EFFICACY OUTCOMES BY SYMPTOM-BASED RESPONSE STATUS AFTER INDUCTION: WEEK-48 RESULTS FROM THE GALAXI 1 TRIAL OF GUSELKUMAB IN CROHN'S DISEASE

E0344

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BACKGROUND/OBJECTIVE

Guselkumab (GUS) is a human selective IL-23 antagonist approved for the treatment of moderate to severe plaque psoriasis and psoriatic arthritis

The Phase 2 GALAXI 1 dose-ranging study evaluated the efficacy and safety of GUS in patients with moderately to severely active Crohn's disease, and used a treat-through design allowing for analysis of both the total population and the subgroup of induction responders

This *post hoc* analysis evaluates clinical and endoscopic outcomes for patients who were in response at week 12 and compares them to outcomes in the overall population that included both induction responders and non-responders

METHODS

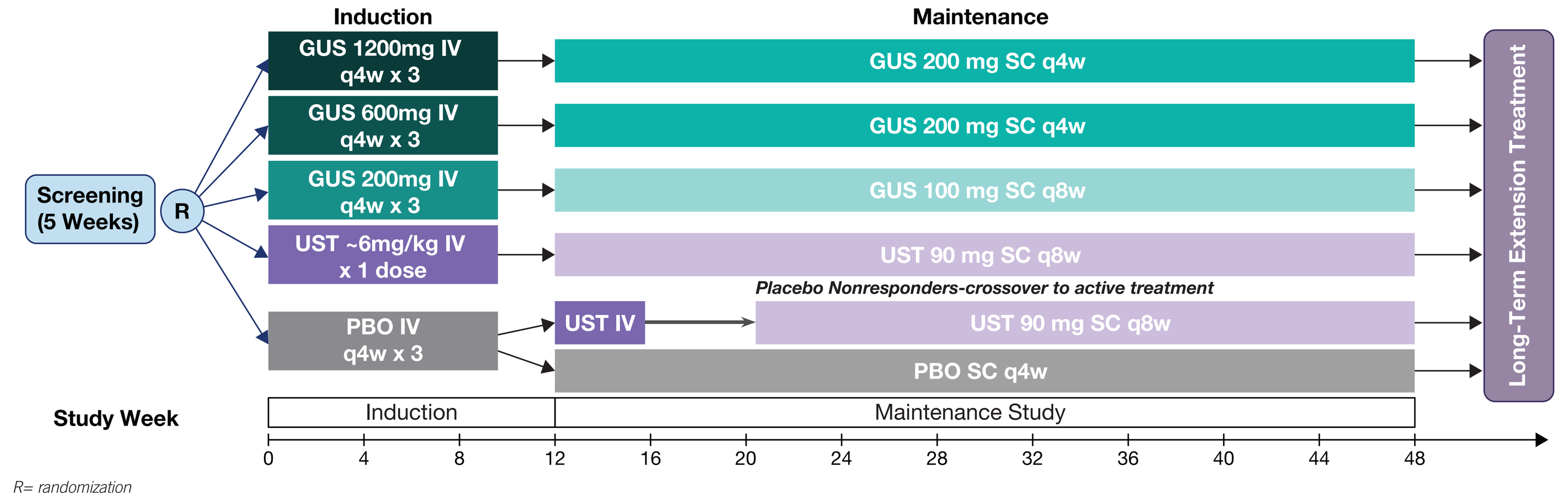
Definitions of Induction Response

- **Symptom-based response:** ≥30% decrease in average daily abdominal pain score and/or ≥30% decrease in average daily stool frequency and both not worse than baseline at week 12
- **CDAI-based response:** ≥100-point reduction from baseline to week 12 in CDAI or CDAI <150 at week 12

Key Outcomes and Measures

- Clinical remission (CDAI <150)
- Corticosteroid-free remission (CDAI <150 and not receiving corticosteroids at the visit)
- PRO-2 remission (unweighted CDAI components of average daily abdominal pain score ≤1 AND average daily stool frequency ≤3, and no worsening from baseline)
- CDAI-based clinical response (≥100-point reduction from baseline in CDAI or CDAI <150)
- Endoscopic response (≥50% improvement from baseline in SES-CD or SES-CD ≤2)

Phase 2 GALAXI-1 Study Design


Induction
Maintenance
Screening (5 Weeks)
R
GUS 1200mg IV q4w x 3
GUS 600mg IV q4w x 3
GUS 200mg IV q4w x 3
UST ~6mg/kg IV x 1 dose
PBO IV q4w x 3
GUS 200 mg SC q4w
GUS 200 mg SC q4w
GUS 100 mg SC q8w
UST 90 mg SC q8w
Placebo Nonresponders-crossover to active treatment
UST IV
UST 90 mg SC q8w
PBO SC q4w
Long-Term Extension Treatment
Study Week
Induction
Maintenance Study
0 4 8 12 16 20 24 28 32 36 40 44 48

R= randomization

CONCLUSIONS

- **Patients in response after induction at week 12 were more likely to achieve clinical and endoscopic outcomes at week 48 compared to the total study population, regardless of induction dose received**
- **Outcomes at week 48 were similar when using either symptom-based or CDAI-based definitions of clinical response at week 12**
- **The treat-through study design allowed for evaluation of outcomes during maintenance for all patients enrolled**

