

# Efficacy and Safety of the First Co-Antibody Therapy, JNJ-78934804, in Patients with Moderately to Severely Active Ulcerative Colitis Refractory to Two or More Systemic Therapy Mechanisms

Raja Atreya,<sup>1</sup> Bruce E. Sands,<sup>2</sup> Séverine Vermeire,<sup>3</sup> Remo Panaccione,<sup>4</sup> Gregory T Moore,<sup>5</sup> John Lynch,<sup>6</sup> Melissa G. Marko,<sup>6</sup> Eun Suk Jung,<sup>6</sup> Ruchi Patel,<sup>6</sup> Siyka Alexandrova,<sup>6</sup> Hayley Perry,<sup>7</sup> Marion L. Vetter,<sup>6</sup> Julián Panés,<sup>8</sup> Maria T. Abreu<sup>9</sup>

<sup>1</sup>Department of Medicine, Erlangen University Hospital, Friedrich-Alexander-Universität Erlangen-Nürnberg, Erlangen, Germany; <sup>2</sup>Dr. Henry D Janowitz Division of Gastroenterology, Icahn School of Medicine at Mount Sinai, New York, NY, USA; <sup>3</sup>University Hospitals Leuven, Leuven, Belgium; <sup>4</sup>Inflammatory Bowel Disease Unit, Division of Gastroenterology and Hepatology, University of Calgary, Calgary, AB, Canada; <sup>5</sup>Monash Health, and Monash University, Melbourne, Australia; <sup>6</sup>Johnson & Johnson, Spring House, PA, USA; <sup>7</sup>Johnson & Johnson Innovative Medicine UK, High Wycombe, England; <sup>8</sup>Hospital Clínic de Barcelona, IDIBAPS, CIBERehd, Barcelona, Spain; <sup>9</sup>Cedars-Sinai, Los Angeles, CA, USA

October 20, 2026, Barcelona, Spain



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



# Raja Atreya

## 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:

Speaker or consultant for or received research grants from AbbVie, Abivax, Amgen, Arena Pharmaceuticals, AstraZeneca, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Cabaletta Bio, Celgene, Celltrion Healthcare, Dr Falk Pharma, Eli Lilly, Galapagos, Gilead, InDex Pharmaceuticals, Johnson & Johnson, Merck Sharp & Dohme, Novartis, Pandion Therapeutics, Pfizer, Roche, Samsung Bioepis, Takeda, and Viartis.

# Background



There is a high unmet need for the treatment of patients with ulcerative colitis (UC) refractory to multiple prior systemic therapies (biologics and oral targeted therapies), a growing population identified as “difficult-to-treat” by the IOIBD



We previously reported results from the DUET-UC study of JNJ-78934804 (JNJ-4804), the first fixed-dose, co-antibody therapy for IBD, developed using a biologically and clinically validated approach targeting the complementary IL-23 and TNF pathways



In DUET-UC, JNJ-4804 conferred the greatest clinical benefit versus guselkumab and golimumab monotherapies in participants with moderately to severely active UC refractory to 2 or more systemic therapy mechanisms,<sup>a</sup> a subgroup comprising nearly half the study population

## Objective



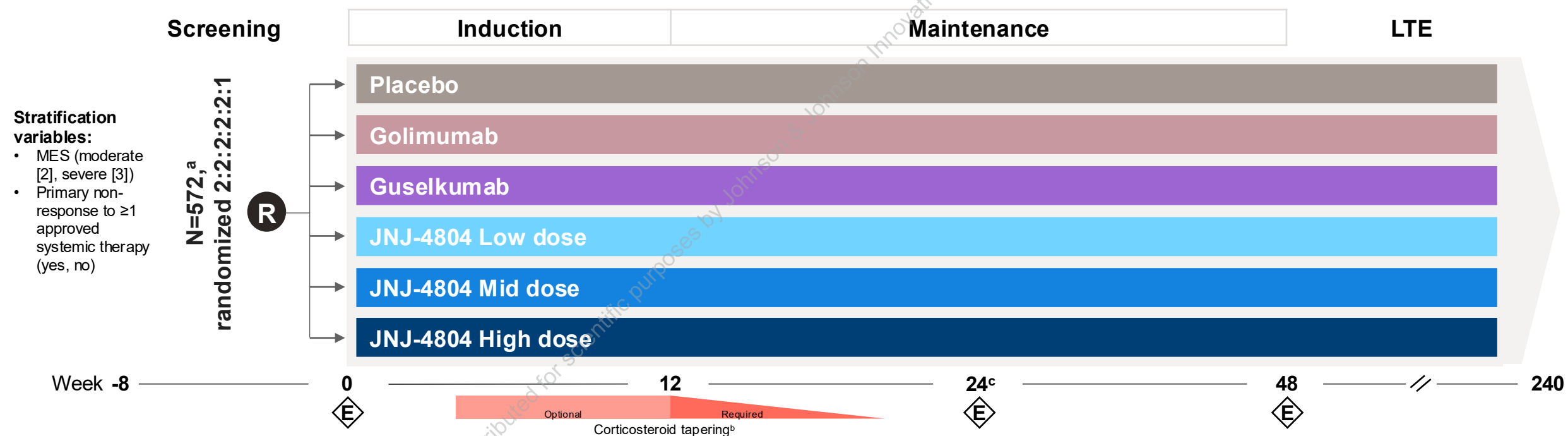
Here, we present additional efficacy and safety data from this treatment-refractory subpopulation

<sup>a</sup>Anti-TNFs, anti-IL-12/23s, anti-IL-23p19s, anti-integrins, JAK inhibitors, S1PR modulators.

IBD=inflammatory bowel disease, IL=interleukin, IOIBD=International Organization for the Study of Inflammatory Bowel Disease, JAK=Janus kinase, S1PR=sphingosine 1-phosphate receptor, TNF=tumor necrosis factor.

