

Extraintestinal Manifestations in Participants with Moderately to Severely Active Crohn’s Disease: Results From the Phase 3 GALAXI 2 & 3 Studies

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Background

Extraintestinal manifestations (EIMs), including joint, skin, and ocular manifestations, are common in patients with inflammatory bowel disease (IBD) and pose additional challenges for treatment

Guselkumab is a dual-acting interleukin (IL)-23p19 subunit inhibitor that binds to IL-23 and CD64, a receptor on cells that produce IL-23¹

GALAXI 2 & 3 Phase 3 studies evaluated guselkumab in participants with moderately to severely active Crohn's disease

Both subcutaneous (SC) maintenance doses were highly effective in the primary study population compared with placebo and ustekinumab² at Week 48 and were approved for use

Objective

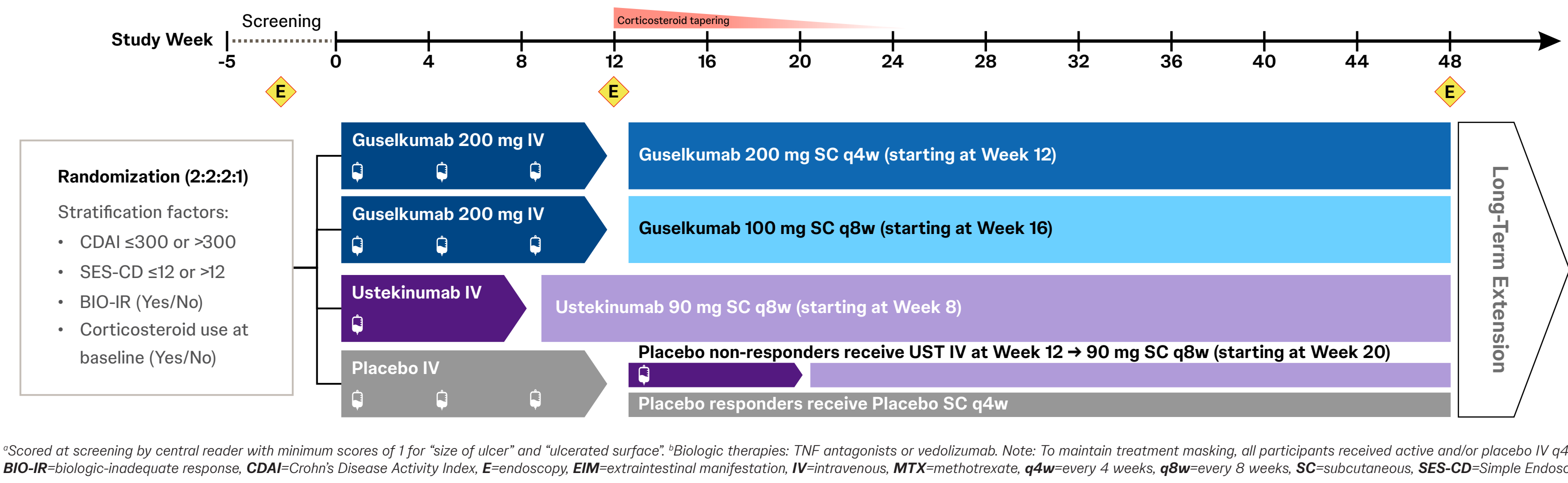
To present data of EIMs reported through Week 48 in the pooled GALAXI 2 & 3 studies

Methods

- GALAXI 2 & 3 are identically-designed, double-blind, treat-through studies

Key eligibility criteria

- Moderately to severely active Crohn's disease: CDAI score 220–450 and mean daily SF count >3 or AP score >1 and SES-CD score^a ≥6 (or ≥4 for isolated ileal disease)
- Inadequate response/intolerance to oral corticosteroids or 6-MP/AZA/MTX, or biologic therapies^b or naïve to biologics



^aScored at screening by central reader with minimum scores of 1 for "size of ulcer" and "ulcerated surface". ^bBiologic therapies: TNF antagonists or vedolizumab. Note: To maintain treatment masking, all participants received active and/or placebo IV q4w through Week 12 and active and/or placebo SC q4w through Week 48. 6-MP=6-mercaptopurine, AP=abdominal pain, AZA=azathioprine, BIO-IR=biologic-inadequate response, CDAI=Crohn's Disease Activity Index, E=endoscopy, EIM=extraintestinal manifestation, IV=intravenous, MTX=methotrexate, q4w=every 4 weeks, q8w=every 8 weeks, SC=subcutaneous, SES-CD=Simple Endoscopic Score for Crohn's Disease, SF=stool frequency, TNF=tumor necrosis factor, UST=ustekinumab.

