OP 981

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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EXHIBIT DATES: MAY 3–5, 2026
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SPEAKER DISCLOSURE

David T. Rubin

I disclose the following financial relationship(s) with a commercial interest:

Consulting and/or speaker fees and/or advisory board participation for AbbVie, Altrubio, Apex, Avalo, Bristol Myers Squibb, Buhlmann Diagnostics, Celgene, Connect BioPharma, Intouch Group, Iterative Health, Johnson & Johnson, Lilly, Pfizer, Samsung Neurologica, 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.

Background and Objective

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

Guselkumab is a dual-acting IL-23p19 subunit inhibitor that potently blocks IL-23 and binds to CD64, a receptor on cells that produce IL-23[1]

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

Both SC maintenance doses were highly effective in the primary study population compared with placebo and ustekinumab[2] at Week 48 and were approved for use

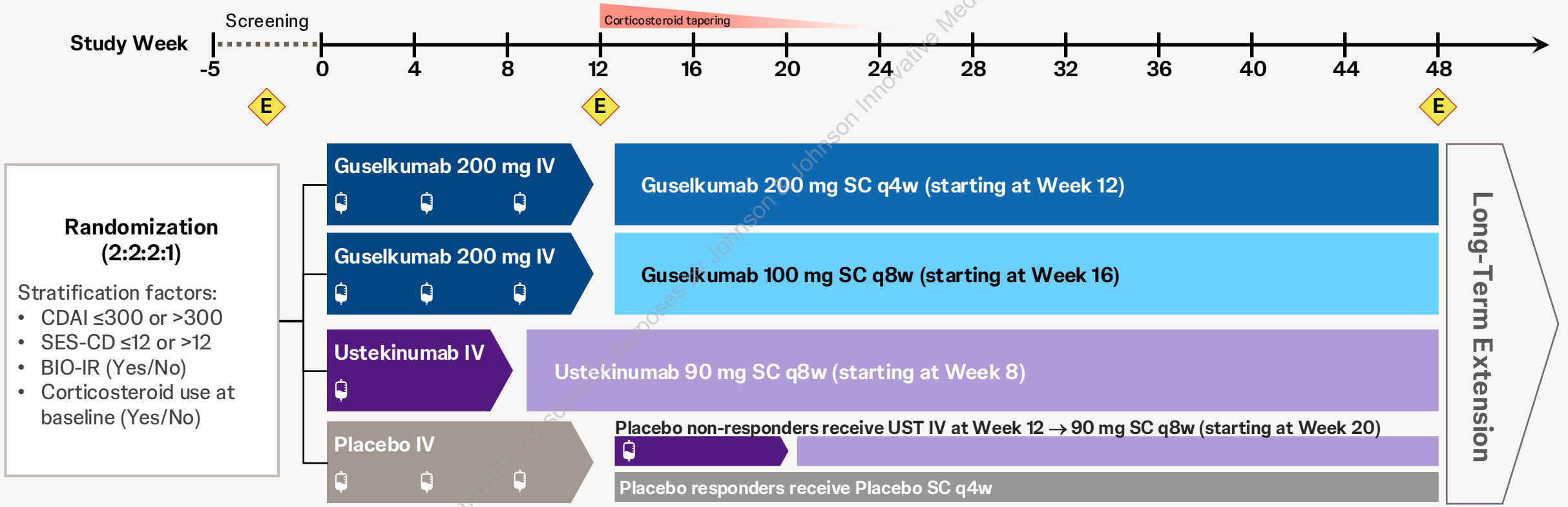
Study Objective: To present data of EIMs reported through Week 48 in the pooled GALAXI 2/3 studies

1. Sachen KL, Hammaker D, Sarabia I, et al. Front Immunol. 2025;16:1532852.
2. Panaccione R, Feagan BG, Afzali A, et al. Lancet. 2025;406(10501):358-375.