RESULTS

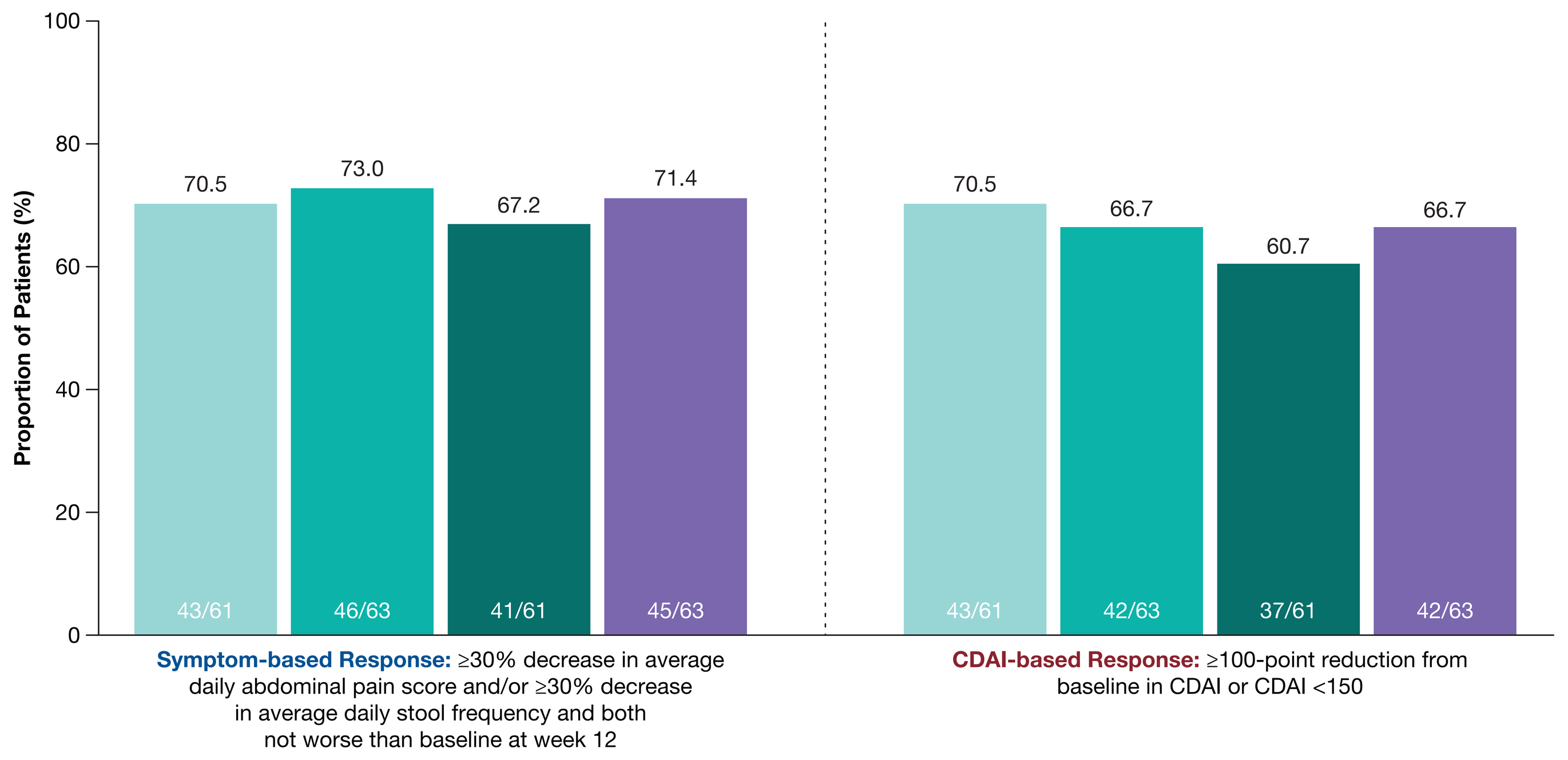
Baseline demographic data were comparable across study cohorts.

Table 1. Baseline Demographics and Disease Characteristics

	Placebo	GUS 200 mg IV / 100 mg SC	GUS 600 mg IV / 200 mg SC	GUS 1200 mg IV / 200 mg SC	UST ~6 mg/kg IV / 90 mg SC	Total
Primary efficacy analysis set	61	61	63	61	63	309
Age, years - mean (SD)	38.9 (12.95)	40.3 (13.67)	39.0 (14.35)	39.6 (13.72)	36.1 (12.02)	38.8 (13.36)
Male, n (%)	37 (60.7%)	38 (62.3%)	36 (57.1%)	31 (50.8%)	41 (65.1%)	183 (59.2%)
Crohn's disease duration, years						
Mean (SD)	8.7 (6.54)	10.7 (12.17)	10.4 (9.74)	6.7 (6.91)	7.4 (6.17)	8.8 (8.70)
Median (IQ range)	7.3 (3.5; 12.4)	6.1 (2.3; 14.3)	7.6 (2.9; 16.2)	4.6 (2.1; 9.7)	5.9 (2.1; 10.6)	6.3 (2.5; 11.7)
CDAI score, mean (SD)	300.8 (49.91)	304.6 (57.24)	305.8 (58.77)	305.8 (54.46)	313.3 (61.30)	306.1 (56.30)
Stool frequency count >3, n (%)	49 (80.3%)	47 (77.0%)	52 (82.5%)	48 (78.7%)	56 (88.9%)	252 (81.6%)
Abdominal pain score >1, n (%)	58 (95.1%)	57 (93.4%)	58 (92.1%)	59 (96.7%)	60 (95.2%)	292 (94.5%)
SES-CD, mean (SD)	12.8 (7.98)	12.6 (7.99)	12.4 (7.37)	11.7 (7.14)	15.1 (8.75)	12.9 (7.91)
Endoscopic severity, n (%)						
SES-CD 3 to 6	13 (21.3%)	13 (21.3%)	16 (25.4%)	20 (32.8%)	13 (20.6%)	75 (24.3%)
SES-CD 7 to 16	31 (50.8%)	32 (52.5%)	31 (49.2%)	25 (41.0%)	23 (36.5%)	142 (46.0%)
SES-CD >16	17 (27.9%)	16 (26.2%)	16 (25.4%)	16 (26.2%)	27 (42.9%)	92 (29.8%)
Involved GI areas by central read, n (%)						
Ileum only	11 (18.0%)	17 (27.9%)	22 (34.9%)	13 (21.3%)	11 (17.5%)	74 (23.9%)
Colon only	26 (42.6%)	27 (44.3%)	18 (28.6%)	31 (50.8%)	29 (46.0%)	131 (42.4%)
Ileum and colon	24 (39.3%)	17 (27.9%)	23 (36.5%)	17 (27.9%)	23 (36.5%)	104 (33.7%)
SES-CD ≥4 for isolated ileal disease or SES-CD ≥6 for colonic or ileocolonic disease at baseline, n (%)	55 (90.2%)	55 (90.2%)	56 (88.9%)	54 (88.5%)	60 (95.2%)	280 (90.6%)

Percentages of patients who were induction responders at week 12 were similar using either the symptom-based or CDAI-based definitions.