Analyses

- EIMs included:
 - arthritis/arthralgia
 - erythema nodosum/pyoderma gangrenosum
 - iritis/uveitis
- EIMs were reported as:
 - a component of the CDAI score at each visit
 - individual EIM resolution at Weeks 12 and 48
 - de novo EIMs at Weeks 12 and 48
- EIM data were pooled for the GALAXI 2 & 3 studies
- Corticosteroids were maintained at baseline doses through Week 12, when mandatory tapering began
- GALAXI 2/3 also included ustekinumab, but the current analyses do not include ustekinumab

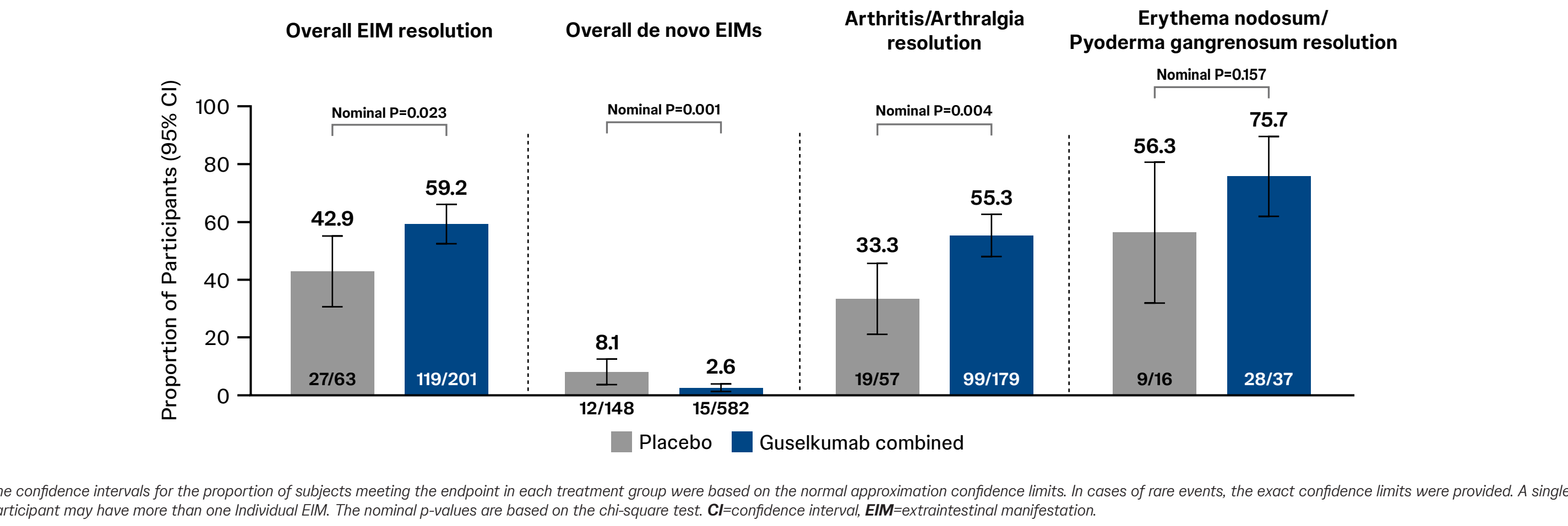
Results

Pooled baseline demographics and disease characteristics

	Placebo	GUS 200 mg IV q4w → 100 mg SC q8w	GUS 200 mg IV q4w → 200 mg SC q4w	GUS Combined
Primary analysis set, N	148	286	296	582
Number of participants with EIMs at baseline, n (%)	63 (42.6%)	115 (40.2%)	86 (29.1%)	201 (34.5%)
Demographics				
Age in years, mean (SD)	37.7 (13.16)	37.2 (12.11)	39.1 (13.81)	38.0 (12.86)
Men, n (%)	36 (57.1%)	57 (49.6%)	44 (51.2%)	101 (50.2%)
CD duration in years, mean (SD)	6.9 (7.34)	7.4 (7.01)	7.9 (8.23)	7.6 (7.54)
Characteristics				
CDAI score at baseline, mean (SD)	291.6 (52.46)	302.8 (55.24)	302.1 (51.77)	302.5 (53.65)
