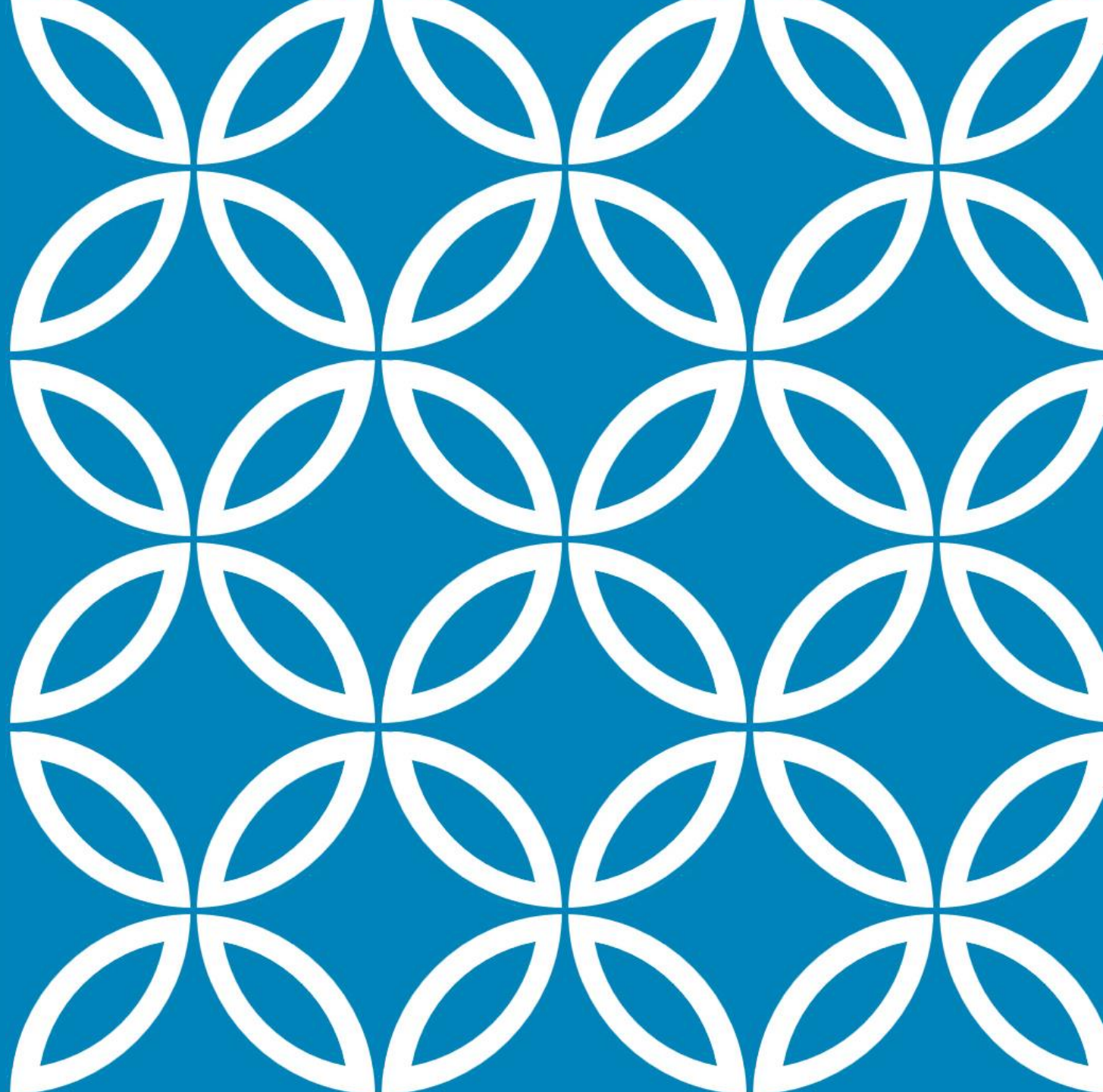


POST-DDW
MALADIES
INFLAMMATOIRES
INTESTINALES

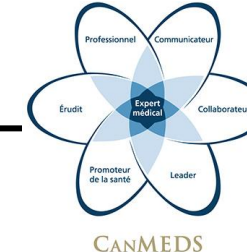
Joannie Ruel, MD, FRCPC
Gastroentérologue
Professeure agrégée
CIUSSS de l'Estrie-CHUS



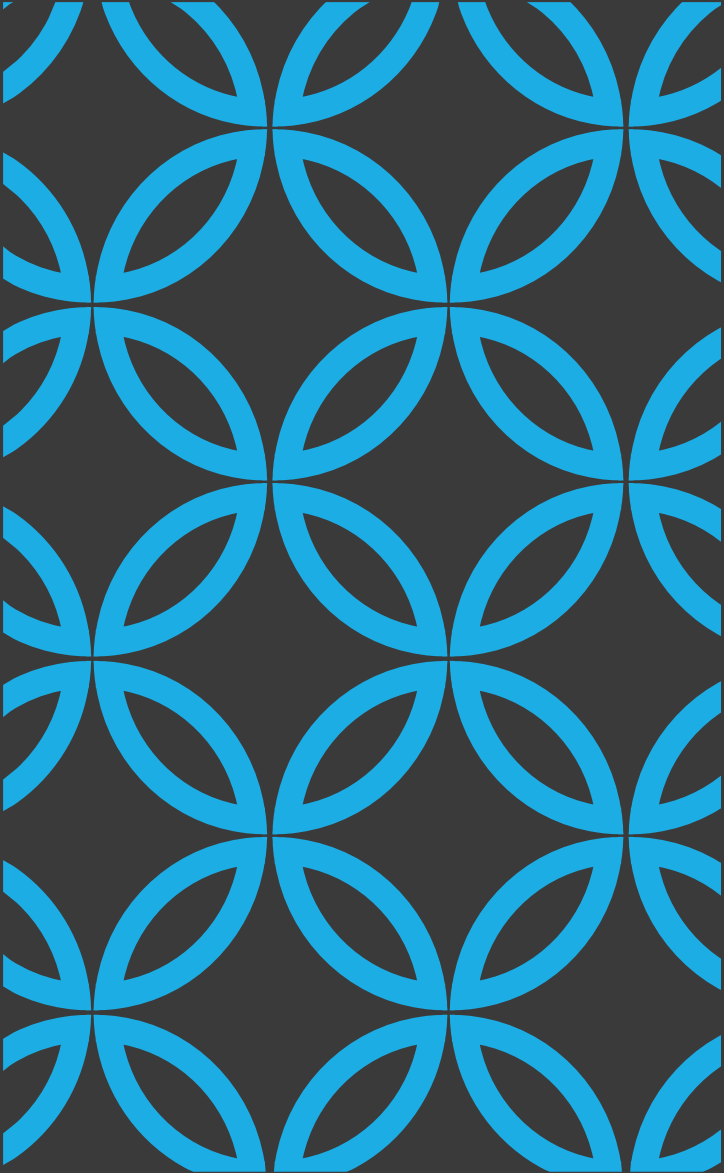
Conflits d'intérêts potentiels

Nature des relations	Nom de l'organisation à but lucratif ou sans but lucratif
Les paiements directs incluant les honoraires	Abbvie, Janssen, Takeda, Eli Lilly, Sandoz, Amgen, Pfizer, Pendopharm, Celltrion
La participation à des comités consultatifs ou des bureaux de conférenciers	Abbvie, Janssen, Takeda, Eli Lilly, Sandoz, Amgen, Pfizer, Pendopharm, Celltrion
Le financement de subventions ou d'essais cliniques	
Les brevets sur un médicament, un produit ou un appareil	
Tout autre investissement ou toute autre relation qu'un participant raisonnable et bien informé pourrait considérer comme un facteur d'influence sur le contenu de l'activité éducative	

