Itching in patients with moderate to severe plaque psoriasis: The relationship between improvements in Psoriasis Area and Severity Index and patient-reported symptoms in the BE RADIANT phase 3b trial

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Presentation Number: 42664

OBJECTIVES:

- To evaluate how complete skin clearance translates into improvements in itching symptoms over two years in patients with moderate to severe plaque psoriasis
- To assess the impact of incremental improvements in the Psoriasis Area and Severity Index (PASI) on the achievement of a score of 0 in:
  - The Psoriasis Symptoms and Impacts Measure (P-SIM) ITCHING ITEM
  - ITEM 1 (how itchy, sore, painful, stinging) of the Dermatology Life Quality Index (DLQI)

Background:

- Understanding the relationship between **clinical response** and **patient-reported symptoms** is important in order to determine whether improvements in disease control have an impact on a patient's quality of life[1]
- We report the impact of PASI improvements on two patient-reported outcome (PRO) items, assessing itching and skin symptoms, in the BE RADIANT (NCT03536884) phase 3b trial of bimekizumab (BKZ) in moderate to severe plaque psoriasis[2]

P-SIM

A novel, reliable, well-defined PRO tool developed to capture key signs, symptoms, and life impacts of plaque psoriasis[3, 4]

Consists of 14 items

*A score of 0 in the **P-SIM ITCHING ITEM** means no itching*

DLQI

Established PRO measure, used to assess the impact of skin disease on patients' health-related quality of life[5]

Consists of 10 items

*A score of 0 in **ITEM 1 of the DLQI** means no itching, soreness, pain, stinging*

1. Augustin M et al. Expert Rev Pharmoecon Outcomes Res 2014;14(4):559–68; **2.** Reich K et al. N Engl J Med 2021;385(2):142–52; **3.** Gottlieb AB et al. Dermatol Ther (Heidelb) 2020;10(6):1,255–72; **4.** Warren RB et al. Dermatol Ther (Heidelb) 2021;11(5):1,551–69; **5.** Finlay AY and Khan GK. Clin Exp Dermatol 1994;19(3):210–6. BKZ: bimekizumab; DLQI: Dermatology Life Quality Index; PASI: Psoriasis Area and Severity Index; PRO: patient-reported outcome; P-SIM: Psoriasis Symptoms and Impacts Measure.

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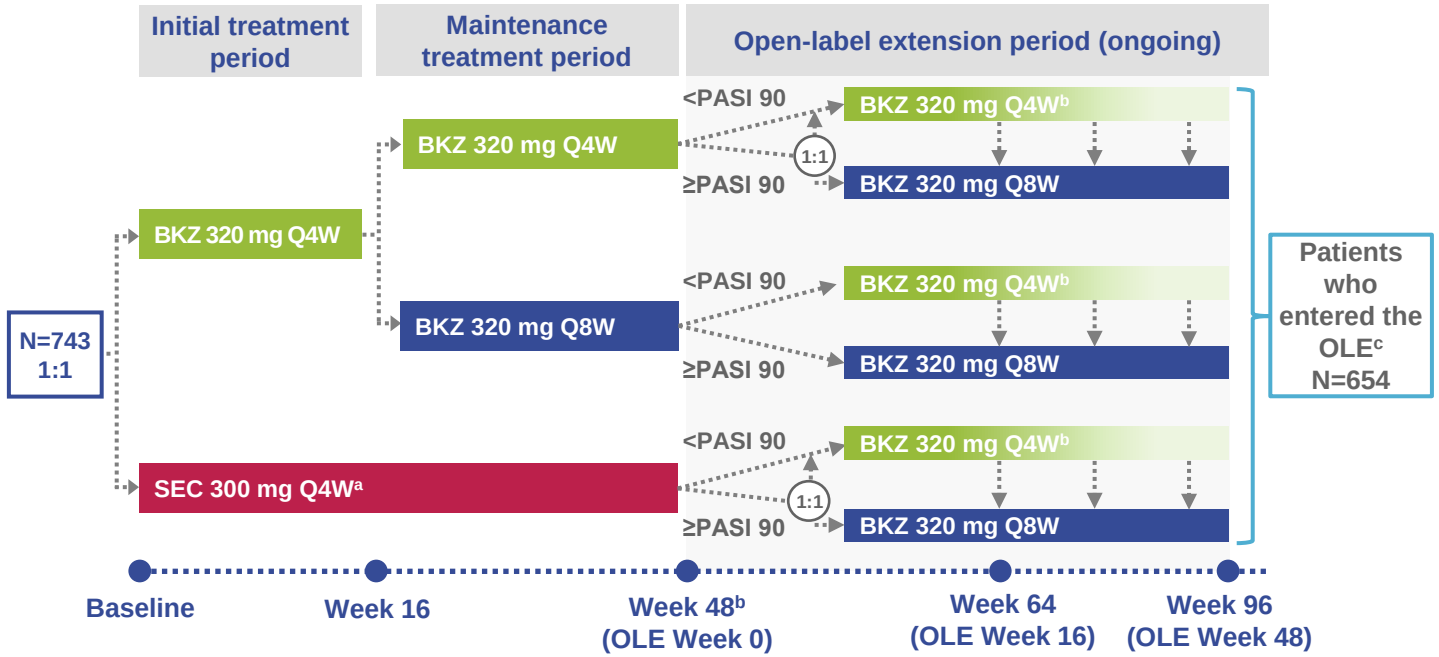
Poster ID: 42664; Link expiration: June 19, 2023

