# Livestream: IBD, IL-23, and Inflammation, Oh My! Following the Yellow Brick Road in Using IL-23 Targeted Therapies in Managing IBD

SYLLABUS & COURSE GUIDE

**A Free, 90-Minute Live Activity**
**Premiere Date: Thursday, February 6, 2025**
**9:30 PM - 11:00 PM ET**

**Login:**
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**Faculty:**
Corey A. Siegel, MD, MS (Moderator)
Bincy P. Abraham, MD, MS, AGAF, FACG, FASGE, FCCF
Marita Kametas, MSN, APN, FNP-BC, CMSRN, COCN
Uma Mahadevan, MD

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# Information for Participants

## Statement of Need

Significant therapeutic advancements have been made over the last decade for treatment of inflammatory bowel disease (IBD), a chronic condition that includes Crohn's disease (CD) and ulcerative colitis (UC). The inflammatory cytokine interleukin (IL)-23 has been established as an active driver of IBD pathogenesis, making the IL-23/Th-17 inflammatory signaling axis a promising therapeutic target. Monoclonal antibodies (mAbs) have rapidly emerged at the forefront of anti-IL-23 targeted therapies, with structural differences between agents yielding unique clinical profiles that impact the durability of patient outcomes. In collaboration with a multidisciplinary care team, clinicians must understand how to tailor decision-making to the evolving science of cytokine-targeting therapies and the individual needs of patients with IBD.

In this CME Outfitters livestream symposium, expert faculty will instruct learners on the role of pro-inflammatory cytokines in the pathogenesis of IBD. Learners will be guided on the role of the IL-23/Th17 inflammatory axis in IBD pathogenesis and how to appraise the clinical implications of anti-IL-23 agents used in the treatment of IBD. Faculty will model the development of individualized treatment plans for patients with IBD that are eligible for treatment with an IL-23-targeted agent.

## Learning Objectives

At the conclusion of this activity, learners will be able to better:

- Identify the role of pro-inflammatory cytokines in driving inflammation in the pathogenesis of IBD
- Evaluate the role of the IL-23/Th17 inflammatory axis in IBD pathogenesis
- Appraise the clinical implications of anti-IL-23 agents used in the treatment of IBD to bind to CD64 receptors on IL-23-producing cells
- Develop individualized treatment plans for patients with IBD that are eligible for treatment with an IL-23-targeted agent

## Financial Support

Supported by an educational grant from Janssen Biotech, Inc., administered by Janssen Scientific Affairs, LLC.

## Target Audience

Gastroenterologists, gastroenterology fellows/trainees, physician associates (PAs), nurse practitioners (NPs), and nurses

# Faculty

**COREY A. SIEGEL, MD, MS (MODERATOR)**
*Director, Center for Digestive Health*
*Section Chief, Gastroenterology and Hepatology*
*Dartmouth Hitchcock Medical Center*
*Constantine and Joyce Hampers Professor of Medicine*
*Geisel School of Medicine at Dartmouth*
*Hanover, NH*

Corey A. Siegel, MD, MS, is the Director of the Center for Digestive Health, Section Chief of Gastroenterology and Hepatology, and the Co-Director of the Inflammatory Bowel Disease (IBD) Center at the Dartmouth-Hitchcock Medical Center in Lebanon, New Hampshire. He is the Constantine and Joyce Hampers Professor of Medicine and a professor at The Dartmouth Institute for Health Policy and Clinical Practice at the Geisel School of Medicine at Dartmouth. Dr. Siegel attended college at Tufts University and then received his medical degree from Tufts University School of Medicine in Boston, Massachusetts. He completed his residency in internal medicine at the Dartmouth Hitchcock Medical Center where he also served as Chief Medical Resident. He then completed a fellowship in gastroenterology at Dartmouth Hitchcock followed by a fellowship in IBD at Massachusetts General Hospital in Boston.

Dr. Siegel's research interests include understanding risk-benefit tradeoffs in IBD, developing models to predict outcomes in Crohn's disease, creating tools to facilitate shared decision-making, expanding telemedicine services to patients with IBD living in rural locations, and improving the quality of care delivered to patients with IBD. He has been funded by the National Institutes of Health (NIH), Agency for Healthcare Research and Quality (AHRQ), the Crohn's and Colitis Foundation, and the Leona M. and Harry B. Helmsley Charitable Trust for this work. Dr. Siegel has lectured nationally and internationally and published numerous journal articles and book chapters on this and other topics in IBD. He is the founder of the BRIDGe group, an international research collaboration of IBD investigators, and is currently the co-chair of the Crohn's and Colitis Foundation Quality of Care Program (IBD Qorus). Dr. Siegel was inducted into the International Organization for the Study of IBD (IOIBD) in 2013 and received the Sherman Prize in 2023. He lives in Hanover, New Hampshire with his wife and three boys.

> **Dr. Siegel** reports the following relationships:
>
> Advisory Board: AbbVie Inc.; Bristol Myers Squibb Company; Buhlmann; Janssen Pharmaceuticals, Inc.; Lilly; Napo Therapeutics; Pfizer Inc.; Prometheus Biosciences, Inc.; Roivant Sciences; Takeda Pharmaceuticals U.S.A., Inc.; and Trellus Health Inc.
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> Consultant: AbbVie Inc.; Boomerang; Bristol Myers Squibb Company; Buhlmann; Janssen Pharmaceuticals, Inc.; Pfizer Inc; Prometheus Biosciences, Inc.; Prometheus Labs; and Takeda Pharmaceuticals U.S.A., Inc.
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> Grants: AbbVie Inc.; Bristol Myers Squibb Company; Janssen Pharmaceuticals, Inc.; Lilly; and Pfizer Inc.
>
> Other financial or material support: Dr. Corey Siegel is co-founder of MiTest Health, LLC (software company). Technology developed by MiTest Health, LLC has been licensed to Takeda.

**BINCY P. ABRAHAM, MD, MS, AGAF, FACG, FASGE, FCCF**
*Professor of Clinical Medicine, Houston Methodist Academic Institute*
*Professor of Clinical Medicine, Weill Cornell Medical College*
*Adjunct Professor of Clinical Education, Texas A&M University, College of Medicine*
*Director, Gastroenterology Fellowship Program, Houston Methodist*
*Distinguished Professor and Director, Underwood Center - Fondren Inflammatory Bowel Disease Program*
*Houston Methodist Gastroenterology Associates*
*Houston, TX*

Bincy P. Abraham, MD, MS, AGAF, FACG, FASGE, FCCF, is the Distinguished Professor and Director of the Fondren Inflammatory Bowel Disease Program at the Underwood Digestive Diseases Center of Houston Methodist Hospital in Texas. She also serves as the Program Director for the Gastroenterology Fellowship at Houston Methodist Hospital. She earned her medical degree from the University of Texas Medical Branch in Galveston, where she continued with residency training in internal medicine and a fellowship in

gastroenterology. During fellowship, she received specialized training in inflammatory bowel disease (IBD) and earned a master's degree in Clinical Investigation.

Dr. Abraham completed a National Visiting Fellow Inflammatory Bowel Disease Rotation program through the Crohn's and Colitis Foundation at Cedars-Sinai Hospital in Los Angeles, California. She has chaired the Southern Regional chapter of the CCFA Medical Advisory Committee, served as President of the Texas Gulf Coast Gastroenterology Society, and is involved in national committees for and is a Fellow of the American College of Gastroenterology, the American Gastroenterology Association, the American Society of Gastrointestinal Endoscopy, and the Crohn's and Colitis Foundation. She is trained in and passionate about intestinal ultrasound in IBD patient care.

**Dr. Abraham** reports the following relationships:

Consultant: AbbVie Inc.; Bristol Myers Squibb; Celltrion Inc.; Johnson & Johnson; Lilly; Medtronic; Pfizer Inc.; Prometheus Laboratories; Samsung Bioepis; and Takeda Pharmaceuticals U.S.A., Inc.

Speakers Bureau: AbbVie Inc.; Bristol Myers Squibb; Johnson & Johnson; Lilly; Pfizer Inc.; and Takeda Pharmaceuticals U.S.A., Inc.

**MARITA KAMETAS, MSN, APN, FNP-BC, CMSRN, COCN**
*Inflammatory Bowel Disease Advanced Practice Nurse*
*Manager of Gastroenterology Advanced Practice Provider Services*
*The University of Chicago Medicine*
*Chicago, IL*

Marita Kametas, MSN, APN, FNP-BC, CMSRN, COCN, is a family nurse practitioner and ostomy specialist who treats adult patients with inflammatory bowel disease (IBD). She serves as the manager for the Advanced Practice Gastroenterology Service at the University of Chicago in Illinois. She volunteers her time as a mentor for the Crohn's and Colitis Advanced Practice Provider (APP) mentorship program and delivers empowering lectures to APPs to optimize their care of patients with IBD. She was awarded the honor of Distinguished APP of 2023 at the University of Chicago. She is currently pursuing a doctorate in nursing practice and a master's degree in public health at Johns Hopkins University in Baltimore, Maryland with an emphasis on diversity, equity, and inclusion.

**Ms. Kametas** reports the following financial relationships:

Advisory Board: Lilly and Pfizer Inc.

Consultant: TKG Therapeutics, Inc.

Grants: GI Research Foundation

Speakers Bureau: Abbvie Inc.; Janssen. Pharmaceuticals, Inc.; and Pfizer Inc.