COMPÉTENCES CANMEDS



X	Expert médical (En tant qu'experts médicaux, les médecins assument tous les rôles CanMEDS et s'appuient sur leur savoir médical, leurs compétences cliniques et leurs attitudes professionnelles pour dispenser des soins de grande qualité et sécuritaires centrés sur les besoins du patient. Pivot du référentiel CanMEDS, le rôle d'expert médical définit le champ de pratique clinique des médecins .)
	Communicateur (En tant que communicateurs, les médecins développent des relations professionnelles avec le patient et ses proches ce qui permet l'échange d'informations essentielles à la prestation de soins de qualité.)
	Collaborateur (En tant que collaborateurs, les médecins travaillent efficacement avec d'autres professionnels de la santé pour prodiguer des soins sécuritaires et de grande qualité centrés sur les besoins du patient.)
X	Leader (En tant que leaders, les médecins veillent à assurer l'excellence des soins, à titre de cliniciens, d'administrateurs, d'érudits ou d'enseignants et contribuent ainsi, avec d'autres intervenants, à l'évolution d'un système de santé de grande qualité.)
X	Promoteur de santé (En tant que promoteurs de la santé, les médecins mettent à profit leur expertise et leur influence en oeuvrant avec des collectivités ou des populations de patients en vue d'améliorer la santé. Ils collaborent avec ceux qu'ils servent afin d'établir et de comprendre leurs besoins, d'être si nécessaire leur porte-parole, et de soutenir l'allocation des ressources permettant de procéder à un changement.)
X	Érudit (En tant qu'érudits, les médecins font preuve d'un engagement constant envers l'excellence dans la pratique médicale par un processus de formation continue, en enseignant à des tiers, en évaluant les données probantes et en contribuant à l'avancement de la science.)
X	Professionnel (En tant que professionnels, les médecins ont le devoir de promouvoir et de protéger la santé et le bien-être d'autrui, tant sur le plan individuel que collectif. Ils doivent exercer leur profession selon les normes médicales actuelles, en respectant les codes de conduite quant aux comportements qui sont exigés d'eux, tout en étant responsables envers la profession et la société. De plus, les médecins contribuent à l'autoréglementation de la profession et voient au maintien de leur santé.)



SCÉNARIOS SPÉCIFIQUES

Grossesse

Maladie fistulisante périanale

Utilisation concomitante de GLP-1

96 - PREGNANCY AND EARLY CHILDHOOD OUTCOMES AFTER IN UTERO EXPOSURE TO JAK INHIBITORS IN WOMEN WITH IBD: A GLOBAL MULTICENTER COHORT STUDY

🕒 11:30 a.m. - 11:45 a.m. HAE

📅 samedi, mai 2, 2026

Pregnancy and Infant Outcomes Following *In Utero* Exposure to JAK Inhibitors in IBD *An ECCO Global Multicenter Cohort Study*

Mette Julsgaard, Cynthia H Seow, Dana Duricova, Sunanda Kane, Neha Zacharias, Kristyna Zdychyncova, Rupert W Leong, Anneline Cremer, Klaartje B. Kok, Anna Kagramanova, Barbora Pipek, Kristina Candido, Irit A Biron, Rachel Cooney, Rafal Filip, Vytautas Kiudelis, Michal Konecny, Sudarshan Paramsothy, Daniela Pugliese, Genoile Santana, Edoardo V Savarino, Brigita Smolovic, Sophie Vieujean, Shu-Chen Wei, Simon MD Baunwall, [Uma Mahadevan](#)

96 - PREGNANCY AND EARLY CHILDHOOD OUTCOMES AFTER IN UTERO EXPOSURE TO JAK INHIBITORS IN WOMEN WITH IBD: A GLOBAL MULTICENTER COHORT STUDY

🕒 11:30 a.m. - 11:45 a.m. HAE

📅 samedi, mai 2, 2026

Contexte

- ❖ Données humaines limitées sans clair signal en faveur d'anomalies congénitales ni de fausses couches.
- ❖ Majorité des données en provenance de mères qui ont arrêté l'inhibiteur de JAK en T1
- ❖ L'impact d'une exposition in utero continue sur les différentes issues (grossesse, enfant à naître, réponse à la vaccination, etc...) demeure incertain

Méthode

- ❖ Étude observationnelle multicentrique rétrospective internationale (25 centres, 17 pays)
- ❖ Appel ouvert (ECCO Newsletter), endossé par ECCO Confer
- ❖ RedCap:
 - ❖ Activité de la maladie
 - ❖ Issues enfant-mère
 - ❖ Anomalies congénitales
 - ❖ Réponse vaccinale
 - ❖ Développement de l'enfant

96 - PREGNANCY AND EARLY CHILDHOOD OUTCOMES AFTER IN UTERO EXPOSURE TO JAK INHIBITORS IN WOMEN WITH IBD: A GLOBAL MULTICENTER COHORT STUDY

🕒 11:30 a.m. - 11:45 a.m. HAE

📅 samedi, mai 2, 2026

Baseline Characteristics

58 JAKi exposed pregnancies

Type of IBD		
• Crohn's disease, n (%)	5	(8.6)
• Ulcerative colitis/U-IBD, n (%)	53	(91.4)
Maternal age, median (range)	32	(22-43)
Previous number of biologics prior to initiation of a JAKi, median (range)	2	(0-5)
Unplanned pregnancy, n (%)	23	(39.7)
Maternal BMI prior to pregnancy, median (range)	22.7	(17.5-53.1)
Type of JAKi		
• Tofacitinib (5 mg or 10 mg BID), n (%)	38	(65.5)
• Upadacitinib (30 or 45 mg daily), n (%)	18	(31.0)
• Filgotinib, (200 mg daily) n (%)	2	(3.5)
Concomitant steroids		
• Systemic prednisolone, n (%)	18	(31.0)
• Budesonide MMX, n (%)	4	(6.9)
Smoking, n (%)	1	(1.7)
Folic acid in pregnancy, n (%)	39	(67.3)

Tofacitinib, n=38

- 5 mg BID or 10 mg BID
- 26 (68%) received treatment **throughout pregnancy**
- 12 discontinued in pregnancy at median GW 7 (Range 5-31)

Upadacitinib, n=18

- 30 mg daily or 45 mg daily
- 12 (80%) received treatment **throughout pregnancy**
- 3 discontinued in pregnancy at median GW 6 (Range 3-6)

Filgotinib, n=2

- 200 mg daily
- 1 received treatment throughout pregnancy
- 1 discontinued in pregnancy at GW 11

96 - PREGNANCY AND EARLY CHILDHOOD OUTCOMES AFTER IN UTERO EXPOSURE TO JAK INHIBITORS IN WOMEN WITH IBD: A GLOBAL MULTICENTER COHORT STUDY

🕒 11:30 a.m. - 11:45 a.m. HAE

📅 samedi, mai 2, 2026

Issues maternelles

- 🦋 32 (55.2%) had active disease in pregnancy
- 🦋 10 (17.3%) initiated JAKi in pregnancy (Tofa n=3 & UPA n=7)
 - Trimester: 1st (n=1, GW 9); 2nd (n=5, GW 13-28); 3rd (n=4, GW 30-35)
- 🦋 39 (67.2%) received treatment with the JAKi through all 3 trimesters
- ⊗ Of 19 (32.8%) that discontinued JAKi, 11 (57.9%) had a disease flare

Overall, low risk of maternal complications



- No DVT, no pre-eclampsia
- 4 (6.9%) with gestational diabetes
- 4 (6.9%) PROM (gestational age 34-37)
- 5 (8.6%) hospitalization due to infection
- 1 (1.7%) colectomy with ileostomy at GW 28

