

Deep Remission in Guselkumab-treated Participants with Moderately to Severely Active Crohn's Disease Through 3 Years: Results from the GALAXI 2 & 3 Studies

David T. Rubin,¹ Anita Afzali,² Christopher Busse,³

Rian Van Rampelbergh,⁴ Wilbert van Duijnhoven,⁴ Marla Dubinsky,⁵

Geert D'Haens⁶

¹University of Chicago Medicine Inflammatory Bowel Disease Center, Chicago, IL, USA; ²Division of Gastroenterology and Hepatology, University of Cincinnati College of Medicine, Cincinnati, OH, USA; ³Johnson & Johnson, Horsham, PA, USA; ⁴Johnson & Johnson, Antwerp, Belgium; ⁵Icahn School of Medicine, Mount Sinai, New York, NY, USA;

⁶Department of Gastroenterology, Amsterdam University Medical Centers, Amsterdam, The Netherlands

October 19, 2026; Barcelona, Spain



Scan the QR code. The QR code is intended to provide scientific information for individual reference, and the information should not be altered or reproduced in any way.



UEG Week

Disclosure of Conflicts of Interest

I herewith declare the following paid or unpaid consultancies, business interests, or sources of honoraria payments for the past three years, and anything else which could potentially be viewed as a conflict of interest:

Consultancy activities for AbbVie, Agomab, Alimentiv, AstraZeneca, AMT, Bristol Meyers Squibb, Boehringer Ingelheim, Celltrion, Eli Lilly, Exeliom, Galapagos, GlaxoSmithKline, Gossamerbio, Immunic, Index, Johnson & Johnson, Kaleido, Origo, Pfizer, Polpharma, Procise Diagnostics, Prometheus Laboratories, Prometheus Biosciences, Progenity, and Protagonist Therapeutics Inc.; speaker's bureau for AbbVie, Bristol Meyers Squibb, Galapagos, Pfizer, and Takeda; and data monitoring board activities for AbbVie, AstraZeneca, Galapagos, and Seres Health.

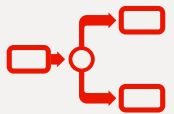
Background and Objective



Crohn's disease treatment goals have evolved from managing symptoms to achieving clinical remission and endoscopic healing¹