**UMA MAHADEVAN, MD**
*Lynne and Marc Benioff Professor of Gastroenterology*
*Director, Colitis and Crohn's Disease Center*
*Director, Advanced IBD Fellowship*
*Division of Gastroenterology, Department of Medicine*
*University of California San Francisco*
*San Francisco, CA*

Uma Mahadevan, MD, is the Lynne and Marc Benioff Professor of Gastroenterology, Director of the Colitis and Crohn's Disease Center, and Director of the Advanced IBD Fellowship at the University of California San Francisco (UCSF). She completed her medical degree at the State University of New York in Brooklyn, her residency in internal medicine at Mount Sinai Medical Center in New York, her fellowship in gastroenterology at UCSF, and her Advanced Fellowship in IBD at the Mayo Clinic in Rochester, Minnesota. For her exceptional work in pregnancy and drug safety and her mentoring of GI fellows and junior faculty, she received the American Gastroenterological Association (AGA) 2022 Immunology, Microbiology & Inflammatory Bowel Diseases (IMIBD) Section Research Mentor Award and the 2022 Sherman Prize.

Dr. Mahadevan is a fellow of the AGA, for whom she was Chair for the IMIBD Section, Chair of the AGA National IBD Parenthood Initiative, and Director (2023) and Co-Director (2022, 2017) of the AGA Postgraduate Course. She is a fellow of the American College of Gastroenterology and served on the Educational Affairs Committee and as a member of the Advanced IBD Fellow Curriculum Committee. She is an inaugural councilor at the ASGE Artificial Intelligence Institute for Gastroenterology. She was Chair of the Crohn's Colitis Foundation Clinical Research Grants committee, a member of the National Scientific Advisory Committee and Taskforce on Women in IBD, and Co-Chair of the annual Crohn's Colitis Congress (2020). Dr. Mahadevan is a member of the International Organization of IBD (IOIBD) and serves on the nominating committee.

Dr. Mahadevan is a global expert on the management of pregnancy and drug safety in patients with IBD. She chairs the Helmsley Global Consensus on Management of Pregnancy in IBD (2024) and the joint AGA and Society of Maternal Fetal Medicine Clinical Care Pathway on the Management of IBD in Pregnancy (2019). She is interested in the role of diet in IBD and has an ongoing original study in this area. Her current projects include a national prospective registry of pregnancy outcomes and drug safety in women with IBD on immunosuppressive and biologic medications (PIANO) and a clinical trial on the impact of nutritional interventions in the management of IBD (SEAMUS). She has an interest in digital health and led the transition of the GI division to telemedicine at the start of the pandemic in March 2020, and developed an IBD chatbot with the Center for Digital Health and Innovation at UCSF as well as the IBD Smartnote.

Dr. Mahadevan has served on many prestigious journals, including special section editor for *Gastroenterology*. She is proud to have mentored several Advanced IBD Fellows who now hold key roles in IBD centers across the United States.

**Dr. Mahadevan** reports the following financial relationships:

Advisory Board: Data Safety Monitoring Board (DSMB): Merck & Co., Inc.

Consultant: AbbVie Inc.; Bristol Myers Squibb; Boehringer Ingelheim; Celltrion Inc; Enveda Biosciences; Gilead Sciences, Inc.; Janssen Pharmaceuticals, Inc.; Lilly; Pfizer Inc; Protagonist Therapeutics Inc.; Rani Therapeutics; Roivant Sciences; and Takeda Pharmaceuticals U.S.A., Inc.

Grants: The Leona M. and Harry B. Helmsley Charitable Trust

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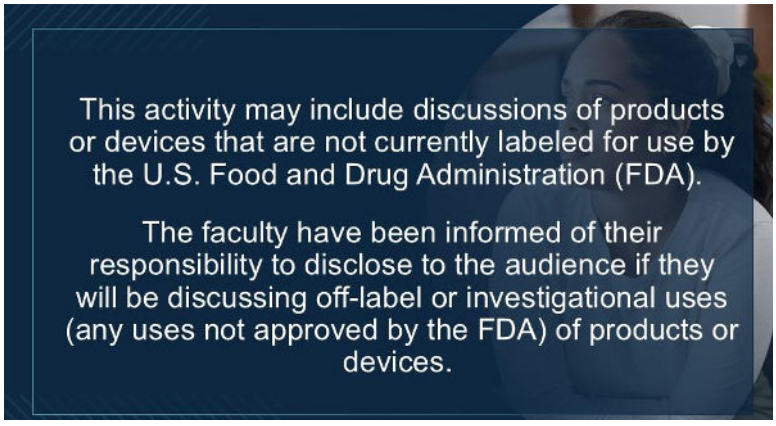


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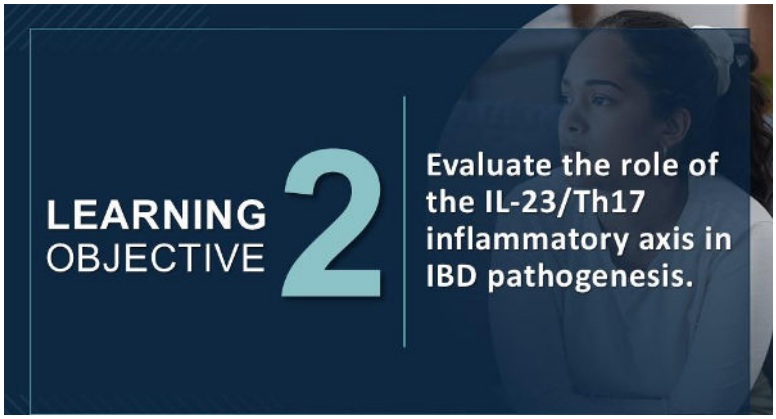
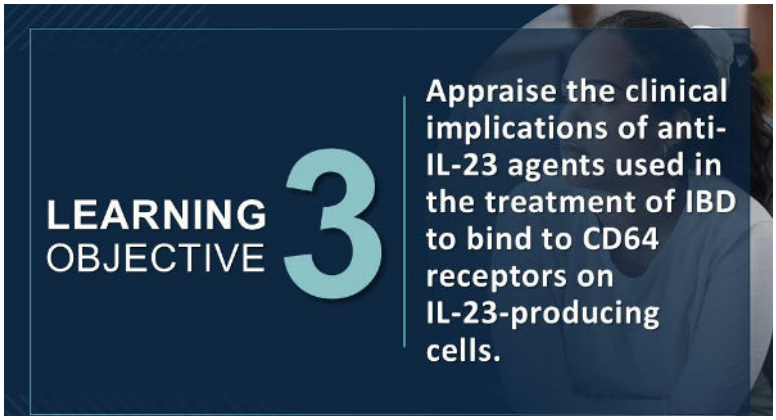
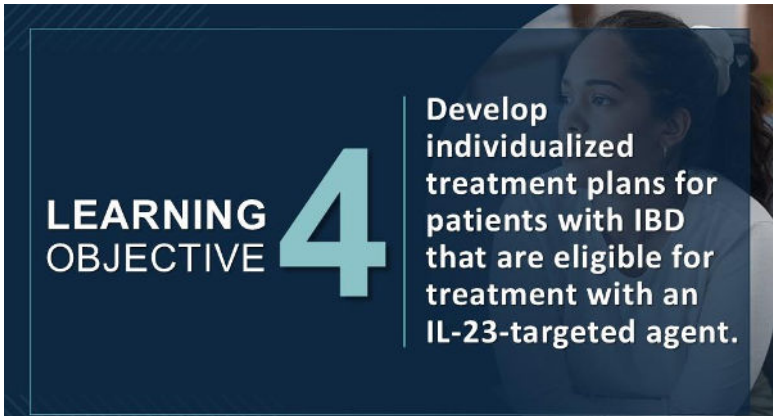
LEARNING OBJECTIVE 1
Identify the role of pro-inflammatory cytokines in the pathogenesis of IBD.


LEARNING OBJECTIVE 2
Evaluate the role of the IL-23/Th17 inflammatory axis in IBD pathogenesis.


LEARNING OBJECTIVE 3
Appraise the clinical implications of anti-IL-23 agents used in the treatment of IBD to bind to CD64 receptors on IL-23-producing cells.


LEARNING OBJECTIVE 4
Develop individualized treatment plans for patients with IBD that are eligible for treatment with an IL-23-targeted agent.

## Audience Response - Icebreaker

**What factors most heavily influence your selection of therapy for IBD? Pick your top 3.**

A. Treatment mechanism of action
B. Clinical trial safety/efficacy data
C. Severity of disease
D. Patient preference
E. Route/ease of administration
F. Experience with a particular treatment

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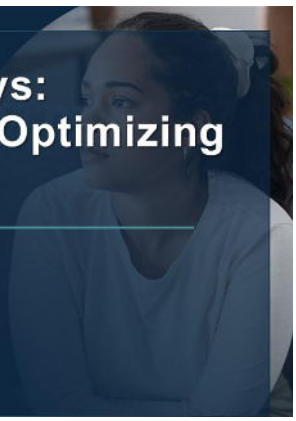
## Illuminating Pathways: IL-23/Th17 Axis and Optimizing IL-23 Inhibition



Uma Mahadevan, MD

## Why Target IL-23 in IBD?

- Inhibition of IL-23
  - Decreases mucosal inflammation
  - Improves epithelial barrier integrity
  - Suppresses gut inflammation in T-cell mediated colitis
- Anti-IL-23 therapy preserves protective IL-17 gut functions
  - Animal models of IL-17 blockade - mixed results
  - Trials of anti-IL-17A/IL-17A receptor antagonists in IBD resulted in worse outcomes vs placebo

IBD = inflammatory bowel disease.
Hohenberger M, et al. *J Dermatolog Treat*. 2018;29(1):13-18. Vuyuru SK, et al. *Drugs*. 2023;83(10):873-891. Wallace KL, et al. *World J Gastroenterol*. 2014;20(1):6-21.