Issues de grossesse et de l'enfant à naître

Spontaneous abortions, <i>n</i> (%)	5 (8.6)
Induced abortions, <i>n</i> (%)	6 (10.3)
Live born infants, <i>n</i> (%)	47 (81.1)
Median (IQR) gestational week for delivery	40 (38-41)
Cesarean section	24 (41.4)
• Elective CS	16 (66.6)
• Emergency CS	8 (33.3)
Median (IQR) birth weight	3050 (2870-3410)
Congenital abnormalities	0 -
Preterm	2 (3.4)
APGAR < 7 at 5 minutes, <i>n</i> (%)	2 (3.4)
Small for Gestational Age (SGA)	4 (6.9)
Low Birth Weight ($\leq$ 2500 gram)	6 (10.3)

96 - PREGNANCY AND EARLY CHILDHOOD OUTCOMES AFTER IN UTERO EXPOSURE TO JAK INHIBITORS IN WOMEN WITH IBD: A GLOBAL MULTICENTER COHORT STUDY

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📅 samedi, mai 2, 2026

45 infants, median follow-up 15 months (range 1-92)



Of those women that breastfed (34; 75.6%), **10/34 (29.4%)** continued JAKi

2 infants (3.9%) hospitalized for infection; IV antibiotics, no sequelae



➤ Omphilitis (newborn) Term GW 41

➤ UPA 30 mg (GW8 ->15 mg)

➤ Flare week 30: steroids GW 30-37.

➤ Suspected sepsis due to neutropenia (birth & day 13). Term GW39

➤ UPA 45 GW28 until birth GW 39

➤ Flare GW 29. Steroids GW 29-37



Normal development in all infants

No adverse effect with inactive and live vaccines, including



➤ 8 (17.7%) who received the **BCG vaccine ~ 1 month of age**

➤ 14 (31.1%) who received the Rotavirus vaccine ~ 1.5-6 months of age

➤ 17 (37.8%) who received the MMR vaccine ~ ≥ 12 months of age



No malignancies observed

96 - PREGNANCY AND EARLY CHILDHOOD OUTCOMES AFTER IN UTERO EXPOSURE TO JAK INHIBITORS IN WOMEN WITH IBD: A GLOBAL MULTICENTER COHORT STUDY

👤 11:30 a.m. - 11:45 a.m. HAE

📅 samedi, mai 2, 2026

Conclusions

- ❖ Le maintien de la rémission en grossesse est le meilleur gage d'issues favorables en grossesse
- ❖ L'utilisation d'un JAKi peut être considérée si et seulement si aucune autre option viable est disponible pour la santé de la mère
- ❖ Importance d'une décision éclairée et partagée
- ❖ Aucun signal adverse de complications maternelles, d'issues défavorables de grossesse, de risque d'infection, de développement ou de réponse vaccinale défavorable mais peu de recul
- ❖ Si vous avez des cas : mjn@clin.au.dk

GUSELKUMAB FOR PERIANAL FISTULIZING CROHN'S DISEASE: WEEK 24 RESULTS FROM THE PHASE 3, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTER FUZION STUDY

🕒 11:45 a.m. - 12:00 p.m. HAE

📅 mardi, mai 5, 2026

GUSELKUMAB FOR PERIANAL FISTULIZING CROHN'S DISEASE: WEEK 24 RESULTS FROM THE PHASE 3, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTER FUZION STUDY

Laurent Peyrin-Biroulet, Vipul Jairath, Ailsa Hart, Geert D'Haens, Axel Dignass, Silvio Danese, Julian Panés, Susan J. Connor, Walter Reinisch, David A. Schwartz, Tadakazu Hisamatsu, Bram Verstockt, Antonino Spinelli, Anton Stift, André D'Hoore, Maciej Nazar, Jacqueline van Denderen, Talia Gramiccia, Takehiko Sakamoto, Stephen Xu, Ivana Bravatà, and Bruce E. Sands on behalf of the FUZION Study Group

O1058b



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DDW2026
Digestive Disease Week®

MAY 2-5, 2026 | CHICAGO, IL

EXHIBIT DATES: MAY 3-5, 2026

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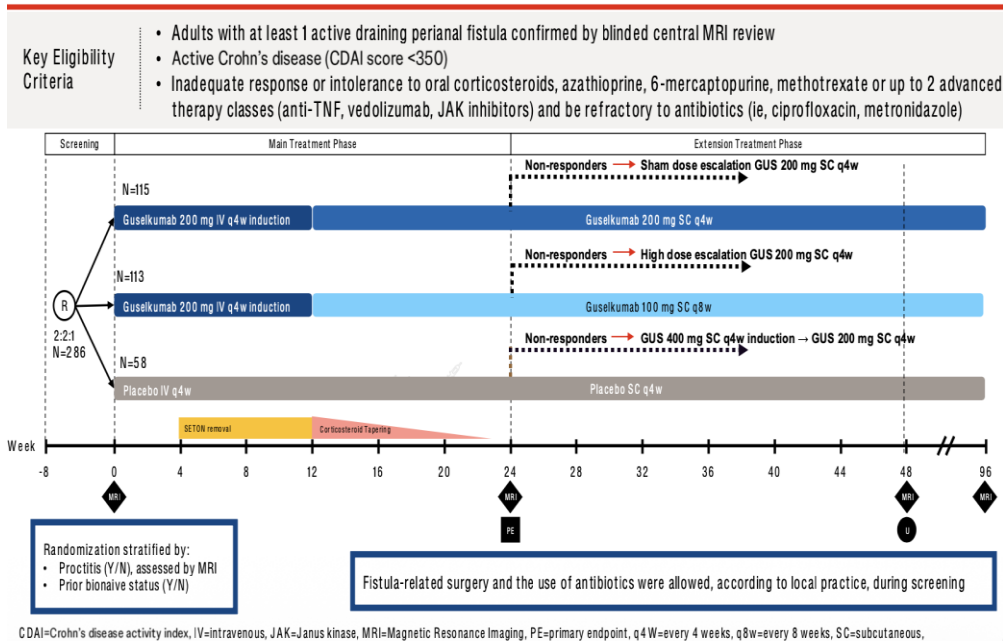
GUSELKUMAB FOR PERIANAL FISTULIZING CROHN'S DISEASE: WEEK 24 RESULTS FROM THE PHASE 3, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTER FUZION STUDY

11:45 a.m. - 12:00 p.m. HAE

mardi, mai 5, 2026

Design

Phase 3, Double-Blind, Treat-Through Study



Issues semaine 24

Endpoints through Week 24*

Primary Endpoint*

Combined fistula remission at week 24 (clinically and radiologically assessed)

Multiplicity-Controlled Secondary Endpoints*

- Clinically assessed fistula remission at week 24
- Clinically assessed fistula response at week 24

Key Secondary Endpoints

- Clinically assessed fistula response at week 12

Assessment Type	Outcome	Definition
Clinical	Clinically assessed fistula remission	100% closure of all treated external openings, without development of new fistulas or abscesses and without any drainage by the external openings, occurring spontaneously or after gentle finger compression
	Clinically assessed fistula response	≥50% reduction from baseline in number of open or draining perianal fistulas
Radiological	Absence of collections >2cm	Absence of collections >2 cm of the perianal fistulas, confirmed by a blinded central review of the MRI results

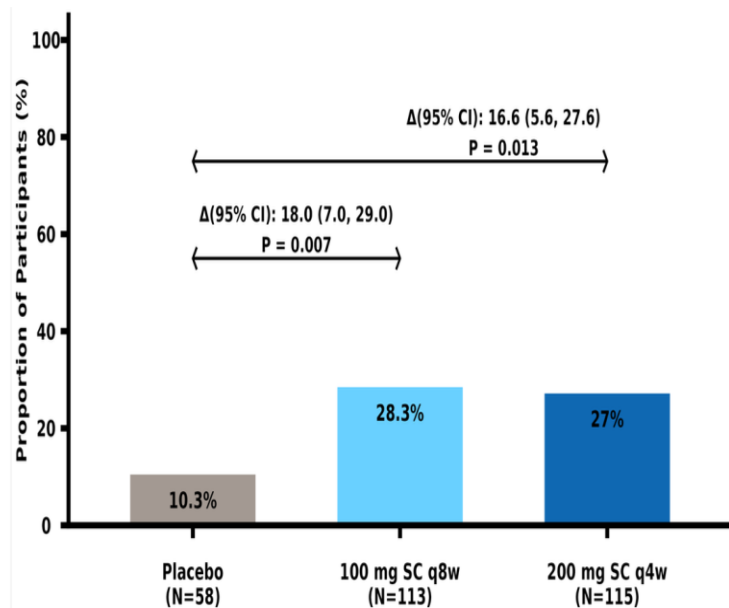
*In the statistical testing procedure, guselkumab 200 mg q4w dose then the 100 mg q8w dose were sequentially tested versus placebo for the primary endpoint then for the multiplicity-controlled secondary endpoints.