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-23²



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

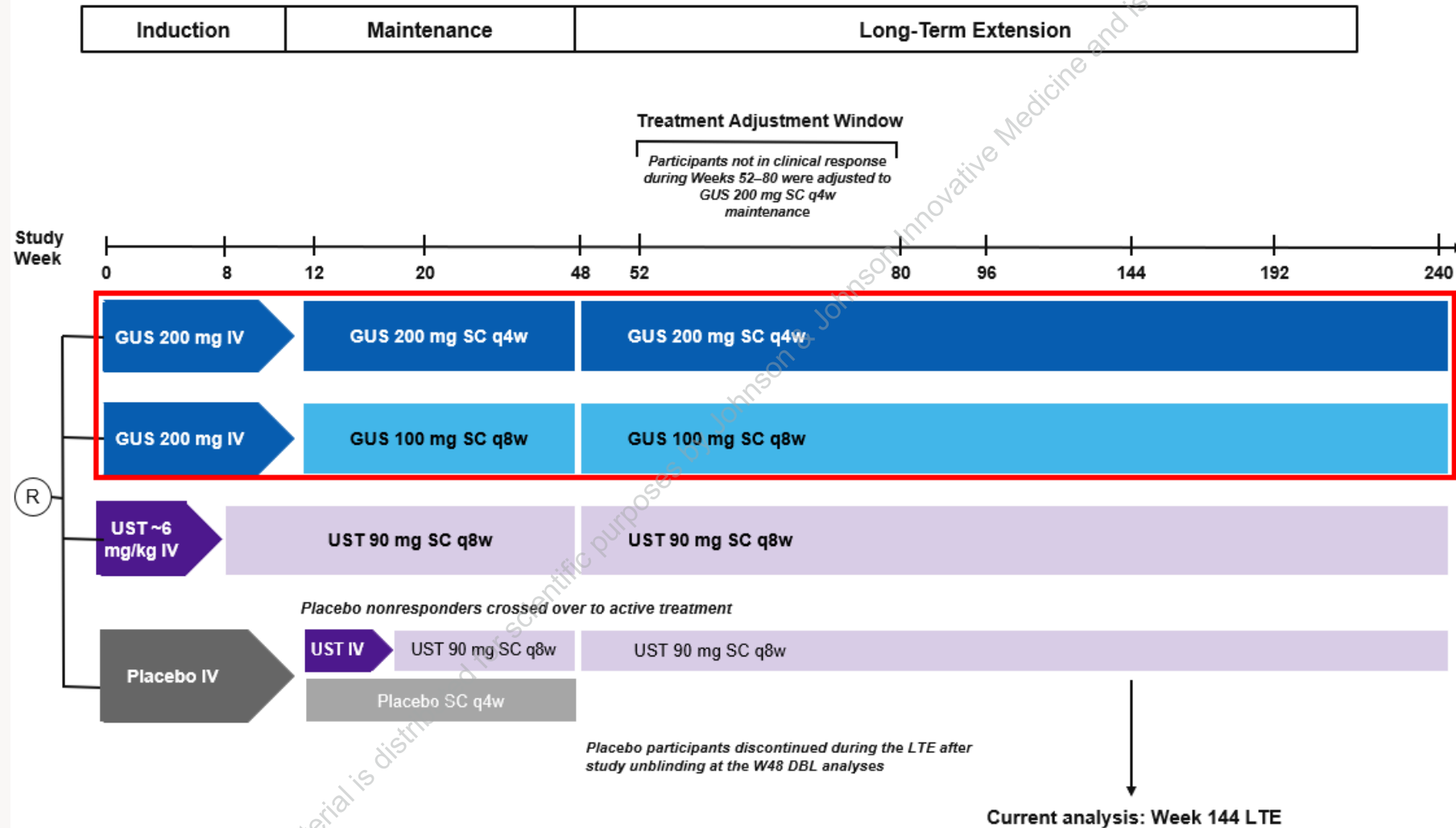


Objective: To assess the achievement of deep remission and other outcomes in guselkumab-treated participants from the pooled GALAXI 2/3 studies through Week 144

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 ≥6 (or ≥4 for isolated ileal disease)
- Inadequate response/intolerance to oral corticosteroids or 6-MP/AZA/MTX, or biologic therapies^a or naïve to biologics



Endpoints and Analysis Populations

Endpoints and criteria

- **Deep remission:** Combination of clinical remission (CDAI score <150) AND endoscopic remission (SES-CD score ≤4 and ≥2-point reduction in SES-CD score and no subscore >1)
- **IBDQ Remission:** Total IBDQ score ≥ 170
- **CD-related hospitalizations and surgeries**
- **Dose Adjustment criteria:** Participants with an inadequate response (not in clinical response [≥100-point reduction in CDAI from Week 0 or CDAI <150] AND CDAI ≥220) were eligible to dose adjust once to GUS 200 mg SC between Week 52 and Week 80

Analysis populations

- **Primary efficacy analysis set (non-responder imputation [NRI]):** all randomized participants who received ≥1 dose of guselkumab evaluated by randomized group
- **LTE As Observed analysis set:** participants who received ≥1 dose in the long-term extension, remained on continuous treatment through each designated timepoint, and had data available at that timepoint

Statistical considerations

- **Non-responder imputation (NRI):**
 - Participants with prohibited CD medication changes before Week 48, dose adjustment (including “sham”) during Weeks 52–80, or CD-related surgery or discontinuation of study intervention at any time were considered not to have met the endpoint at the designated timepoint
 - Missing endpoint data were imputed as non-response
- **As Observed Analysis:** no nonresponder imputation; only participants with available data at the assessment timepoint were included in the analysis

