# Efficacy of Intravenous and Subcutaneous Guselkumab Induction by Weight and Body Mass Index in Patients With Crohn's Disease: Phase 3 GALAXI and GRAVITI Results

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## Background

- Guselkumab is a dual-acting interleukin (IL)-23p19 subunit inhibitor that potently neutralizes IL-23 and binds to cluster of differentiation-64 (CD64), a receptor on immune cells that produce IL-23[1]
- Similar efficacy and safety of intravenous (IV) and subcutaneous (SC) induction with guselkumab in participants with moderately to severely active Crohn's disease (CD) has been established in the phase 3 GALAXI and GRAVITI studies[2,3]
- Obesity has the potential to impact the pharmacokinetic and pharmacodynamic parameters of SC administered medications[4–7]

## Objective

- **The aim of this post-hoc analysis was to evaluate whether weight and body mass index (BMI) in participants with CD differentially affect the efficacy of guselkumab SC induction compared to IV induction**

## GALAXI 2 & 3 and GRAVITI Study Designs Through Week 48

**Key eligibility criteria**

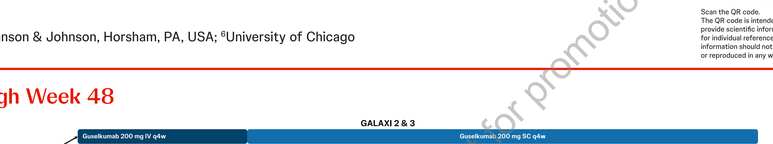
- Moderately to severely active CD (CDAI score 220–450 AND either mean daily SF OR AP above protocol thresholds[a]) and SES-CD score ≥6 (or ≥4 for isolated ileal disease)
- Inadequate response/loss of response/intolerance to oral corticosteroids, 6-MP/AZA/MTX, or biologic therapies[b]

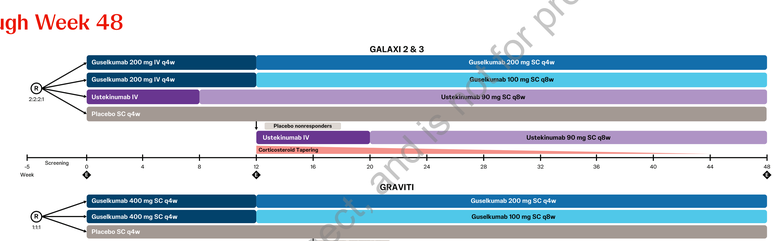
**Randomization stratified by:**

- CDAI score (≤300 or >300)
- SES-CD (≤12 or >12)
- Prior BIO-failure status
- Corticosteroid use at baseline (GALAXI only)

**Endpoints**

- **Clinical remission:** CDAI score <150
- **Endoscopic response:** ≥50% improvement from baseline in SES-CD
- **Endoscopic remission:** SES-CD score ≤4 and at least a 2-point reduction from baseline and no subscore greater than 1 in any individual component
- **Deep remission:** Combination of clinical remission and endoscopic remission




*Note: Only the study designs through Week 48 are shown. GRAVITI included data handling rules for rescue treatment at Week 16 in participants meeting prespecified criteria; these data handling rules were suspended for the Week 48 analyses shown below. The GRAVITI study designs can be found in primary trial publications (references 2 and 3 for GALAXI 2 & 3 and GRAVITI, respectively).*
*[a]GALAXI: Mean daily SF count >3 OR AP score >1; GRAVITI: Mean daily SF count ≥4 OR AP score ≥2. [b]Biologic therapies: TNF antagonists or vedolizumab. **6-MP**=6-mercaptopurine, **AP**=abdominal pain, **AZA**=azathioprine, **BIO-failure**=biologic therapy failure, **CD**=Crohn's disease, **CDAI**=Crohn's Disease Activity Index, **IV**=intravenous, **MTX**=methotrexate, **q4w**=every 4 weeks, **q8w**=every 8 weeks, **R**=randomization, **SC**=subcutaneous, **SES-CD**=simple endoscopic score for Crohn's disease, **SF**=stool frequency, **TNF**=tumor necrosis factor.*

## Key Takeaways

- **Guselkumab IV and SC induction were similarly effective in participants with moderately to severely active CD compared with placebo at Week 12 regardless of participants' baseline body weight or BMI**
- **Similar efficacy was observed at Week 48 between participants treated with either guselkumab IV or SC induction regardless of participants' baseline body weight or BMI**
- **Efficacy of guselkumab does not appear to be impacted by body weight or BMI, irrespective of route of induction treatment administration**