Involved GI areas (as assessed by central reader), n (%)				
Ileum only	17 (27.0%)	30 (26.1%)	32 (37.2%)	62 (30.8%)
Colon only	23 (36.5%)	40 (34.8%)	26 (30.2%)	66 (32.8%)
Ileum and colon	23 (36.5%)	45 (39.1%)	28 (32.6%)	73 (36.3%)
EIMs, n (%) ^a				
Arthritis/Arthralgia	57 (90.5%)	102 (88.7%)	77 (89.5%)	179 (89.1%)
Erythema nodosum/Pyoderma gangrenosum	16 (25.4%)	23 (20.0%)	14 (16.3%)	37 (18.4%)
Iritis/Uveitis	2 (3.2%)	5 (4.3%)	6 (7.0%)	11 (5.5%)
Corticosteroid use, n (%)				
Oral corticosteroids	16 (25.4%)	37 (32.2%)	23 (26.7%)	60 (29.9%)
Budesonide	12 (20.6%)	17 (14.8%)	13 (15.1%)	30 (14.9%)
Prior use of biologics, n (%)				
Adalimumab	19 (30.2%)	45 (39.1%)	29 (33.7%)	74 (36.8%)
Infliximab	22 (34.9%)	37 (32.2%)	27 (31.4%)	64 (31.8%)
Vedolizumab	6 (9.5%)	13 (11.3%)	6 (7.0%)	19 (9.5%)
Certolizumab pegol	1 (1.6%)	4 (3.5%)	3 (3.5%)	7 (3.5%)

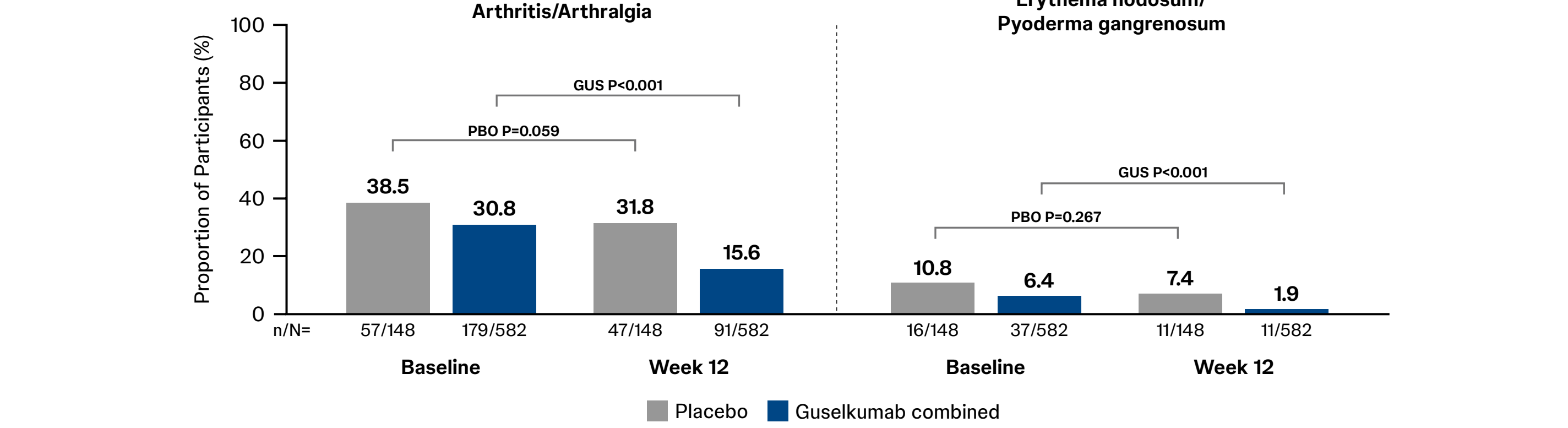
^aA single participant may have had more than one EIM. CD=Crohn's disease, CDAI=Crohn's Disease Activity Index, EIM=extraintestinal manifestation, GI=gastrointestinal, GUS=guselkumab, IV=intravenous, q4w=every 4 weeks, q8w=every 8 weeks, SC=subcutaneous, SD=standard deviation.