Figure 1. Induction Response at Week 12


Proportion of Patients (%)
70.5 73.0 67.2 71.4
43/61 46/63 41/61 45/63
70.5 66.7 60.7 66.7
43/61 42/63 37/61 42/63
Symptom-based Response: ≥30% decrease in average daily abdominal pain score and/or ≥30% decrease in average daily stool frequency and both not worse than baseline at week 12
CDAI-based Response: ≥100-point reduction from baseline in CDAI or CDAI <150

Among induction responders at week 12 (regardless of definition), percentages of patients who were in clinical remission, corticosteroid-free remission, PRO-2 remission, CDAI-based clinical response, and endoscopic response at Week 48 were greater than the overall study population that included both induction responders and non-responders.

Figure 2A. Clinical Remission at Week 48

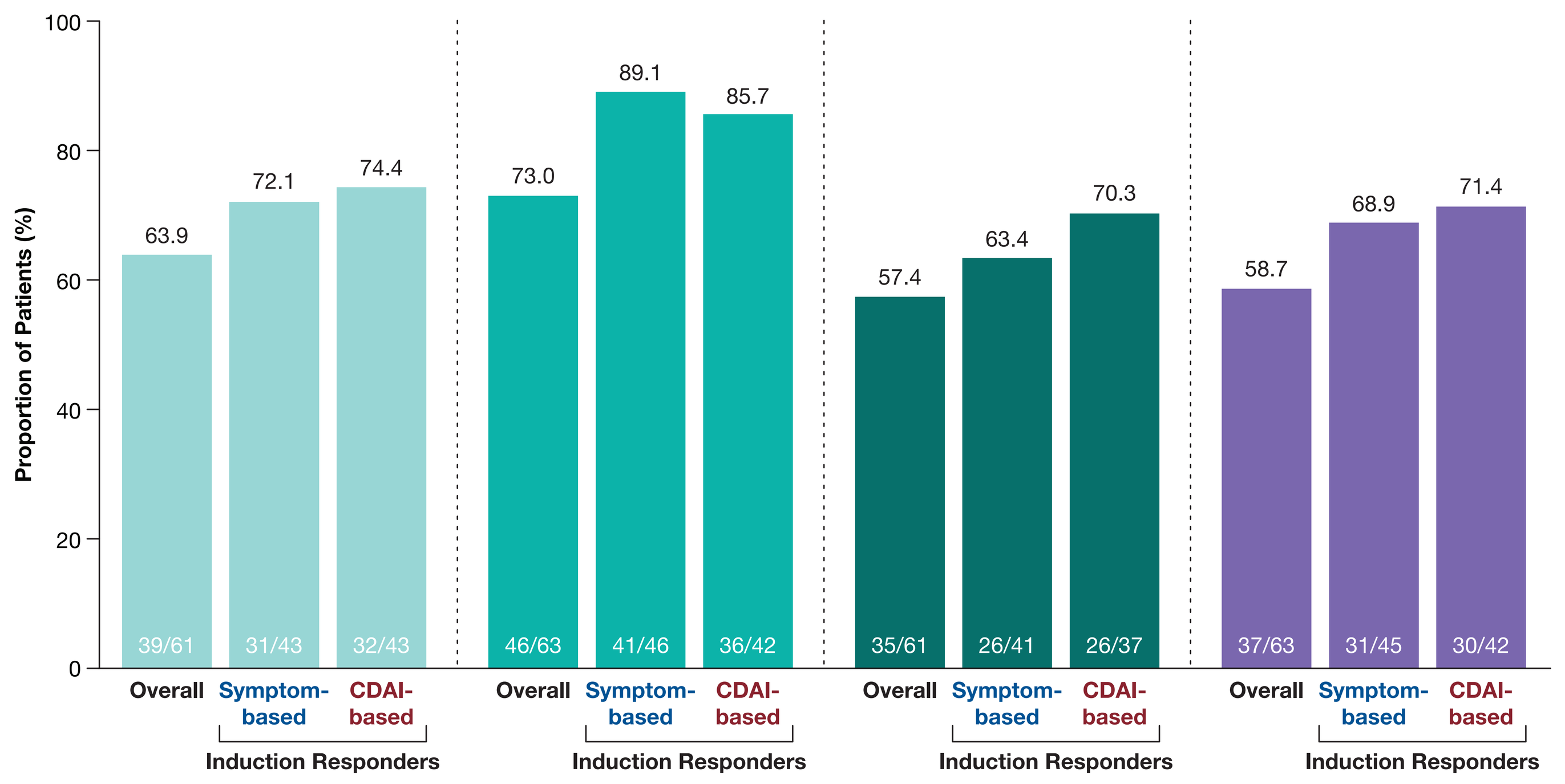


Figure 2B. Corticosteroid-free Remission at Week 48

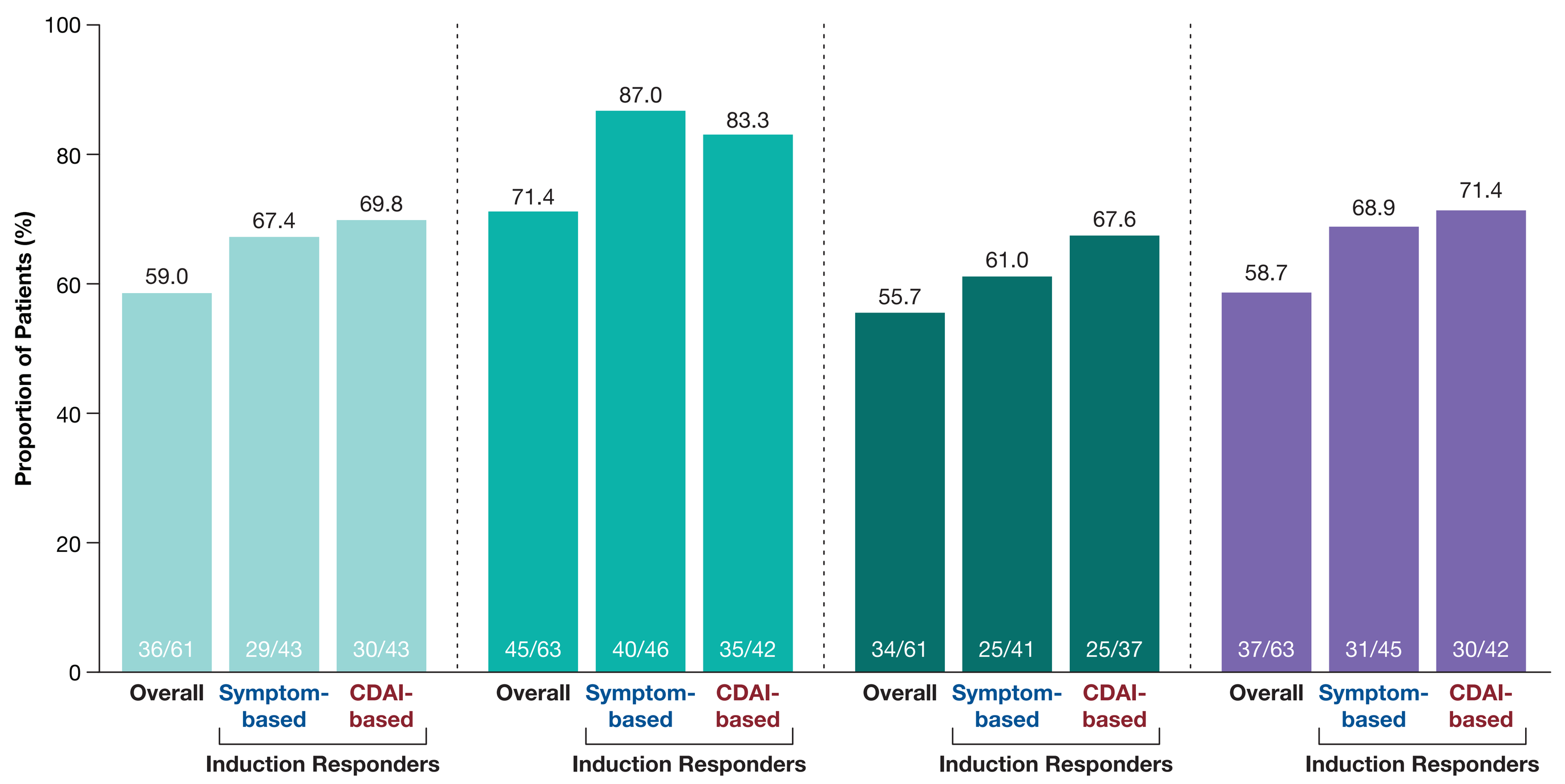


Figure 2C. PRO-2 Remission at Week 48

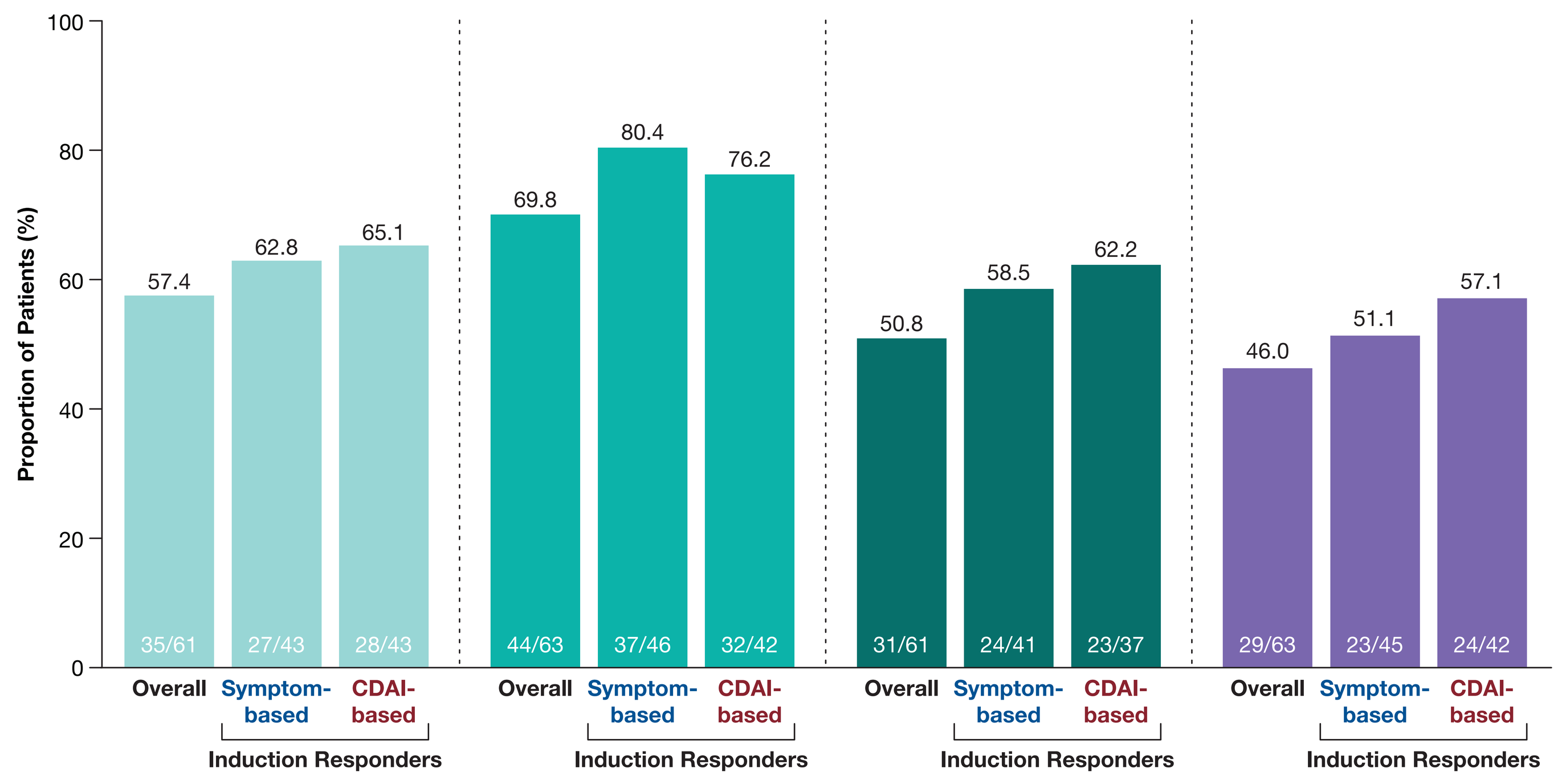


Figure 2D. CDAI-based Clinical Response at Week 48

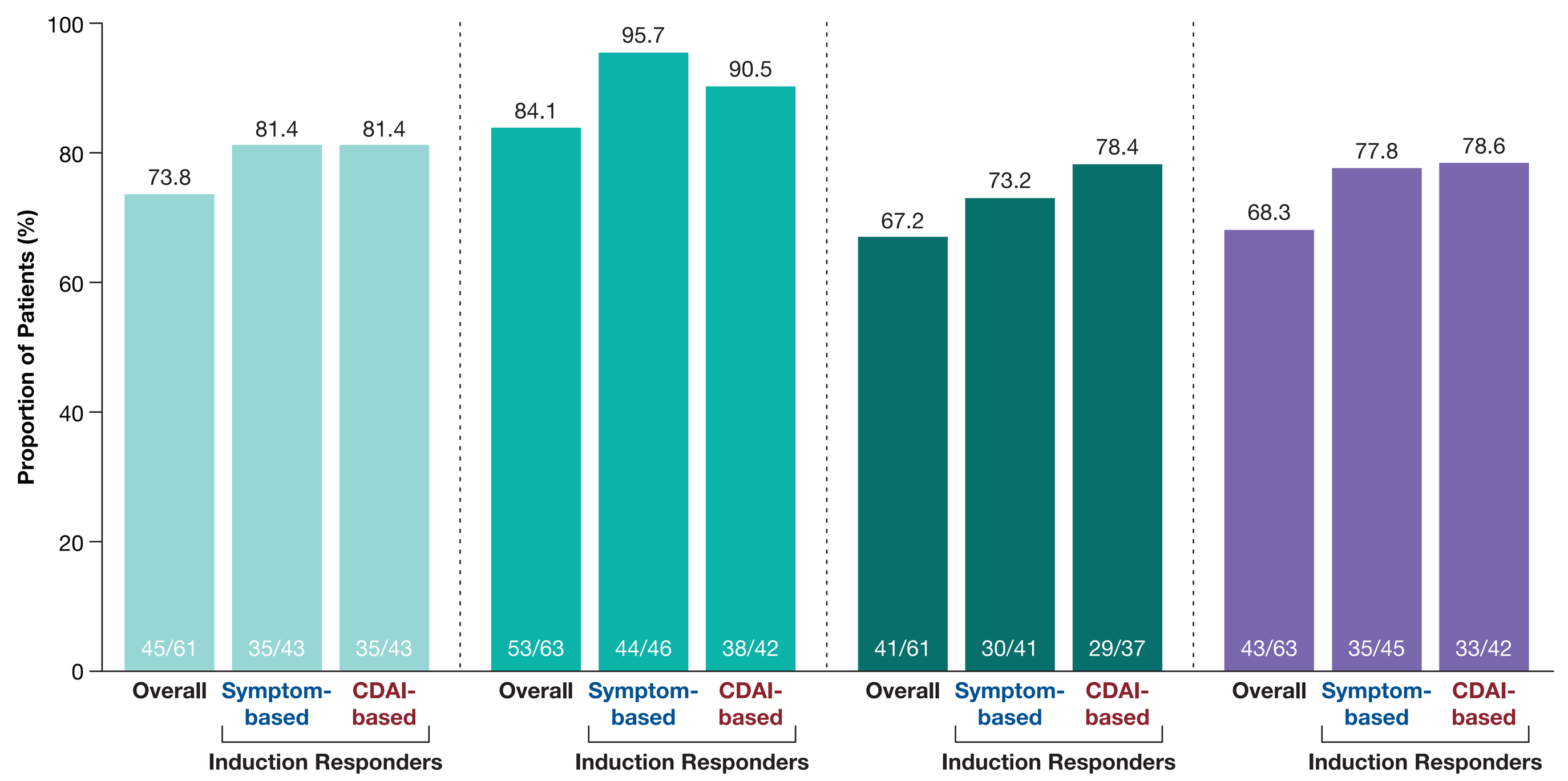
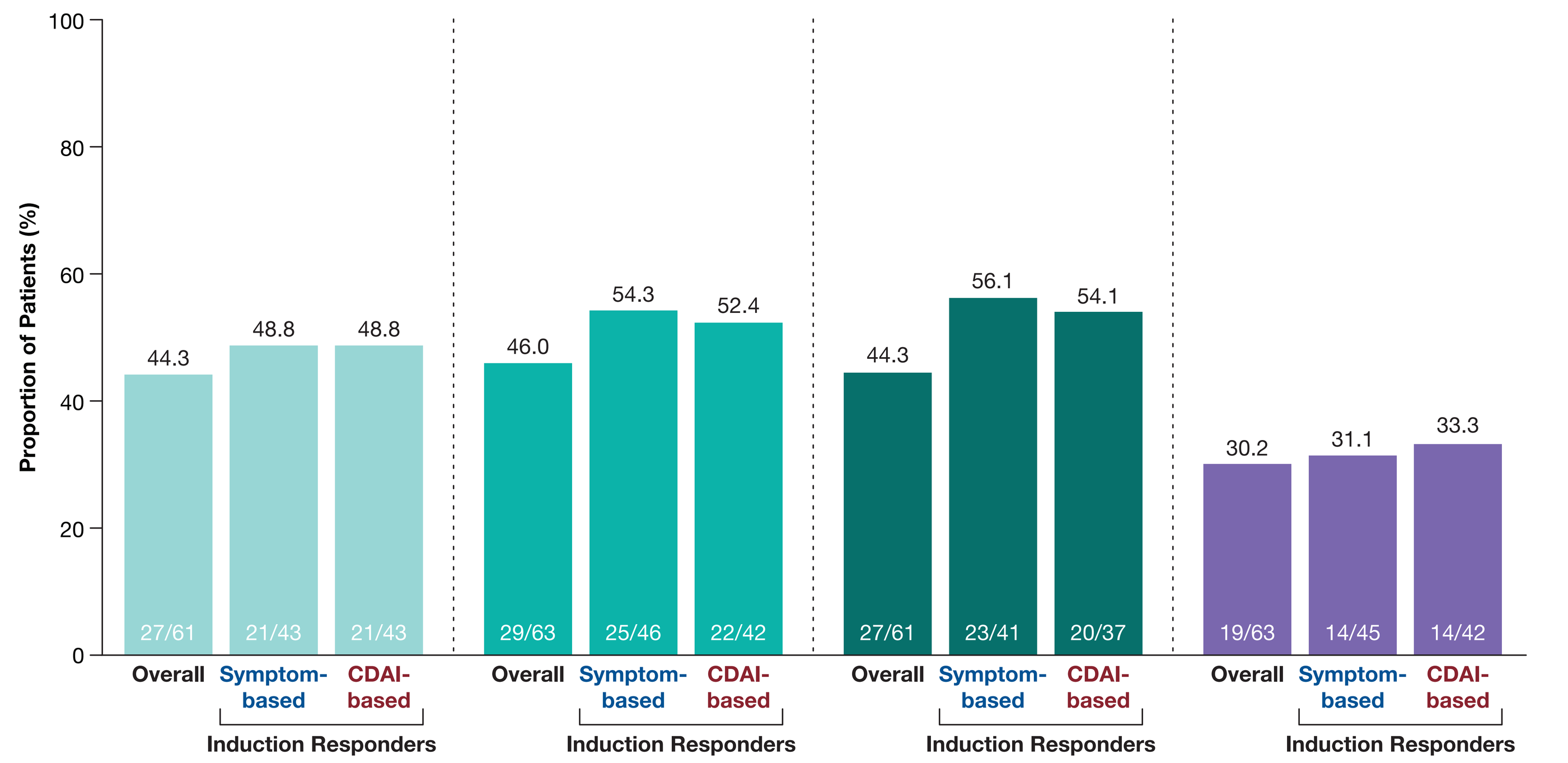