Identically-designed, Double-blind, Treat-through studies: GALAXI 2 & 3

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



[a] *Scored at screening by central reader with minimum scores of 1 for "size of ulcer" and "ulcerated surface"*
[b] *Biologic 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; CDAI = Crohn's disease activity index; E = endoscopy; IV = intravenous; MTX = methotrexate; q4w/q8w = every 4 or 8 weeks; SC = subcutaneous; SES-CD = Simple Endoscopic Score for Crohn's Disease; SF = stool frequency

Pooled Baseline Demographics and Disease Characteristics

Among participants with EIMs at baseline

	Placebo	GUS 100 mg SC q8w	GUS 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%)
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%)

CD, Crohn's disease; CDAI, Crohn's Disease Activity Index; EIM, extraintestinal manifestation; GI, gastrointestinal; GUS, guselkumab, IV, intravenous; q4w/q8w, every 4 or 8 weeks; SC, subcutaneous; SD, standard deviation

EIMs at Baseline

	Placebo	GUS 100mg SC q8w	GUS 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%)
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%)

[a]A single participant may have had >1 EIM

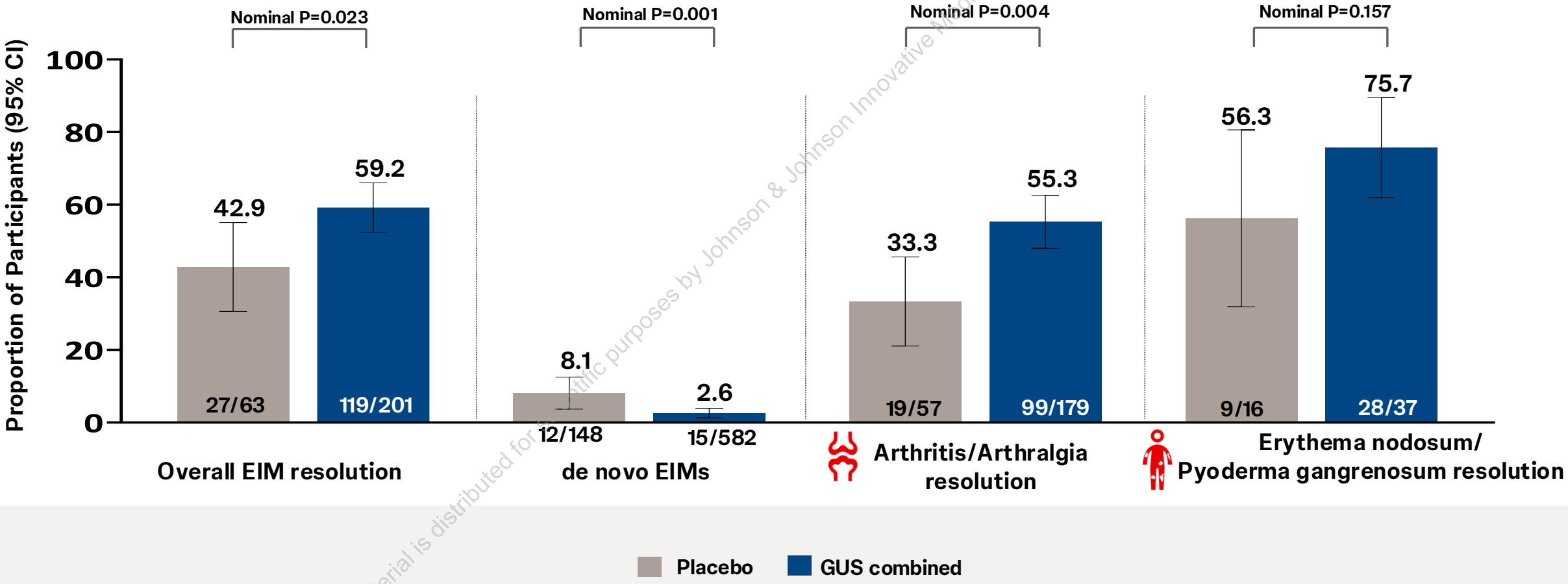
EIMs were collected as a component of the CDAI as presence or absence of:

- Joint (arthritis/arthralgia)
- Skin (erythema nodosum/pyoderma gangrenosum)
- Eye (iritis/uveitis) involvement

Assessments were performed by the GALAXI study investigators, not Rheumatologists or Dermatologists