# DUET-UC: Phase 2b, Randomized, Double-Blind, Active- and Placebo-Controlled Treat-Through Study in a Treatment-Refractory Population

- Moderately to severely active UC
- Inadequate response or intolerance to  $\geq 1$  systemic therapy mechanism (anti-TNF, IL-12/23, IL-23p19, integrin, JAK inhibitor, or S1PR modulator)
- Caps for prior approved systemic therapy mechanisms: 1 (50%), 2 (35%),  $>2$  (15%)
- All study medications were administered subcutaneously every 4 weeks



<sup>a</sup>Full analysis set; 559 were included in the modified full analysis set (13 participants did not meet mMayo inclusion criteria at baseline and were excluded).

<sup>b</sup>Participants taking corticosteroids at Week 0 could begin tapering as early as Week 4 but no later than Week 12.

<sup>c</sup>Participants who met inadequate response criteria at Week 24 received a JNJ-4804 regimen (regardless of treatment assignment).

**E**=endoscopy, **IL**=interleukin, **JAK**=Janus kinase, **LTE**=long-term extension, **MES**=Mayo Endoscopic Score, **mMayo**=modified Mayo, **R**=randomization, **S1PR**=sphingosine-1-phosphate receptor, **TNF**=tumor necrosis factor, **UC**=ulcerative colitis.

# Endpoints and Statistical Considerations

Based on the totality of efficacy findings in the overall population and prespecified subgroups, the JNJ-4804 high dose regimen was selected for focused exploratory comparisons with the monotherapies and placebo in participants with inadequate response or intolerance to 2 or more approved systemic therapy mechanisms

## Endpoints (Week 48)

- Clinical remission (primary endpoint in the overall population)
- Endoscopic improvement
- Histologic remission AND endoscopic improvement
- Corticosteroid-free clinical remission
- Fecal calprotectin (change from baseline)

## Statistical considerations

- Participants who met prespecified treatment failure rules or had missing data were considered not to have met endpoints<sup>a</sup>
- Participants who met rescue criteria were considered treatment failures at Week 48<sup>a</sup>
- Post hoc analyses were conducted in the combined subpopulation with inadequate response or intolerance to 2 or more systemic therapy mechanisms, informed by prespecified analyses of 2 and >2 prior mechanism failures<sup>b</sup>
- All subgroup analyses were exploratory and were not controlled for multiplicity

<sup>a</sup>Participants were considered not to have met the Week 48 endpoint if any of the following occurred prior to Week 48: An ostomy or colectomy (partial or total); prohibited change in UC medication; treatment escalation due to inadequate response at Week 24; discontinuation of study treatment due to lack of efficacy or an AE of worsening UC; discontinuation of study treatment due to COVID-19 infection or any other reason. Participants who discontinued study treatment for COVID-19-related reasons (excluding COVID-19 infection) had their observed data used, if available. Missing data imputation: After accounting for these conditions, participants with missing Mayo subscores (any or all) at Week 48 (for clinical remission and corticosteroid-free clinical remission), missing endoscopy subscores at Week 48 (for endoscopic improvement and HREI), or missing histology data at Week 48 (for HREI) were considered not to have met the endpoint at Week 48.

<sup>b</sup>Analyses of subpopulations with 1, 2, and >2 prior systemic therapy mechanisms-IR were prespecified; the combined ≥2 systemic therapy mechanisms-IR subpopulation was evaluated post hoc based on these results.

**AE**=adverse event, **HREI**=histologic remission and endoscopic improvement, **IR**=inadequate response or intolerance, **UC**=ulcerative colitis.

# Baseline Demographics and Disease Characteristics in the $\geq 2$ Systemic Therapy Mechanisms-IR Subpopulation Reflect a Refractory Population