BE RADIANT Study Design and Methods



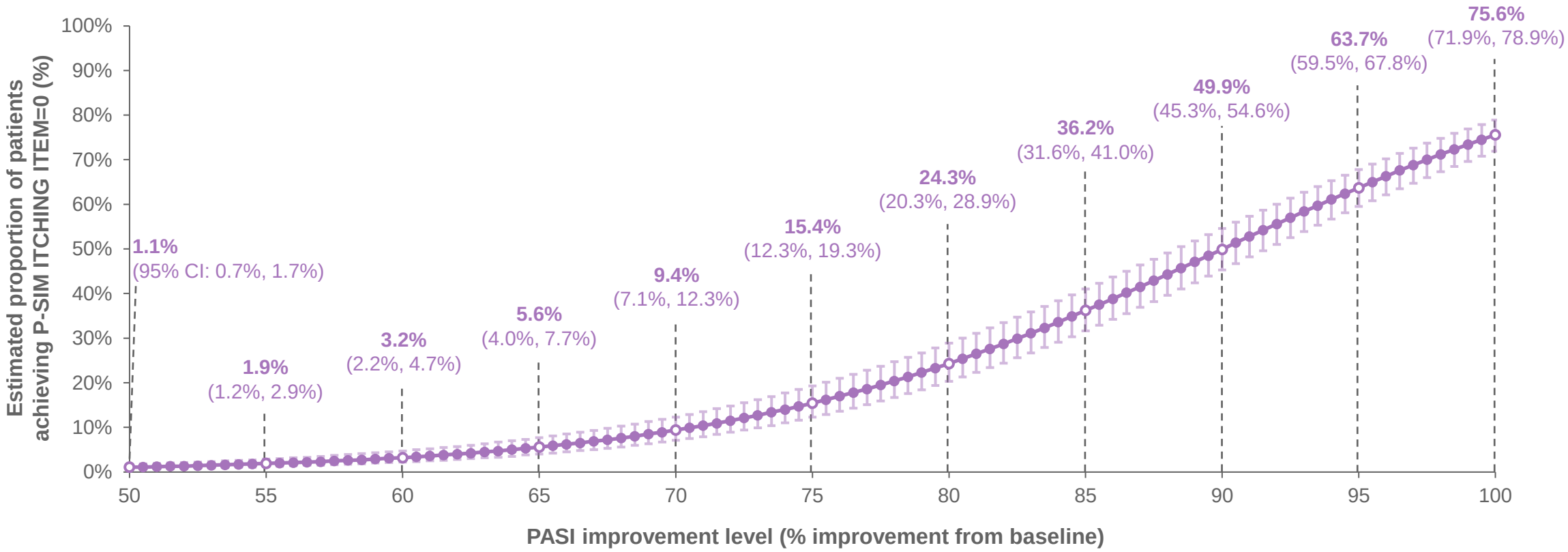
- Two-year data from the BE RADIANT trial were pooled across **all visits and treatments**. Analyses included patients who **entered the open-label extension** (OLE); all received BKZ in the OLE
- Mixed-effects logistic regression models assessed the relationship between skin clearance and **P-SIM ITCHING ITEM=0**, and **DLQI (ITEM 1)=0** (observed case)
- Model-estimated **P-SIM ITCHING ITEM=0** and **DLQI (ITEM 1)=0** rates are reported with 95% confidence intervals (CI)