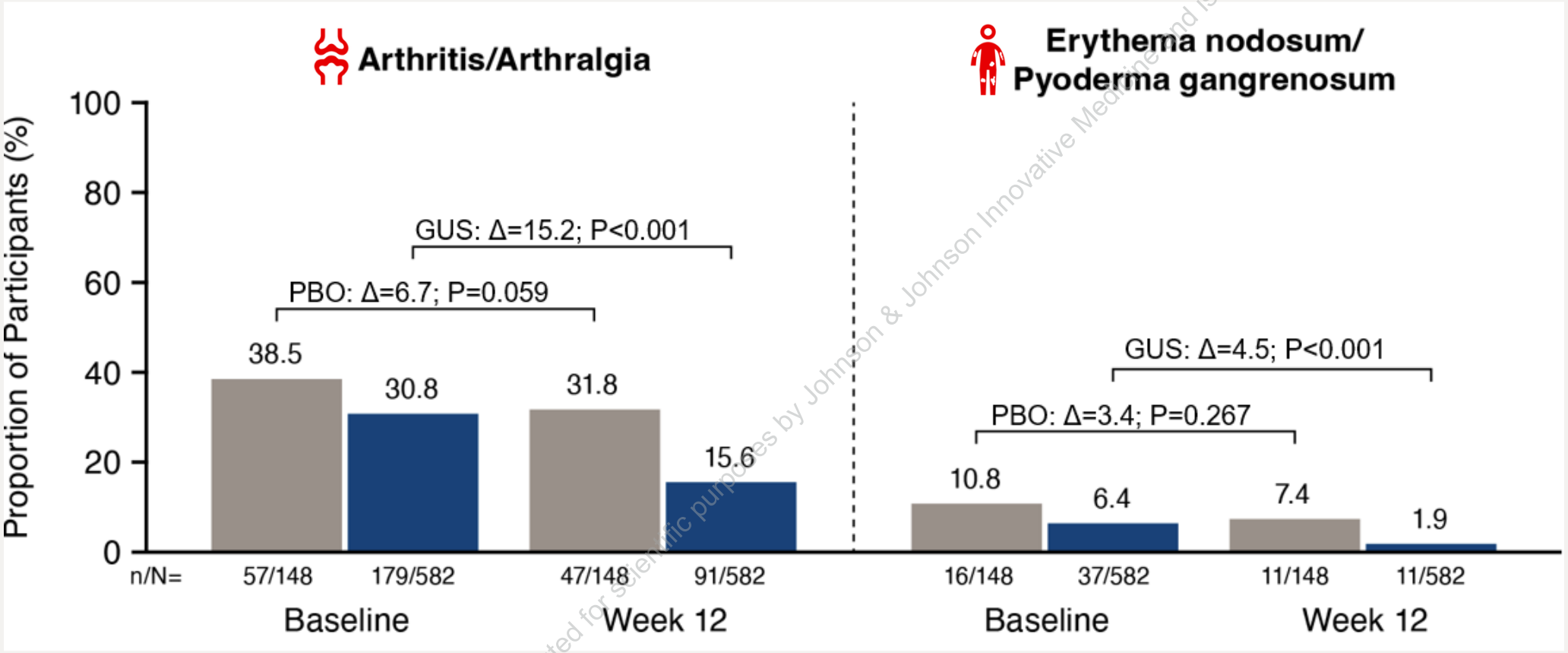
EIMs After Induction (Week 12)

Among patients 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.