|                                                                                     |                                                              |                        | Placebo      | Golimumab    | Guselkumab   | JNJ-4804<br>Low dose | JNJ-4804<br>Mid dose | JNJ-4804<br>High dose | Total        |
|-------------------------------------------------------------------------------------|--------------------------------------------------------------|------------------------|--------------|--------------|--------------|----------------------|----------------------|-----------------------|--------------|
| Modified full analysis set <sup>a</sup>                                             |                                                              |                        | 51           | 103          | 98           | 101                  | 103                  | 103                   | 559          |
| <u>Participants with IR to ≥2 ST mechanisms</u>                                     |                                                              |                        | 21           | 47           | 50           | 38                   | 45                   | 45                    | 246          |
| Demographics and disease characteristics                                            |                                                              |                        |              |              |              |                      |                      |                       |              |
|    | Age in years, mean (SD)                                      |                        | 36.3 (11.41) | 39.6 (13.20) | 39.7 (12.93) | 35.4 (12.36)         | 36.6 (13.37)         | 36.8 (12.22)          | 37.7 (12.71) |
|                                                                                     | Sex, n (%)                                                   | Male                   | 14 (66.7%)   | 29 (61.7%)   | 28 (56.0%)   | 22 (57.9%)           | 32 (71.1%)           | 35 (77.8%)            | 160 (65.0%)  |
|    | UC duration, years                                           | Mean (SD)              | 8.10 (5.185) | 7.92 (7.419) | 9.69 (6.556) | 8.77 (6.765)         | 8.46 (5.714)         | 8.15 (6.376)          | 8.56 (6.450) |
|                                                                                     | Extent of disease                                            | Extensive              | 11 (52.4%)   | 22 (46.8%)   | 32 (64.0%)   | 21 (55.3%)           | 28 (62.2%)           | 18 (40.0%)            | 132 (53.7%)  |
|                                                                                     | mMayo Score                                                  | Mean (SD)              | 7.0 (1.20)   | 7.3 (0.93)   | 7.0 (1.01)   | 7.0 (1.01)           | 7.1 (1.19)           | 7.2 (1.11)            | 7.1 (1.07)   |
|                                                                                     | Severity of UC disease, n (%)                                | Severe (mMayo 7–9)     | 13 (61.9%)   | 37 (78.7%)   | 32 (64.0%)   | 28 (73.7%)           | 31 (68.9%)           | 34 (75.6%)            | 175 (71.1%)  |
|  | Mayo Endoscopy Subscore, n (%)                               | Subscore of 3 (severe) | 17 (81.0%)   | 38 (80.9%)   | 37 (74.0%)   | 25 (65.8%)           | 31 (68.9%)           | 33 (73.3%)            | 181 (73.6%)  |
|                                                                                     | Concomitant medications                                      |                        |              |              |              |                      |                      |                       |              |
|   | Immunomodulators, n (%)                                      |                        | 2 (9.5%)     | 5 (10.6%)    | 4 (8.0%)     | 3 (7.9%)             | 4 (8.9%)             | 5 (11.1%)             | 23 (9.3%)    |
|                                                                                     | Oral corticosteroids, n (%)                                  |                        | 8 (38.1%)    | 20 (42.6%)   | 24 (48.0%)   | 18 (47.4%)           | 25 (55.6%)           | 28 (62.2%)            | 123 (50.0%)  |
| Inflammatory pharmacodynamic markers                                                |                                                              |                        |              |              |              |                      |                      |                       |              |
|  | Elevated fecal calprotectin (>250 mg/kg), n (%) <sup>b</sup> |                        | 18 (85.7%)   | 42 (97.7%)   | 38 (86.4%)   | 33 (100.0%)          | 35 (92.1%)           | 38 (92.7%)            | 204 (92.7%)  |
|                                                                                     | Elevated CRP (>5mg/L), n (%) <sup>c</sup>                    |                        | 10 (47.6%)   | 25 (56.8%)   | 27 (54.0%)   | 19 (50.0%)           | 20 (44.4%)           | 20 (44.4%)            | 121 (49.8%)  |

<sup>a</sup>Modified full analysis set: full analysis set excluding participants with a modified Mayo <5 or missing at baseline.

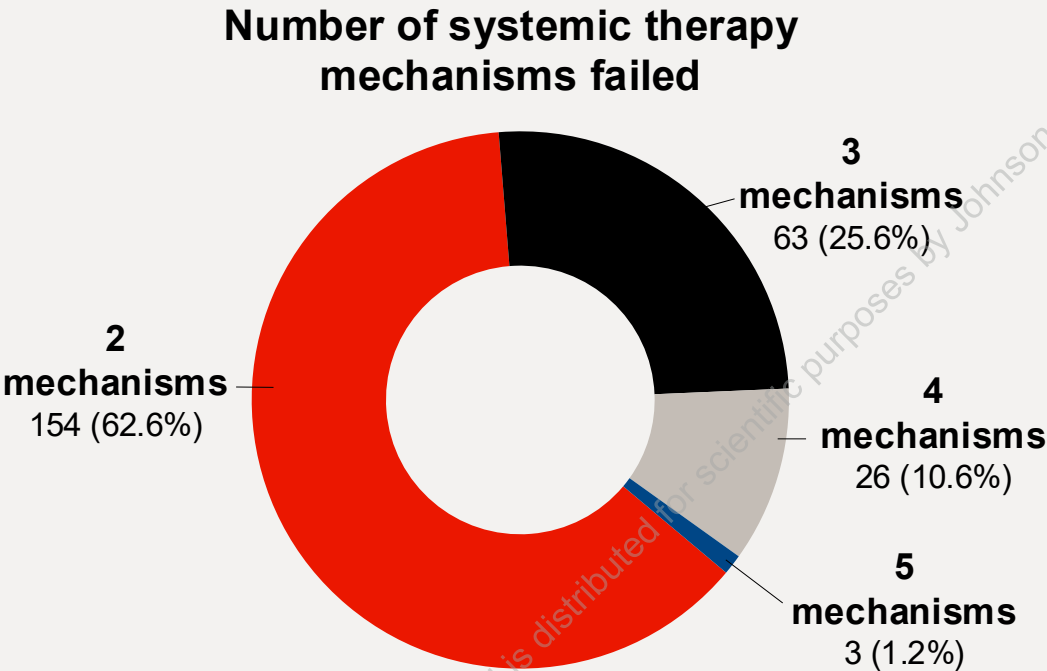
<sup>b</sup>Numbers and percentages are based on the following numbers of participants with non-missing data: 21 (PBO), 43 (GOL), 44 (GUS), 33 (JNJ-4804 low dose), 38 (JNJ-4804 mid dose), 41 (JNJ-4804 high dose).

<sup>c</sup>Numbers and percentages are based on the following numbers of participants with non-missing data: 21 (PBO), 44 (GOL), 50 (GUS), 38 (JNJ-4804 low dose), 45 (JNJ-4804 mid dose), 45 (JNJ-4804 high dose).

**CRP**=C-reactive protein, **IR**=inadequate response or intolerance, **mMayo**=modified Mayo, **n**=number, **UC**=ulcerative colitis, **SD**=standard deviation, **ST**=systemic therapy.