Baseline Characteristics: Included Patients

	Patients who entered the BE RADIANT OLE[c] N=654
Age (years), mean ± SD	45.0 ± 14.4
Male, n (%)	436 (66.7)
White, n (%)	613 (93.7)
Weight (kg), mean ± SD	89.7 ± 20.3
Duration of psoriasis (years), mean ± SD	18.0 ± 12.6
PASI, mean ± SD	19.9 ± 7.0
BSA (%), mean ± SD	24.2 ± 14.8
IGA, n (%)	
3: moderate	448 (68.5)
4: severe	204 (31.2)
DLQI total, mean ± SD	11.0 ± 7.0
DLQI (item 1), mean ± SD	2.0 ± 0.8
DLQI (item 1) score, n (%)	
0	18 (2.8)
1	156 (23.9)
2	275 (42.0)
3	205 (31.3)
P-SIM item score, mean ± SD	
Itching	6.6 ± 2.8
Skin pain	4.6 ± 3.2
Scaling	6.7 ± 2.4
Any prior systemic therapy, n (%)	478 (73.1)
Any prior biologic therapy, n (%)	219 (33.5)

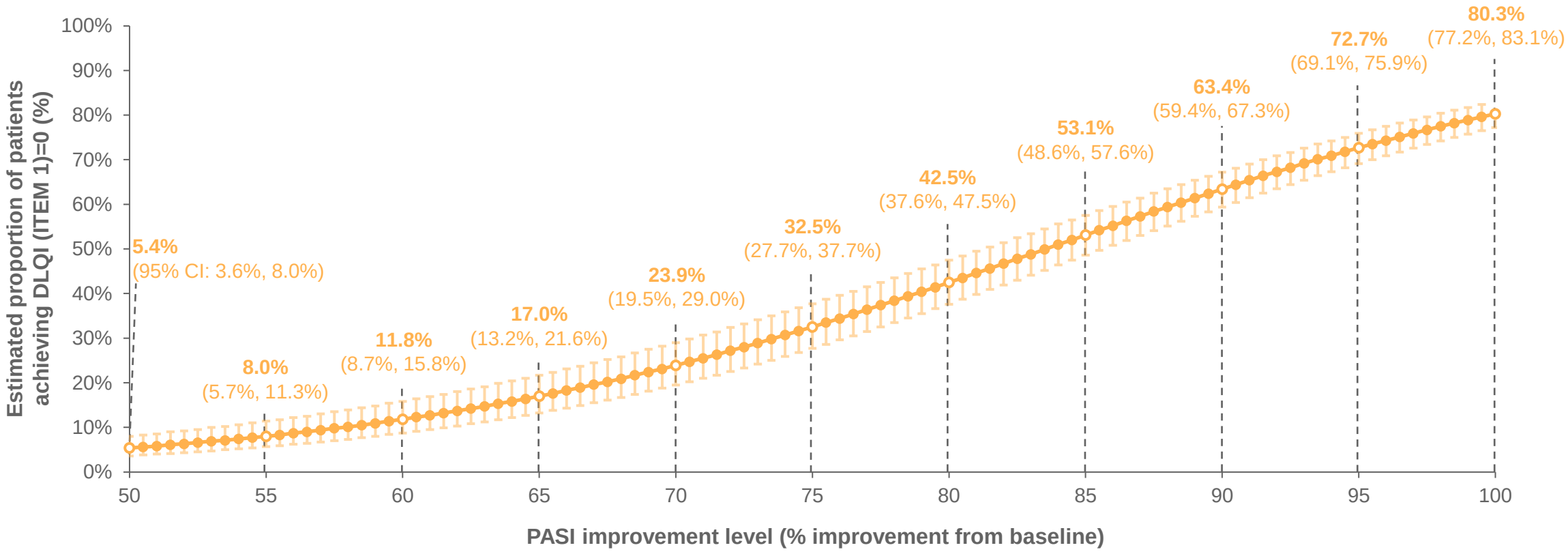
[a] SEC 300 mg administered at baseline, weekly to Week 4, then Q4W for the remainder of the double-blinded treatment period; [b] At Week 64, or the next scheduled clinic visit, after the implementation of a protocol amendment, patients switched from BKZ 320 mg Q4W to Q8W; [c] Data are reported for all BKZ- and SEC-treated patients who entered the OLE, irrespective of OLE BKZ dosing regimen. BKZ: bimekizumab; BSA: body surface area; CI: confidence interval; DLQI: Dermatology Life Quality Index; IGA: Investigator's Global Assessment; OLE: open-label extension; PASI: Psoriasis Area and Severity Index; P-SIM: Psoriasis Symptoms and Impacts Measure; Q4W: every 4 weeks; Q8W: every 8 weeks; SD: standard deviation; SEC: secukinumab.