Pooled Demographics and Disease Characteristics-LTE

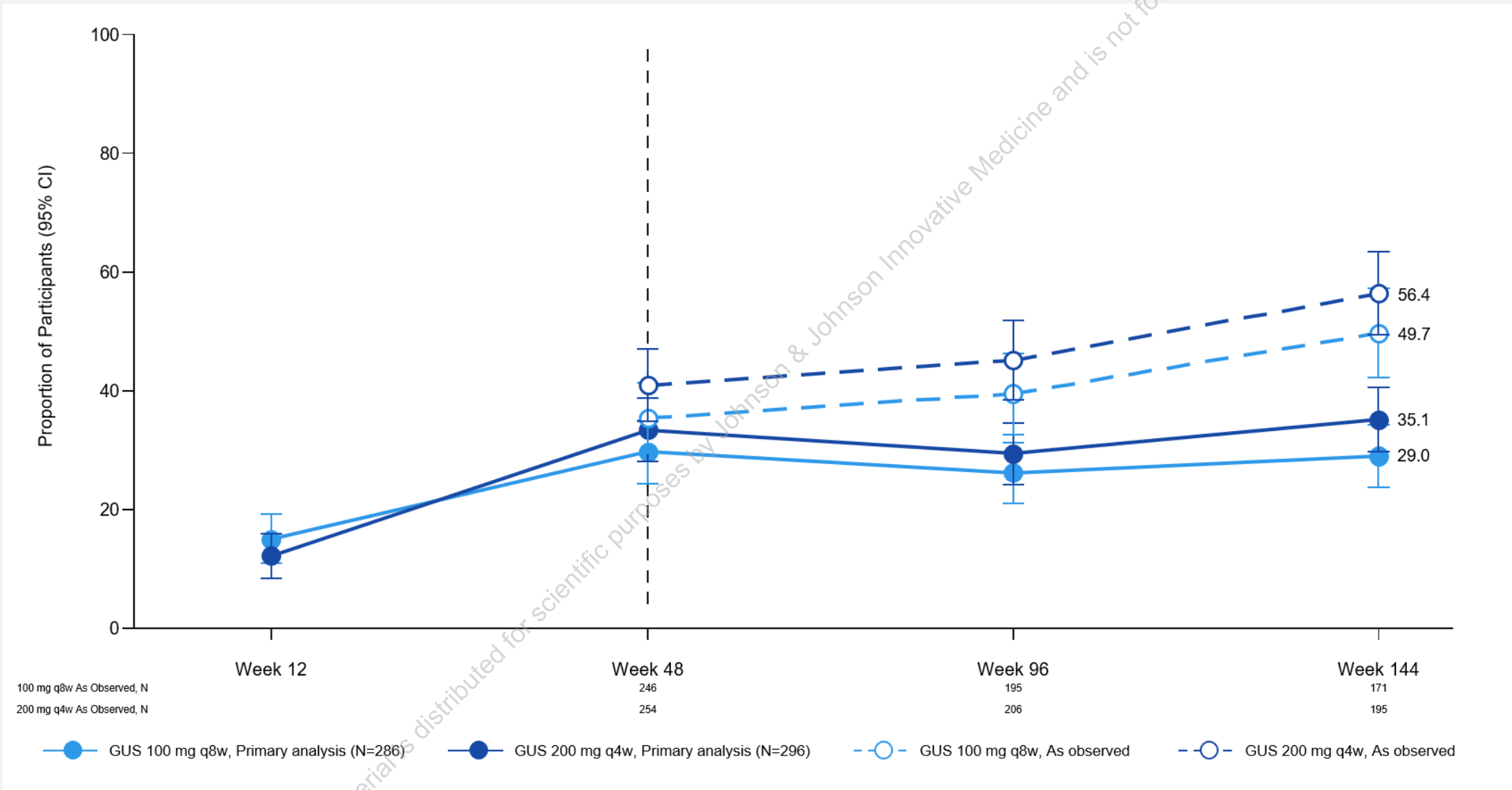
LTE Efficacy Analysis Set

	GUS 100 mg SC q8w ^a	GUS 200 mg SC q4w ^a	GUS Combined
Primary analysis set, N	251	256	507
Demographics			
Age in years, mean (SD)	35.8 (12.17)	36.6 (13.14)	36.2 (12.66)
Men, n (%)	141 (56.2%)	158 (61.7%)	299 (59.0%)
CD duration in years, mean (SD)	7.00 (6.44)	6.67 (6.60)	6.83 (6.52)
Characteristics, mean (SD)			
CDAI score	293.5 (53.47)	295.2 (53.28)	294.3 (53.33)
SES-CD	13.1 (7.54)	12.7 (7.38)	12.9 (7.46)
IBDQ score	126.8 (32.31)	128.6 (29.80)	127.7 (31.06)
Biomarkers, mean (SD)			
CRP, (mg/L)	16.0 (21.63)	15.8 (21.92)	15.9 (21.76)
Fecal calprotectin, (µg/g)	1614.3 (1982.97)	1745.8 (3134.80)	1680.8 (2627.83)
Involved GI areas (as assessed by central reader), n (%)			
Ileum only	49 (19.5%)	66 (25.8%)	115 (22.7%)
Colon only	99 (39.4%)	98 (38.3%)	197 (38.9%)
Ileum and colon	103 (41.0%)	92 (35.9%)	195 (38.5%)

CD, Crohn's disease; CDAI, Crohn's Disease Activity Index; CRP, C-reactive protein; GI, gastrointestinal; GUS, guselkumab; IBDQ, Inflammatory Bowel Disease Questionnaire; LTE, long-term extension; q4w/q8w, every 4 or 8 weeks; SC, subcutaneous; SD, standard deviation, SES-CD, Simple Endoscopic Score-Crohn's Disease
^aTreatment group at the start of the LTE period