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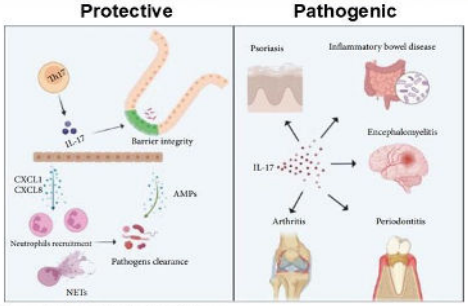
## Role of IL-17: Pathogenic and Protective Immunity




AMPs = antimicrobial peptides; NETs = neutrophil extracellular traps; Th = T helper cell.
Sun L, et al. *J Immunol Res*. 2023;1:3360310.

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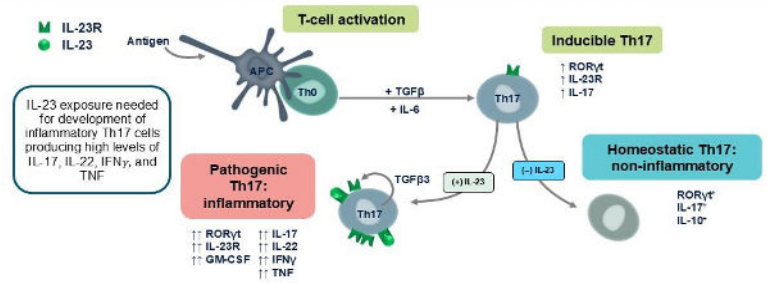
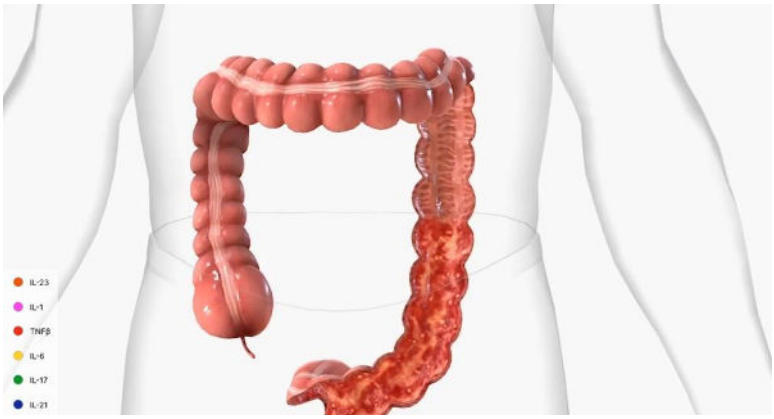
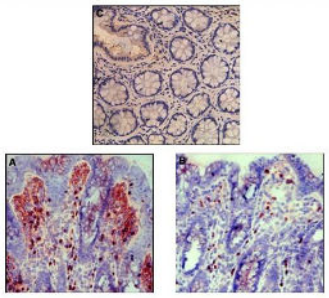
## IL-23 Drives Development of Inflammatory Pathogenic Th17 Cells

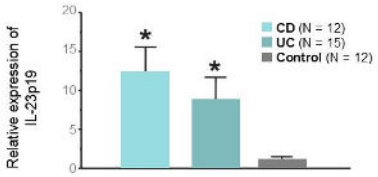



APC = antigen-presenting cell; GM-CSF = granulocyte-macrophage colony-stimulating factor; IFN = interferon; RORγt = retinoic acid receptor-related orphan receptor gamma t; TGF = transforming growth factor; TNF = tumor necrosis factor.
Adapted from Zúñiga LA, et al. *Immunol Rev*. 2013;252(1):78-89. Gaffen SL, et al. *Nat Rev Immunol*. 2014;14(9):585-600. Schmitt H, et al. *Front Immunol*.



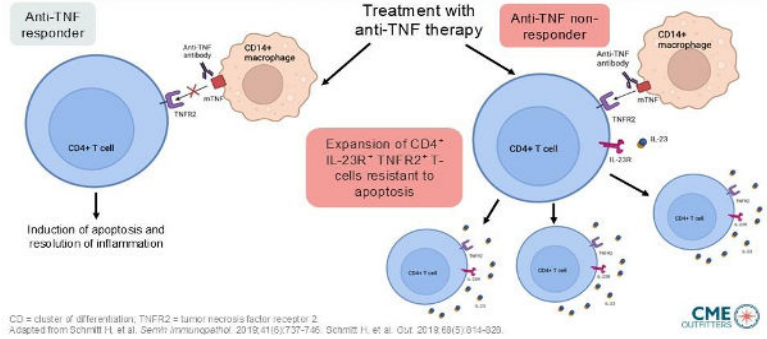

## IL-23 Expression in Patients with IBD



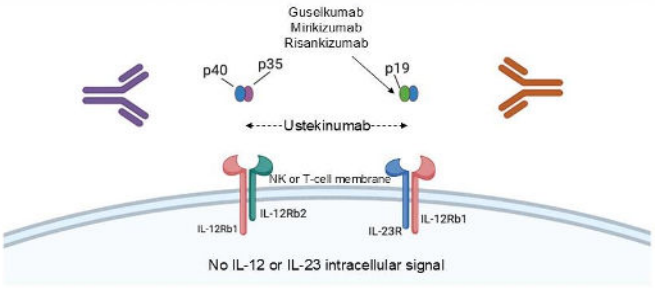

CD = Crohn's disease; UC = ulcerative colitis.

## IL-23 Mediated Resistance to Anti-TNF




CD = cluster of differentiation; TNFR2 = tumor necrosis factor receptor 2.
Adapted from Schmitt H, et al. *Semin Immunopathol*. 2019;41(6):737-746. Schmitt H, et al. *Gut*. 2019;68(5):814-828.

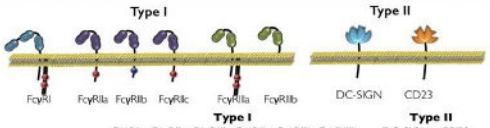
## Anti-p40 (IL-12/23) and Anti-p19 (IL-23)




NK = natural killer cell.
Adapted from Gately MK, et al. *Annu Rev Immunol*. 1998;16(1):495-521. Wilson NJ, et al. *Nat Immunol*. 2007;8(9):950-957. Nickoloff BJ, et al. *J Clin Invest*. 2004;113(12):1664-1675. Nestle FO, et al. *J Invest Dermatol*. 2004;123(6):xiii-xv. Created with Biorender.

## Importance of Fcγ Receptors and CD64 Receptors

- Fcγ receptors: surface receptors on immune cells that recognize the Fc portion of IgG
- CD64 (FcγRI) is the only Fcγ receptor with high affinity for IgG1
- CD64+ cells are the primary cellular source of IL-23 in IBD



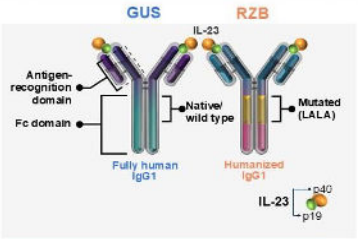

| | Type I | | | | | | Type II | |
|---|---|---|---|---|---|---|---|---|
| | FcγRI | FcγRIIa | FcγRIIb | FcγRIIc | FcγRIIIa | FcγRIIIb | DC-SIGN | CD23 |
| Neutrophils | # | + | + | - | - | + | - | # |
| Eosinophils | # | + | + | - | - | # | - | # |
| Basophils | # | + | + | - | - | +/- | - | # |
| Monocytes | + | + | + | - | +/- | - | - | # |
| Macrophages | +/- | + | + | - | +/- | - | +/- | # |
| Dendritic cells | -/# | + | + | - | -/# | - | + | - |
| Platelets | - | + | - | - | - | - | - | - |

\+ Constitutive expression
\- No expression
\# Inducible expression

IgG = immunoglobulin G.
Bournazos S, et al. *Microbiol Spectr*. 2018;4(6):10.

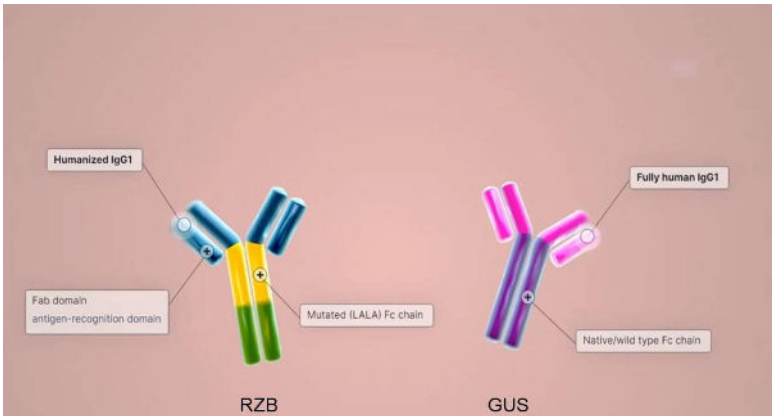
## Differences Between GUS and RZB Molecular Attributes