Figure 2E. Endoscopic Response at Week 48



Pts who had a prohibited change in concomitant Crohn's disease medication, a Crohn's disease-related surgery, discontinued study agent due to lack of efficacy, an adverse event of worsening Crohn's disease, or insufficient data to calculate the endpoint parameter at the timepoint were considered not to have met the endpoint at the timepoint. Pts who had discontinued study agent due to any other reasons prior to the timepoint had their observed data used, if available, to determine responder and nonresponder status at the timepoint.

GUS 200mg IV q4w → 100mg SC q8w; GUS 600mg IV q4w → 200mg SC q4w; GUS 1200mg IV q4w → 200mg SC q4w; UST

Acknowledgments

The authors thank the patients, investigators, and study personnel who made the GALAXI study possible
Under the direction of the authors and in accordance with Good Publication Practices, Rick Mearhoff and Christine Eichelberger of Janssen Scientific Affairs, LLC provided writing and editorial assistance
This work was supported by Janssen Research & Development, LLC

Disclosures

AA reports consulting fees from AbbVie, Takeda, Janssen, Bristol Myers Squibb/Celgene, Pfizer, Eli Lilly, Gilead, DiaSorin, and TLL Pharmaceuticals; speaker fees from Abbvie, Takeda, Janssen, Bristol Myers Squibb, Pfizer; served on advisory boards for Abbvie, Takeda, Janssen, Bristol Myers Squibb, Pfizer, Eli Lilly, Gilead; has received research/education support from AbbVie, Janssen, Pfizer, Bristol Myers Squibb, and Takeda; and Co-Founder of IBD Horizons. **JP** has received research grants from AbbVie and Pfizer; speaker's fees from AbbVie, Janssen, Pfizer, , Takeda, and Theravance; and has been a consultant for AbbVie, Arena, Athos, Boehringer Ingelheim, Celgene, Celltrion, Ferring, Galapagos, Genentech, GlaxoSmithKline, Janssen, Mirum, Morphic, Nestlé, Origo, Pandion, Pfizer, Progenity, Protagonist, Revolo, Robarts Clinical Trials, Roche, Takeda, Theravance, and Wassermann. **DTR** Research funding from Takeda, and has served as a consultant to AbbVie, Altrubio, Allergan, Inc., Arena Pharmaceuticals, Aslan Pharmaceuticals, Athos Therapeutics, Bellatrix Pharmaceuticals, Boehringer Ingelheim, Ltd., Bristol Myers Squibb, Celgene Corp/Syneos, Connect BioPharma, GalenPharma/Atlantica, Genentech/Roche, InDex Pharmaceuticals, Ironwood Pharmaceuticals, Iterative Scopes, Janssen Pharmaceuticals, Eli Lilly, Materia Prima, Pfizer, Prometheus Biosciences, Reistone, Takeda, Techlab, Inc and is a co-founder of Cornerstones Health, Inc. **BES** discloses research grants from Takeda, Pfizer, Theravance Biopharma R&D, Janssen; consulting fees from 4D Pharma, Abivax, Abbvie, Alimentiv, Allergan, Amgen, Arena Pharmaceuticals, AstraZeneca, Bacainn Therapeutics, Boehringer-Ingelheim, Boston Pharmaceuticals, Bristol-Myers Squibb, Calibr, Capella Bioscience, Celgene, Celltrion Healthcare, ClostraBio, Enthera, F.Hoffmann-La Roche, Ferring, Galapagos, Gilead, Glaxo SmithKline, GossamerBio, Immunic, Index Pharmaceuticals, Innovation Pharmaceuticals, Ironwood Pharmaceuticals, Janssen, Kaleido, Kallyope, Lilly, MiroBio, Morphic Therapeutic, Oppilan Pharma, OSE Immunotherapeutics, Otsuka, Palatin Technologies, Pfizer, Progenity, Prometheus Biosciences, Prometheus Laboratories, Protagonist Therapeutics, Q32 Bio, Redhill Biopharma, Rheos Medicines, Salix Pharmaceuticals, Seres Therapeutics, Shire, Sienna Biopharmaceuticals, Sun Pharma, Surrozen, Takeda, Target PharmaSolutions, Teva Branded Pharmaceutical Products R&D, Thelium, Theravance Biopharma R&D, TLL Pharma, USWM Enterprises, Ventyx Biosciences, Viela Bio, Vivante Health, Vivelix Pharmaceuticals; and stock for Vivante Health and Ventyx Biosciences. **WR** Speaker for Abbott Laboratories, AbbVie, Aesca, Aptalis, Astellas, Centocor, Celltrion, Danone Austria, Elan, Falk Pharma GmbH, Ferring, Immundiagnostik, Mitsubishi Tanabe Pharma Corporation, MSD, Otsuka, PDL, Pharmacosmos, PLS Education, Schering-Plough, Shire, Takeda, Therakos, Vifor, and Yakult; consultant for Abbott Laboratories, AbbVie, Aesca, Algernon, Amgen, AM Pharma, AMT, AOP Orphan, Arena Pharmaceuticals, Astellas, Astra Zeneca, Avaxia, Roland Berger GmBH, Bioclinica, Biogen IDEC, Boehringer-Ingelheim, Bristol Myers Squibb, Cellerix, Chemocentryx, Celgene, Centocor, Celltrion, Covance, Danone Austria, DSM, Elan, Eli Lilly, Ernest & Young, Falk Pharma GmbH, Ferring, Galapagos, Gatehouse