Week-12 EIMs after Induction

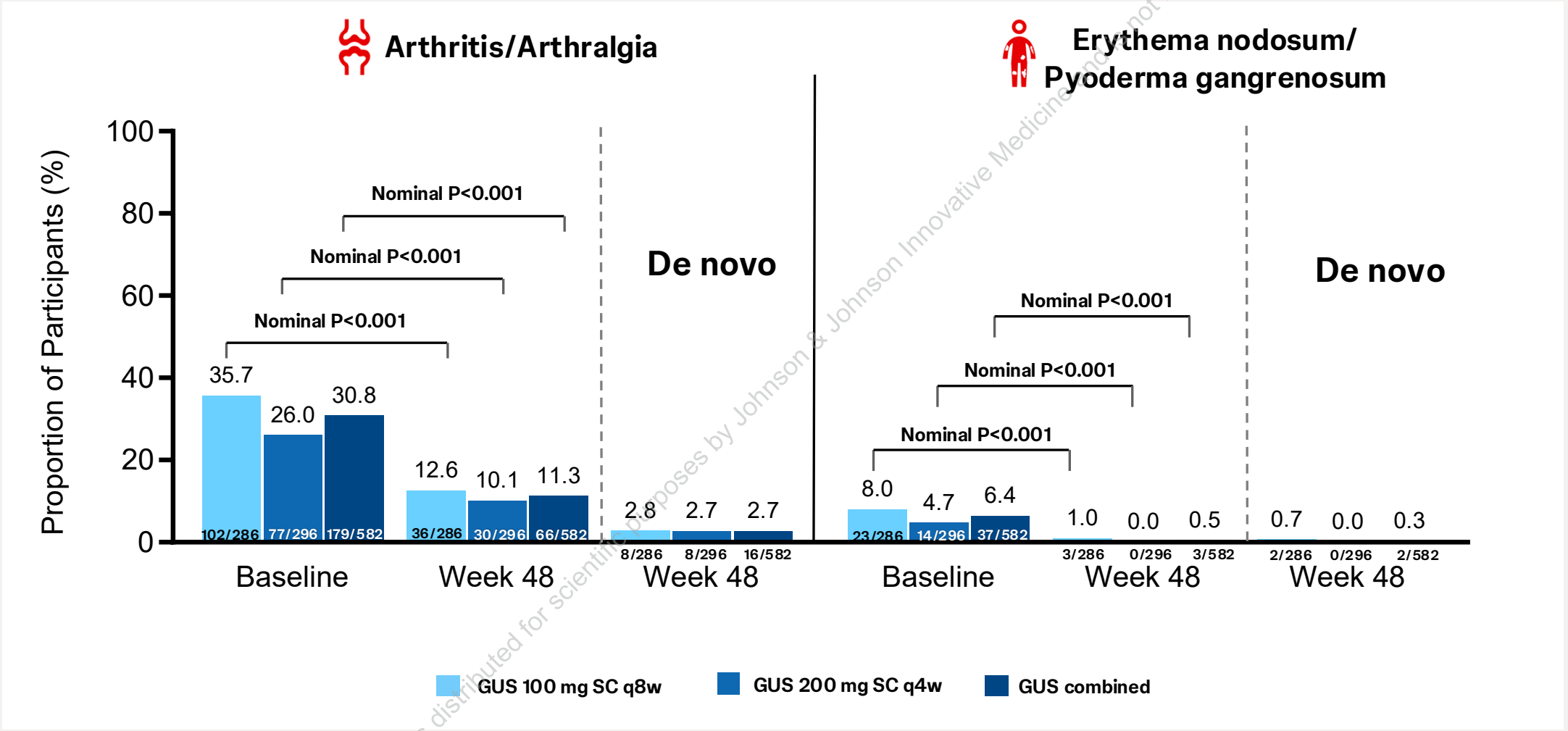


Note: All p-values are nominal

Placebo GUS combined

EIM, extraintestinal manifestation; GUS, guselkumab; IV, intravenous; PBO, placebo; q4w/q8w, every 4 or 8 weeks; SC, subcutaneous
The nominal p-values are based on the McNemar's test comparing prevalence of EIMs at Week 12 to baseline.

Week-48 EIMs after Induction and Maintenance



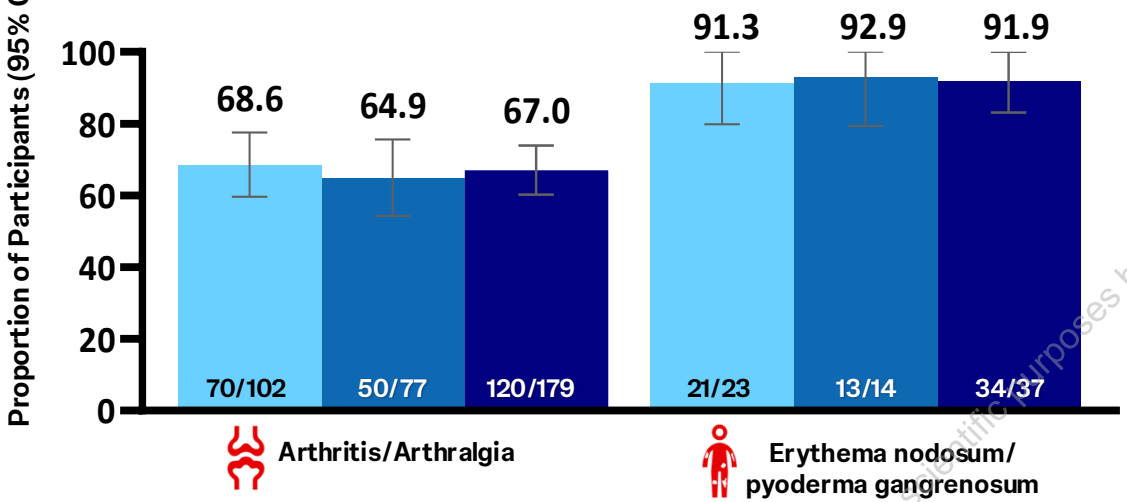
EIM, extraintestinal manifestation; IV, intravenous; q4w/q8w, every 4 or 8 weeks; SC, subcutaneous
The nominal p-values are based on the McNemar's test comparing prevalence of EIMs at Week 48 to baseline.