# Treatment-Refractory Population With Inadequate Response or Intolerance to ≥2 Systemic Therapy Mechanisms

|                                                              | Placebo    | Golimumab  | Guselkumab | JNJ-4804<br>Low dose | JNJ-4804<br>Mid dose | JNJ-4804<br>High dose | Total       |
|--------------------------------------------------------------|------------|------------|------------|----------------------|----------------------|-----------------------|-------------|
| Modified full analysis set <sup>a</sup>                      | 51         | 103        | 98         | 101                  | 103                  | 103                   | 559         |
| Participants with IR to ≥2 ST mechanisms, n (%) <sup>b</sup> | 21 (41.2%) | 47 (45.6%) | 50 (51.0%) | 38 (37.6%)           | 45 (43.7%)           | 45 (43.7%)            | 246 (44.0%) |



| Previously failed ST mechanism | Participants, n | % of ≥ST mechanisms-IR subset (N=246) |
|--------------------------------|-----------------|---------------------------------------|
| Anti-TNF                       | 222             | 90.2%                                 |
| Anti-integrin                  | 169             | 68.7%                                 |
| JAK inhibitor                  | 113             | 45.9%                                 |
| IL-12/23 antagonist            | 93              | 37.8%                                 |
| S1PR modulator                 | 15              | 6.1%                                  |
| IL-23 antagonist               | 4               | 1.6%                                  |

### Most common combinations:

- Anti-TNF + Anti-integrin (28.5%)
- Anti-TNF + JAK inhibitor (14.2%)
- Anti-TNF + Anti-integrin + JAK inhibitor (13.0%)

<sup>a</sup>Modified full analysis set: full analysis set excluding participants with a modified Mayo <5 or missing at baseline.  
<sup>b</sup>Anti-TNF, anti-IL-12/23, anti-IL-23p19, anti-integrin, JAK inhibitor, and S1PR modulator  
**JAK**=Janus kinase, **IR**=inadequate response or intolerance, **S1PR**=sphingosine-1-phosphate receptor, **ST**=systemic therapy, **TNF**=tumor necrosis factor.

# Treatment Disposition in the $\geq 2$ Systemic Therapy Mechanisms-IR Subpopulation

|                                                                  | Placebo   | Golimumab  | Guselkumab | JNJ-4804<br>Low dose | JNJ-4804<br>Mid dose | JNJ-4804<br>High dose |
|------------------------------------------------------------------|-----------|------------|------------|----------------------|----------------------|-----------------------|
| <b>Modified full analysis set<sup>a</sup></b>                    | 51        | 103        | 98         | 101                  | 103                  | 103                   |
| <b>Participants with IR to <math>\geq 2</math> ST mechanisms</b> | 21        | 47         | 50         | 38                   | 45                   | 45                    |
| <b>Discontinued study treatment before Week 48</b>               | 8 (38.1%) | 14 (29.8%) | 18 (36.0%) | 10 (26.3%)           | 11 (24.4%)           | 9 (20.0%)             |
| <b>Reason for discontinuing study treatment</b>                  |           |            |            |                      |                      |                       |
| Lack of efficacy                                                 | 2 (9.5%)  | 3 (6.4%)   | 10 (20.0%) | 4 (10.5%)            | 2 (4.4%)             | 4 (8.9%)              |
| Adverse event - worsening of UC                                  | 3 (14.3%) | 5 (10.6%)  | 3 (6.0%)   | 2 (5.3%)             | 3 (6.7%)             | 4 (8.9%)              |
| Withdrawal by participant                                        | 3 (14.3%) | 4 (8.5%)   | 3 (6.0%)   | 1 (2.6%)             | 5 (11.1%)            | 1 (2.2%)              |
| Adverse event - other                                            | 0         | 1 (2.1%)   | 0          | 2 (5.3%)             | 1 (2.2%)             | 0                     |
| Initiated prohibited medication                                  | 0         | 0          | 2 (4.0%)   | 0                    | 0                    | 0                     |
| Protocol deviation                                               | 0         | 0          | 0          | 1 (2.6%)             | 0                    | 0                     |
| Other                                                            | 0         | 1 (2.1%)   | 0          | 0                    | 0                    | 0                     |

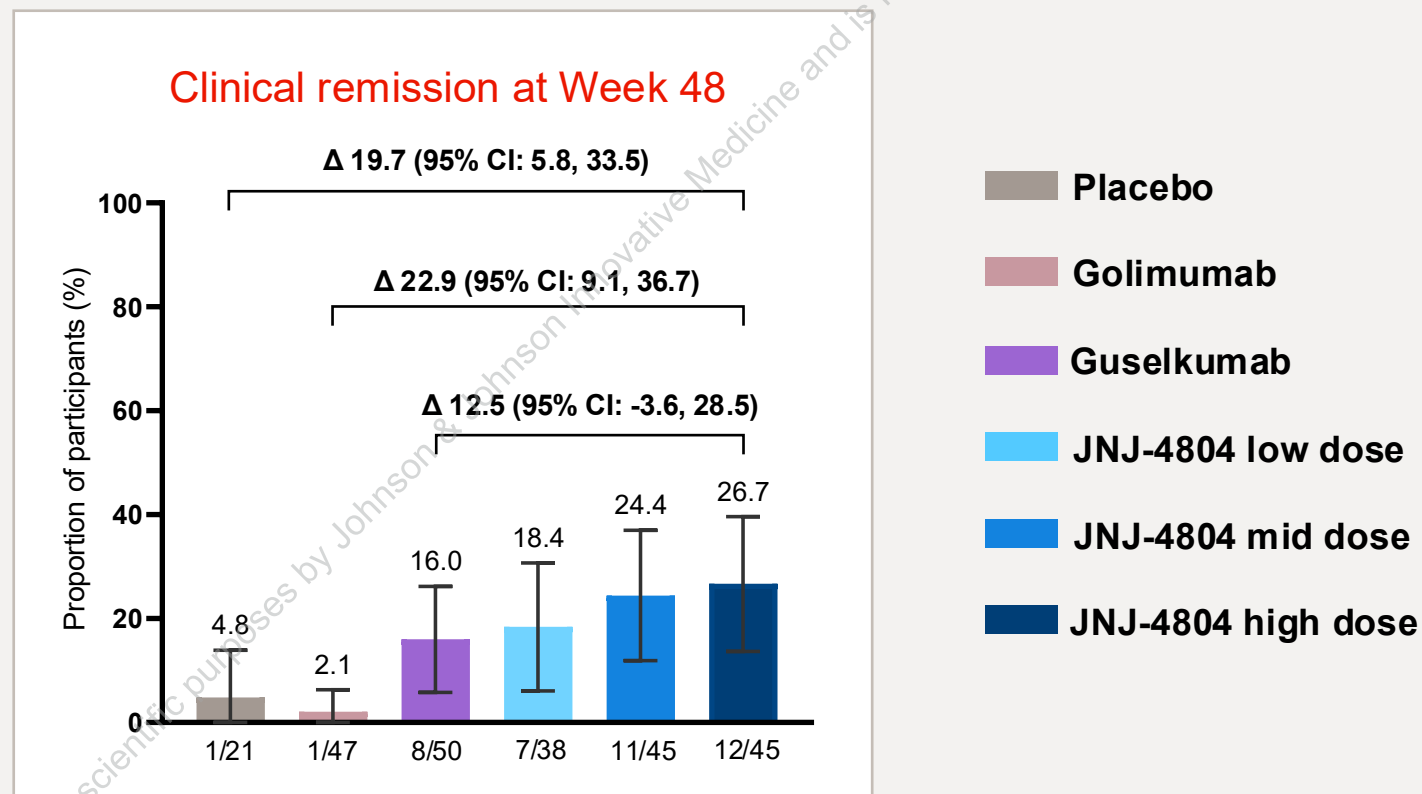
Participants are presented in the treatment group assigned at Week 0.

