EFFICACY AND SAFETY OF THE FIRST CO-ANTIBODY THERAPY, JNJ-78934804, IN PATIENTS WITH MODERATELY TO SEVERELY ACTIVE CROHN'S DISEASE REFRACTORY TO SYSTEMIC THERAPIES

Bruce E. Sands,[1] Geert D'Haens,[2] Iris Dotan,[3] Nat A. Terry,[4] Monica Walker,[4] Vanessa Bundy,[4] Hayley Perry,[5] Marion L. Vetter,[4] Taku Kobayashi,[6] Stefan Schreiber,[7] Vipul Jairath[8]

[1]Dr. Henry D Janowitz Division of Gastroenterology, Icahn School of Medicine at Mount Sinai, New York, NY, USA; [2]Department of Gastroenterology, Amsterdam University Medical Centers, Amsterdam, The Netherlands; [3]Division of Gastroenterology, Rabin Medical Center, Petah Tikva and the Gray Faculty of Medical and Health Sciences, Tel Aviv University, Israel; [4]Johnson & Johnson, Spring House, PA, USA; [5]Johnson & Johnson Innovative Medicine UK, High Wycombe, England; [6]Center for Advanced IBD Research and Treatment, Kitasato University Kitasato Institute Hospital, Tokyo, Japan; [7]Department of Internal Medicine I – Gastroenterology, Hepatology, Nutrition and Geriatric Medicine, University Hospital Schleswig-Holstein, Campus Kiel, Germany; [8]Department of Medicine, Schulich School of Medicine & Dentistry I, Western University, London, ON, Canada

DDW2026
Digestive Disease Week®
MAY 2–5, 2026 | CHICAGO, IL
EXHIBIT DATES: MAY 3–5, 2026
@DDWMeeting | #DDW2026

Disclosure Information

Bruce E. Sands

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

Grants from Johnson & Johnson

Personal fees from AbbVie, Abivax, Aclaris Therapeutics, Adiso Therapeutics, Agomab Therapeutics, Alfasigma, Alimentiv, Amgen, AnaptysBio, AstraZeneca, Attovia Therapeutics, Biolojic Design, BiomeBank, Boehringer-Ingelheim, Bristol Myers Squibb, Caldera Therapeutics, Cellarity, Celltrion, Cytoki Pharma, Disc Medicine, Eli Lilly & Company, Ensho Therapeutics, Enthera, Enveda Biosciences, Equillium Bio, Evommune, Ferring, Fzata, Galapagos, Genentech (Roche), Genesis Therapeutics, Gilead Sciences, GlaxoSmithKline, Ignite Biomedical, Imhotex, Immunitas Therapeutics, Immunyx Pharma, Johnson & Johnson, Kallyope, Kyowa Kirin, Inc., LifeMine Therapeutics, Merck & Co., Merck Sharp & Dohme, Metagen Therapeutics, Microba, Microbiotica, Mirador Therapeutics, Mitsubishi Tanabe Pharma, Mobius Care, MRM Health, Nexus Therapeutics, Nimbus Discovery, Novartis, Numab Therapeutics, Odyssey Therapeutics, ONO Pharmaceutical Co., Ltd., OSE Immunotherapeutics, Palisade Bio, Pfizer, Pioneering Medicines Explorations, Protagonist Therapeutics, Q32 Bio, Quotient Therapeutics, Rasayana Therapeutics, Recludix Pharma, Reistone Biopharma, Sanofi, Slate Bio, Sorriso Pharmaceuticals, Spyre Therapeutics, Synlogic Operating Company, Takeda, Target RWE, Teva, Thetis Pharmaceuticals, Tr1X, TRex Bio, Union Therapeutics, VectivBio, Vedanta Biosciences, Ventyx Biosciences, Vividion Therapeutics, and Xencor

Non-financial support from Bristol Myers Squibb, Johnson & Johnson, Eli Lilly & Company, Merck, Pfizer, and Takeda

Stock/stock options from Ventyx Biosciences

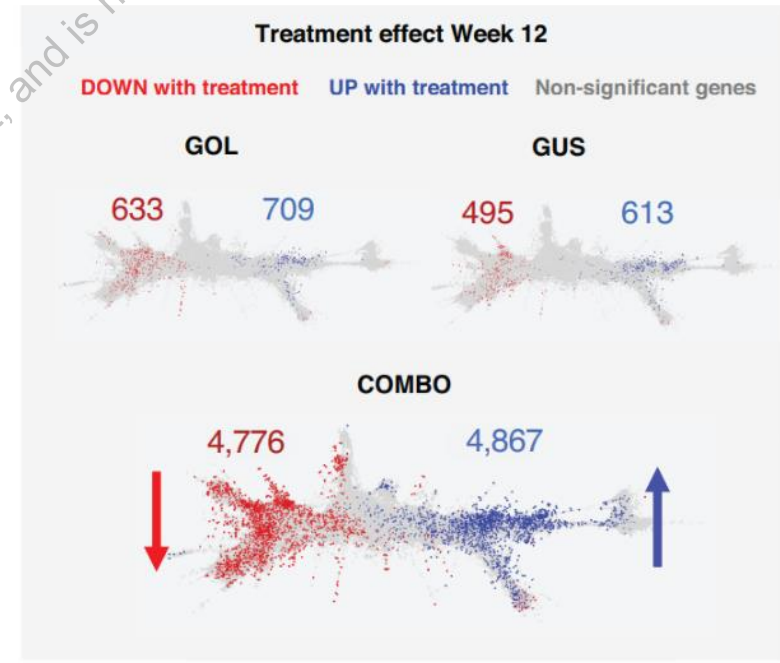
Background and Objective

In the Phase 2a VEGA study in ulcerative colitis,[1,2] guselkumab and golimumab combination therapy showed higher efficacy over either monotherapy

