n/N	302/325	281/307	264/289	243/270

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CONCLUSIONS:

- Pooled data from three trials and their open-label extension found that, among Week 16 responders, high clinical responses were maintained through 4 years of bimekizumab 320 mg treatment.
- High levels of response were also maintained in those who received bimekizumab Q4W/Q8W/Q8W, the approved dosing regimen for most patients with psoriasis.

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has acted as a clinical study investigator (institution has received clinical study funds) for AbbVie, Acelyrin, Allakos, Almirall, Alumis, Amgen, Arcutis, Athenex, Boehringer Ingelheim, Bristol Myers Squibb, Concert, Dermavant, DermBiont, Eli Lilly & Company, Evelo, Evommune, Galderma, Incyte, Janssen, LEO Pharma, Merck, Novartis, Pfizer, Regeneron, Sanofi, Sun Pharma, Takeda, UCB Pharma, and Ventyx. **PF:** Grant support from AbbVie, Amgen, Bristol Myers Squibb, Celgene, Eli Lilly & Company, Janssen, LEO Pharma, Merck, Novartis, Pfizer, Sanofi, and Sun Pharma; served as an investigator for AbbVie, Akaal, Amgen, Arcutis, Argenx, Aslan, AstraZeneca, Boehringer Ingelheim, Botanix, Bristol Myers Squibb, Celgene, Celtaxsys, CSL, Cutanea, Dermira, Eli Lilly & Company, Evelo, Galderma, Geneseq, Genentech, GenesisCare, GSK, Hexima, Incyte, Janssen, Kymab, LEO Pharma, MedImmune, Merck, Novartis, Pfizer, Regeneron, Reistone, Roche, Sanofi, Sun Pharma, Takeda, Teva, UCB Pharma, and Valeant; served on advisory boards for AbbVie, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly & Company, Galderma, GSK, Janssen, LEO Pharma, Mayne Pharma, Merck, Novartis, Pfizer, Sanofi, Sun Pharma, UCB Pharma, and Valeant; served as a consultant for Aslan, Bristol Myers Squibb, Eli Lilly & Company, Galderma, GenesisCare, Janssen, LEO Pharma, Mayne Pharma, MedImmune, Novartis, Pfizer, Roche, UCB Pharma, and Wintermute; received travel grants from AbbVie, Eli Lilly & Company, Galderma, Janssen, LEO Pharma, Merck, Novartis, Pfizer, Roche, Sun Pharma, and Sanofi; served as a speaker for or received honoraria from AbbVie, Almirall, Amgen, Celgene, Eli Lilly & Company, Galderma, GSK, Janssen, LEO Pharma, Merck, Novartis, Pfizer, Roche, Sanofi, Sun Pharma, UCB Pharma, and Valeant. **RGL:** Principal investigator for AbbVie, Amgen, Boehringer Ingelheim, Celgene, Eli Lilly & Company, LEO Pharma, Merck, Novartis, Pfizer, and UCB Pharma; served on scientific advisory boards for AbbVie, Amgen, Boehringer Ingelheim, Celgene, Eli Lilly & Company, LEO Pharma, Merck, Novartis, Pfizer, and UCB Pharma; provided lectures for AbbVie, Amgen, Celgene, Eli Lilly & Company, LEO Pharma, Merck, Novartis, and Pfizer. **CC:** Consultant and or/principal investigator in clinical trials for AbbVie, Actelion, Almirall, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly & Company, Incyte, Janssen, LEO Pharma, MSD, Novartis, Pfizer, Samsung, Sanofi, and UCB Pharma. **DR:** Received honoraria as a consultant for AbbVie, Abcuro, AltruBio, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Concert, Dermavant, Dermira, Eli Lilly & Company, Incyte, Janssen, Kyowa Kirin, Novartis, Pfizer, Regeneron, Sanofi, Sun Pharma, UCB Pharma, and VielaBio; 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Q4W: every 4 weeks; Q8W: every 8 weeks.