Week-12 EIM outcomes among participants with EIMs at baseline



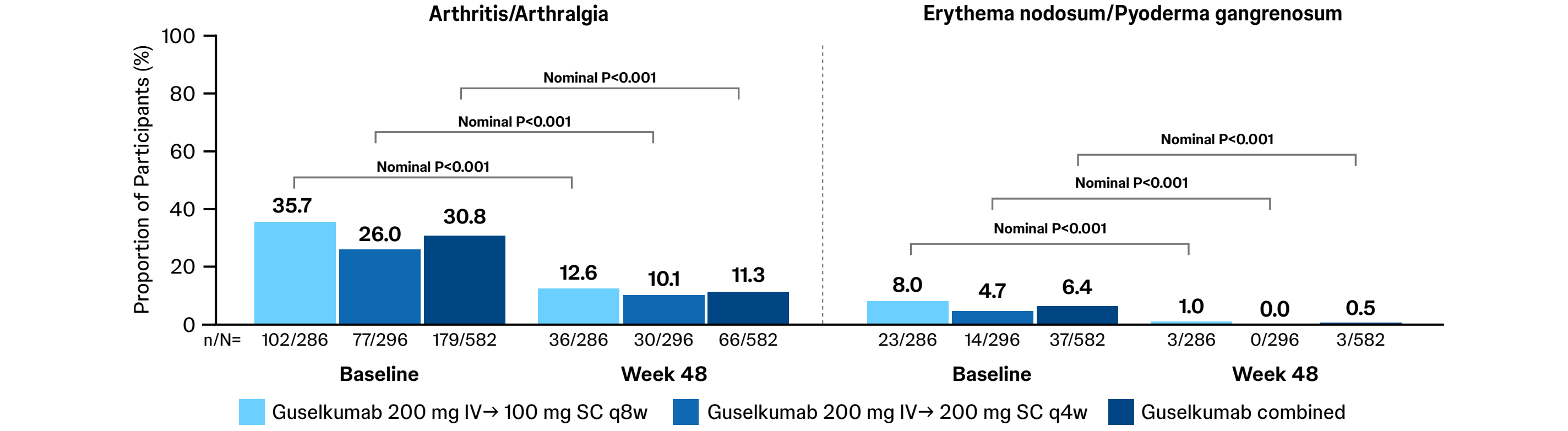
The confidence intervals for the proportion of subjects meeting the endpoint in each treatment group were based on the normal approximation confidence limits. In cases of rare events, the exact confidence limits were provided. A single participant may have more than one individual EIM. The nominal p-values are based on the chi-square test. CI=confidence interval, EIM=extraintestinal manifestation.

Week-12 EIMs after induction



All p-values are nominal. The nominal p-values are based on the McNemar's test comparing prevalence of EIMs at Week 12 to baseline. EIM=extraintestinal manifestation, GUS=guselkumab, PBO=placebo.

Week-48 EIMs



The nominal p-values are based on the McNemar's test comparing prevalence of EIMs at Week 48 to baseline. EIM=extraintestinal manifestation, IV=intravenous, q4w=every 4 weeks, q8w=every 8 weeks, SC=subcutaneous.