Deep Remission Through 3 Years

Primary Efficacy Analysis Set

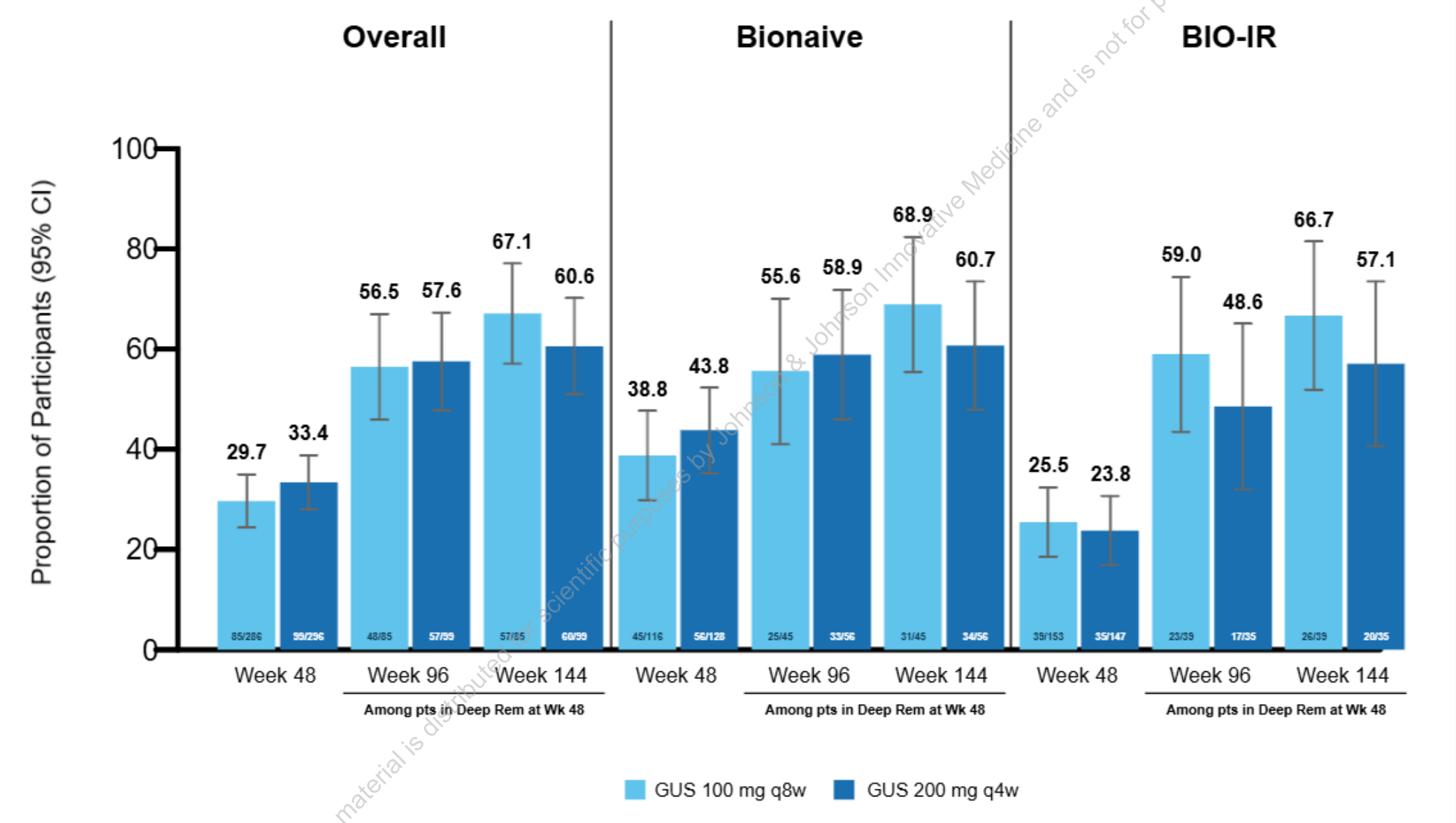


Deep remission: Combination of clinical remission and endoscopic remission

CI, confidence interval; GUS, guselkumab; q4w/q8w, every 4 or 8 weeks