This combination was informed by preclinical evidence of complementary and distinct IL-23 and TNF-α activity, with molecular synergy demonstrated in VEGA

JNJ-4804 (JNJ-78934804; guselkumab and golimumab fixed-dose combination), the first co-antibody therapy in IBD, aims to address the high unmet need in patients with disease refractory to current systemic therapies

Molecular synergy observed in VEGA



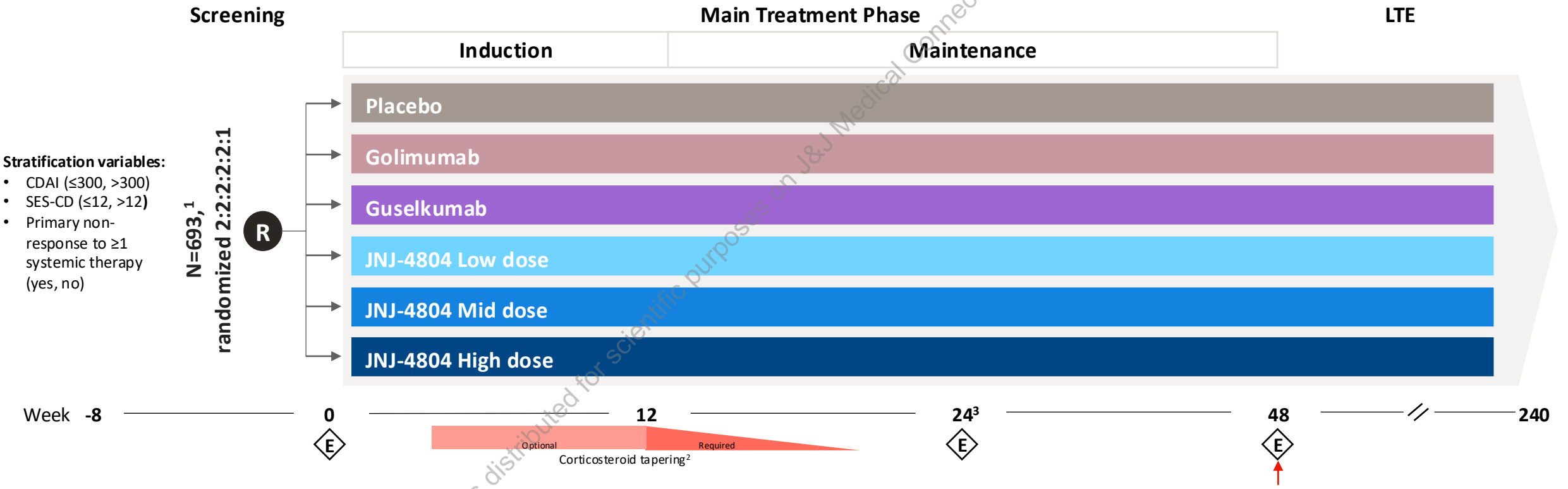
Combination associated with reduced inflammation and restoration of epithelial repair[3]

Objective: The Phase 2b DUET-CD trial (NCT05242471) evaluated the efficacy and safety of **JNJ-4804** compared with the component monotherapies in patients with moderately to severely active Crohn's disease refractory to systemic therapies

[1]Feagan BG, et al. *Lancet Gastroenterol Hepatol.* 2023;8(4):307–320. [2]VEGA was an anti-TNF-naïve study population. [3]Desai P, et al. *Am J Gastroenterol*. 2022;117(10S):e527.
"Systemic therapies" are also referred to as "advanced therapies" (biologics and small molecules).
***CD**=Crohn's disease, **COMBO**=combination golimumab + guselkumab, **GOL**=golimumab, **GUS**=guselkumab, **IBD**=inflammatory bowel disease, **IL**=interleukin, **TNF**=tumor necrosis factor.*

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

- Moderately to severely active CD
- Inadequate response or intolerance to ≥1 systemic therapy mechanism (anti-TNF, IL-12/23, IL-23p19, integrin, or JAK inhibitors)
- Caps for prior systemic therapy mechanisms: 1 (50%), 2 (35%), >2 (15%)
- All study medications were administered subcutaneously



Co-primary endpoints: Clinical remission at Week 48 and endoscopic response at Week 48

[1]Full Analysis Set.
[2]All participants taking corticosteroids at Week 0 could begin tapering as early as Week 4 but no later than Week 12.
[3]Patients who met inadequate response criteria, regardless of treatment assignment, received a JNJ-4804 regimen based on their initial study intervention group assignment.
***CD**=Crohn's disease, **CDAI**=Crohn's Disease Activity Index, **E**=endoscopy, **JAK**=Janus kinase, **LTE**=long-term extension, **R**=randomization, **SES-CD**=Simple Endoscopic Score for Crohn's Disease, **TNF**=tumor necrosis factor.*

Endpoints and Statistical Considerations

Co-primary endpoints

- Clinical remission at Week 48
- Endoscopic response at Week 48

Other key endpoints

- Corticosteroid-free clinical remission at Week 48
- Endoscopic remission at Week 48
- Deep remission at Week 48

Study powering and statistical considerations

- The study had >80% power to detect >20% difference in both co-primary endpoints for high-dose JNJ-4804 vs both monotherapies
- Participants who met prespecified treatment failure rules or had missing data were considered not to have met endpoints[1]
- Participants who met rescue criteria were considered treatment failures at Week 48[1]
- Analyses of subpopulations by systemic therapy history were prespecified[2] but not multiplicity controlled

[1]Participants were considered not to have met the Week 48 endpoint if any of the following occurred prior to Week 48: CD-related surgery (except minor procedures such as drainage of a superficial abscess or seton placement); prohibited change in CD medication; treatment escalation due to inadequate response at Week 24; discontinuation of study treatment due to lack of efficacy or an AE of worsening CD; 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. After accounting for these conditions, participants with a missing CDAI score (for clinical remission, corticosteroid-free clinical remission, and deep remission) or SES-CD (for endoscopic response, endoscopic remission, and deep remission) were considered not to have met the endpoint.