GUSELKUMAB FOR PERIANAL FISTULIZING CROHN'S DISEASE: WEEK 24 RESULTS FROM THE PHASE 3, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTER FUZION STUDY

11:45 a.m. - 12:00 p.m. HAE

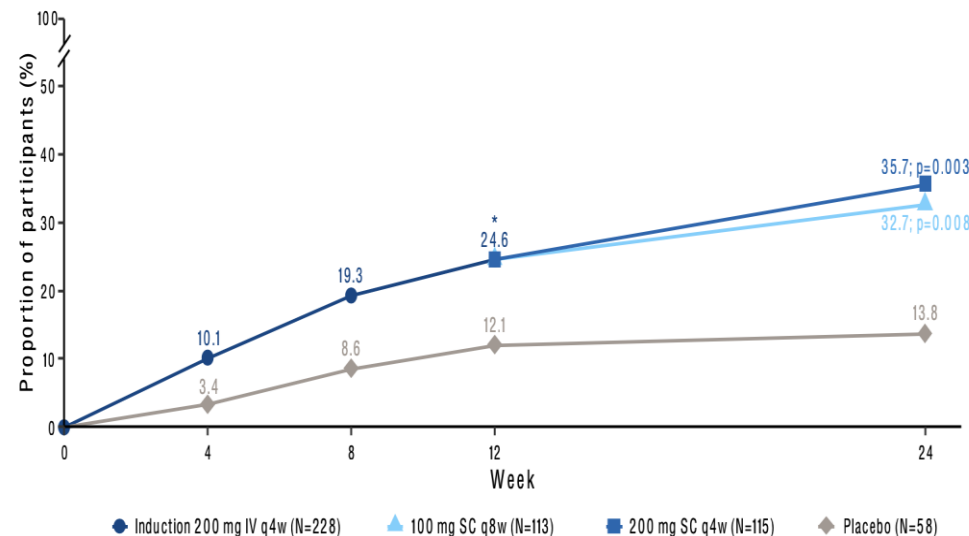
mardi, mai 5, 2026

Combined Fistula Remission at Week 24 Primary Endpoint



Combined Fistula Remission: 100% closure of all treated external openings, without development of new fistulas or abscesses and without any drainage by the external openings, occurring spontaneously or after gentle finger compression AND absence of collections >2 cm of the perianal fistulas, confirmed by a blinded central review of the MRI results

Clinically Assessed Fistula Response through Week 24 Guselkumab showed meaningful difference versus placebo during induction



Clinically Assessed Fistula Response: ≥50% reduction from baseline in number of open or draining perianal fistulas

*Nominal p=0.041

Missing Data Imputation: After applying the ICE strategy, missing data were imputed as not having achieved a combined fistula remission at Week 24. The adjusted risk difference and CI were based on Wald statistics using Mantel-Haenszel stratum weights stratified by baseline proctitis (yes, no) and baseline bio-naïve status (yes, no). The p-values are based on the CMH test, stratified by baseline proctitis (yes, no) and baseline bio-naïve status (yes, no). CI=confidence interval, CMH=Cochran-Mantel-Haenszel, ICE=intercurrent event, IV=intravenous, MRI=magnetic resonance imaging, q4w=every 4 weeks, q8w=every 8 weeks, SC=subcutaneous.

GUSELKUMAB FOR PERIANAL FISTULIZING CROHN'S DISEASE: WEEK 24 RESULTS FROM THE PHASE 3, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTER FUZION STUDY

 11:45 a.m. - 12:00 p.m. HAE

 mardi, mai 5, 2026

Conclusions

- ❖ FUZION est une étude de phase 3 internationale évaluant une issue primaire combinant la clinique et l'imagerie par IRM
- ❖ Guselkumab démontré efficace à 24 semaines chez une population bio-naïve et bio-exposée avec un Crohn périanal vs pbo
- ❖ Aucun nouveau signal d'innocuité

624 - GLP-1 RECEPTOR AGONISTS REDUCE LONG-TERM STEROID, BIOLOGIC, AND ACUTE CARE UTILIZATION IN ULCERATIVE COLITIS AND CROHN'S DISEASE: A 5-YEAR TRINETX STUDY WITH LANDMARK ANALYSIS

🕒 9:00 a.m. - 9:15 a.m. HAE

📅 lundi, mai 4, 2026



Long-Term Effects of GLP-1 Receptor Agonists on Corticosteroid, Biologic, and Acute Care Utilization in Inflammatory bowel disease: A 5-Year Real-World Study with Landmark Analysis

Yan Sun¹, Donovan Veccia², Marc Landsman²

¹Department of Internal Medicine, Case Western Reserve University/MetroHealth, Cleveland, OH

²Department of Gastroenterology and Hepatology, Case Western Reserve University/MetroHealth, Cleveland, OH



CASE WESTERN RESERVE
UNIVERSITY
School of Medicine

624 - GLP-1 RECEPTOR AGONISTS REDUCE LONG-TERM STEROID, BIOLOGIC, AND ACUTE CARE UTILIZATION IN ULCERATIVE COLITIS AND CROHN'S DISEASE: A 5-YEAR TRINETX STUDY WITH LANDMARK ANALYSIS

👤 9:00 a.m. - 9:15 a.m. HAE

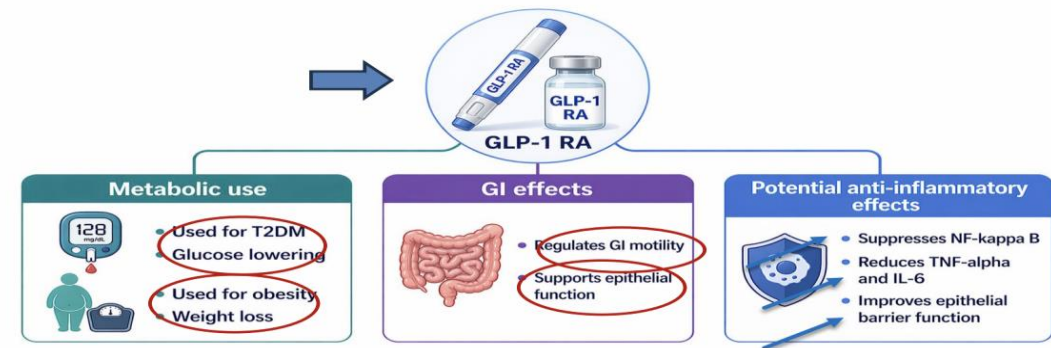
📅 lundi, mai 4, 2026

Contexte

- ❖ Études récentes suggérant que les agonistes GLP-1 peuvent être associés à certaines issues favorables chez les patients MII
- ❖ Données provenant de cohortes limitées
- ❖ Efficacité pour la perte de poids chez nos patients avec MII pour qui des conditions métaboliques peuvent coexister

Objectif

- ❖ Large cohorte real-world
- ❖ Évaluer l'association entre l'utilisation de GLP-1 et certaines issues MII avec un focus particulier sur l'innocuité et les marqueurs de progression de la maladie