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Key Takeaways

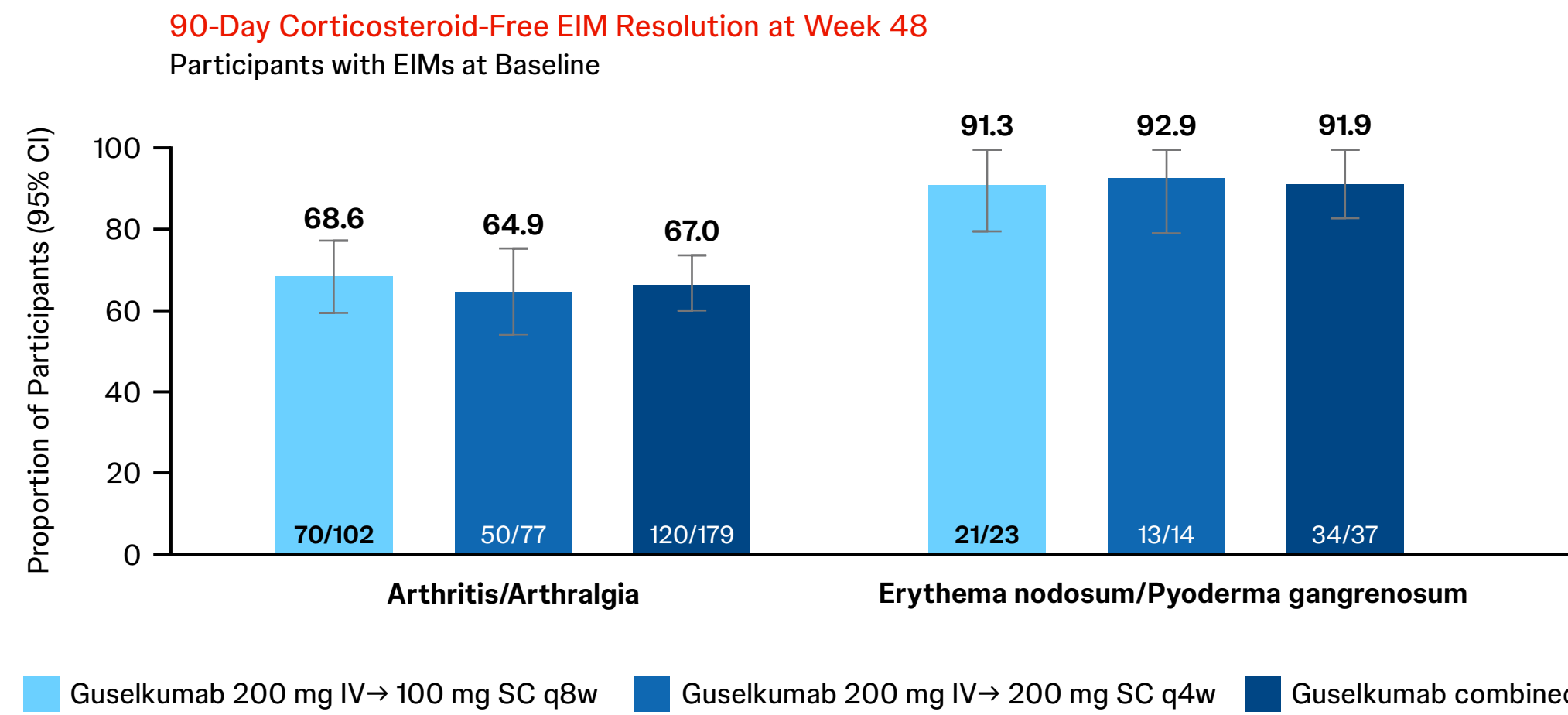
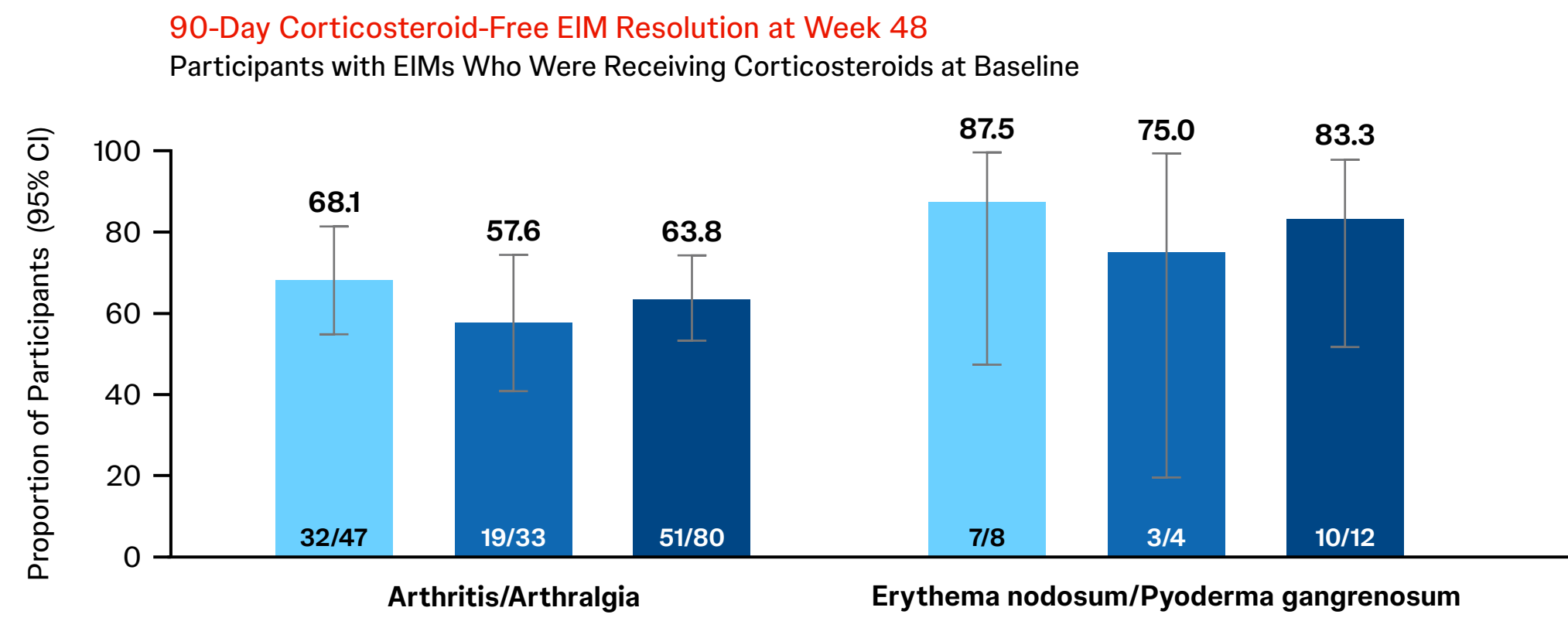