[2]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 based on these results.

***AE**=adverse event, **CD**=Crohn's disease, **CDAI**=Crohn's Disease Activity Index, **IR**=inadequate response or intolerance, **SES-CD**=Simple Endoscopic Score for Crohn's Disease.*

Baseline Demographics, Disease Characteristics, and Concomitant Medications

		Placebo	Golimumab	Guselkumab	JNJ-4804 Low dose	JNJ-4804 Mid dose	JNJ-4804 High dose	Total
Full analysis set		64	126	127	127	123	126	693
Age in years, mean (SD)		36.8 (13.47)	37.1 (12.25)	35.2 (11.33)	37.7 (12.26)	36.7 (11.50)	36.6 (12.73)	36.7 (12.15)
Sex, n (%)	**Male**	43 (67.2%)	74 (58.7%)	68 (53.5%)	72 (56.7%)	75 (61.0%)	65 (51.6%)	397 (57.3%)
Crohn's disease duration, years	**Mean (SD)**	10.7 (8.80)	10.2 (7.61)	10.3 (7.56)	12.0 (8.94)	10.1 (8.15)	11.4 (9.46)	10.8 (8.42)
	>10 years	25 (39.1%)	50 (39.7%)	51 (40.2%)	57 (44.9%)	49 (39.8%)	54 (42.9%)	286 (41.3%)
Disease location	**Ileum only**	15 (23.4%)	36 (28.6%)	30 (23.6%)	23 (18.1%)	27 (22.0%)	32 (25.4%)	163 (23.5%)
	Colon only	16 (25.0%)	43 (34.1%)	40 (31.5%)	50 (39.4%)	37 (30.1%)	37 (29.4%)	223 (32.2%)
	Ileum and colon	33 (51.6%)	47 (37.3%)	57 (44.9%)	54 (42.5%)	59 (48.0%)	57 (45.2%)	307 (44.3%)
CDAI score, mean (SD)[1]		322.2 (56.17)	322.5 (60.75)	327.8 (56.89)	320.8 (62.12)	321.4 (61.83)	325.4 (63.05)	323.5 (60.37)
SES-CD, mean (SD)		13.5 (7.98)	13.4 (7.52)	14.2 (8.41)	13.7 (7.82)	13.4 (7.34)	13.6 (8.31)	13.7 (7.88)
Concomitant medications at baseline								
Immunomodulators		9 (14.1%)	24 (19.0%)	26 (20.5%)	25 (19.7%)	26 (21.1%)	21 (16.7%)	131 (18.9%)
Oral corticosteroid drugs		20 (31.3%)	40 (31.7%)	35 (27.6%)	38 (29.9%)	38 (30.9%)	34 (27.0%)	205 (29.6%)
CRP (mg/L), median[2]		6.9	9.7	8.1	8.8	8.1	9.3	8.2
Fecal calprotectin (mg/kg), median[3]		1214.0	1554.7	1362.0	1689.5	1070.0	1260.0	1362.0

[1]Means are based on the following numbers of participants with non-missing data: 63 (PBO), 124 (GOL), 126 (GUS), 126 (JNJ-4804 low dose), 122 (JNJ-4804 mid dose), 125 (JNJ-4804 high dose), 686 (total).
[2]Medians are based on the following numbers of participants with non-missing data: 64 (PBO), 123 (GOL), 127 (GUS), 127 (JNJ-4804 low dose), 123 (JNJ-4804 mid dose), 125 (JNJ-4804 high dose), 689 (total).
[3]Medians are based on the following numbers of participants with non-missing data: 57 (PBO), 111 (GOL), 113 (GUS), 108 (JNJ-4804 low dose), 109 (JNJ-4804 mid dose), 115 (JNJ-4804 high dose), 613 (total).
***CDAI**=Crohn's Disease Activity Index, **CRP**=C-reactive protein, **GOL**=golimumab, **GUS**=guselkumab, **PBO**=placebo, **SES-CD**=Simple Endoscopic Score for Crohn's Disease.*

Highly Treatment-Refractory Population With Inadequate Response or Intolerance to Systemic Therapies

		Placebo	Golimumab	Guselkumab	JNJ-4804 Low dose	JNJ-4804 Mid dose	JNJ-4804 High dose	Total
Analysis set, n		64	126	127	127	123	126	693
Participants with inadequate response to 1 or more systemic therapy mechanisms[1], n (%)								
Number of systemic therapy mechanisms - inadequate responders, n (%)[2]	**1**	29 (45.3%)	61 (48.4%)	72 (56.7%)	53 (42.1%)	68 (55.3%)	63 (50.0%)	346 (50.0%)[3]
	≥2	35 (54.7%)	65 (51.6%)	55 (43.3%)	73 (57.9%)	55 (44.7%)	63 (50.0%)	346 (50.0%)