Deep Remission Among Participants in Deep Remission at Week 48

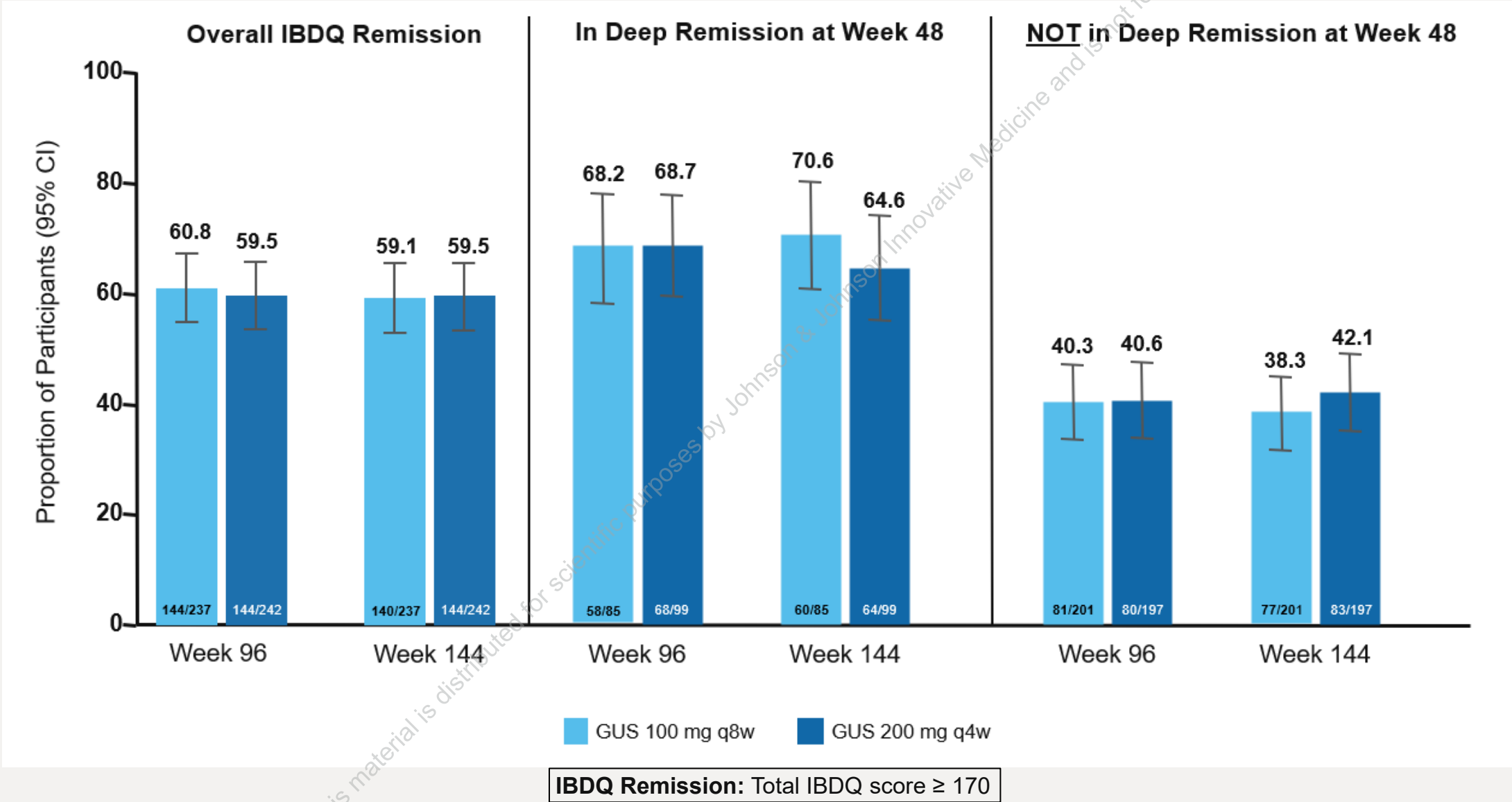
Primary Efficacy Analysis Set



BIO-IR, inadequate response or intolerance to biologics; CI, confidence interval; GUS, guselkumab; pts, participants; q4/8w, every 4 or 8 weeks; Rem, remission; Wk, week