<sup>a</sup>Modified full analysis set: full analysis set excluding participants with a modified Mayo <5 or missing at baseline.

**IR**=inadequate response or intolerance, **ST**=systemic therapy, **UC**=ulcerative colitis.

# Clinical Remission at Week 48

≥2 Systemic Therapy Mechanisms-IR Subpopulation: Modified Full Analysis Set<sup>a</sup>



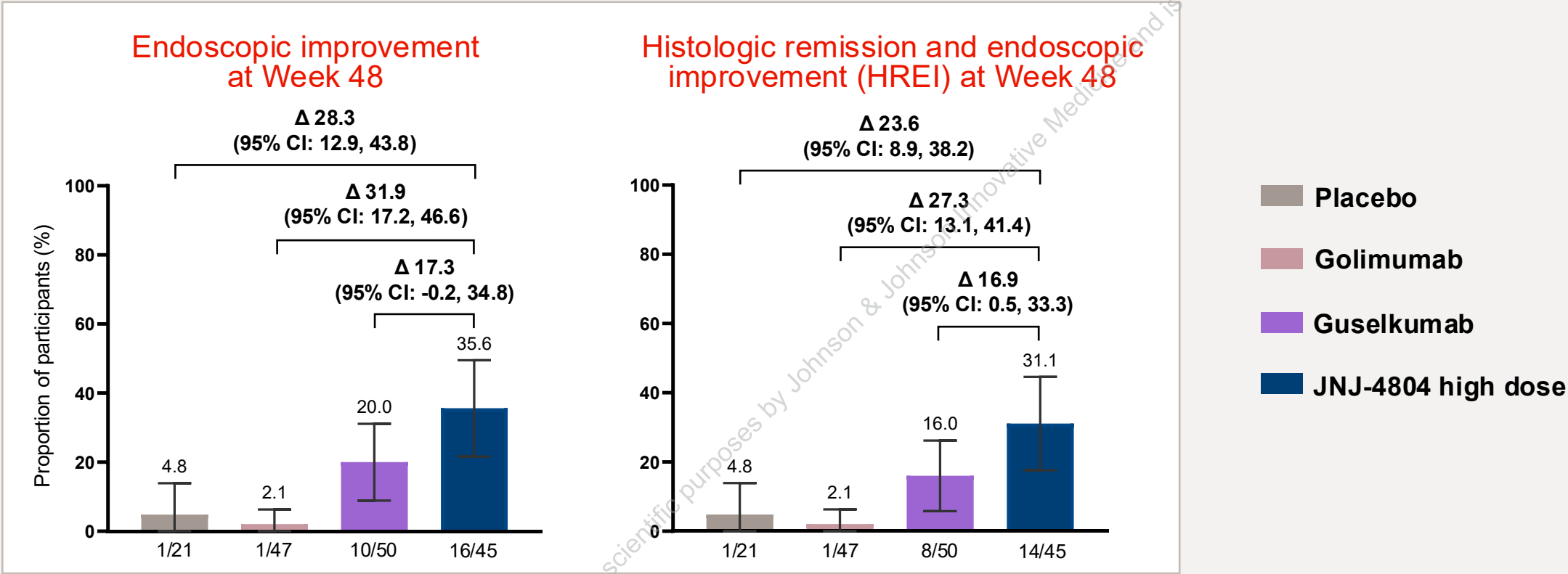
**Clinical remission:** a stool frequency subscore of 0 or 1, a rectal bleeding subscore of 0, and an endoscopy subscore of 0 or 1 per central review of the video endoscopy

<sup>a</sup>Modified full analysis set: full analysis set excluding participants with a modified Mayo <5 or missing at baseline.

CI=confidence interval, IR=inadequate response or intolerance.