624 - GLP-1 RECEPTOR AGONISTS REDUCE LONG-TERM STEROID, BIOLOGIC, AND ACUTE CARE UTILIZATION IN ULCERATIVE COLITIS AND CROHN'S DISEASE: A 5-YEAR TRINETX STUDY WITH LANDMARK ANALYSIS

🕒 9:00 a.m. - 9:15 a.m. HAE

📅 lundi, mai 4, 2026

Designs

TriNetX Network

Identified diabetes or obesity patients with UC/CD who initiated GLP-1 RA or comparator after IBD diagnosis
January 1, 2015 to December, 1st 2025

Exclusions:

- Autoimmune disease
- Immunodeficiency disease
- Cancer therapy
- Organ or cell transplant
- Bariatric surgery
- Vascular intestinal disease, etc

Two cohorts:

Exposure: GLP-1 RA
Comparator: Other 2nd line diabetes medicines

Propensity Score Matching (1:1):

- Demographics
- Comorbidities
- BMI
- HbA1c
- Baseline steroid/biologic use
- IBD severity
- ER Utilization, etc

Primary Outcomes:

- Steroid initiation
- Biologic Treatment escalation

Secondary Outcome:

- ER/Inpatient encounters

Study Design:

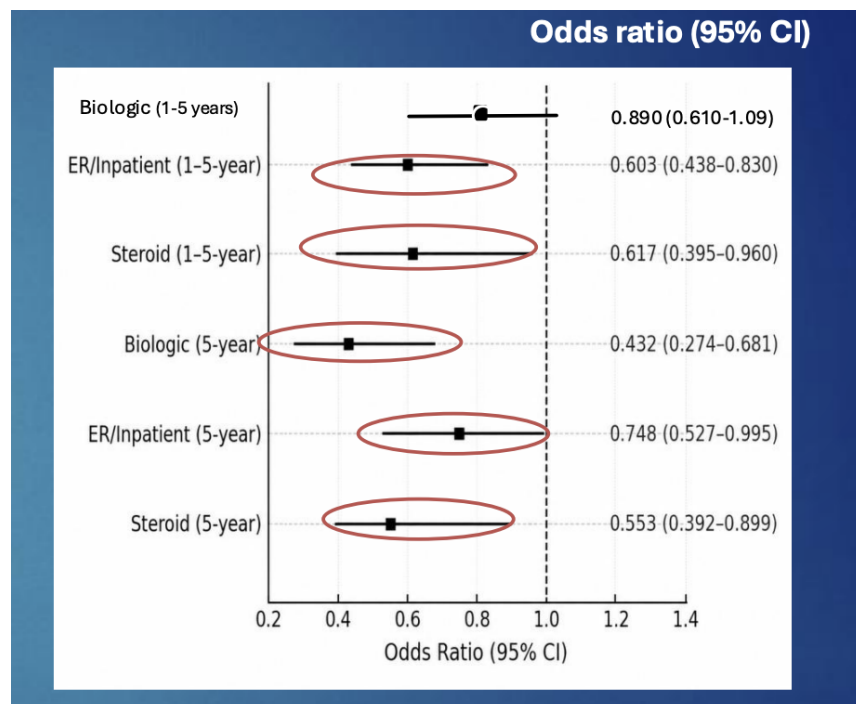
- Follow-up: up to 5 years
- Landmark analysis: 1–5 years
- Subgroup analysis: UC vs CD

624 - GLP-1 RECEPTOR AGONISTS REDUCE LONG-TERM STEROID, BIOLOGIC, AND ACUTE CARE UTILIZATION IN ULCERATIVE COLITIS AND CROHN'S DISEASE: A 5-YEAR TRINETX STUDY WITH LANDMARK ANALYSIS

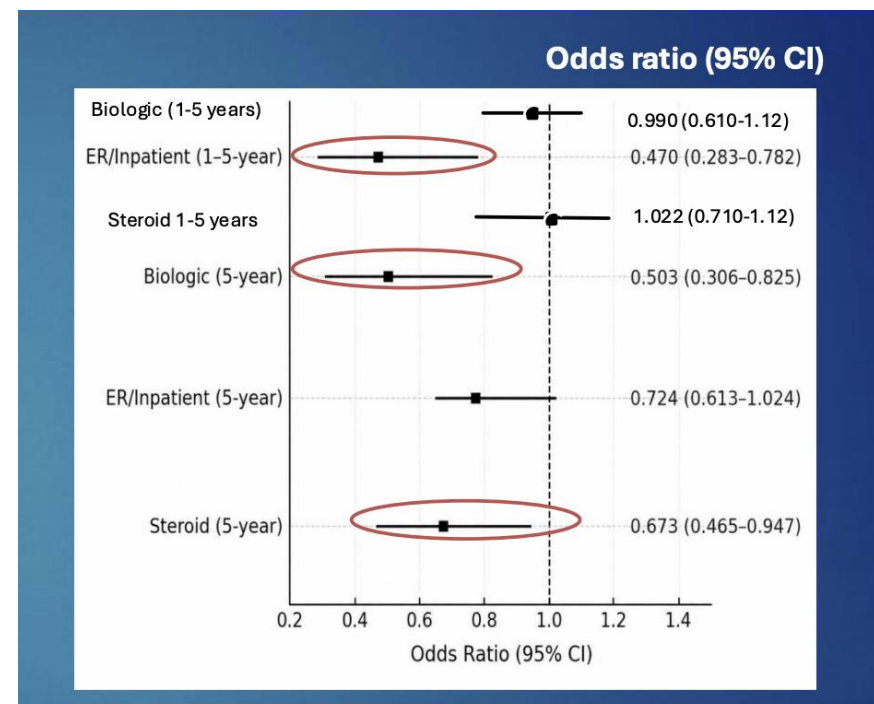
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lundi, mai 4, 2026

Colite ulcéreuse



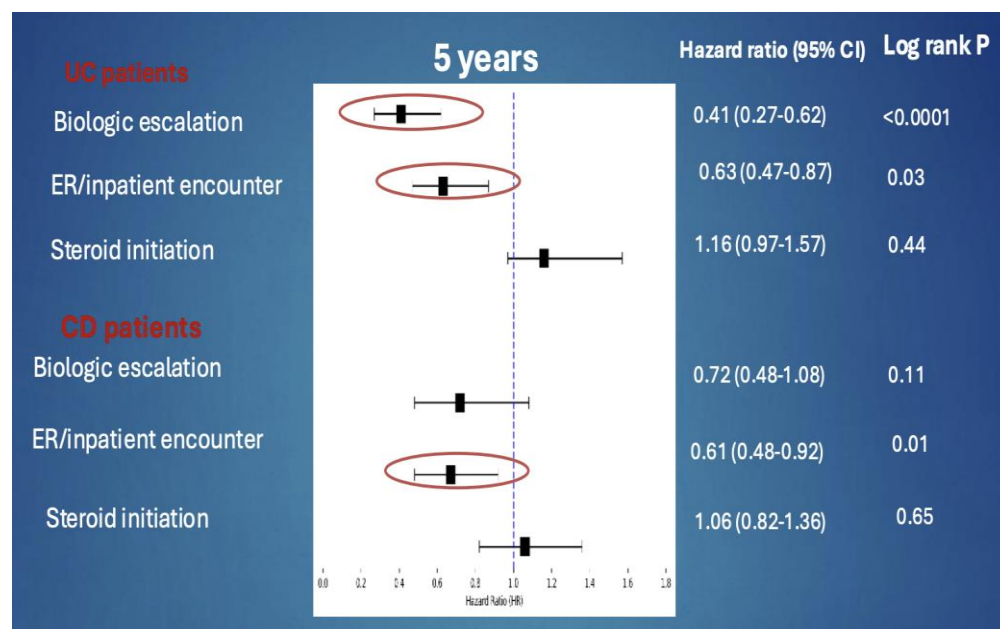
Crohn



624 - GLP-1 RECEPTOR AGONISTS REDUCE LONG-TERM STEROID, BIOLOGIC, AND ACUTE CARE UTILIZATION IN ULCERATIVE COLITIS AND CROHN'S DISEASE: A 5-YEAR TRINETX STUDY WITH LANDMARK ANALYSIS