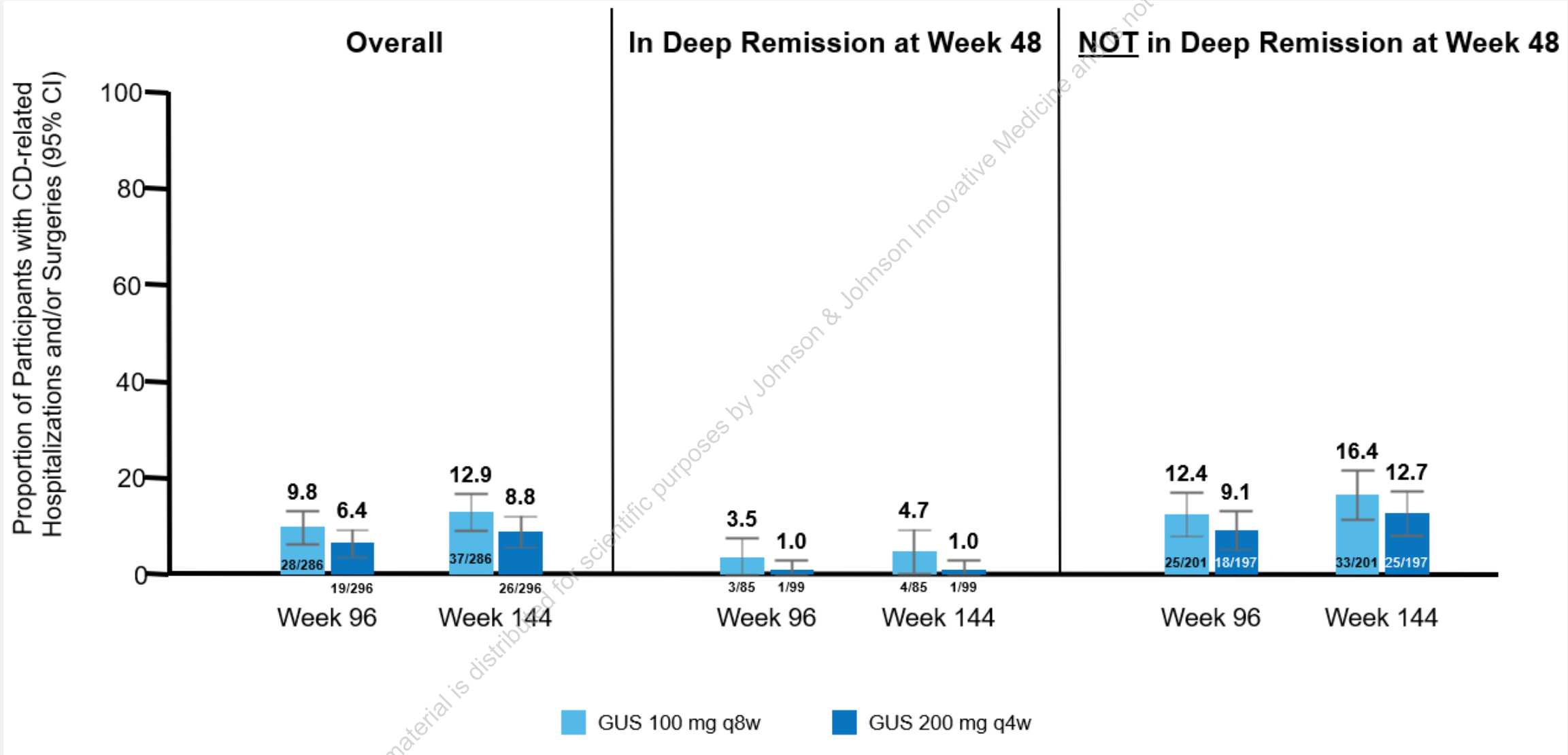
IBDQ Remission

Primary Efficacy Analysis Set



Fewer Participants in Deep Remission had CD-Related Hospitalizations and/or Surgeries