50% were refractory to
2 or more systemic therapy mechanisms

History of inadequate response or intolerance by systemic therapy mechanism in the overall population

- Anti-TNF: 90% (82% of the 1 systemic therapy-IR subgroup)
- Anti-IL-12/23: 47% (8% of the 1 systemic therapy-IR subgroup)
- Anti-integrin: 26% (8% of the 1 systemic therapy-IR subgroup)
- JAK inhibitor: 3%
- Anti-IL-23p19: 3%

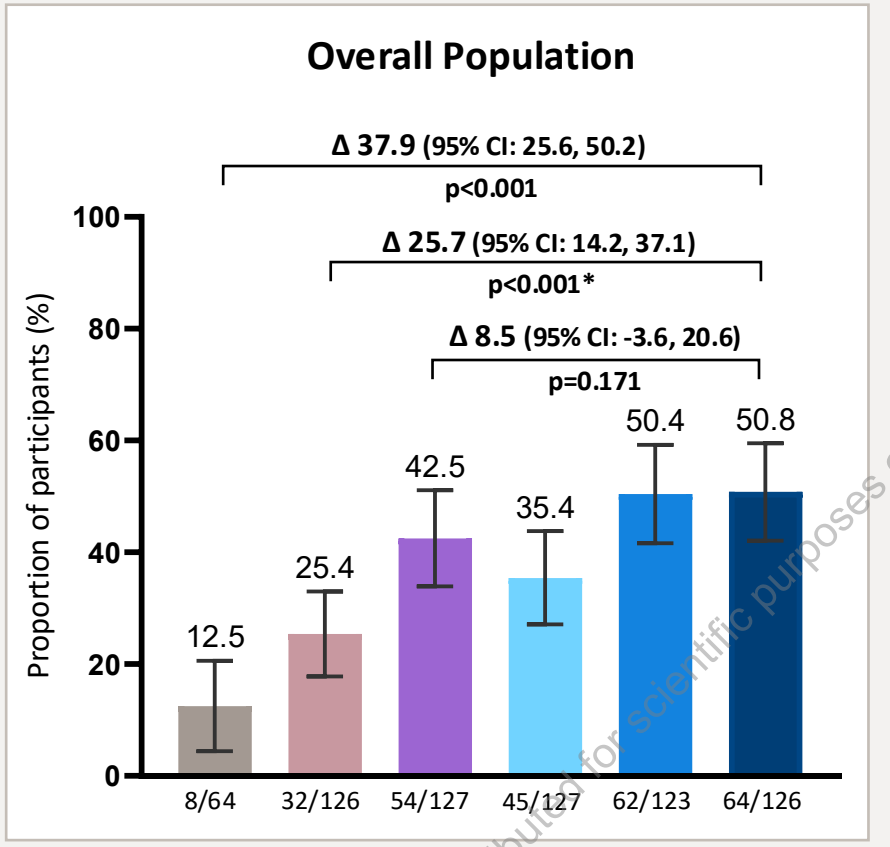
[1]Anti-TNF, anti-IL-12/23, anti-IL-23p19, anti-integrin, and JAK inhibitor.
[2]Denominators are the numbers of participants with inadequate response to 1 or more systemic therapy mechanisms.
[3]Among patients with inadequate response to 1 systemic therapy mechanism in DUET-CD, 17% had inadequate response to 2 anti-TNF agents.
***IL**=interleukin, **JAK**=Janus kinase, **TNF**=tumor necrosis factor.*

Treatment Disposition Through Week 48: Lowest Discontinuation Rates Observed in JNJ-4804 Mid-Dose and High-Dose Groups

	Placebo	Golimumab	Guselkumab	JNJ-4804 Low dose	JNJ-4804 Mid dose	JNJ-4804 High dose	Total
Full analysis set	64	126	127	127	123	126	693
Number of participants who:							
Discontinued study treatment before Week 48	33 (51.6%)	51 (40.5%)	31 (24.4%)	37 (29.1%)	24 (19.5%)	24 (19.0%)	200 (28.9%)
Most common reasons for discontinuation							
Lack of efficacy	9 (14.1%)	15 (11.9%)	11 (8.7%)	13 (10.2%)	9 (7.3%)	6 (4.8%)	63 (9.1%)
Withdrawal by participant	9 (14.1%)	13 (10.3%)	4 (3.1%)	6 (4.7%)	4 (3.3%)	5 (4.0%)	41 (5.9%)
Adverse event - worsening of CD	12 (18.8%)	10 (7.9%)	4 (3.1%)	6 (4.7%)	3 (2.4%)	5 (4.0%)	40 (5.8%)
Adverse event - other	2 (3.1%)	5 (4.0%)	5 (3.9%)	7 (5.5%)	2 (1.6%)	5 (4.0%)	26 (3.8%)
Initiated prohibited medication	0	3 (2.4%)	3 (2.4%)	1 (0.8%)	3 (2.4%)	0	10 (1.4%)

Note: Final dosing for the main treatment period was received 4 weeks prior to Week 48. Participants are presented in the treatment group assigned at Week 0.
***CD**=Crohn's disease.*