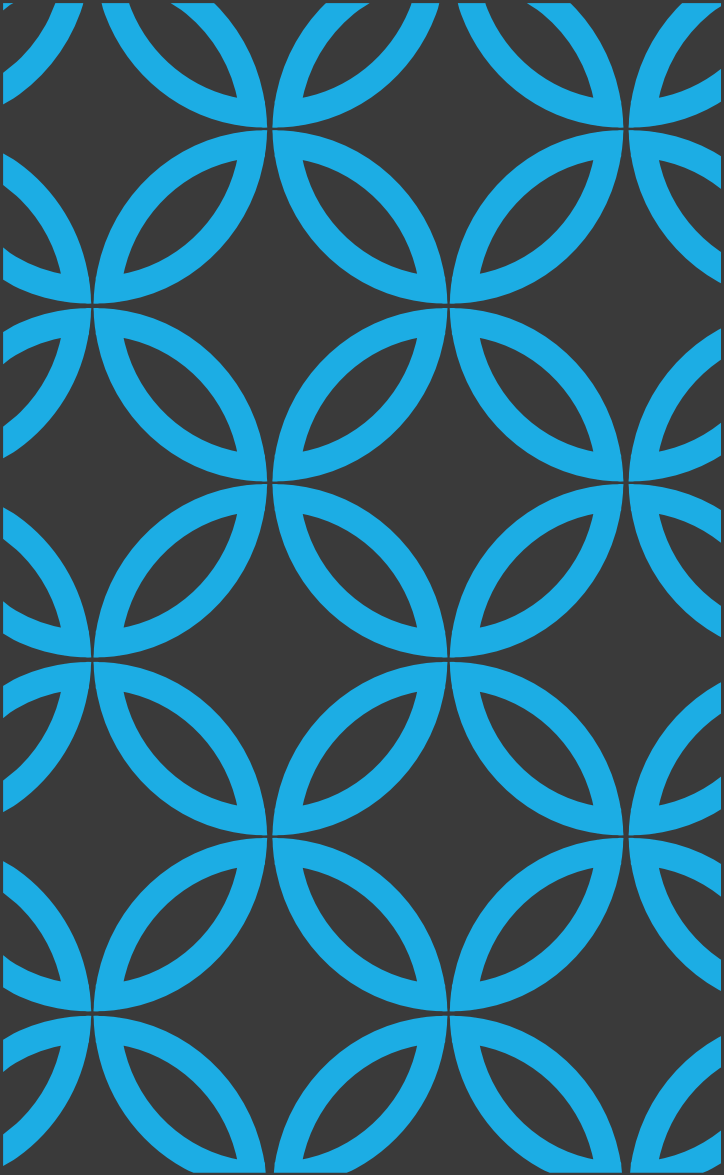
9:00 a.m. - 9:15 a.m. HAE

lundi, mai 4, 2026



Conclusions

- ❖ GLP-1 associés à des issues favorables chez les patients MII ayant des comorbidités métaboliques, particulièrement en colite ulcéreuse
- ❖ Études prospectives requises afin de déterminer si les GLP-1 peuvent modifier le cours de la MII
- ❖ Pas de signal d'innocuité



THÉRAPEUTIQUE

Efficacité comparative

Combinaison

Nouveautés d'intérêt

538 - COMPARATIVE EFFECTIVENESS OF JAK INHIBITORS VERSUS IL-23 INHIBITORS IN USTEKINUMAB FAILURES IN MODERATE-TO-SEVERE CROHN'S DISEASE

5:45 p.m. - 6:00 p.m. HAE

dimanche, mai 3, 2026



Comparative Effectiveness of JAK Inhibitors Versus Il-23 Inhibitors in Ustekinumab Failures in Moderate-to-Severe Crohn's Disease: A COMPARE-IBD Study

Maryam K Ibrahim, Wasuwit Wanchaitanawong, Ryan Stidham,
Nisha Mathur, Benjamin Click, Manasi Agrawal, Adam S. Faye,
Siddharth Singh, Ashwin Ananthakrishnan

538 - COMPARATIVE EFFECTIVENESS OF JAK INHIBITORS VERSUS IL-23 INHIBITORS IN USTEKINUMAB FAILURES IN MODERATE-TO-SEVERE CROHN'S DISEASE

👤 5:45 p.m. - 6:00 p.m. HAE

📅 dimanche, mai 3, 2026

Objectif

Évaluer l'efficacité comparative JAKi vs IL23i en termes de rémission clinique à 3 et 12 mois et la rémission endoscopique chez les pts avec Crohn modéré à sévère précédemment exposés à l'ustekinumab

Étude de cohorte rétrospective

Methods

Study design

✓ Retrospective cohort study

Inclusion criteria

- ✓ Adult patients (≥ 18 years)
- ✓ Moderate to severe CD
- ✓ MGB Health System, or University of Michigan
- ✓ Between 2018 and 2025
- ✓ Previously on ustekinumab (any duration)

Compare-IBD



538 - COMPARATIVE EFFECTIVENESS OF JAK INHIBITORS VERSUS IL-23 INHIBITORS IN USTEKINUMAB FAILURES IN MODERATE-TO-SEVERE CROHN'S DISEASE

👤 5:45 p.m. - 6:00 p.m. HAE

📅 dimanche, mai 3, 2026

Primary Outcome

- Steroid-free clinical remission at **3 months**
- Defined by:
 - Physician's global assessment of clinical remission (clinical symptoms, physical exam, inflammatory biomarkers, radiology) OR
 - CDAI score <150 OR
 - HBI <5
 - AND no use of oral corticosteroids at assessment

Secondary Outcomes

- Steroid-free clinical remission at **12 months**
- Endoscopic remission on post-treatment endoscopy
 - Defined by:
 - Normal endoscopy (absence of any endoscopic evidence of inflammation) OR
 - SES-CD 0-2

538 - COMPARATIVE EFFECTIVENESS OF JAK INHIBITORS VERSUS IL-23 INHIBITORS IN USTEKINUMAB FAILURES IN MODERATE-TO-SEVERE CROHN'S DISEASE