# Endoscopic and Histologic Endpoints at Week 48

≥2 Systemic Therapy Mechanisms-IR Subpopulation: Modified Full Analysis Set<sup>a</sup>

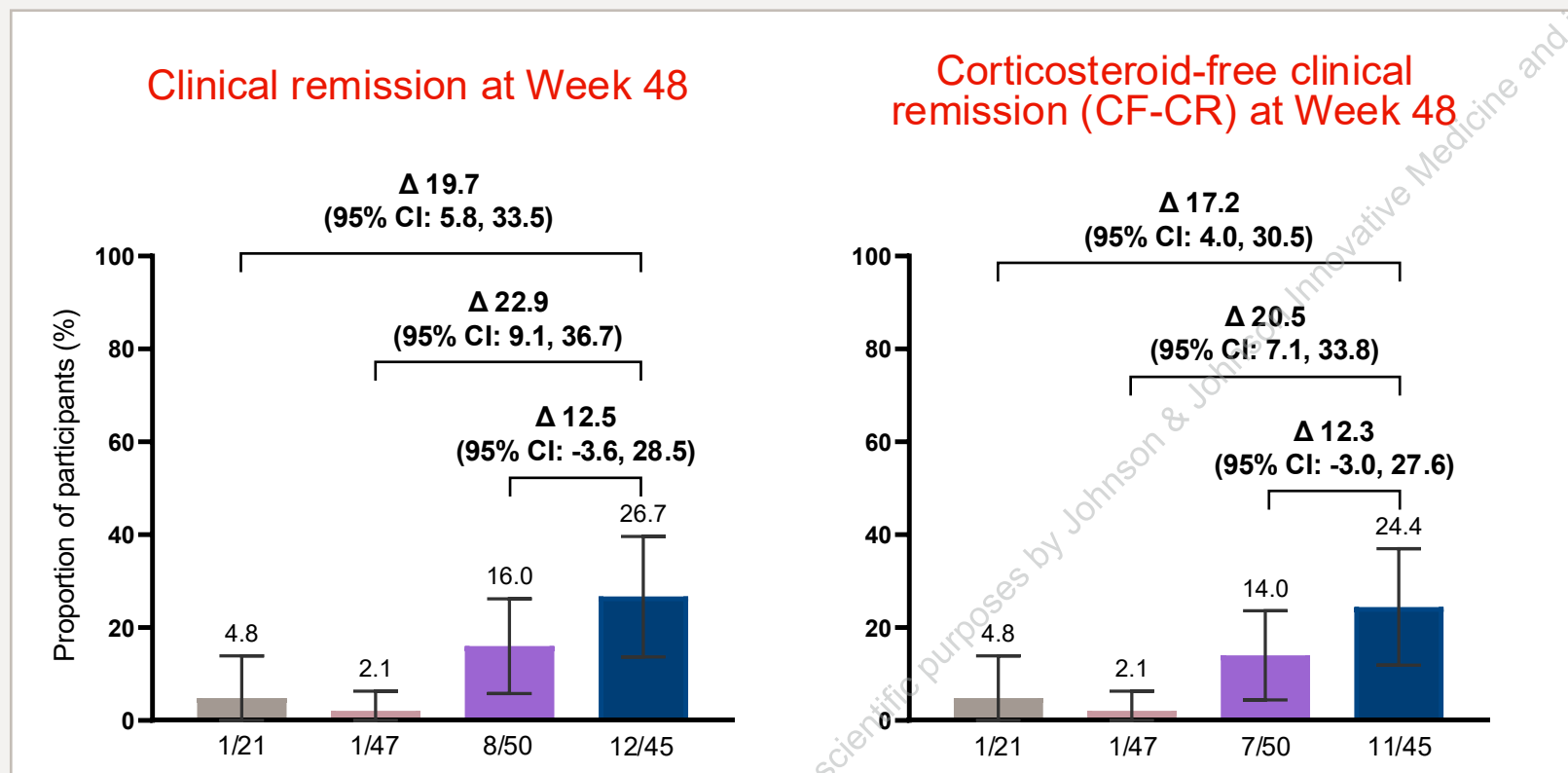


**Endoscopic improvement:** an endoscopy subscore of 0 or 1 per central review of the video endoscopy  
**HREI:** both histologic remission (absence of neutrophils from the mucosa [both lamina propria and epithelium], no crypt destruction, and no erosions, ulcerations, or granulation tissue [Geboes score ≤2B.0]) and endoscopic improvement

<sup>a</sup>Modified full analysis set: full analysis set excluding participants with a modified Mayo <5 or missing at baseline.  
**CI**=confidence interval, **HREI**=histologic remission and endoscopic improvement, **IR**=inadequate response or intolerance.

# Corticosteroid-Free Clinical Remission at Week 48

≥2 Systemic Therapy Mechanisms-IR Subpopulation: Modified Full Analysis Set<sup>a</sup>



Nearly all participants in clinical remission at Week 48 were corticosteroid-free