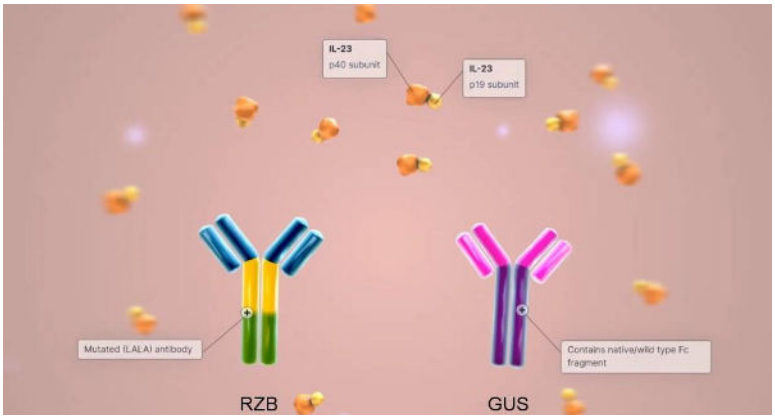
- Guselkumab (GUS) and risankizumab (RZB) are mAbs that selectively target the p19 subunit of IL-23
- GUS and RZB have shown efficacy in the treatment of inflammatory bowel diseases
- Potential differences in the therapeutic profiles may be related to their unique molecular attributes
- GUS and RZB have differences in the Fc region that affect binding to Fc-gamma receptors

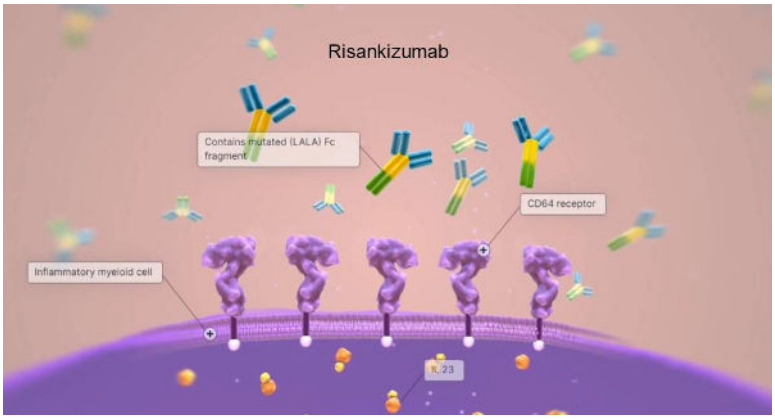


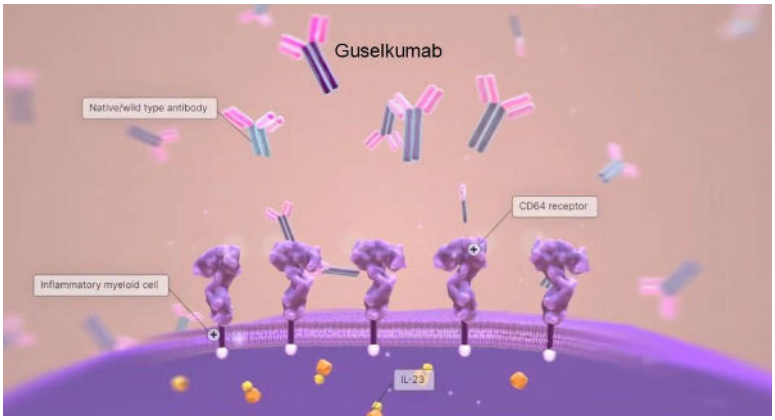

**Objective:** Examine the binding and functional characteristics of the antigen-binding and Fc regions of GUS and RZB

Fc = fragment crystallizable; LALA = leucine to alanine substitutions at positions 234 and 235; mAbs = monoclonal antibodies.
Guselkumab is indicated for the treatment of adults with moderately to severely active UC. Risankizumab is indicated for the treatment of adults with moderately to severely active CD and treatment of adults with moderately to severely active UC.
D'Haens G, et al. *Lancet*. 2022;399(10340):2015-2030. Ferrante M, et al. *Lancet*. 2022;399(10340):2031-2046. Sandborn WJ, et al. *Gastroenterology*. 2022;162(6):1650-1664. Digiorgio A, et al. *J Crohns Colitis*. 2022;16(Suppl 1):i025-i026. Louis E, et al. *Aliment Pharmacol Ther*. 2004;19(5):511-519. Vos AC, et al. *Gastroenterology*. 2011;140(1):221-230. Wajjal KA, et al. *PLoS One*. 2012;7(8):e43361.



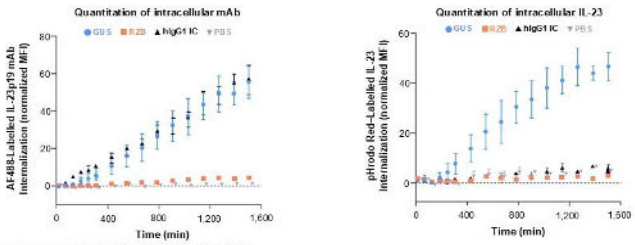



## In Vitro Evaluations of CD64 and IL-23 Binding: Guselkumab and Risankizumab

**Quantitation of mAb MFI and IL-23 MFI in intracellular compartments of CD64+ inflammatory macrophages following treatment with IL-23p19 mAbs and IL-23**

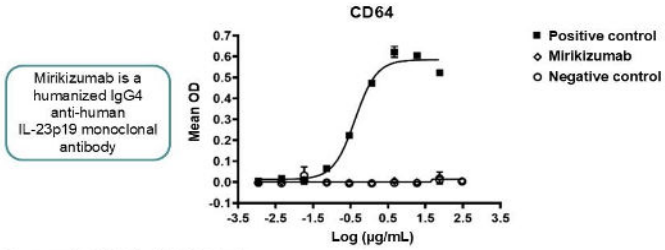



MFI = mean fluorescence intensity; PBS = phosphate buffered saline.
Guselkumab is indicated for the treatment of adults with moderately to severely active UC. Risankizumab is indicated for the treatment of adults with moderately to severely active CD and treatment of adults with moderately to severely active UC.
Atreya R, et al. *J Crohns Colitis*. 2024;18(Suppl 1):i470.

CME OUTFITTERS

## In Vitro Evaluations of CD64 and IL-23 Binding: Mirikizumab (MIRI)

**Assessment of Fc Receptor Activation and Complement Binding**




Data are mean ± standard deviation (SD) of duplicate wells.
Mirikizumab is indicated for the treatment of adults with moderately to severely active UC.
Steere B, et al. *J Pharmacol Exp Ther*. 2023;387(2):190-197.

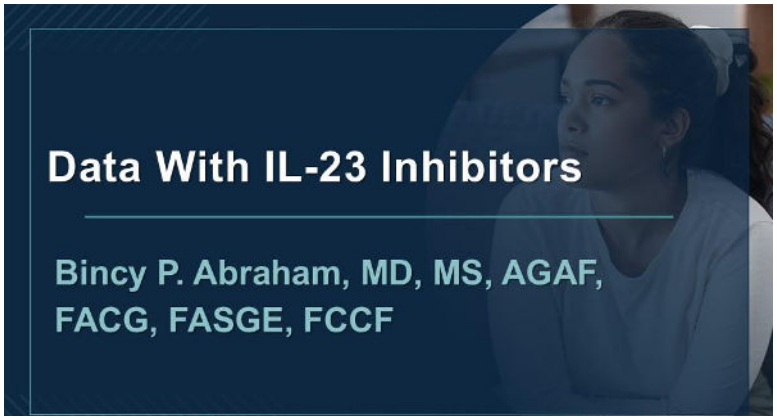
CME OUTFITTERS

## Audience Response

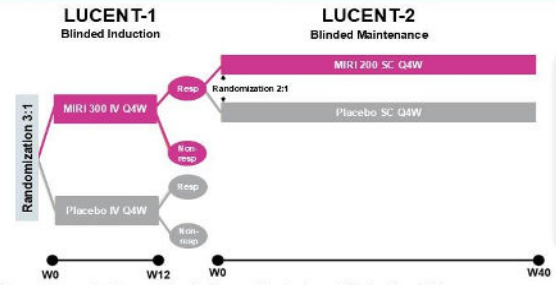
**Which of the following is true regarding binding affinity of IL-23 inhibitors to CD64 receptors?**

A. Binding of CD64 occurs with only risankizumab
B. Binding of CD64 occurs with only guselkumab
C. Binding of CD64 occurs with only mirikizumab
D. Binding of CD64 occurs with risankizumab, guselkumab, and mirikizumab

CME OUTFITTERS




## Mirikizumab in UC: LUCENT-1 and LUCENT-2

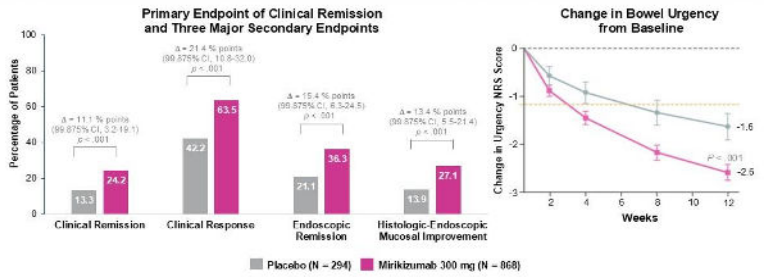



**Induction:** N = 1,281 adults with an incomplete response to, loss of response to, or inability to take conventional treatment, biologic therapy, or JAKis were assigned in a 3:1 ratio to receive MIRI (300 mg) or placebo IV every 4 weeks for 12 weeks

**Maintenance:** N = 544 adults with a clinical response to MIRI at week 12 were reassigned in a 2:1 ratio to receive MIRI (200 mg) or placebo SC every 4 weeks for 40 weeks

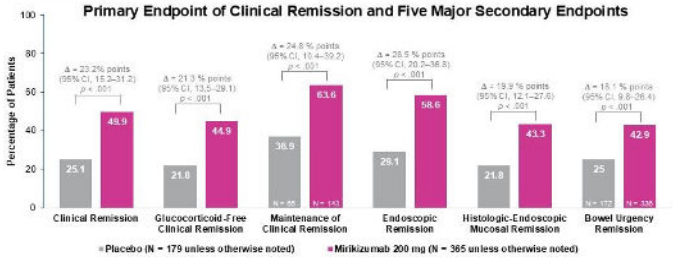
Non-resp = non-responders; Resp = responders; IV = intravenous; SC = subcutaneous; JAKi = Janus kinase inhibitor.
Clinical response: ≥ 2-point and ≥ 30% decrease in the modified Mayo score (MMS) from baseline with RB = 0 or 1, or ≥ 1-point decrease from baseline.
Maintenance randomization was stratified by induction remission status, biologic failure status, baseline corticosteroid use, and world region.
Mirikizumab is indicated for the treatment of adults with moderately to severely active UC.
D'Haens G, et al. *N Engl J Med*. 2023;388(26):2444-2455.