5:45 p.m. - 6:00 p.m. HAE

dimanche, mai 3, 2026

N=430

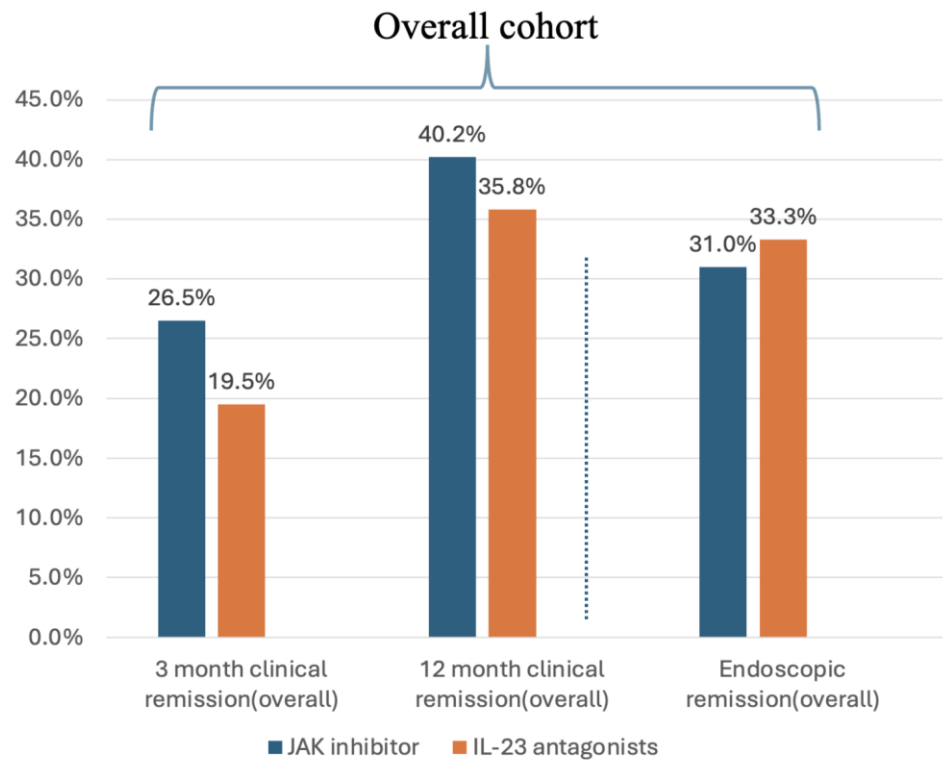


Table 2: Comparison of JAK inhibitors and IL-23 antagonists on achieving clinical and endoscopic outcomes using stabilized IPTW models

Outcome	IPTW-OR (JAK-inhibitor vs IL-23) [95% CI] †	p-value
Clinical remission at 3 months	1.58 [0.97, 2.6]	0.066
Clinical remission at 12 months	1.57[0.99,2.48]	0.055
Endoscopic remission	0.87 [0.5, 1.5]	0.6

† Stabilized IPTW-weighted model using age, sex, race, smoking, disease location, disease phenotype, perianal disease, disease duration, history of IBD surgery, prior TNF, prior vedolizumab, steroid at baseline, study site, reason for stopping ustekinumab, escalation of ustekinumab dose

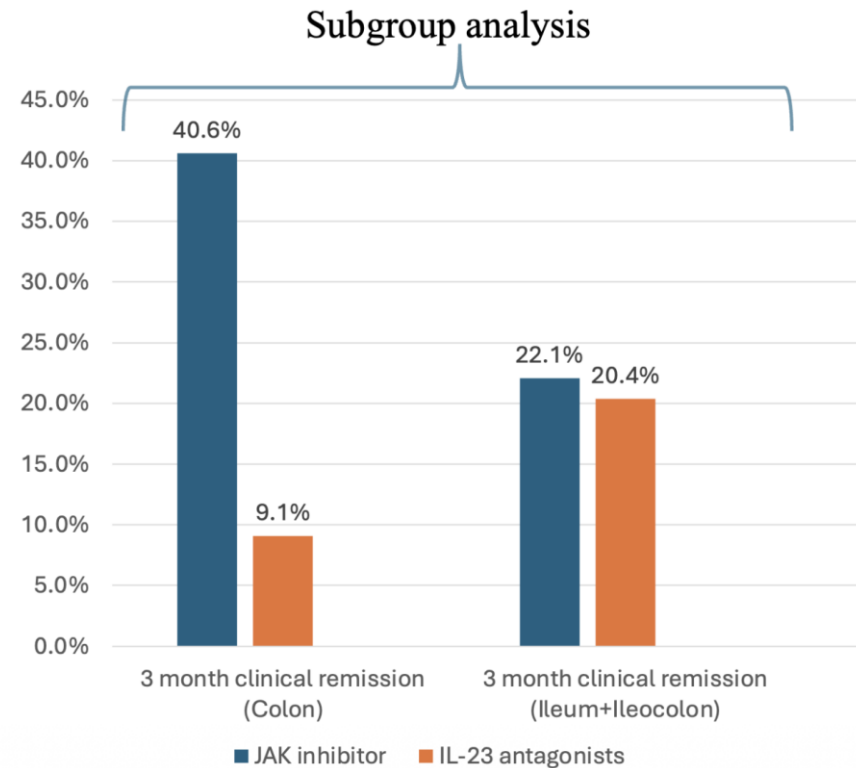
538 - COMPARATIVE EFFECTIVENESS OF JAK INHIBITORS VERSUS IL-23 INHIBITORS IN USTEKINUMAB FAILURES IN MODERATE-TO-SEVERE CROHN'S DISEASE

5:45 p.m. - 6:00 p.m. HAE

dimanche, mai 3, 2026

Outcome	Variable		No. of patients	OR (JAK-inhibitor vs IL-23) [95% CI] †	p-interaction
Clinical remission at 3 months	Disease location	L2(colon)	76	9.2 [2.5, 34.3]	0.004
		L1 (Ileum)+L3 (Ileocolon)	354	1.1[0.64, 1.91]	
	Disease phenotype	Inflammatory (B1)	107	2.1 [0.85, 5.17]	0.42
		Complicated phenotype (B2/B3)	323	1.3[0.75, 2.41]	
	History of IBD surgery	Yes	228	1.1[0.53, 2.11]	0.093
		No	202	2.5[1.2, 5.0]	
	Reason for stopping ustekinumab	Loss of efficacy	371	1.8[1.1, 3.1]	0.190
		Other*	59	0.74[0.22, 2.58]	
	Escalation of ustekinumab dose	Yes	323	1.6[0.89, 2.87]	0.91
		No	107	1.5[0.62, 3.65]	
	Steroid at baseline	Yes	148	1.5[0.62, 3.57]	0.87
		No	282	1.6[0.9, 2.9]	
	Site	Mass General Brigham	334	1.6[0.91, 2.70]	0.95
		University of Michigan	96	1.6[0.54, 4.94]	

† Propensity score model with IPTW stabilized weights using age, sex, race, smoking, disease location, disease phenotype, perianal disease, disease duration, history of IBD surgery, prior TNF, prior vedolizumab, steroid at baseline, study site, reason for stopping ustekinumab, escalation of ustekinumab dose



538 - COMPARATIVE EFFECTIVENESS OF JAK INHIBITORS VERSUS IL-23 INHIBITORS IN USTEKINUMAB FAILURES IN MODERATE-TO-SEVERE CROHN'S DISEASE

👤 5:45 p.m. - 6:00 p.m. HAE

📅 dimanche, mai 3, 2026

Conclusions

- ❖ Tendence vers la supériorité des JAKi vs IL23i pour induire la rémission clinique à 3 et 12 mois chez les pts avec échec antérieur à l'ustekinumab
- ❖ Avantage en Crohn colique à favoriser les JAKi
- ❖ Toutefois, absence de différences au niveau des issues endoscopiques ce qui suggère que les 2 thérapies représentent des options adéquates après un échec à l'ustekinumab
- ❖ Nécessité d'obtenir d'autres études sans caractère rétrospectif

REAL WORLD OUTCOMES OF UPADACITINIB COMPARED WITH USTEKINUMAB, RISANKIZUMAB, MIRIKIZUMAB, AND GUSELKUMAB AS SECOND-LINE THERAPY IN ULCERATIVE COLITIS AFTER INFLIXIMAB EXPOSURE

🕒 6:15 p.m. - 6:30 p.m. HAE

📅 dimanche, mai 3, 2026

Real-World Outcomes Of Upadacitinib Versus IL-23–Based Therapies as Second-Line Therapy in Ulcerative Colitis After Infliximab Exposure

Adalberto E Guzman, Lina AlQirem, Urveesh Sharma, Manesh Kumar Gangwani, Yash Shah*, Evelyn J Calderon Martinez, Mohammad Alomari

University of Arkansas for Medical Sciences, Little Rock, AR
Cedars-Sinai Medical Center, Los Angeles, CA

DDW — May 2026 | Oral Presentation

REAL WORLD OUTCOMES OF UPADACITINIB COMPARED WITH USTEKINUMAB, RISANKIZUMAB, MIRIKIZUMAB, AND GUSELKUMAB AS SECOND-LINE THERAPY IN ULCERATIVE COLITIS AFTER INFLIXIMAB EXPOSURE