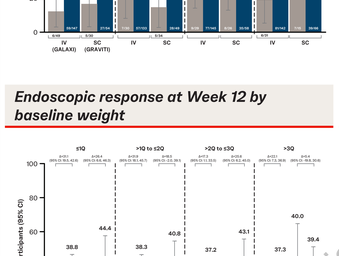
## Results

### Baseline demographics and disease characteristics

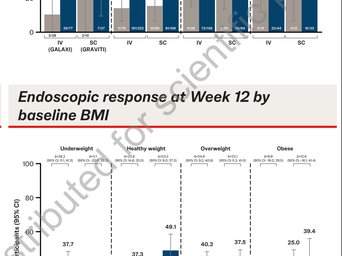
| | GALAXI 2 & 3 | | | | GRAVITI | | | |
|---|---|---|---|---|---|---|---|---|
| Full analysis set | Placebo IV (N=149) | GUS 200 mg IV → 100 mg SC q8w (N=298) | GUS 200 mg IV → 200 mg SC q4w (N=296) | GUS Combined (N=582) | Placebo SC (N=117) | GUS 400 mg SC → 100 mg SC q8w (N=115) | GUS 400 mg SC → 200 mg SC q4w (N=115) | GUS Combined (N=230) |
| **Demographics** | | | | | | | | |
| Weight in kg, mean (SD) | 67.12 (18.14) | 67.36 (16.52) | 68.21 (16.36) | 67.79 (16.43) | 68.13 (16.20) | 70.88 (19.00) | 72.88 (19.28) | 71.88 (19.13) |
| Body mass index in kg/m², mean (SD) | 22.77 (5.28) | 23.08 (4.60) | 23.23 (4.77) | 23.15 (4.68) | 23.85 (4.88) | 24.28 (5.62) | 24.84 (6.27) | 24.56 (5.95) |
| Age in years, mean (SD) | 34.8 (12.15) | 36.0 (12.24) | 36.9 (13.27) | 36.5 (12.77) | 36.0 (12.71) | 37.4 (13.32) | 39.1 (12.56) | 38.2 (12.95) |
| Male, n (%) | 88 (59.5%) | 154 (53.8%) | 178 (60.1%) | 332 (57.0%) | 67 (57.3%) | 66 (57.4%) | 70 (60.9%) | 136 (59.1%) |
| **Characteristics** | | | | | | | | |
| CD duration in years, mean (SD) | 7.15 (7.53) | 7.12 (6.72) | 7.07 (7.24) | 7.09 (6.98) | 6.96 (7.75) | 9.17 (9.08) | 7.89 (7.13) | 8.53 (8.17) |
| CDAI score, mean (SD) | 293.4 (52.72) | 296.3 (54.27) | 295.9 (52.74) | 296.1 (53.45) | 293.0 (49.09) | 300.4 (54.32) | 297.3 (54.69) | 298.8 (54.41) |
| SES-CD score, mean (SD) | 13.3 (7.55) | 13.2 (7.43) | 12.5 (7.24) | 12.8 (7.34) | 12.0 (6.89) | 12.2 (6.85) | 11.8 (7.12) | 12.0 (6.97) |
| Endoscopic disease severity (SES-CD score), n (%) | | | | | | | | |
| Moderate (7–16) | 77 (52.0%) | 164 (57.3%) | 147 (49.7%) | 311 (53.4%) | 61 (52.1%) | 64 (55.7%) | 49 (42.6%) | 113 (49.1%) |