## Mirikizumab in UC Induction: LUCENT-1




NRS = numeric rating scale
Mirikizumab is indicated for the treatment of adults with moderately to severely active UC.
D'Haens G, et al. *N Engl J Med*. 2023;388(26):2444-2455.

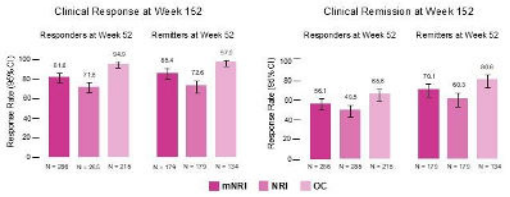
## Mirikizumab in UC Maintenance: LUCENT-2 Week 40 Endpoints




Clinical remission: stool frequency (SF) = 0, or SF = 1 with ≥ 1-point decrease from baseline; rectal bleeding (RB) = 0; endoscopic subscore (ES) = 0 or 1 (excluding friability); endoscopic remission: ES = 0 or 1 (excluding friability), clinical remission at week 40, remission of symptoms at week 28, and no glucocorticoid use for ≥ 12 weeks before week 40.
Mirikizumab is indicated for the treatment of adults with moderately to severely active UC.
D'Haens G, et al. *N Engl J Med*. 2023;388(26):2444-2455.

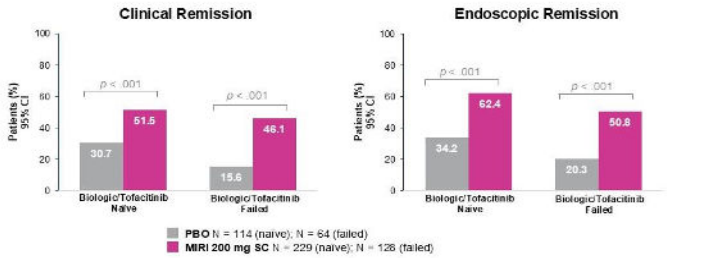
## Mirikizumab Maintenance in UC: Long-Term Follow-up from LUCENT-3

**LUCENT-3 open-label extension study of patients completing 52 weeks of maintenance treatment in LUCENT-2**



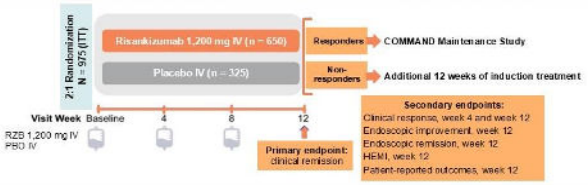

NRI = non-responder imputation; mNRI = modified NRI; OC = observed case.
Clinical remission: SF = 0 or 1 with ≥ 1-point decrease in modified Mayo score (MMS) from baseline, RB = 0, and ES = 0 or 1 (excluding friability).
Clinical response: ≥ 2-point and ≥ 30% decrease in the MMS from baseline, RB = 0 or 1, or RB ≥ 1-point decrease from baseline.
Mirikizumab is indicated for the treatment of adults with moderately to severely active UC.
Sands BE, et al. *Inflamm Bowel Dis*. 2024 ise253.

## Mirikizumab in Treatment-Naïve and Treatment-Experienced Patients with UC: LUCENT-2




PBO = placebo.
Mirikizumab is indicated for the treatment of adults with moderately to severely active UC.
D'Haens G, et al. *N Engl J Med*. 2023;388(26):2444-2455.

## Risankizumab in UC: INSPIRE/COMMAND

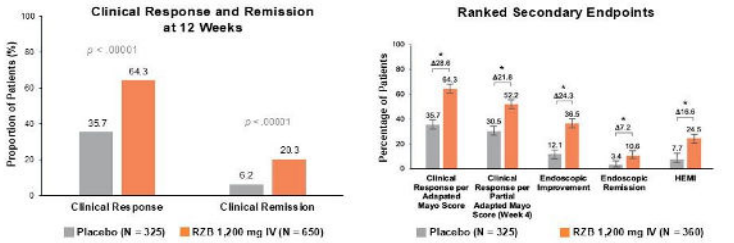



**Key Inclusion Criteria:**

- Age 18 to 80
- **Moderately to severely active UC:** Adapted Mayo score of 5-9 and endoscopic subscore of 2-3 (central review) with biopsy-confirmed diagnosis at least 3 months prior to baseline
- **Intolerance or inadequate response to conventional (non-advanced) and/or advanced therapies** (biologics, JAKis, and S1P receptor modulators)
- No prior exposure to ustekinumab or IL-23 inhibitors was permitted

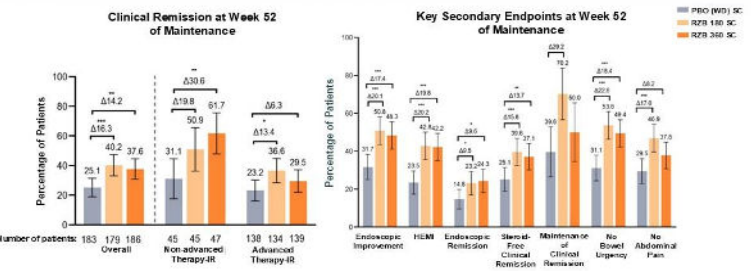
HEMI = histologic-endoscopic mucosal improvement.
Louis E, et al. *JAMA*. 2024;332(11):881-897.

## Risankizumab Induction in UC: INSPIRE



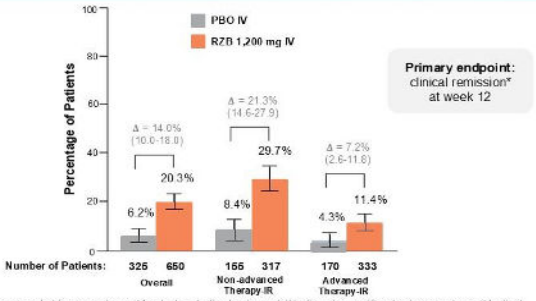

*p value < .00001 vs PBO.
Clinical remission per Adapted Mayo Score is defined as stool frequency subscore (SFS) ≤ 1 and not greater than baseline, rectal bleeding subscore (RBS) of 0 and endoscopic subscore ≤ 1 without friability. Clinical response is defined as a decrease from baseline in the Adapted Mayo score ≥ 2 points and ≥ 30% from baseline, plus a decrease in RBS ≥ 1 or an absolute RBS ≤ 1.
Risankizumab is indicated for the treatment of adults with moderately to severely active UC.
Louis E, et al. *Am J Gastroenterol*. 2023;118(10S):S624-S625.

## Risankizumab Maintenance in UC: COMMAND




PBO (WD) = placebo-controlled withdrawal.
*p ≤ .05; **p ≤ .01; ***p ≤ .001 versus PBO (WD) SC.
Risankizumab is indicated for the treatment of adults with moderately to severely active UC and CD.
Louis E, et al. *J Crohns Colitis*. 2024;18(Suppl 1):i10-i12.

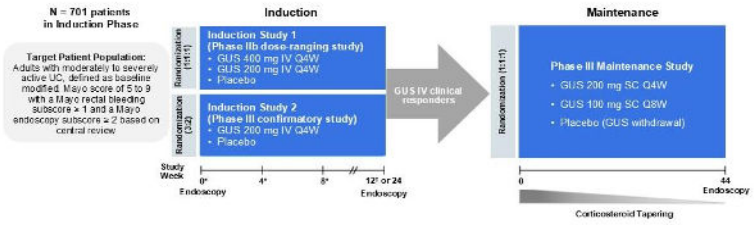
## Risankizumab in Treatment-Naïve and Treatment-Experienced Patients with UC: INSPIRE




IR = inadequate responders.
*Clinical remission per adapted Mayo score; stool frequency subscore ≤ 1 and not greater than baseline, rectal bleeding subscore of 0, and endoscopic subscore ≤ 1 without friability.
Risankizumab is indicated for the treatment of patients with moderately to severely active UC.
Louis E, et al. JAMA. 2024;332(11):881-897.