Corticosteroid-Free EIM Resolution

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

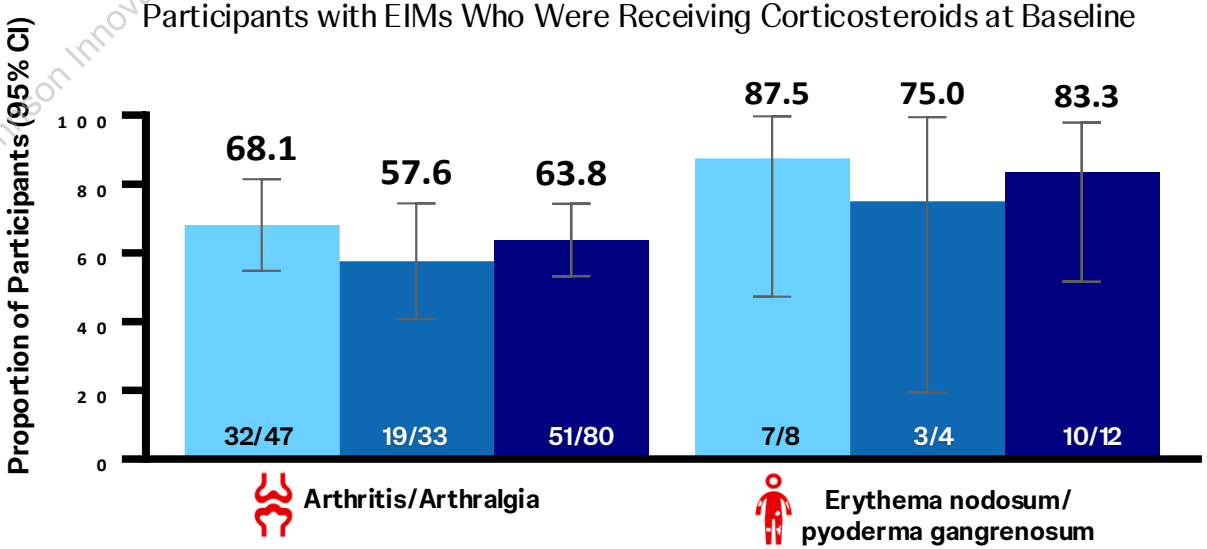
90-Day Corticosteroid-Free EIM Resolution at Week 48

Participants with EIMs at Baseline



90-Day Corticosteroid-Free EIM Resolution at Week 48

Participants with EIMs Who Were Receiving Corticosteroids at Baseline



GUS 100 mg SC q8w GUS 200 mg SC q4w GUS combined

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

ACKNOWLEDGEMENTS

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- Medical writing support was provided by Kristin Ruley Sharples, PhD of Johnson & Johnson under the direction of the authors in accordance with Good Publication Practice guidelines

Methods

- 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

Week-12 Iritis/Uveitis Outcomes Among Participants with EIMs at Baseline

	Placebo	GUS Combined
Primary analysis set, N	**148**	**582**
Number of participants with EIMs at baseline, n (%)	63 (42.6%)	201 (34.5%)
EIMs at baseline, n (%)[a]		
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Erythema nodosum/Pyoderma gangrenosum	16 (25.4%)	37 (18.4%)
Iritis/Uveitis	2 (3.2%)	11 (5.5%)
Iritis/Uveitis at baseline	2/63 (3.2%)	11/201 (5.5%)
Iritis/Uveitis resolution at Week 12	2/2 (100%)	6/11 (62.5%)