- Placebo
- Golimumab
- Guselkumab
- JNJ-4804 high dose

**CF-CR (60-day):** clinical remission with no concomitant corticosteroids for ≥60 days prior to Week 48

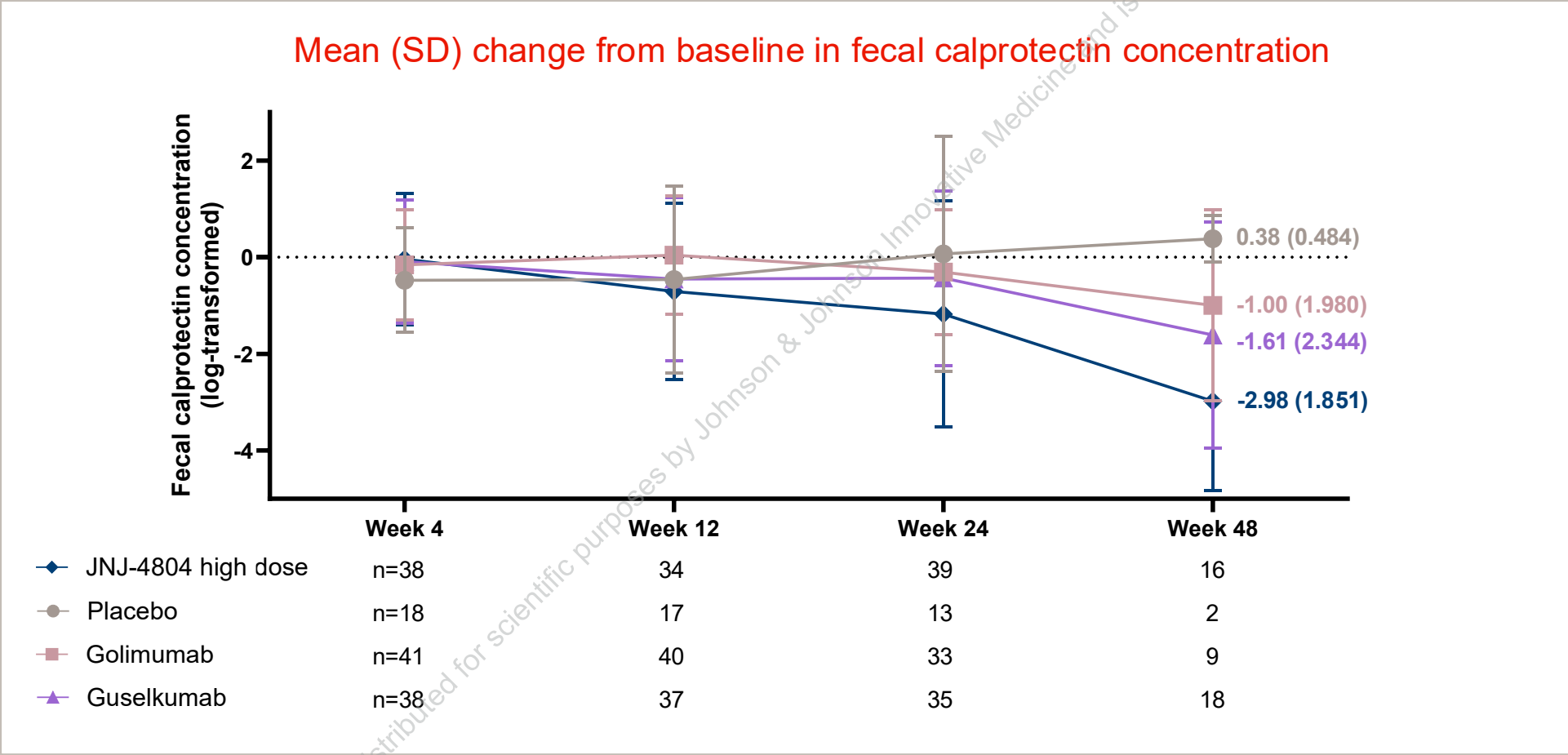
**Clinical remission:** a stool frequency subscore of 0 or 1, a rectal bleeding subscore of 0, and an endoscopy subscore of 0 or 1 per central review of the video endoscopy

<sup>a</sup>Modified full analysis set: full analysis set excluding participants with a modified Mayo <5 or missing at baseline.

CF-CR=corticosteroid-free clinical remission, CI=confidence interval, IR=inadequate response or intolerance.

# Fecal Calprotectin: Mean Change From Baseline to Week 48

≥2 Systemic Therapy Mechanisms-IR Subpopulation: Modified Full Analysis Set<sup>a</sup>



Data are as-observed, log-transformed (natural log), and exclude inadequate responders after Week 24 treatment escalation.

<sup>a</sup>Modified full analysis set: full analysis set excluding participants with a modified Mayo <5 or missing at baseline.

IR=inadequate response or intolerance.

# Summary of Exposure-Adjusted Adverse Events Through Week 48

## ≥2 Systemic Therapy Mechanisms-IR Subpopulation

|                                                                         | Placebo                        | Golimumab                       | Guselkumab                      | JNJ-4804<br>Low dose            | JNJ-4804<br>Mid dose            | JNJ-4804<br>High dose           |
|-------------------------------------------------------------------------|--------------------------------|---------------------------------|---------------------------------|---------------------------------|---------------------------------|---------------------------------|
| <b>Safety analysis set</b>                                              | 52                             | 104                             | 103                             | 103                             | 105                             | 105                             |
| <b>Participants with IR to ≥2 ST mechanisms</b>                         | 21 (40.4%)                     | 48 (46.2%)                      | 52 (50.5%)                      | 40 (38.8%)                      | 47 (44.8%)                      | 46 (43.8%)                      |
| <b>Total patient-years of follow-up</b>                                 | 9.3                            | 27.0                            | 33.0                            | 25.1                            | 33.8                            | 33.8                            |
| <b>Event rate per hundred patient-years [number of events] (95% CI)</b> |                                |                                 |                                 |                                 |                                 |                                 |
| <b>AEs</b>                                                              | 568.4 [53]<br>(425.74, 743.43) | 618.0 [167]<br>(527.82, 719.17) | 587.6 [194]<br>(507.82, 676.36) | 454.3 [114]<br>(374.72, 545.72) | 497.3 [168]<br>(424.98, 578.49) | 679.5 [230]<br>(594.52, 773.23) |
| <b>SAEs</b>                                                             | 32.2 [3]<br>(6.63, 94.02)      | 29.6 [8]<br>(12.78, 58.33)      | 18.2 [6]<br>(6.67, 39.56)       | 19.9 [5]<br>(6.47, 46.50)       | 11.8 [4]<br>(3.23, 30.32)       | 23.6 [8]<br>(10.20, 46.57)      |
| <b>AEs leading to discontinuation of study treatment</b>                | 32.2 [3]<br>(6.63, 94.02)      | 22.2 [6]<br>(8.15, 48.33)       | 9.1 [3]<br>(1.87, 26.55)        | 19.9 [5]<br>(6.47, 46.50)       | 11.8 [4]<br>(3.23, 30.32)       | 8.9 [3]<br>(1.83, 25.90)        |
| <b>Infections</b>                                                       | 64.3 [6]<br>(23.61, 140.05)    | 129.5 [35]<br>(90.22, 180.13)   | 121.2 [40]<br>(86.55, 164.98)   | 107.6 [27]<br>(70.90, 156.54)   | 136.2 [46]<br>(99.70, 181.64)   | 100.4 [34]<br>(69.56, 140.37)   |
| <b>Serious infections</b>                                               | 0.0 [0]<br>(0.00, 32.13)       | 7.4 [2]<br>(0.90, 26.74)        | 0.0 [0]<br>(0.00, 9.07)         | 4.0 [1]<br>(0.10, 22.20)        | 5.9 [2]<br>(0.72, 21.39)        | 8.9 [3]<br>(1.83, 25.90)        |
| <b>Deaths</b>                                                           | 0.0 [0]<br>(0.00, 32.13)       | 0.0 [0]<br>(0.00, 11.09)        | 0.0 [0]<br>(0.00, 9.07)         | 0.0 [0]<br>(0.00, 11.94)        | 0.0 [0]<br>(0.00, 8.87)         | 0.0 [0]<br>(0.00, 8.85)         |