CME OUTFITTERS

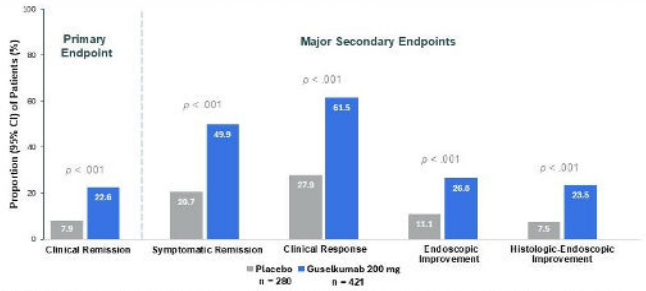
## Guselkumab in UC: QUASAR




Q4W = every 4 weeks; Q8W = every 8 weeks.
*Study treatment administered. †Study treatment administered to week 12 clinical non-responders.
Guselkumab is indicated for the treatment of adults with moderately to severely active UC.
Peyrin-Biroulet L, et al. Gastroenterology. 2023;165(6):1443-1457. Allegretti JR, et al. Gastroenterology. 2023;164(6):S-1572.

CME OUTFITTERS

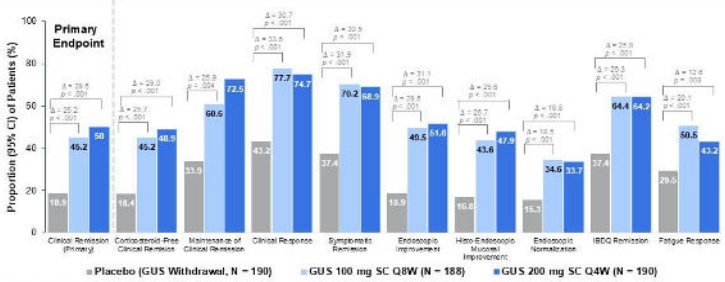
## Guselkumab in UC Induction: QUASAR Phase III Week 12 Endpoints




Clinical remission defined as a Mayo stool frequency subscore of 0 or 1 with no increase from baseline, a rectal bleeding subscore of 0, and a Mayo endoscopy subscore of 0 or 1 with no friability.
Guselkumab is indicated for the treatment of adults with moderately to severely active UC.
Allegretti J. Digestive Disease Week (DDW); 2023. Abstract No. 913b. Gastroenterol Hepatol. 2023;19(7 Suppl 3):9-10. https://pmc.ncbi.nlm.nih.gov/articles/PMC10910368/.

CME OUTFITTERS

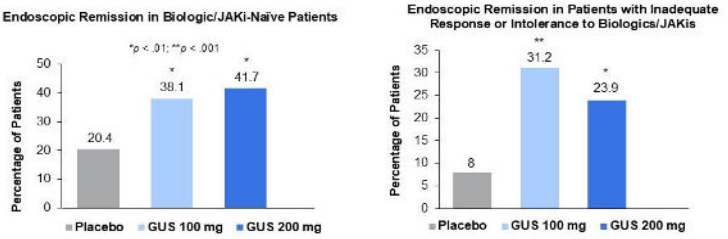
## Guselkumab in UC Maintenance: QUASAR Phase III Week 44 Endpoints




IBDQ = IBD questionnaire.
Primary analysis population: randomized patients with a modified Mayo score of 5-9 at induction who received at least one maintenance study treatment dose.
Guselkumab is indicated for the treatment of adults with moderately to severely active UC.
Rubin DT, DDW; 2024. Abstract No. 759. https://ddw.digitellinc.com/p/s/the-efficacy-and-safety-of-guselkumab-as-maintenance-therapy-in-patients-with-moderately-to-severely-active-ulcerative-colitis-results-from-the-phase-3-quasar-maintenance-study/759

CME OUTFITTERS

## GUS in Treatment-Naïve and Treatment-Experienced Patients with UC at Week 44: QUASAR




BIO = biologic.
Guselkumab is indicated for the treatment of adults with moderately to severely active UC.
Allegretti JR, et al. United European Gastroenterology Week (UEGW). 2024. Abstract No. OP082. https://www.ueg.eu/UEGWeek/ueg-journal-abstracts-2024/index.php#/p/74.

## Mirikizumab Safety in UC

| Outcome, n (%) | 200 mg Mirikizumab Q4W SC (n = 289) |
|---|---|
| TEAEs | 184 (63.7) |
| AEs of special interest: | |
| Infections (all) | 87 (30.1) |
| Infections (serious) | 3 (1.0) |
| Cerebrocardiovascular events | 2 (0.7) |
| Malignancies | 0 (0) |
| Immediate hypersensitivity reaction | 4 (1.4) |
| Injection site reactions | 16 (5.5) |
| Death | 0 (0) |
| Discontinuation due to AE | 8 (2.8) |

AE = adverse event.
Sands BE, et al. *Inflamm Bowel Dis*. 2024;30(12):2245-2258.

## Rizankizumab Safety in UC

**Treatment-Emergent AEs Among Safety Population Through Week 52[a]**

| Events/100 Patient Years | PBO (WD) SC n = 196; PY = 174.9 | RZB 180 mg SC n = 193; PY = 185.4 | RZB 360 mg SC n = 195; PY = 173.5 |
|---|---|---|---|
| Any AE | 399 (228.1) | 399 (215.2) | 406 (234.0) |
| AE related to COVID-19 | 28 (16.0) | 21 (11.3) | 29 (16.7) |
| AE with reasonable possibility of being drug-related[b] | 75 (42.9) | 85 (45.9) | 61 (35.2) |
| Severe AE | 14 (8.0) | 3 (1.6) | 7 (4.0) |
| Serious AE | 20 (11.4) | 11 (5.9) | 11 (6.3) |
| AE leading to discontinuation of study drug | 4 (2.3) | 5 (2.7) | 5 (2.9) |
| All deaths | 0 | 0 | 1 (0.6)[c] |
| Serious infections[d] | 4 (2.3) | 2 (1.1) | 1 (0.6) |
| Infusion/injection site reactions[e] | 3 (1.7) | 14 (7.6) | 10 (5.8) |

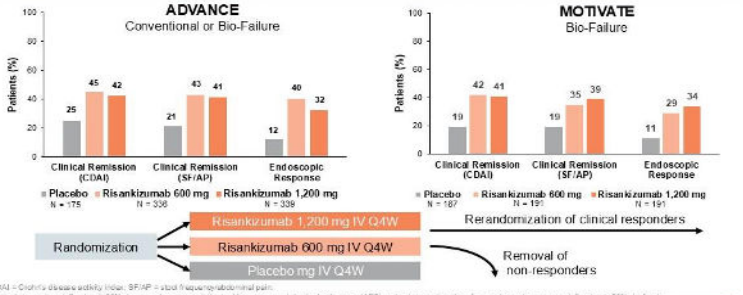
PY = patient years.
[a]The safety population included all patients who clinically responded to IV RZB at 12 or 24 weeks, were randomized to COMMAND at maintenance week 0 and received at least one dose of study drug during 52-week maintenance period. [b]As assessed by the investigator. [c]One death was reported in the RZB 360 mg arm in a patient diagnosed with colon adenocarcinoma, which was retrospectively found in the screening biopsy tissue. [d]Serious infections in RZB-treated patients included COVID-19, COVID-19 pneumonia, abscess limb, and pneumonia. [e]All infusion/injection site reaction events were nonserious and did not lead to study discontinuation.
Louis E, et al. *J Crohns Colitis*. 2024;18(Suppl 1):i10-i12.

## Guselkumab Safety in UC

| Outcome | Placebo (n = 105) | Guselkumab 200 mg IV (n = 101) | Guselkumab 400 mg IV (n = 107) | Combined (n = 208) |
|---|---|---|---|---|
| Any AE | 59 (56.2) | 45 (44.6) | 53 (49.5) | 98 (47.1) |
| AE within 1 hour of infusion | 2 (1.9) | 2 (2.0) | 0 | 2 (1.0) |
| Serious AE | 6 (5.7) | 1 (1.0) | 3 (2.8) | 4 (1.9) |
| Death | 0 | 0 | 0 | 0 |
| Discontinuation for AE | 3 (2.9) | 1 (1.0) | 0 | 1 (0.5) |
| Malignancy | 0 | 0 | 0 | 0 |
| Infection | 13 (12.4) | 14 (13.9) | 10 (9.3) | 24 (11.5) |
| Serious Infection | 2 (1.9) | 0 | 0 | 0 |

Peyrin-Biroulet L, et al. *Gastroenterology*. 2023;165(6):1443-1457.

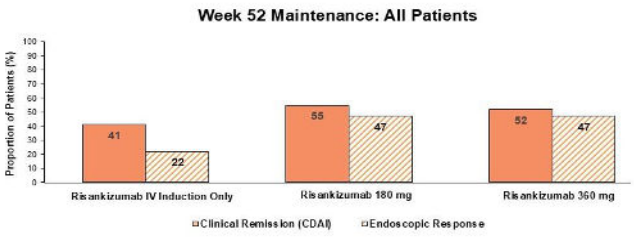

## ADVANCE and MOTIVATE: Risankizumab Induction in CD




CDAI = Crohn's disease activity index; SF/AP = stool frequency/abdominal pain.
Clinical responders defined as ≥ 30% decrease in average daily stool frequency or abdominal pain score (APS) and not worse than baseline; endoscopic response defined as ≥ 50% decline in simple endoscopic score (SES-CD) vs baseline by central reviewer (or in patients with SES-CD of 4 at baseline, ≥ 2-point decrease vs baseline); CDAI clinical remission = a CDAI < 150.
Risankizumab is approved for the treatment of adults with moderately to severely active CD.
D'Haens G, et al. *Lancet*. 2022;399(10340):2015-2030. Ferrante M, et al. *Lancet*. 2022;399(10340):2031-2046.