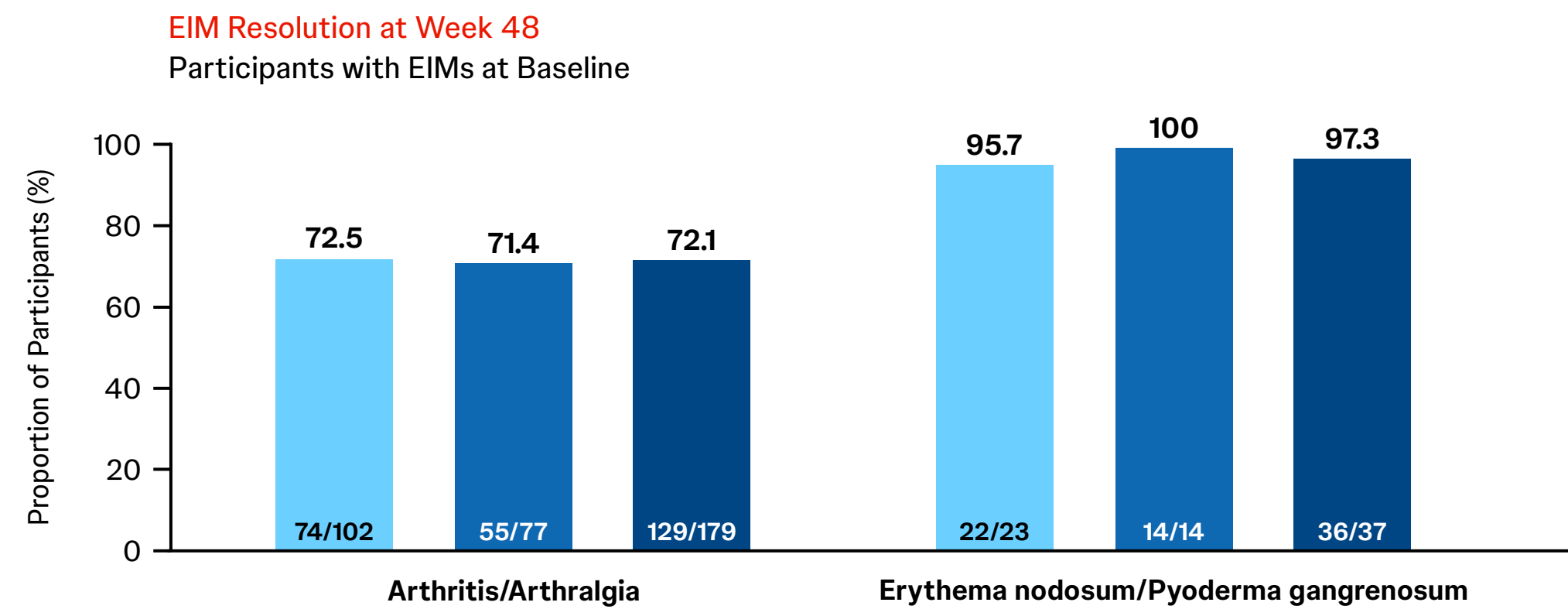
✓ Guselkumab-treated participants with Crohn's disease had greater EIM resolution and lower rates of de novo EIMs at Week 12 vs placebo