Model-Estimated Proportions of Patients Achieving P-SIM ITCHING ITEM=0 at Different PASI Improvement Levels Over Two Years



A mixed-effects logistic regression model used data pooled across all trial visits and treatments over two years of BE RADIANT to estimate the proportions of patients achieving P-SIM ITCHING ITEM=0 at specific PASI improvement levels. The model included PASI % change from baseline and baseline P-SIM ITCHING ITEM score as covariates, with a patient-level random intercept to account for repeated observations at the patient level. The curve corresponds to model estimates calculated with baseline P-SIM ITCHING ITEM equal to the baseline median (7). Data were not equally available for each PASI improvement level; more patient data were available for improvement levels closer to PASI 100. CI: confidence interval; PASI 100: 100% improvement from baseline in Psoriasis Area and Severity Index; P-SIM: Psoriasis Symptoms and Impacts Measure.

Model-Estimated Proportions of Patients Achieving DLQI (ITEM 1)=0[a] at Different PASI Improvement Levels Over Two Years



A mixed-effects logistic regression model used data pooled across all trial visits and treatments over two years of BE RADIANT to estimate the proportions of patients achieving DLQI (ITEM 1)=0 at specific PASI improvement levels. The model included PASI % change from baseline and baseline DLQI (ITEM 1) score as covariates, with a patient-level random intercept to account for repeated observations at the patient level. The curve corresponds to model estimates calculated with baseline DLQI (ITEM 1) equal to the baseline median (2). Data were not equally available for each PASI improvement level; more patient data were available for improvement levels closer to PASI 100. [a] DLQI (ITEM 1)=0 means no itching, soreness, pain, stinging. CI: confidence interval; DLQI: Dermatology Life Quality Index; PASI 100: 100% improvement from baseline in Psoriasis Area and Severity Index.

CONCLUSIONS:

- Incremental PASI improvements corresponded with more patients reporting no itching on the P-SIM and no skin symptoms on **ITEM 1 of the DLQI** (itching, soreness, pain, stinging) over two years
- In patients who responded to treatment without achieving clear skin, residual disease had a greater impact on itching and skin symptoms than in patients who achieved complete skin clearance
- These results reflect the importance of complete skin clearance as a treatment outcome