Week-48 Iritis/Uveitis Outcomes Among Participants with EIMs at Baseline

	GUS 200 mg IV q4w→ 100mg SC q8w	GUS 200 mg IV q4w→ 200 mg SC q4w	GUS Combined
Primary analysis set, N	**286**	**296**	**582**
Number of participants with EIMs at baseline, n (%)	115 (40.2%)	86 (29.1%)	201 (34.5%)
EIMs at baseline, n (%)[a]			
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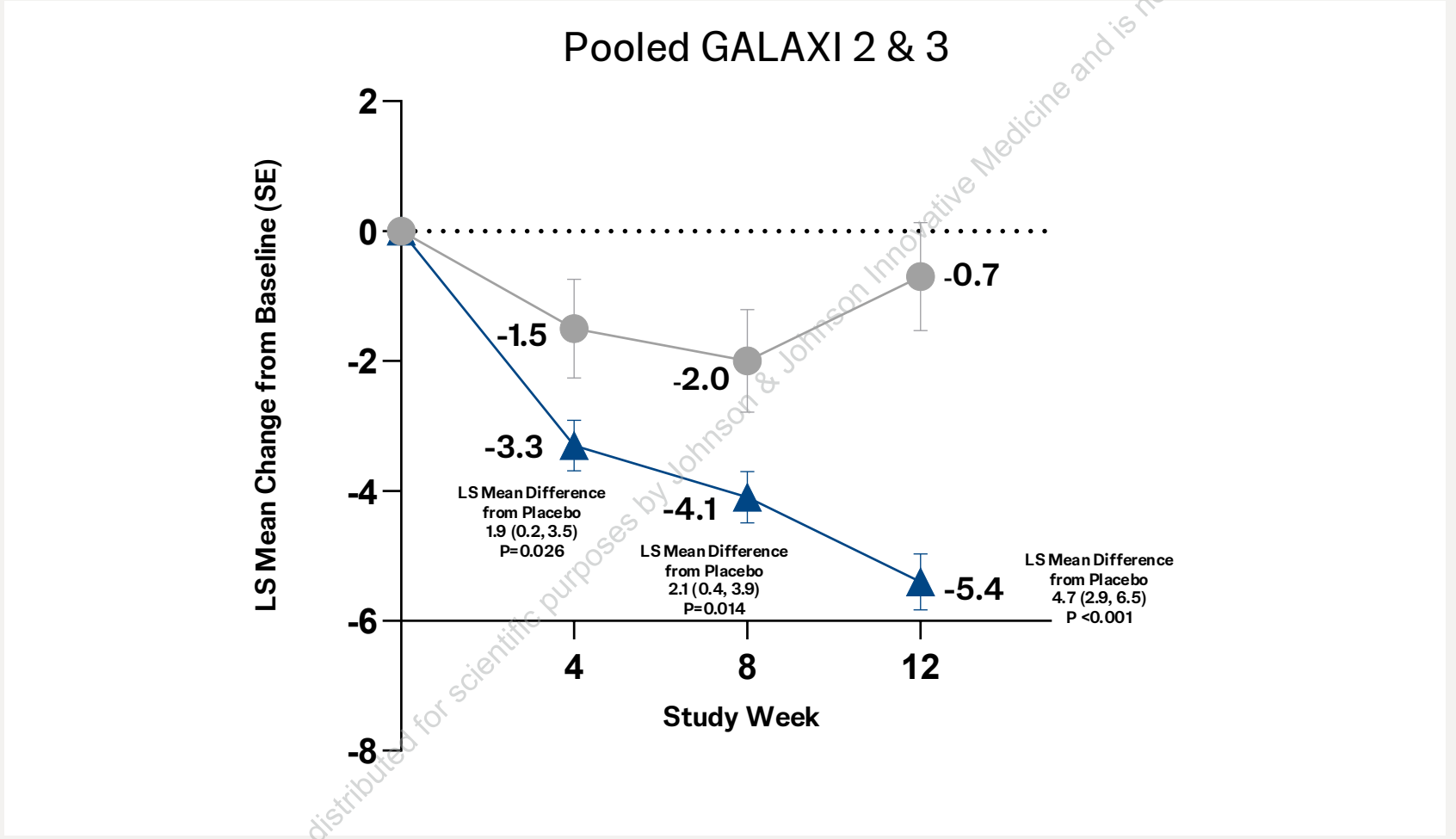