| Severe (>16) | 43 (29.1%) | 81 (28.3%) | 79 (26.7%) | 160 (27.5%) | 25 (21.4%) | 26 (22.6%) | 27 (23.5%) | 53 (23.0%) |
| Involved disease location by central reader, n (%) | | | | | | | | |
| Colon only | 62 (41.9%) | 113 (39.5%) | 112 (37.8%) | 225 (38.7%) | 40 (34.2%) | 41 (35.7%) | 40 (34.8%) | 81 (35.2%) |
| Ileum only | 31 (20.9%) | 59 (20.6%) | 80 (27.0%) | 139 (23.9%) | 22 (18.8%) | 25 (21.7%) | 27 (23.5%) | 52 (22.6%) |
| Ileum and Colon | 55 (37.2%) | 114 (39.9%) | 104 (35.1%) | 218 (37.5%) | 55 (47.0%) | 49 (42.6%) | 48 (41.7%) | 97 (42.2%) |
| **Biomarkers** | | | | | | | | |
| C-reactive protein in mg/L, median (IQR) | 5.1 (1.5; 15.8) | 7.7 (2.6; 21.8) | 6.2 (2.7; 21.3) | 6.7 (2.6; 21.8) | 7.9 (2.1; 14.7) | 5.2 (1.7; 13.3) | 5.7 (1.7; 16.1) | 5.5 (1.7; 14.9) |
| Fecal calprotectin in µg/g², median (IQR) | 962.0 (255.0; 2595.0) | 969.0 (404.0; 3085.0) | 1045.5 (323.0; 2006.0) | 1011.0 (372.0; 2054.0) | 712.0 (243.0; 1724.0) | 610.0 (226.0; 1554.0) | 600.5 (235.0; 1650.0) | 610.0 (228.0; 1608.0) |
| **Biologic medication history, n (%)** | | | | | | | | |
| Bionalve | 61 (41.2%) | 116 (40.6%) | 128 (43.2%) | 244 (41.9%) | 56 (47.9%) | 53 (46.1%) | 52 (45.2%) | 105 (45.7%) |
| History of inadequate response/intolerance to biologic therapy[a] | 78 (52.7%) | 153 (53.5%) | 147 (49.7%) | 300 (51.5%) | 53 (45.3%) | 55 (47.8%) | 53 (46.1%) | 108 (47.0%) |
| **Concomitant CD medications at baseline, n (%)** | | | | | | | | |
| 6-MP/AZA | 36 (24.3%) | 85 (29.7%) | 89 (30.1%) | 174 (29.9%) | 32 (27.4%) | 28 (24.3%) | 36 (31.3%) | 64 (27.8%) |
| MTX | 4 (2.7%) | 2 (0.7%) | 7 (2.4%) | 9 (1.5%) | 1 (0.9%) | 1 (0.9%) | 1 (0.9%) | 2 (0.9%) |
| Oral corticosteroids | 51 (34.5%) | 109 (38.1%) | 106 (35.8%) | 215 (36.9%) | 33 (28.2%) | 32 (27.8%) | 38 (33.0%) | 70 (30.4%) |