Author Contributions: Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **MA, RGL, RBW, ML, BE, JC, RW, MK, SW, VC, ABG**; Drafting of the publication, or revising it critically for important intellectual content: **MA, RGL, RBW, ML, BE, JC, RW, MK, SW, VC, ABG**; Final approval of the publication: **MA, RGL, RBW, ML, BE, JC, RW, MK, SW, VC, ABG**. **Disclosures: MA**: Consulting fees from AbbVie, Almirall, Amgen, Biogen, Boehringer Ingelheim, Celgene, Centocor, Eli Lilly, GSK, Hexal, Janssen, LEO Pharma, Medac, Merck, MSD, Mundipharma, Novartis, Pfizer, Sandoz, UCB Pharma, and Xenoport. **RGL**: Principal investigator for AbbVie, Amgen, Boehringer Ingelheim, Celgene, Eli Lilly, LEO Pharma, Merck, Novartis, Pfizer, and UCB Pharma; served on scientific advisory boards for AbbVie, Amgen, Boehringer Ingelheim, Celgene, Eli Lilly, LEO Pharma, Merck, Novartis, Pfizer, and UCB Pharma; provided lectures for AbbVie, Amgen, Celgene, Eli Lilly, LEO Pharma, Merck, Novartis, and Pfizer. **RBW**: Consulting fees from AbbVie, Almirall, Amgen, Arena, Astellas, Avillion, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly, GSK, Janssen, LEO Pharma, Novartis, Pfizer, Sanofi, and UCB Pharma; research grants to his institution from AbbVie, Almirall, Janssen, LEO Pharma, Novartis, and UCB Pharma; honoraria from Astellas, DiCE, GSK, and Union. **ML**: Employee of Mount Sinai and receives research funds from AbbVie, Amgen, Arcutis, Avotres Therapeutics, Boehringer Ingelheim, Cara Therapeutics, Dermavant, Eli Lilly, Incyte, Janssen, LLC, Ortho Dermatologics, Regeneron, and UCB Pharma; consultant for Aditum Bio, Almirall, AltruBio Inc., AnaptysBio, Arcutis, Aristea Therapeutics, Arrive Technologies, Avotres Therapeutics, BiomX, Boehringer Ingelheim, Bristol Myers Squibb, Cara Therapeutics, Castle Biosciences, CorEvitas, Dermavant, Dr. Reddy's Laboratories, Evelo Biosciences, Evommune Inc., Facilitatation of International Dermatology Education, Forte Biosciences, Foundation for Research and Education in Dermatology, Helsinn Therapeutics, Hexima, LEO Pharma, Meiji Seika Pharma, Mindera, Pfizer, Seanergy, and Verrica. **BE**: Received research support as funding to Case Western Reserve University from AbbVie, AnaptysBio, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly, Incyte, LEO Pharma, Menlo, Merck, Novartis, Pfizer, Regeneron, Sun Pharma, Valeant, and Vanda; consultant (honoraria) for Arcutis, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli Lilly, LEO Pharma, Menlo, Novartis, Pfizer, Sun Pharma, UCB Pharma, Valeant, and Verrica. **JC**: Received research/grant support from AbbVie, Amgen, Boehringer Ingelheim, Eli Lilly, Janssen, MC2 Therapeutics, Merck, Novartis, Pfizer, Regeneron, Sandoz, Sanofi, Sun Pharma, UCB Pharma, and Verrica; has served as consultant for AbbVie, Amgen, Celgene, Dermira, Eli Lilly, Novartis, Sun Pharma, and UCB Pharma; has worked on speakers bureaus for AbbVie, Eli Lilly, Janssen, Novartis, Regeneron, Sanofi, and UCB Pharma. **RW**: Veramed statistical consultant for UCB Pharma. **MK, VC**: Employees of UCB Pharma. **SW**: Employee and shareholder of UCB Pharma. **ABG**: Honoraria as an advisory board member, non-promotional speaker or consultant for Amgen, AnaptysBio, Avotres Therapeutics, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, DICE Therapeutics, Eli Lilly, Janssen, Novartis, Pfizer, Sanofi, Sun Pharma, UCB Pharma, and XBiotech (stock options for an RA project); research/educational grants from AnaptysBio, Bristol Myers Squibb, Janssen, Novartis, Ortho Dermatologics, Sun Pharma, and UCB Pharma; all funds go to the Icahn School of Medicine at Mount Sinai.

This study was funded by UCB Pharma. We would like to thank the patients and their caregivers in addition to all the investigators and their teams who contributed to this study. The authors acknowledge Radhika Bhatia, PhD, UCB Pharma, Slough, UK, for publication coordination, and Poppy Wilson, MBiol, Costello Medical, London, UK, for medical writing support and editorial assistance. All costs associated with development of this presentation were funded by UCB Pharma.

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