CME OUTFITTERS

## FORTIFY: Risankizumab Maintenance in CD

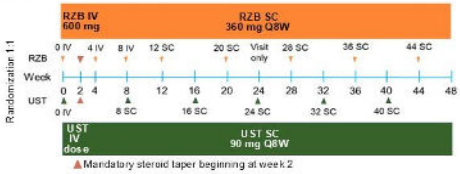



Endoscopic response defined as > 50% decline in SES-CD vs baseline by central reviewer (or in patients with SES-CD of 4 at baseline, ≥ 2-point decrease vs baseline); CDAI clinical remission a CDAI < 150.
Risankizumab is approved for the treatment of adults with moderately to severely active CD.
Ferrante M, et al. *Lancet*. 2022;399(10340):2031-2046.

CME OUTFITTERS

## RZB vs UST in Patients with CD: Phase IIIb SEQUENCE Trial

**Stratification Factors:**
- Number of prior anti-TNF failure (1, > 1)
- Corticosteroid use at baseline (yes or no)




**Key Eligibility Criteria:**

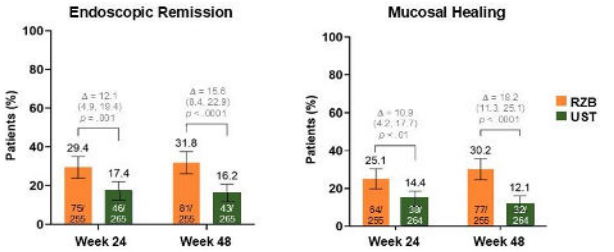
Moderate to severe CD: CDAI 220-450
- Average daily SF ≥ 4 and/or average daily APS ≥ 2
- SES-CD, excluding the narrowing component, ≥ 6 (≥ 4 for isolated ileal disease), as scored by the site investigator and confirmed by a central reader

Prior failure of ≥ 1 anti-TNF therapies
- Prior biologic therapy that could potentially influence the therapeutic impact on CD was exclusionary, including vedolizumab

Risankizumab and ustekinumab are approved for the treatment of adults with moderately to severely active CD.
Peyrin-Biroulet L, et al. *N Engl J Med*. 2024;391:213-223.

CME OUTFITTERS

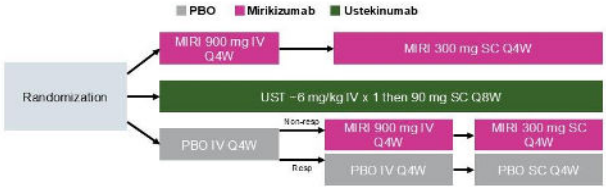
## RZB vs UST in Patients with CD: Phase IIIb SEQUENCE Trial




Risankizumab and ustekinumab are approved for the treatment of adults with moderately to severely active CD.
Peyrin-Biroulet L, et al. *N Engl J Med*. 2024;391:213-223.

CME OUTFITTERS

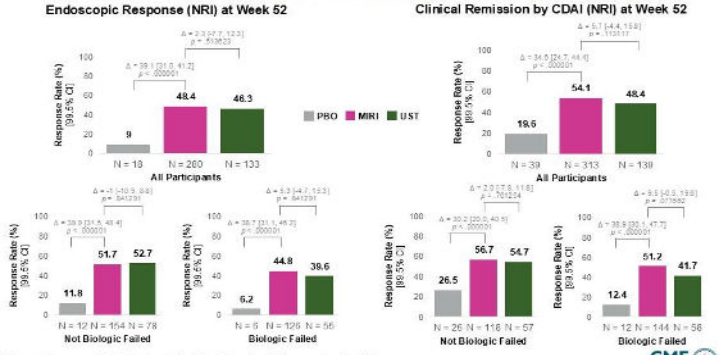
## VIVID-1: MIRI vs UST in Moderate-to-Severe CD




Mirikizumab is approved for the treatment of adults with moderately to severely active CD.
Ferrante M, et al. *Lancet*. 2024;404(10470):2423-2436.

CME OUTFITTERS

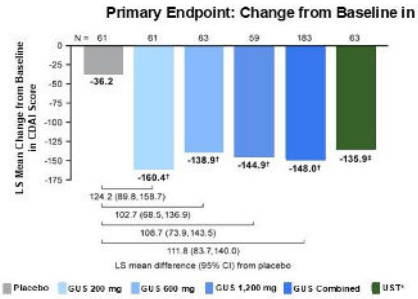
## VIVID-1: MIRI vs UST in Moderate-to-Severe CD




Mirikizumab is approved for the treatment of adults with moderately to severely active CD.
Ferrante M, et al. *Lancet*. 2024;404(10470):2423-2436.

CME OUTFITTERS

## GUS vs UST in CD at 12 Weeks: GALAXI-1



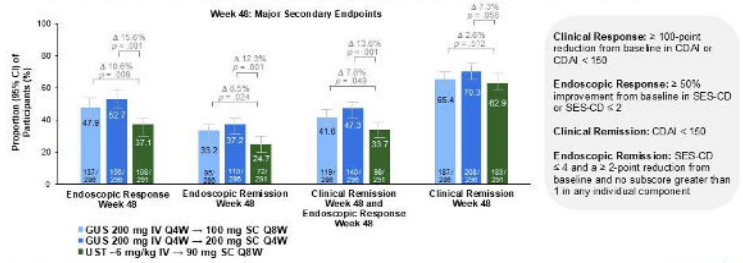

- GALAXI-1 is a DBPC trial
- Randomized patients 1:1:1:1 to
  - IV GUS at weeks 0, 4, 8
  - IV UST at week 8
  - Placebo
- UST was a reference arm
- N = 309

DBPC = double-blind placebo controlled; LS = least squares.
*UST 6 mg/kg IV → 90 mg S.C.; †p value < .05 for GUS vs placebo; ‡nominal p value < .05 from post hoc analysis of UST vs placebo.
Guselkumab is not currently FDA-approved for CD.

CME OUTFITTERS

## GUS vs UST in CD at 48 Weeks: GALAXI 2 and 3

**GALAXI 2 and 3 are identical 48-week, randomized, double-blind, double-dummy, placebo, and active-comparator (UST) treat-through trials assessing the efficacy and safety of GUS in patients with moderately to severely active CD**




**Clinical Response:** ≥ 100-point reduction from baseline in CDAI or CDAI < 150

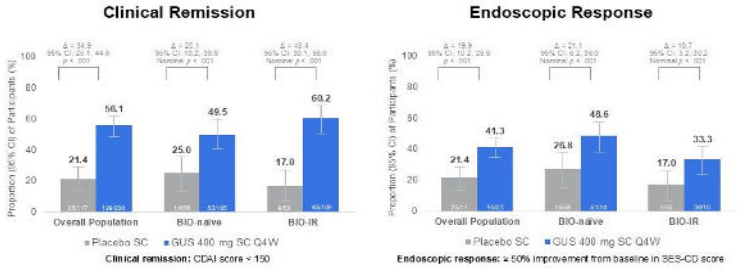
**Endoscopic Response:** ≥ 50% improvement from baseline in SES-CD or SES-CD ≤ 2

**Clinical Remission:** CDAI < 150

**Endoscopic Remission:** SES-CD ≤ 4 and a ≥ 2-point reduction from baseline and no subscore greater than 1 in any individual component

Guselkumab is not currently FDA-approved for CD.
Panaccione R, et al. DDW. 2024. Abstract No. 1057b. https://acrabstracts.org/abstract/efficacy-and-safety-of-guselkumab-therapy-in-patients-with-moderately-to-severely-active-crohns-disease-results-of-the-galaxi-2-3-phase-3-studies/

## Subcutaneous GUS in CD: Phase III GRAVITI Study




**Clinical remission:** CDAI score < 150

**Endoscopic response:** ≥ 50% improvement from baseline in SES-CD score

Guselkumab is not FDA-approved for use in CD.
Panaccione R, et al. American College of Gastroenterology [ACG] Annual Scientific Meeting; 2024. Abstract No. S1052. https://journals.lww.com/ajg/fulltext/2024/10001/s1052_efficacy_and_safety_of_subcutaneous_1053.aspx

## Safety of IL-23 Inhibitors in CD

| Adverse Event | Guselkumab N = 595 | Mirikizumab N = 630 | Risankizumab N = 373 |
|---|---|---|---|
| AEs | 458 (77.0%) | 495 (78.6%) | 210 (56%) |
| Serious AEs | 53 (8.9%) | 65 (11.5%) | 27 (7%) |
| Discontinuation due to AE | 40 (6.7%) | 32 (5.1) | 9 (2%) |
| Serious Infections | 4 (0.6%) | 14 (2.2%) | 0 |

D'Haens G, et al. Lancet. 2022;399(10340):2015-2030. Ferrante M, et al. Lancet. 2024;404(10470):2423-2436. Panaccione R, et al. DDW. 2024. Abstract No. 1057b. https://acrabstracts.org/abstract/efficacy-and-safety-of-guselkumab-therapy-in-patients-with-moderately-to-severely-active-crohns-disease-results-of-the-galaxi-2-3-phase-3-studies/

## Dosing of IL-23 Inhibitors in IBD

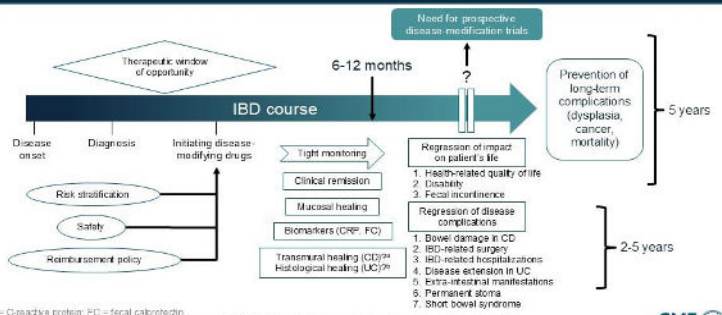
| Agent | UC Dose | | CD Dose | |
|---|---|---|---|---|
| | Induction | Maintenance | Induction | Maintenance |
| Guselkumab | 200 mg IV at week 0, 4, and 8 | 100 mg SC at week 16 and every 8 weeks thereafter **OR** 200 mg SC at week 12 and every 4 weeks thereafter | Not currently FDA approved for CD | - |
| Mirikizumab | 300 mg at week 0, 4, and 8 | 200 mg SC at week 12 and every 4 weeks thereafter | 900 mg IV at week 0, 4, and 8 | 300 mg SC at week 12 and every 4 weeks thereafter |
| Risankizumab | 1200 mg IV at week 0, 4, and 8 | 180 or 360 mg SC at week 12 and every 8 weeks thereafter | 600 mg IV at week 0, 4, and 8 | 180 or 360 mg SC at week 12 and every 8 weeks thereafter |

Guselkumab [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761061s000lbl.pdf. Mirikizumab [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761279s000lbl.pdf. Risankizumab [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/761105s000lbl.pdf.