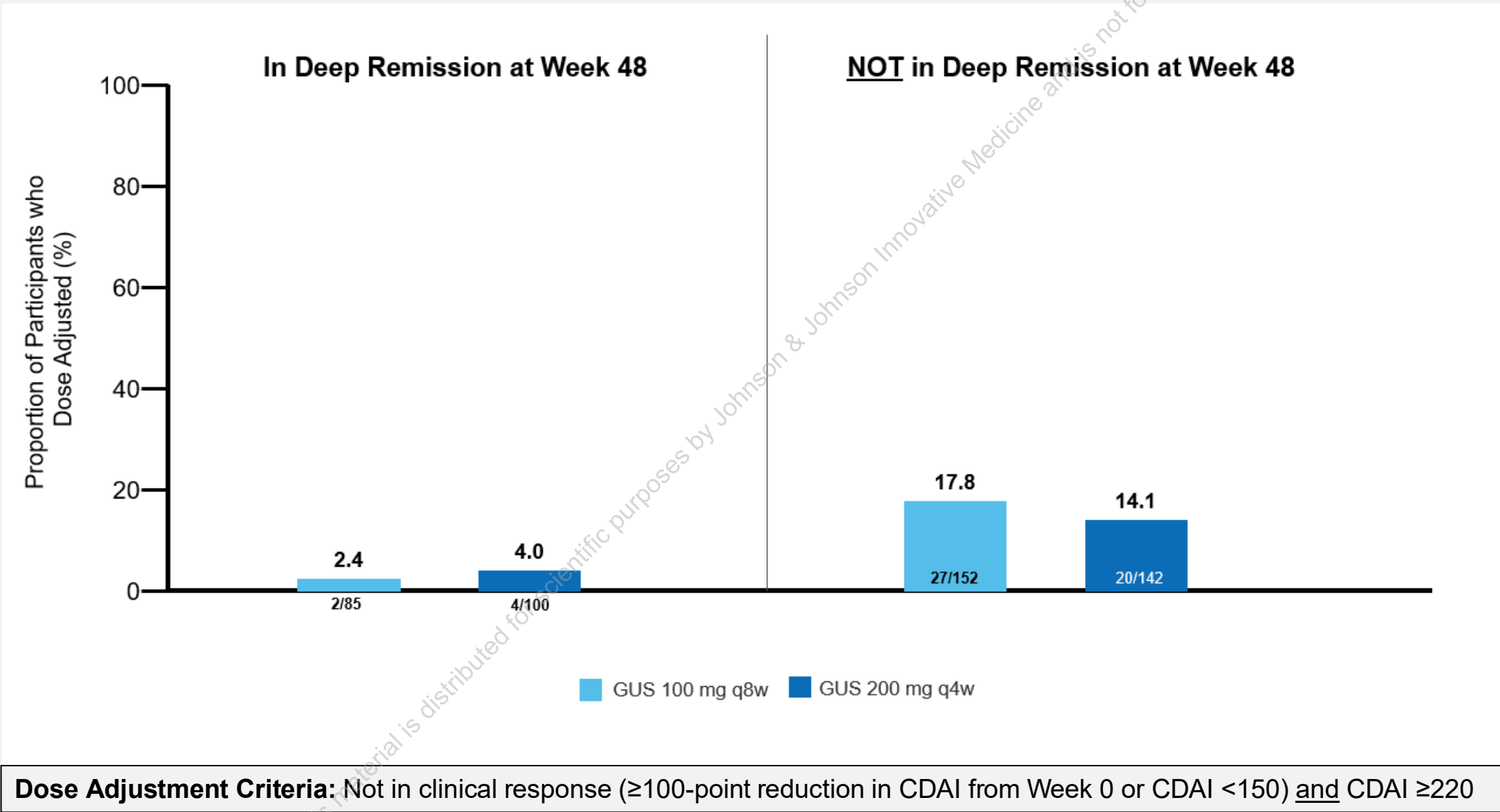
Primary Efficacy Analysis Set



CI, confidence interval; CD, Crohn's disease; GUS, guselkumab; q4w/q8w, every 4 or 8 weeks

Fewer Participants in Deep Remission Required Dose Adjustment Between Weeks 52 and 80

Primary Efficacy Analysis Set



Key Takeaways



Guselkumab was effective in maintaining the high-bar endpoint of deep remission through up to 3 years in participants with moderately to severely active Crohn's disease



Deep remission was achieved regardless of prior biologic history



Improved health-related quality of life and fewer hospitalizations and/or surgeries were reported through 3 years in guselkumab-treated participants in deep remission at Week 48

Acknowledgements

- The authors thank the participants, investigators, and study personnel who made the GALAXI 2 & GALAXI 3 studies possible
- This work was supported by Johnson & Johnson
- 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



Scan the QR code. The QR code is intended to provide scientific information for individual reference, and the information should not be altered or reproduced in any way.