Co-Primary Endpoint: Clinical Remission at Week 48

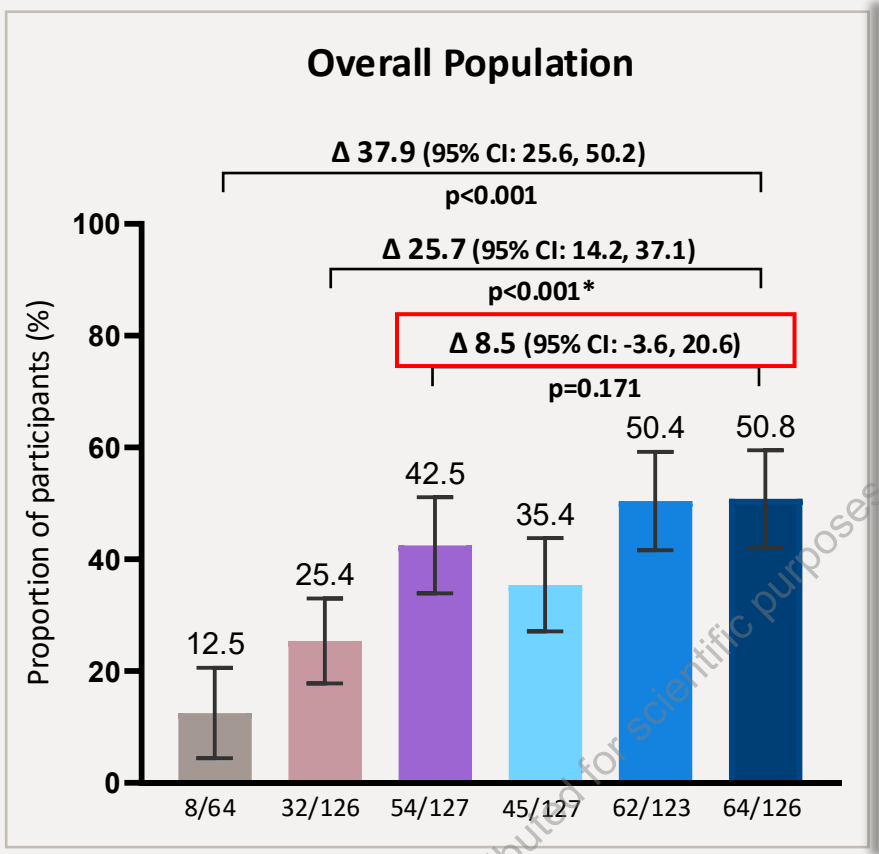


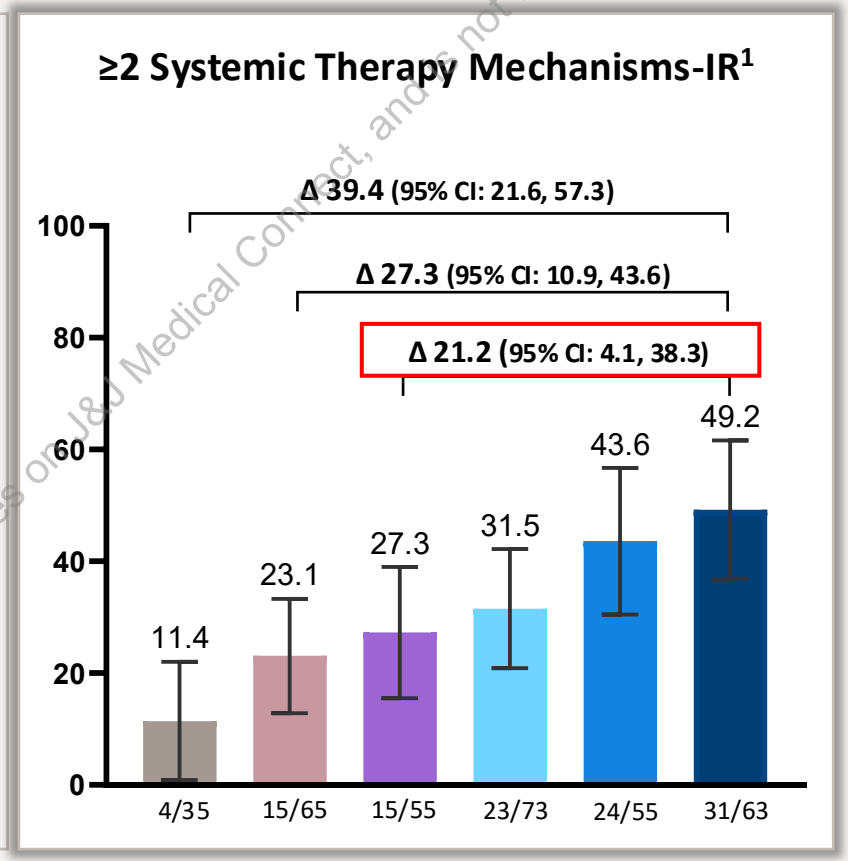
Clinical remission: CDAI score of <150

*Statistically significant. All other p-values are nominal.