✓ EIM resolution continued through Week 48, and was not dependent on corticosteroid use

✓ These results suggest guselkumab may improve and prevent EIMs in patients with Crohn's disease

Corticosteroid-free EIM resolution

- Most participants in EIM resolution at Week 48 were corticosteroid-free



Legend: Light blue = Guselkumab 200 mg IV → 100 mg SC q8w; Dark blue = Guselkumab 200 mg IV → 200 mg SC q4w; Medium blue = Guselkumab combined.

CI=confidence interval, EIM=extraintestinal manifestation, IV=intravenous, q4w=every 4 weeks, q8w=every 8 weeks, SC=subcutaneous.

PRESENTED BY: Jody Purifoy Reeves at Gastroenterology & Hepatology Advanced Practice Providers (GHAPP) Ninth Annual National Conference, October 1–3, 2026; Chula Vista, CA, USA. **REFERENCES:** 1. Sachin KL, et al. *Front Immunol*. 2025;16(1532852). 2. Panacione R, et al. *Lancet*. 2025;406(10501):358–375. **ACKNOWLEDGEMENTS:** The authors thank the participants, investigators, and study personnel who made the GALAXI 2 and 3 studies possible. Medical writing support was provided by Kristin Raley Sharples, PhD of Johnson & Johnson under the direction of the authors in accordance with Good Publication Practice guidelines (Ann Intern Med. 2022;175(1298–1304). Layout design for this poster was provided by Ganesh Karpe (SIRO Medical Writing Pvt. Ltd., India). This study was sponsored by Johnson & Johnson. **DISCLOSURES:** DTR reports consulting and/or speaker fees and/or advisory board participation for AbbVie, Altrubio, Apex, Avalo, Bristol Myers Squibb, Buhmann Diagnostics, Celgene, Connect BioPharma, Intouch Group, Iterative Health, Johnson & Johnson, Eli Lilly, Pfizer, Samsung Neurologics, and Takeda; Altrubio, Datos Health, and Iterative Health stock options; grants from Takeda; and membership on the Board of Directors of Cornerstones Health, Inc and on the Crohn's & Colitis Foundation's Board of Trustees. **TH** reports grant support from AbbVie GK, Boston Scientific Corporation, EA Pharma Co. Ltd., JIMRO Co. Ltd., Kissei Pharmaceutical Co. Ltd., Kyorin Pharmaceutical Co. Ltd., Mitsubishi Tanabe Pharma Corporation, Mochida Pharmaceutical Co. Ltd., Nippon Kayaku Co. Ltd., Pfizer, Takeda, and Zeria Pharmaceutical Co. Ltd.; consulting fees from AbbVie GK, Bristol Myers Squibb, EA Pharma Co. Ltd., Eli Lilly, Gilead Sciences, Johnson & Johnson, Mitsubishi Tanabe Pharma Corporation, Nichi-ko Pharmaceutical Co. Ltd., and Pfizer; and lecture fees from AbbVie GK, EA Pharma Co. Ltd., JIMRO Co. Ltd., Johnson & Johnson, Kissei Pharmaceutical Co. Ltd., Kyorin Pharmaceutical Co. Ltd., Mitsubishi Tanabe Pharma Corporation, Mochida Pharmaceutical Co. Ltd., Pfizer, and Takeda. **RVR, WVD, GS, SA, and JPR (presenter)** are employees of Johnson & Johnson and may own stock/stock options in Johnson & Johnson. **SD** reports consultancy fees from AbbVie, Alimentiv, Allergan, Amgen, AstraZeneca, Athos, Biogen, Boehringer Ingelheim, Celgene, Celltrion, Eli Lilly, Entera, Ferring, Gilead, Hospira, Intrem, Johnson & Johnson, MSD, Mundipharma, Mylan, Pfizer, Roche, Sandoz, Sublimity, Takeda, Tigenix, UCB and Vifor; and reports lecture fees from AbbVie, Amgen, Ferring, Gilead, Johnson & Johnson, Mylan, Pfizer, and Takeda. **PREVIOUSLY PRESENTED AT:** The 21st Congress of the European Crohn's and Colitis Organisation (ECCO); February 18–21, 2026; Stockholm, Sweden.