Bio Inc., Genentech, Gilead, Grünenthal, ICON, Index Pharma, Inova, Intrinsic Imaging, Janssen, Johnson & Johnson, Kyowa Hakko Kirin Pharma, Lipid Therapeutics, LivaNova, Mallinckrodt, Medahead, MedImmune, Millenium, Mitsubishi Tanabe Pharma Corporation, MSD, Nash Pharmaceuticals, Nestle, Nippon Kayaku, Novartis, Ocera, OMass, Otsuka, Parexel, PDL, Periconsulting, Pharmacosmos, Philip Morris Institute, Pfizer, Procter & Gamble, Prometheus, Protagonist, Provention, Quell Therapeutics, Robarts Clinical Trial, Sandoz, Schering-Plough, Second Genome, Seres Therapeutics, Setpointmedical, Sigmoid, Sublimity, Takeda, Therakos, Theravance, Tigenix, UCB, Vifor, Zealand, Zyngenia, and 4SC; advisory board member for Abbott Laboratories, AbbVie, Aesca, Amgen, AM Pharma, Astellas, Astra Zeneca, Avaxia, Biogen IDEC, Boehringer-Ingelheim, Bristol Myers Squibb, Cellerix, Chemocentryx, Celgene, Centocor, Celltrion, Danone Austria, DSM, Elan, Ferring, Galapagos, Genentech, Grünenthal, Inova, Janssen, Johnson & Johnson, Kyowa Hakko Kirin Pharma, Lipid Therapeutics, MedImmune, Millenium, Mitsubishi Tanabe Pharma Corporation, MSD, Nestle, Novartis, Ocera, Otsuka, PDL, Pharmacosmos, Pfizer, Procter & Gamble, Prometheus, Sandoz, Schering-Plough, Second Genome, Setpointmedical, Takeda, Therakos, Tigenix, UCB, Zealand, Zyngenia, and 4SC; Research funding from Abbott Laboratories, AbbVie, Aesca, Centocor, Falk Pharma GmbH, Immundiagnostik, Janssen, MSD, Sandoz, and Takeda. GRDH served as advisor for Abbvie, Ablynx, Amakem, Amgen, AM Pharma, Avaxia, Biogen, Bristol Meiers Squibb, Boerhinger Ingelheim, Celgene/Receptos, Celltrion, Cosmo, Covidien/Medtronics, Ferring, DrFALK Pharma, Eli Lilly, Engene, Galapagos, Genentech/Roche, Gilead, Glaxo Smith Kline, Immunic, Johnson and Johnson, Lycera, Medimetrics, Millenium/Takeda, Mitsubishi Pharma, Merck Sharp Dome, Mundipharma, Nextbiotics, Novonordisk, Otsuka, Pfizer/Hospira, Prometheus laboratories/Nestle, Protagonist, Robarts Clinical Trials, Salix, Samsung Bioepis, Sandoz, Setpoint, Shire, Teva, Tigenix, Tillotts, Topivert, Versant and Vifor; received speaker fees from Abbvie, Biogen, Ferring, Johnson and Johnson, Merck Sharp Dome, Mundipharma, Norgine, Pfizer, Samsung Bioepis, Shire, Millenium/Takeda, Tillotts and Vifor. **MG**, **NT, AS, MEF** and **ZY** were employees of Janssen Research & Development, LLC. at the time of the study and own stock/stock options. **WJS** reports research grants from AbbVie, Abivax, Arena Pharmaceuticals, Boehringer Ingelheim, Celgene, Genentech, Gilead Sciences, Glaxo Smith Kline, Janssen, Eli Lilly, Pfizer, Prometheus Biosciences, Seres Therapeutics, Shire, Takeda, Theravance Biopharma; consulting fees from AbbVie, Abivax, Admirx, Alfasigma, Alimentiv (previously Robarts Clinical Trials, owned by Alimentiv Health Trust), Alivio Therapeutics, Allakos, Amgen, Applied Molecular Transport, Arena Pharmaceuticals, Bausch Health (Salix), Beigene, Bellatrix Pharmaceuticals, Boehringer Ingelheim, Boston Pharmaceuticals, Bristol Meyers Squibb, Celgene, Celltrion, Cellularity, Cosmo Pharmaceuticals, Escalier Biosciences, Equillium, Forbion, Genentech/Roche, Gilead Sciences, Glenmark Pharmaceuticals, Gossamer Bio, Immunic (Vital Therapies), Index Pharmaceuticals, Intact Therapeutics, Janssen, Kyverna Therapeutics, Landos Biopharma, Eli Lilly, Oppilan Pharma, Otsuka, Pandion Therapeutics, Pfizer, Progenity, Prometheus Biosciences, Prometheus Laboratories, Protagonists Therapeutics, Provention Bio, Reistone Biopharma, Seres Therapeutics, Shanghai Pharma Biotherapeutics, Shire, Shoreline Biosciences, Sublimity Therapeutics, Surrozen, Takeda, Theravance Biopharma, Thetis Pharmaceuticals, Tillotts Pharma, UCB, Vendata Biosciences, Ventyx Biosciences, Vimalan Biosciences, Vivelix Pharmaceuticals, Vivreon Biosciences, Zealand Pharma; stock or stock options from Allakos, BeiGene, Gossamer Bio, Oppilan Pharma, Prometheus Biosciences, Prometheus Laboratories Progenity, Shoreline Biosciences, Ventyx Biosciences, Vimalan Biosciences, Vivreon Biosciences; and employee at Shoreline Biosciences. Spouse: Iveric Bio - consultant, stock options; Progenity - stock; Oppilan Pharma - consultant, stock options; Prometheus Biosciences - employee, stock, stock options; Prometheus Laboratories – stock, stock options, consultant; Ventyx Biosciences – stock, stock options; Vimalan Biosciences – stock, stock options. **RP** has