***CDAI**=Crohn's Disease Activity Index, **CI**=confidence interval.*

Co-Primary Endpoint: Clinical Remission at Week 48



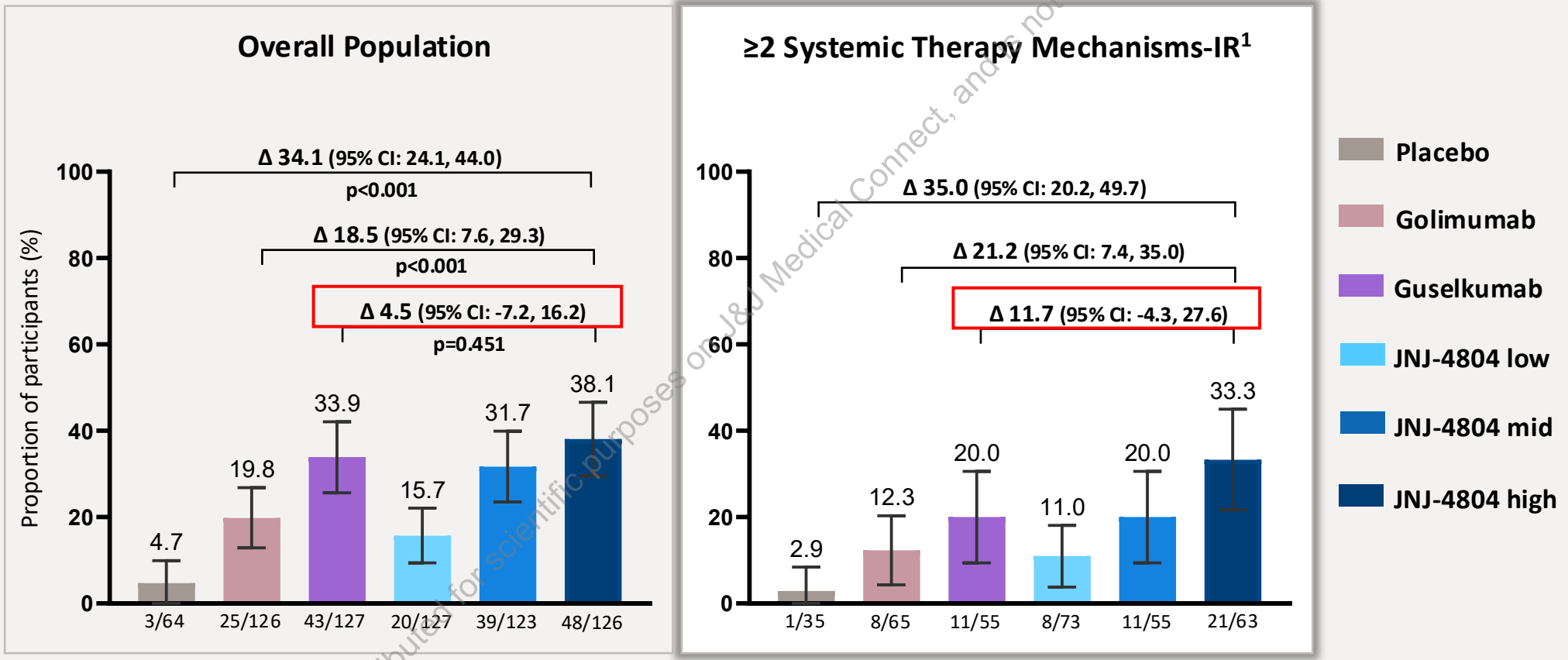


Placebo
Golimumab
Guselkumab
JNJ-4804 low
JNJ-4804 mid
JNJ-4804 high

Clinical remission: CDAI score of <150

*Statistically significant. All other p-values are nominal.
[1]Patients who were inadequate responders to two or more mechanisms of systemic therapies
***CDAI**=Crohn's Disease Activity Index, **CI**=confidence interval, **IR**=inadequate response or intolerance.*

Co-Primary Endpoint: Endoscopic Response at Week 48



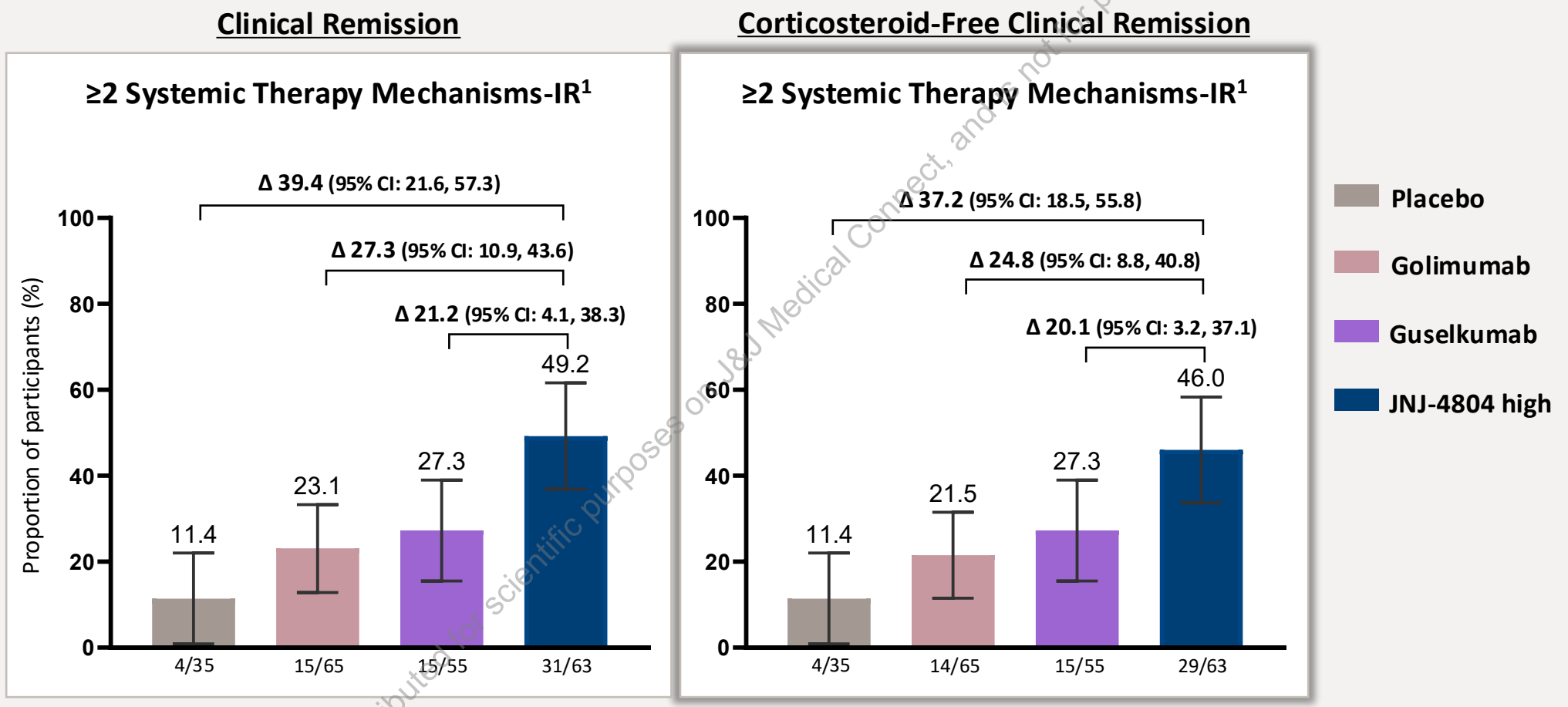
Endoscopic response: >50% improvement from baseline in SES-CD or an SES-CD ≤2, as assessed by central endoscopy reading