Safety events per 100 patient-years with JNJ-4804 in the subpopulation were overall similar to or lower than those in the monotherapy groups

# Treatment-Emergent Adverse Events of Interest Through Week 48

## ≥2 Systemic Therapy Mechanisms-IR Subpopulation

|                                                    | Placebo    | Golimumab  | Guselkumab | JNJ-4804<br>Low dose | JNJ-4804<br>Mid dose | JNJ-4804<br>High dose |
|----------------------------------------------------|------------|------------|------------|----------------------|----------------------|-----------------------|
| <b>Safety analysis set</b>                         | 52         | 104        | 103        | 103                  | 105                  | 105                   |
| <b>Participants with IR to ≥2 ST mechanisms</b>    | 21 (40.4%) | 48 (46.2%) | 52 (50.5%) | 40 (38.8%)           | 47 (44.8%)           | 46 (43.8%)            |
| <b>Participants with ≥1 AE of interest</b>         | 0          | 2 (4.2%)   | 1 (1.9%)   | 2 (5.0%)             | 2 (4.3%)             | 3 (6.5%)              |
| <b>Participants with ≥1 AE of special interest</b> | 0          | 2 (4.2%)   | 0          | 2 (5.0%)             | 2 (4.3%)             | 2 (4.3%)              |
| <b>Serious infection</b>                           | 0          | 2 (4.2%)   | 0          | 1 (2.5%)             | 2 (4.3%)             | 2 (4.3%)              |
| <b>Invasive fungal infection</b>                   | 0          | 0          | 0          | 0                    | 0                    | 0                     |
| <b>Hepatitis B reactivation</b>                    | 0          | 0          | 0          | 0                    | 0                    | 0                     |
| <b>Tuberculosis</b>                                | 0          | 0          | 0          | 0                    | 0                    | 0                     |
| <b>Malignancy</b>                                  | 0          | 0          | 0          | 0                    | 0                    | 0                     |
| <b>Hypersensitivity reaction</b>                   | 0          | 0          | 0          | 1 (2.5%)             | 0                    | 0                     |
| <b>Congestive heart failure</b>                    | 0          | 0          | 0          | 0                    | 0                    | 0                     |
| <b>Demyelinating disorders</b>                     | 0          | 0          | 0          | 0                    | 0                    | 0                     |
| <b>Lupus-like syndrome</b>                         | 0          | 0          | 0          | 0                    | 0                    | 0                     |
| <b>Major adverse cardiovascular events</b>         | 0          | 0          | 0          | 0                    | 0                    | 0                     |
| <b>Venous thromboembolism</b>                      | 0          | 1 (2.1%)   | 0          | 0                    | 0                    | 1 (2.2%)              |
| <b>Drug-related hepatic disorders</b>              | 0          | 0          | 0          | 0                    | 0                    | 0                     |
| <b>Opportunistic infection</b>                     | 0          | 0          | 1 (1.9%)   | 0                    | 0                    | 0                     |

Excludes inadequate responder events after treatment escalation at Week 24.  
**AE**=adverse event, **IR**=inadequate response or intolerance, **ST**=systemic therapy.

# Conclusions



JNJ-4804, the first co-antibody therapy in development for IBD, delivered substantial and clinically meaningful efficacy across all endpoints in participants with ulcerative colitis refractory to 2 or more approved systemic therapy mechanisms, a growing population of high unmet need identified as “difficult to treat” by the IOIBD



The magnitude of benefit observed with JNJ-4804 high dose was greater than that observed with either component monotherapy across multiple symptoms-based and objective endpoints



No new safety signals were identified in this exploratory subgroup through Week 48, though interpretation is limited by small treatment groups and low numbers of individual events



These exploratory findings should be interpreted in the context of the post hoc combined subgroup, limited sample sizes, and lack of multiplicity control



These results support advancement to Phase 3 in the rapidly increasing population of patients with disease refractory to systemic therapies

# ACKNOWLEDGMENTS

---

- The authors thank the participants, investigators, and study personnel who made the DUET-UC clinical study possible
- Under the direction of the authors and in accordance with Good Publication Practices, Jen Ciarochi, PhD, provided writing and editorial assistance
- This work was supported by Johnson & Johnson



# Thank you

This material is distributed for scientific purposes by Johnson & Johnson Innovative Medicine and is not for promotional use.