received consulting fees from AbbVie, Abbott, Alimentiv (formerly Robarts), Amgen, Arena, AstraZeneca, Bristol Myers Squibb, Boehringer Ingelheim Celgene, Celltrion, Cosmos Pharmaceuticals, Eisai, Elan, Eli Lilly, Ferring, Galapagos, Genentech, Gilead Sciences, GlaxoSmithKline, Janssen, Merck, Mylan, Oppilan Pandion, Pharma, Pandion Pharma, Pfizer, Progenity, Protagonist Therapeutics, Roche, Satisfai Health, Sandoz, Schering-Plough, Shire, Sublimity Therapeutics, Theravance, UCB, and Takeda; speaker fees from AbbVie, Arena, Celgene, Eli Lilly, Ferring, Gilead Sciences, Janssen, Merck, Pfizer, Roche, Sandoz, Shire, and Takeda; research/educational support from AbbVie, Ferring, Janssen, Pfizer, and Takeda; and has served on an advisory board for AbbVie, Amgen, Arena, Bristol Myers Squibb, Celgene, Celltrion, Eli Lilly, Ferring, Galapagos, Genentech, Gilead Sciences, GlaxoSmith Kline, Janssen, Merck, Mylan, Oppilan Pharma, Pandion Pharma, Pfizer, Sandoz, Shire, Sublimity Therapeutics, Theravance, and Takeda. **TH** has performed joint research with Alfresa Pharma Co. Ltd., and EA Pharma Co. Ltd.; grant support from Mitsubishi Tanabe Pharma Corporation, EA Pharma Co. Ltd., AbbVie GK, JIMRO Co. Ltd., Zeria Pharmaceutical Co. Ltd., Daiichi-Sankyo, Kyorin Pharmaceutical Co. Ltd., Nippon Kayaku Co. Ltd., Takeda Pharmaceutical Co. Ltd., Pfizer Inc., Mochida Pharmaceutical Co., Ltd, JIMRO Co. Ltd; consulting fees from EA Pharma Co. Ltd., AbbVie GK, Celgene K.K., Janssen Pharmaceutical K.K., Pfizer Inc., Nichi-Iko Pharmaceutical Co., Ltd; and lecture fees 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., and Pfizer Inc. **SD** reports receiving consulting fees from Allergan, Amgen, AstraZeneca, Biogen, Boehringer Ingelheim, Celgene, Celltrion Healthcare, Ferring, Gilead Sciences, Hospira, Inc., Janssen Research & Development, LLC., Johnson & Johnson Health Care Systems, Inc., Pfizer, Sandoz, UCB, Vifor International Inc. **JMA** served as a consultant for, received speakers' fees and/or research support from Abbott, AbbVie, Allergan, Anatara, AstraZeneca, Bayer, BMS, Celegene, Celltrion, Falk, Ferring, Gilead, Hospira, Immunic, Janssen, MSD, Nestle, Novartis, Pfizer, Sandoz, Shire, Takeda, and Vifor. **BGF** received grant/research support from AbbVie Inc., Amgen Inc., AstraZeneca/MedImmune Ltd., Atlantic Pharmaceuticals Ltd., Boehringer-Ingelheim, Celgene Corporation, Celltech, Genentech Inc/Hoffmann-La Roche Ltd., Gilead Sciences Inc., GlaxoSmithKline, Janssen Research & Development LLC., Pfizer Inc., Receptos Inc./Celgene International, Sanofi, Santarus Inc., Takeda Development Center Americas Inc., Tillotts Pharma AG, UCB; a consultant for Abbott/AbbVie, AdMIRx Inc., Akebia Therapeutics, Allergan, Amgen, Applied Molecular Transport Inc., Aptevo Therapeutics, Asta Pharma, Astra Zeneca, Atlantic Pharma, Avir Pharma, Biogen Idec, BioMx Israel, Boehringer-Ingelheim, Boston Pharmaceuticals, Bristol Myers Squibb, Calypso Biotech, Celgene, Elan/Biogen, EnGene, Ferring Pharma, Roche/Genentech, Galapagos, Galen/Atlantica, GiCare Pharma, Gilead, Gossamer Pharma, GlaxoSmithKline, Inception IBD Inc, Intact Therapeutics, Johnson & Johnson/Janssen, Kyowa Kakko Kirin Co Ltd., Lexicon, Eli Lilly, Lycera BioTech, Merck, Mesoblast Pharma, Millennium, Nestles, Nextbiotix, Novonordisk, ParImmune, Parvus Therapeutics Inc., Pfizer, Prometheus Therapeutics and Diagnostics, Progenity, Protagonist, Qu Biologics, Rebiotix, Receptos, Salix Pharma, Shire, Sienna Biologics, Sigmoid Pharma, Sterna Biologicals, Synergy Pharma Inc., Takeda, Teva Pharma, TiGenix, Tillotts, UCB Pharma, Vertex Pharma, Vivelix Pharma, VHsquared Ltd., Zyngenia; a member of the speakers bureau for Abbott/AbbVie, Johnson & Johnson/Janssen, Eli Lilly, Takeda, Tillotts, UCB Pharma; a member of the scientific advisory board for Abbott/AbbVie, Allergan, Amgen, Astra Zeneca, Atlantic Pharma, Avaxia Biologics Inc., Boehringer-Ingelheim, Bristol Myers Squibb, Celgene, Centocor Inc., Elan/Biogen, Galapagos, Genentech/Roche, Johnson & Johnson/Janssen, Merck, Nestles, Novartis, Novonordisk, Pfizer, Prometheus Laboratories, Protagonist, Salix Pharma, Sterna Biologicals, Takeda, Teva, TiGenix, Tillotts Pharma AG, UCB Pharma; and Senior Scientific Officer – Robarts Clinical Trials Inc.

American College of Gastroenterology 2022; October 21-26, 2022.
Originally presented at United European Gastroenterology Week 2022.