All p-values are nominal.

[1]Patients who were inadequate responders to two or more mechanisms of systemic therapies

***CI**=confidence interval, **IR**=inadequate response or intolerance, **SES-CD**=Simple Endoscopic Score for Crohn's Disease.*

Key Secondary Endpoint: Corticosteroid-Free Clinical Remission at Week 48 (≥2 Systemic Therapy Mechanisms-IR Population)



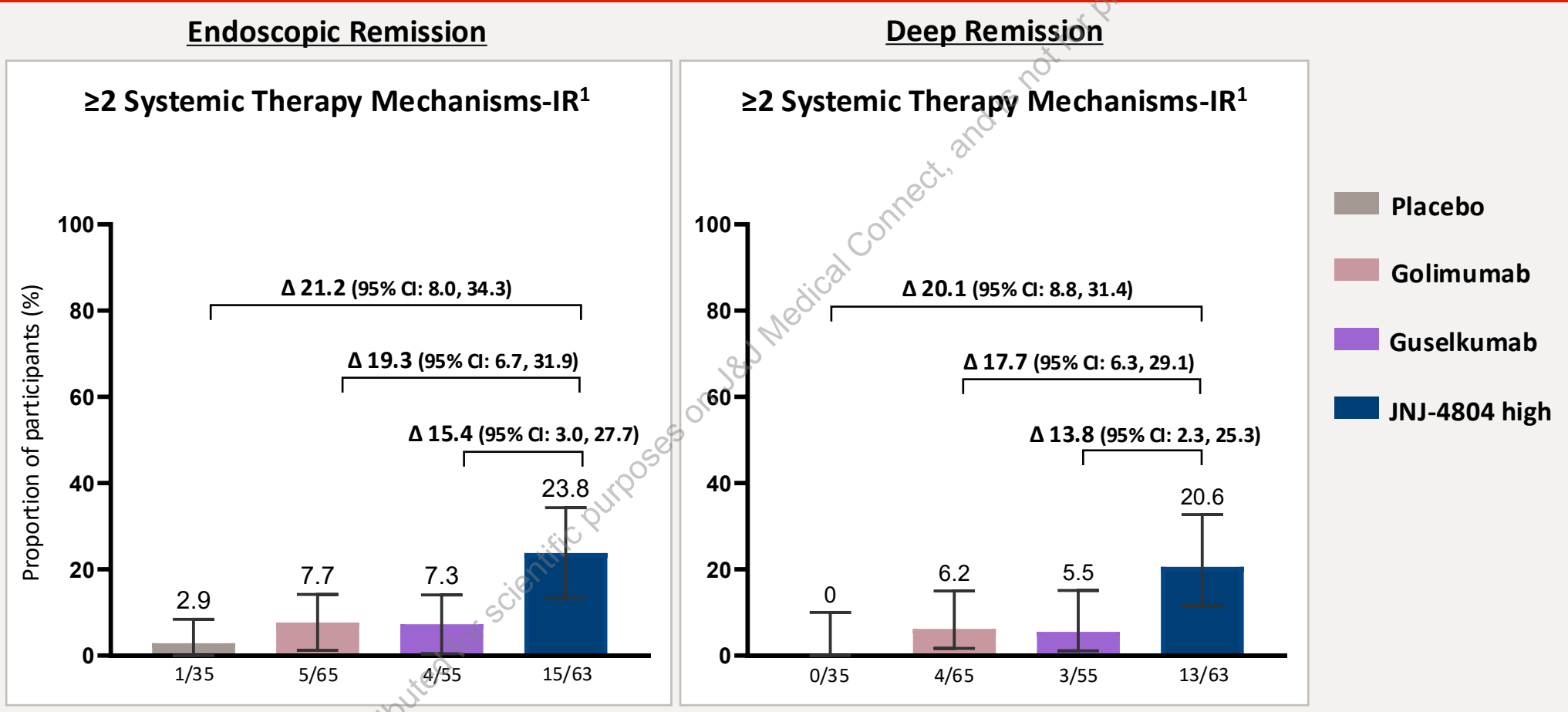
Corticosteroid-free (60-day) clinical remission: CDAI score <150, with no corticosteroids received for at least 60 days

Of the participants in clinical remission at Week 48 in the high-dose group, 29/31 (93.5%) were corticosteroid-free

[1]Patients who were inadequate responders to two or more mechanisms of systemic therapies