[1]Based on N=147 for placebo, N=283 for GUS 100 mg, N=294 for GUS 200 mg, and N=577 for GUS Combined in GALAXI; and N=117 for placebo, N=115 for GUS 100 mg, N=114 for GUS 200 mg, and N=229 for GUS Combined in GRAVITI. *Primary nonresponse, secondary nonresponse, or intolerance.* ***6-MP***=6-mercaptopurine, ***AZA***=azathioprine, ***CD***=Crohn's disease, ***CDAI***=Crohn's Disease Activity Index, ***GUS***=guselkumab, ***IQR***=interquartile range, ***IV***=intravenous, ***MTX***=methotrexate, ***q4w***=every 4 weeks, ***q8w***=every 8 weeks, ***SC***=subcutaneous, ***SD***=standard deviation, ***SES-CD***=simple endoscopic score for Crohn's disease.

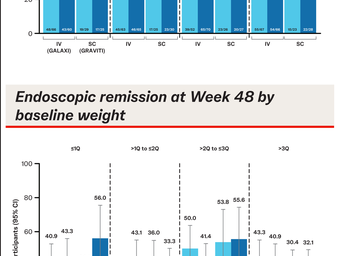
### Clinical remission at Week 12 by baseline weight



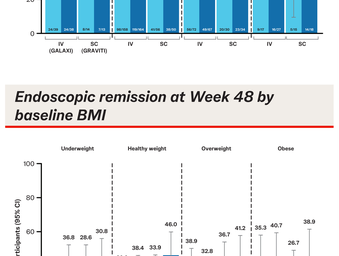

### Clinical remission at Week 12 by baseline BMI



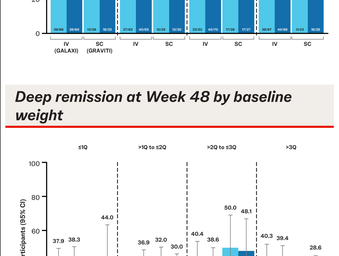

### Clinical remission at Week 48 by baseline weight



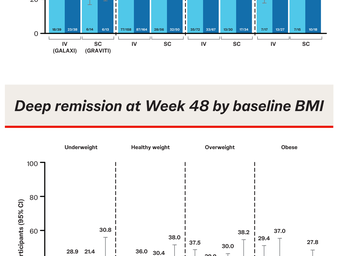

### Clinical remission at Week 48 by baseline BMI




### Endoscopic response at Week 48 by baseline weight




### Endoscopic response at Week 48 by baseline BMI




### Endoscopic response at Week 12 by baseline weight




### Endoscopic response at Week 12 by baseline BMI




### Endoscopic remission at Week 48 by baseline weight




### Endoscopic remission at Week 48 by baseline BMI




### Deep remission at Week 48 by baseline weight




### Deep remission at Week 48 by baseline BMI




Placebo (IV or SC) | GUS Induction (200 mg IV or 400 mg SC) → 100 mg SC q8w | GUS Induction (200 mg IV or 400 mg SC) → 200 mg SC q4w | GUS Induction (200 mg IV or 400 mg SC)

*A represents mean change measured as 12W minus baseline. Note: Standard deviations (SD) of the analyses were used (i.e., underweight [<18 kg/m²], healthy weight [≥18 to <25 kg/m²], overweight [≥25 to <30 kg/m²], and obese [≥30 kg/m²]). Weight quartiles were calculated for each timepoint using only the treatment arms assessed at that timepoint (i.e., placebo and guselkumab for Week 12 and only guselkumab for Week 48). Weight quartiles for Week 12 analyses were based on participants in the primary analysis set as follows: GALAXI—57 kg (1Q), 67.1 kg (2Q), 79 kg (3Q); and GRAVITI—59 kg (1Q), 69.5 kg (2Q), 81 kg (3Q). Weight quartiles for Week 48 analyses were based on participants in the primary analysis set as follows: GALAXI—58.6 kg (1Q), 70 kg (2Q), 81 kg (3Q); and GRAVITI—62 kg (1Q), 73 kg (2Q), 85 kg (3Q). Participants who had a CD-related surgery (with the exception of minor procedures such as drainage of superficial abscess or seton placement, etc.), a prohibited change in CD medication, or discontinued study intervention for any reason (other than COVID-19 related reasons [excluding COVID-19 infection] or regional crisis) were considered not to have met the endpoint at the designated timepoint. Participants who discontinued study intervention due to COVID-19 related reasons (excluding COVID-19 infection) or regional crisis had their observed data used, if available. After accounting for the aforementioned data handling rules, participants who were missing data pertaining to an endpoint at the timepoint were considered not to have achieved the endpoint. The adjusted treatment difference(s) and confidence interval(s) were based on the common risk difference by use of Mantel-Haenszel stratum weights and the Sato variance estimator. The stratification factors are baseline CDAI score (≤300 or >300), baseline SES-CD score (≤12 or >12), BIO-failure status at baseline (yes or no), and baseline corticosteroid use (yes or no, GALAXI only).* ***BIO-failure***=biologic therapy failure, ***BMI***=body mass index, ***CD***=Crohn's disease, ***CDAI***=Crohn's Disease Activity Index, ***CI***=confidence interval, ***COVID-19***=coronavirus disease 2019, ***GUS***=guselkumab, ***IV***=intravenous, ***Q***=quartile, ***q4w***=every 4 weeks, ***q8w***=every 8 weeks, ***SC***=subcutaneous, ***SES-CD***=Simple Endoscopic Score for Crohn's Disease.