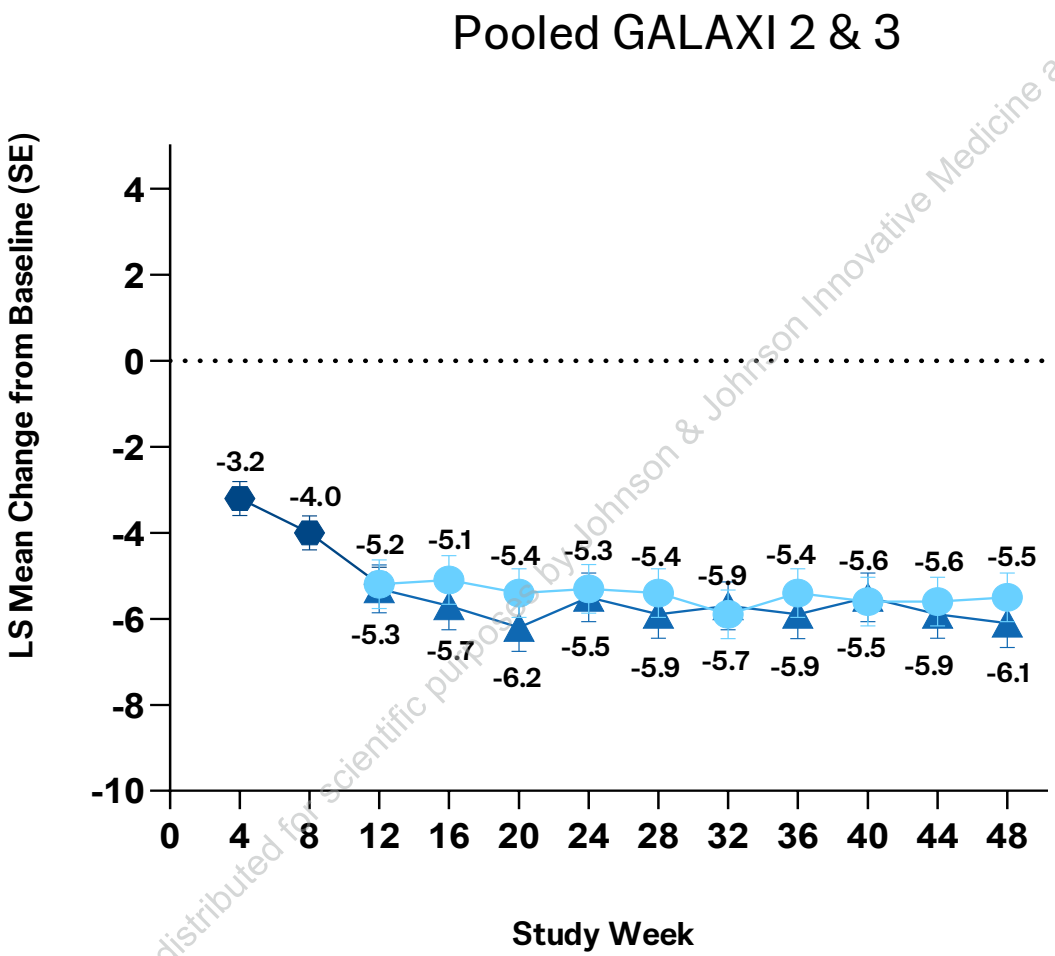
Erythema nodosum/Pyoderma gangrenosum	23 (20.0%)	14 (16.3%)	37 (18.4%)
Iritis/Uveitis	5 (4.3%)	6 (7.0%)	11 (5.5%)
Iritis/Uveitis resolution at Week 48	4/5 (80.8%)	5/6 (83.3%)	9/11 (81.8%)

Change from Baseline to Week 12 in EIM CDAI Component Score



LS, least-squares
All p-values are nominal.

Change from Week 0 to Week 48 in CDAI EIM Component Score



LS, least-squares
All p-values are nominal.