# Where the Rubber Meets the Yellow Brick Road: Making IL-23 Targeted Agents Work in Practice

Corey A. Siegel, MD, MS

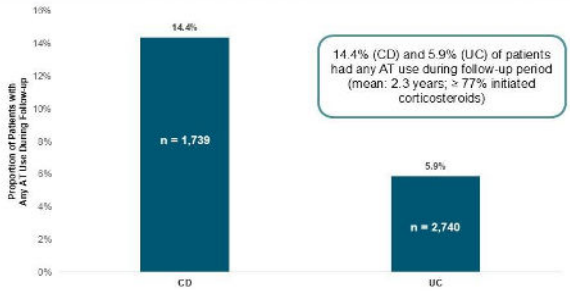
## Defining Goals for Treatment




CRP = C-reactive protein; FC = fecal calprotectin.
[a]Transmural healing may be the ultimate therapeutic goal in CD. [b]Histologic healing may be the ultimate therapeutic goal in UC.
Le Berre C, et al. *Gastroenterology*. 2022;162(5):1424-1438.

CME OUTFITTERS

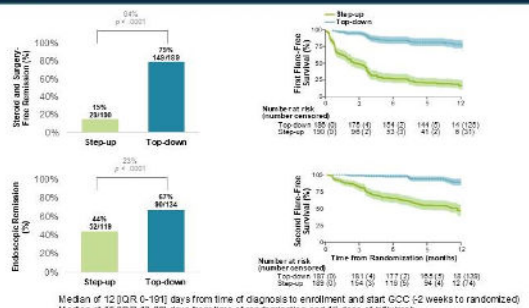
## Advanced Treatment (AT) Uptake Is Low Within the First Two Years of IBD Diagnosis




Siegel CA, et al. *Crohns Colitis 360*. 2024;6(3):otae040.

CME OUTFITTERS

## Early Effective Advanced Therapy Predicts CD Outcomes

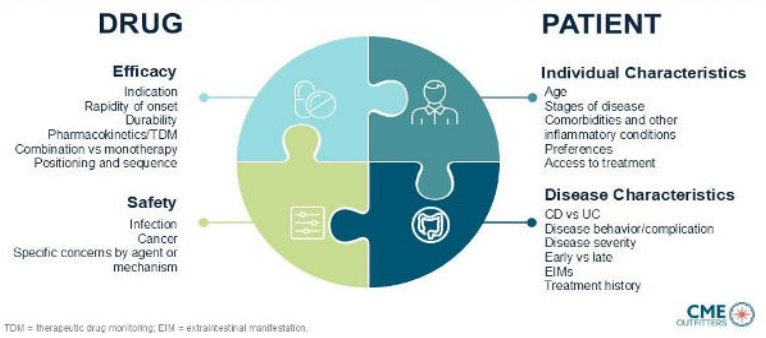



Median of 12 [IQR 6-191] days from time of diagnosis to enrollment and start GCC (≤2 weeks to randomized)
Median of 15 [IQR 13-20] days from time of randomization and 1st dose of infliximab

IQR = interquartile range; GCC = glucocorticoids.
Noor V, et al. *Lancet Gastroenterol Hepatol*. 2024;9(5):415-427.

CME OUTFITTERS

## How Do We Put Together the Puzzle of Therapy Selection?

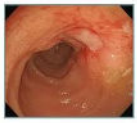



TDM = therapeutic drug monitoring; EIM = extraintestinal manifestation.

CME OUTFITTERS

## Patient Case: Jordan F.

- 19-year-old college student
- Concerned about changes in bathroom habits
- Weight: 89 kg, height: 191 cm (75 in)
- Current symptoms:
  - 3-month history of abdominal cramping
  - Approximately 3-4 loose stools/day
  - Unexplained weight loss (~10 pounds)
- Diagnosis:
  - Moderately active ileal Crohn's disease
- Medications:
  - Self-treatment with loperamide over the counter prior to diagnosis
  - No history of treatment with biologic agents or steroids



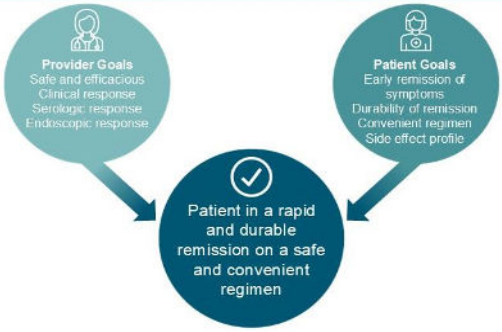
## Audience Response

### How would you treat this patient?

A. Initiate budesonide
B. Start mesalamine
C. Start vedolizumab
D. Start anti-TNF
E. Start IL-23 inhibitor
F. I'm not sure

CME OUTFITTERS

## Aligning on Treatment Goals with Patients




CME OUTFITTERS

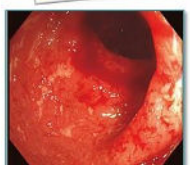
## Education to Ensure Alignment

| | | |
|---|---|---|
| **Treatment Selection** | Review the evidence in an accessible way | Foster shared decision-making |
| **Treat to Target** | Review goals during the treatment selection visit | Lean into immediate goals for symptom management and long-term goals to prevent complications in the future |
| **Treatment Maintenance** | Right dose of the right medication at the right time to capture adequate response | Treatment intensity dictated by inflammatory burden - be dynamic |

CME OUTFITTERS

## Patient Case: Halley J.

- 38-year-old woman with 2-year history of UC
- Currently being treated with adalimumab every 2 weeks
- Annual review of treatment plan
  - Concern for poor control of inflammation
- Current symptoms:
  - 5-8 stools per day, urgency and rectal bleeding
- Colonoscopy:
  - Active disease up to 65 cm, Mayo 2
- Labs:
  - Calprotectin 950 µg/mg
- CRP 3.9
- *C. diff* and infectious workup negative



## Audience Response

### What would you do next?

A. Change adalimumab dosing to weekly
B. Switch to infliximab
C. Switch to vedolizumab
D. Switch to ustekinumab
E. Switch to IL-23 inhibitor
F. Switch to S1P modulator
G. Switch to JAK inhibitor
H. I'm not sure

CME OUTFITTERS

## New AGA Living Guidelines on Treatment of Moderate to Severe UC

**ADVANCED THERAPY-NAÏVE PATIENTS (FIRST-LINE THERAPY)**

**SUGGEST** using a **HIGHER** efficacy or **INTERMEDIATE** efficacy medication, rather than a lower efficacy medication.
*(Conditional recommendation, low certainty of evidence)*

HIGHER EFFICACY MEDICATIONS: Infliximab, Vedolizumab, Ozanimod, Etrasimod, Upadacitinub*, Risankizumab, Guselkumab
INTERMEDIATE EFFICACY MEDICATIONS: Golimumab, Ustekinumab, Tofacitinib*, Filgotinib*, Mirikizumab
LOWER EFFICACY MEDICATIONS: Adalimumab

**PRIOR EXPOSURE TO ONE OR MORE ADVANCED THERAPIES, PARTICULARLY TNF ANTAGONISTS**

**SUGGEST** using a **HIGHER** efficacy or **INTERMEDIATE** efficacy medication, rather than a lower efficacy medication.
*(Conditional recommendation, low certainty of evidence)*

HIGHER EFFICACY MEDICATIONS: Tofacitinib, Upadacitinub, Ustekinumab
INTERMEDIATE EFFICACY MEDICATIONS: Filgotinib, Mirikizumab, Risankizumab, Guselkumab
LOWER EFFICACY MEDICATIONS: Adalimumab, Vedolizumab, Ozanimod, Etrasimod

*The FDA label recommends the use of JAKis only in patients with prior failure or intolerance to TNF antagonists. Filgotinib is not available for use in the United States.

Singh S, et al. *Gastroenterology*. 2024;167(7):1307-1343.

CME OUTFITTERS


## SMART Goals
**Specific, Measurable, Attainable, Relevant, Timely**

- Appreciate the role of the IL-23/Th17 axis in driving the inflammatory pathogenesis of IBD
- Differentiate between IL-23 targeted therapies based on their unique characteristics to individualize and optimize patient treatment
- Consider early use of IL-23 therapies in appropriate patients based on the latest evidence and recommendations
- Collaborate with your patients to identify the best treatment option for their goals



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