***CDAI**=Crohn's Disease Activity Index, **CI**=confidence interval, **IR**=inadequate response or intolerance.*

Key Endpoints: Endoscopic Remission at Week 48 and Deep Remission at Week 48 (≥2 Systemic Therapy Mechanisms-IR Population)



Endoscopic remission: SES-CD ≤4, with at least a 2-point reduction from baseline and no sub-score greater than 1 on any individual component
Deep remission: both clinical remission and endoscopic remission

[1]Patients who were inadequate responders to two or more mechanisms of systemic therapies
CI=*confidence interval,* ***IR***=*inadequate response or intolerance,* ***SES-CD***=*Simple Endoscopic Score for Crohn's Disease.*

Summary of Exposure-Adjusted Adverse Events Through Week 48[1] (Overall Population)

	Placebo	Golimumab	Guselkumab	JNJ-4804 Low dose	JNJ-4804 Mid dose	JNJ-4804 High dose	JNJ-4804 Combined
Safety analysis set	64	126	127	127	123	126	376
Total patient-years of follow-up	38.5	86.0	98.6	97.6	98.6	104.3	300.5
Events per hundred patient-years [number of events]							
AEs	646.8 [249]	603.2 [519]	561.0 [553]	572.6 [559]	489.0 [482]	496.4 [518]	518.7 [1559]
SAEs	31.2 [12]	44.2 [38]	14.2 [14]	36.9 [36]	15.2 [15]	18.2 [19]	23.3 [70]
AEs leading to discontinuation of study treatment	41.6 [16]	23.2 [20]	11.2 [11]	12.3 [12]	6.1 [6]	10.5 [11]	9.6 [29]
Infections	127.3 [49]	122.0 [105]	95.4 [94]	134.2 [131]	102.5 [101]	116.9 [122]	117.8 [354]
Serious infections	2.6 [1]	7.0 [6]	4.1 [4]	8.2 [8]	3.0 [3]	2.9 [3]	4.7 [14]
Deaths[2]	0.0 [0]	1.2 [1]	0.0 [0]	0.0 [0]	0.0 [0]	0.0 [0]	0.0 [0]

Most infections were mild or moderate and did not result in treatment discontinuation

The most frequently reported treatment-emergent AEs (reported in ≥5% of participants for all groups) were nasopharyngitis, upper respiratory tract infection, Crohn's disease, and pyrexia

[1]Excludes inadequate responder events after treatment escalation at Week 24
[2]1 participant with a MACE of unwitnessed cardio-respiratory arrest/respiratory failure (golimumab)
***AE**=adverse event, **MACE**=major adverse cardiovascular event, **SAE**=serious adverse event.*

Treatment-Emergent AEs of Interest Through Week 48[1]

	Placebo	Golimumab	Guselkumab	JNJ-4804 Low dose	JNJ-4804 Mid dose	JNJ-4804 High dose
Safety analysis set	64	126	127	127	123	126
Major adverse cardiovascular events	0	1 (0.8%)	0	0	0	0
Venous thromboembolism	0	0	0	0	0	0
Clinically important hepatic disorders	0	2 (1.6%)	1 (0.8%)	2 (1.6%)	0	0
Opportunistic infection	1 (1.6%)	1 (0.8%)	0	3 (2.4%)	0	1 (0.8%)
Participants with ≥1 AE of special interest[2]						
Invasive fungal infection	0	0	0	0	0	0
Hepatitis B reactivation	0	0	0	0	0	0
Tuberculosis	0	0	0	1 (0.8%)	0	0
Malignancy	0	1 (0.8%)	0	2 (1.6%)	1 (0.8%)	1 (0.8%)
Hypersensitivity reaction	0	0	0	0	0	0
Congestive heart failure	0	0	0	0	0	0
Demyelinating disorders	0	0	0	0	0	0
Lupus-like syndrome	0	0	0	0	0	0

Malignancies were carcinoma in situ of the larynx (golimumab), dermatofibrosarcoma protuberans (low dose), squamous cell carcinoma (low dose and high dose), and basal cell carcinoma (mid dose)

Opportunistic infections were CMV infection (placebo and low dose), EBV reactivation (golimumab), esophageal candidiasis (low dose), tuberculosis (low dose), and herpes zoster disseminated cutaneous (high dose)

[1]Excludes inadequate responder events after treatment escalation at Week 24
[2]Serious infections were also an AE of special interest and were presented in the previous slide.
***AE**=adverse event, **CMV**=cytomegalovirus, **EBV**=Epstein-Barr virus*

Conclusions

- JNJ-4804, the first co-antibody therapy in development for IBD, demonstrated clinically meaningful efficacy exceeding that of the monotherapies in patients with treatment-refractory Crohn's disease
- In the overall population, efficacy of high-dose JNJ-4804 was superior to golimumab and numerically greater than guselkumab
- In patients with disease refractory to two or more systemic therapy mechanisms, high-dose JNJ-4804 exceeded golimumab and guselkumab, with more than additive benefits in high-bar endoscopic and deep remission outcomes
- The safety profile of JNJ-4804 through 48 weeks was consistent with the well-established safety profiles of the component monotherapies
- Building on the molecular synergy seen in VEGA, the DUET-CD results support advancement to Phase 3 in the rapidly growing population of patients with disease refractory to systemic therapies

ACKNOWLEDGMENTS

- The authors thank the participants, investigators, and study personnel who made DUET-CD 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

DUET-UC
Presenter: Maria Abreu
Session: Late-Breakers in IBD
Presentation Date/Time: Tuesday, 05 May 2026, 11:15-11:30 (Central Time)
Room: Skyline Ballroom (W375c)