**PRESENTED BY:** Kathleen Packard at Congress of Clinical Rheumatology – East 2026 (CCR – East); April 30 – May 3, 2026; Destin, FL. **REFERENCES: 1.** Sachen KL, Hammaker D, Saraiva L et al. *Front Immunol* 2022;13:1033892. **2.** Panaccione R, Feagan BG, Afzali A, et al. *Lancet* 2025;406(10501):358–75. **3.** Hart A, Panaccione R, Steinwurz F, et al. *Gastroenterology* 2025;169(2):308–25. **4.** Katsuno RP, Park HJ, Bak JE, et al. *Front Physiol* 2020;11:459. **5.** Westcott GP and Rosen ED. *Endocrinology* 2022;163(1):bqab224. **6.** Gao X, Vonsidi G, Generaux C, et al. *Pharm Res* 2020;37(8):155. **7.** Richter WF, Bhansali SG, Morris ME. *AAPS J* 2012;14(3):559–570. **ACKNOWLEDGMENTS: The authors thank the participants, investigators, and study personnel who made the GALAXI and GRAVITI studies possible. This work was supported by Johnson & Johnson.** Under the direction of the authors and in accordance with Good Publication Practice guidelines (Ann Intern Med. 2022;175:1286–1304), Rick Moorhoff of Johnson & Johnson provided writing and editorial assistance. Layout design and formatting for this encore presentation were provided by Sandeep Chopra (SIRO Medical Writing Pvt. Ltd., India). **DISCLOSURES: PD** has received research support under a sponsored research agreement unrelated to the data in the abstract from AbbVie, Johnson & Johnson, Sanofi, Merck, Teva, Direct Biologics, TVA, Boehringer Ingelheim, Bristol Myers Squibb, Pfizer, Prometheus Biosciences, Takeda Pharmaceuticals, Roche Genentech, Eli Lilly, AstraZeneca, Sygnis, and Agomab; has received consulting fees from Johnson & Johnson, AbbVie, Merck, Sobi, Celltrion, Fresenius Fuhs, Asahi Kasei Pharma, Sandoz, and Cor-Fuse, LLC; and has served on the board of the Strategic Alliance for Intestinal Advocacy in GI. **AJY** reports personal fees: Consultant for Takeda, Pfizer, Roche, Merck, AbbVie, Eli Lilly, Bristol Myers Squibb, Celltrion, and Johnson & Johnson. **TH** received grant support from Mitsubishi Tanabe Pharma Corporation, EA pharma Co, Ltd., AbbVie GK., JIMRO Co. Ltd., Zeria Pharmaceutical Co. Ltd., Kyorin Pharmaceutical Co. Ltd., Nippon Kayaku Co. Ltd., Takeda Pharmaceutical Co. Ltd., Pfizer Inc., Mochida Pharmaceutical Co. Ltd., Boston Scientific Corporation, and Kissei Pharmaceutical Co. Ltd.; consulting fees from Mitsubishi Tanabe Pharma Corporation, EA pharma Co. Ltd., AbbVie GK, Janssen Pharmaceutical K.K., Pfizer Inc., Nichi-Ko Pharmaceutical Co. Ltd., Eli Lilly, Gilead Sciences, and Bristol Myers Squibb; and lecture fee from Mitsubishi Tanabe Pharma Corporation, AbbVie GK, EA pharma Co. Ltd., Kyorin Pharmaceutical Co. Ltd., JIMRO Co., Janssen Pharmaceutical K.K., Mochida Pharmaceutical Co., Ltd., Takeda Pharmaceutical Co. Ltd., Pfizer Inc., Kissei Pharmaceutical Co. Ltd. **RVR, WVD, SA, DD, and KP (Presenter)** are employees of Johnson & Johnson and own company stock/stock options. **DTR** has received grant support from Takeda; and has served as a consultant for AbbVie, Allexia SA, Arbutus, Altos Therapeutics, Inc, Bristol Myers Squibb, Celltrion, Connect BioPharma, Eli Lilly & Co., Genentech (Roche) Inc., Iterative Health, Janssen Pharmaceuticals, Johnson & Johnson, Merck & Co., Mirador, Odyssey Therapeutics, Pfizer, Sanofi, Spyre, Takeda Pharmaceuticals, Vedanta Biosciences, and Ventyx. Board of Directors: Cornerstones Health (non-profit), IUSCAN (non-profit). **SD** reports consultancy fees from AbbVie, Almentis, Allergan, Amgen, AstraZeneca, Athos, Biogen, Boehringer Ingelheim, Celgene, Celltrion, Eli Lilly, Enthera, Ferring, Gilead, Hospira, Inotrem, Janssen, Johnson & Johnson, MSD, Mundipharma, Mylan, Pfizer, Roche, Sandoz, Sublimity, Takeda, TGenix, UCB and Vifor; and reports lecture fees from AbbVie, Amgen, Ferring, Gilead, Janssen, Mylan, Pfizer, and Takeda. **Previously presented at:** 27th Congress of the European Crohn's and Colitis Organisation (ECCO); February 18–21, 2026; Stockholm, Sweden.

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