👤 6:15 p.m. - 6:30 p.m. HAE

📅 dimanche, mai 3, 2026

Objectif

Comparer les issues à 12 mois

JAKi vs ustekinumab, risankizumab, mirikizumab, guselkumab

chez les patients avec CU

en utilisant le TriNetX Research Network

TriNetX: 60+ US Health Systems | >100M Patients

INCLUSION CRITERIA

- 1 Adults ≥18 yrs with confirmed UC (ICD-10: K51.x)
- 2 Infliximab exposure ≥12 months (documented anti-TNF)
- 3 Transition to index therapy: Upadacitinib OR an IL-23 or IL12-23 inhibitor
- 4 ≥12 months follow-up after index therapy initiation

1:1 PROPENSITY SCORE MATCHING

Matching Variables:

- Age • Sex
- Prior biologic exposure

Matched Cohort Sizes (per group):

7,854 vs USTE

1,389 vs GUSE

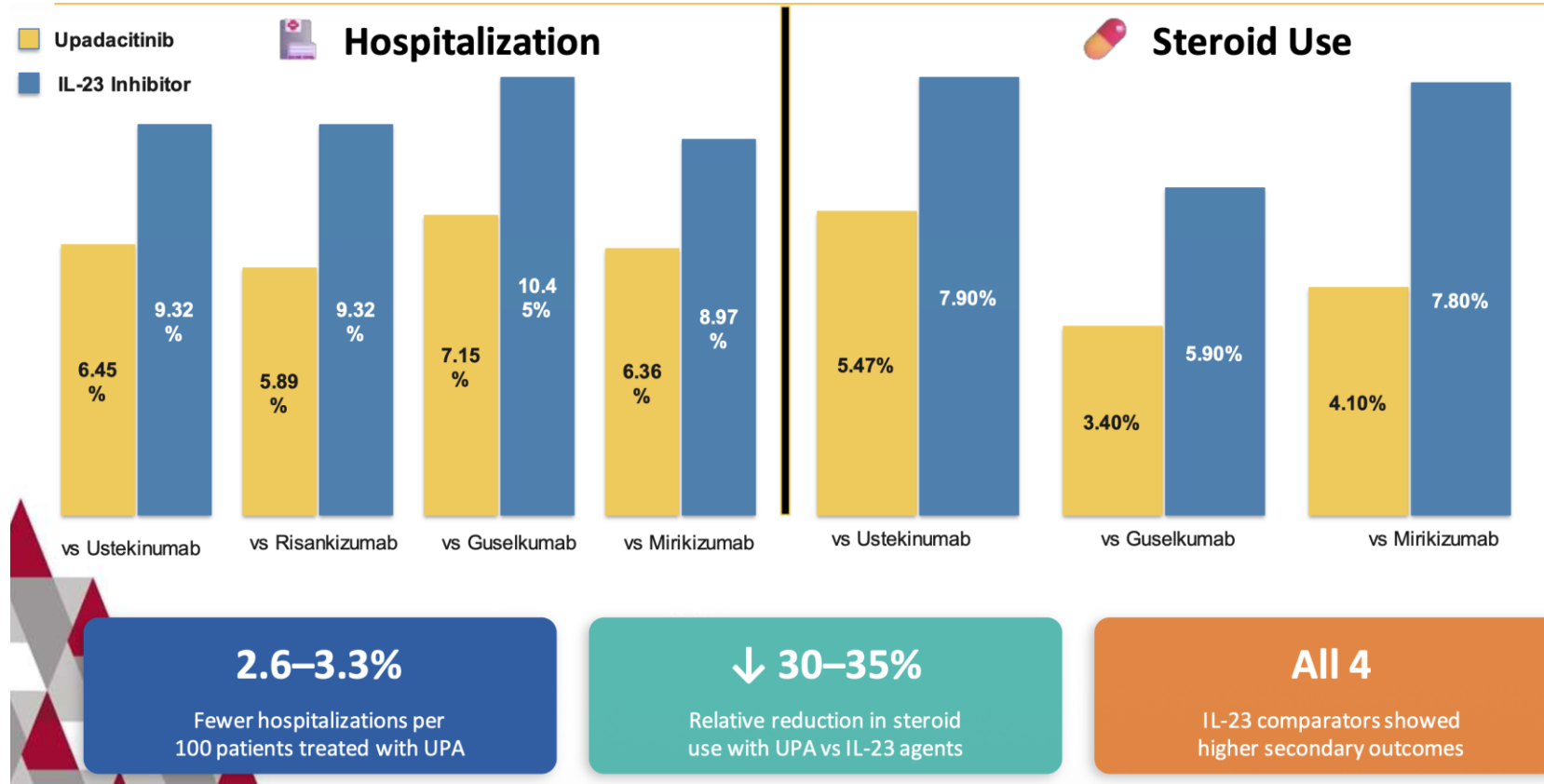
5,322 vs RISA

279 vs MIRI

REAL WORLD OUTCOMES OF UPADACITINIB COMPARED WITH USTEKINUMAB, RISANKIZUMAB, MIRIKIZUMAB, AND GUSELKUMAB AS SECOND-LINE THERAPY IN ULCERATIVE COLITIS AFTER INFLIXIMAB EXPOSURE

6:15 p.m. - 6:30 p.m. HAE

dimanche, mai 3, 2026



REAL WORLD OUTCOMES OF UPADACITINIB COMPARED WITH USTEKINUMAB, RISANKIZUMAB, MIRIKIZUMAB, AND GUSELKUMAB AS SECOND-LINE THERAPY IN ULCERATIVE COLITIS AFTER INFLIXIMAB EXPOSURE

6:15 p.m. - 6:30 p.m. HAE
dimanche, mai 3, 2026

RESULTS: Complete Outcome Summary

UPA vs Each IL-23 Inhibitor | 12-Month Follow-Up

Outcome	vs UST (n=7,854)		vs RISA (n=5,322)		vs GUSE (n=1,181)		vs MIRI (n=279)		All Favor
	UPA	IL-23	UPA	IL-23	UPA	IL-23	UPA	IL-23	
 Surgery	1.45%	1.67%	2.23%	3.57%	1.39%	2.69%	1.79%	3.99%	UPA ✓
 Steroid Use	5.48%	7.90%	—	—	3.4%	5.9%	4.1%	7.8%	UPA ✓
 Hospitalization	6.45%	9.32%	5.89%	9.32%	7.15%	10.5%	6.36%	8.97%	UPA ✓
 Biomarkers (CRP >10, ESR >30, Fecal Calprotectin >150)	↓	↑	↓	↑	↓	↑	↓	↑	UPA ✓

— = not reported for this comparison | ↓ = lower in UPA group | UPA values in gold; IL-23 in blue

REAL WORLD OUTCOMES OF UPADACITINIB COMPARED WITH USTEKINUMAB, RISANKIZUMAB, MIRIKIZUMAB, AND GUSELKUMAB AS SECOND-LINE THERAPY IN ULCERATIVE COLITIS AFTER INFLIXIMAB EXPOSURE

👤 6:15 p.m. - 6:30 p.m. HAE

📅 dimanche, mai 3, 2026

Conclusions

❖ Ces données comparatives supportent

l'utilisation JAKi chez un pt avec CU réfractaire à un TNFi

❖ L'utilisation d'un IL23i ou IL12-23i demeure une option adéquate mais semble avoir des issues inférieures vs upadacitinib



COMBINAISON DE THÉRAPIES AVANCÉES (DAT)

Therapeutic Synergy of Combined IL-23 and JAK-I Inhibition in Difficult-To-Treat Crohn's Disease

Patricia M. Hughes, Shouli Tung, Elizabeth A. Spencer, Marla C. Dubinsky

Department of Pediatrics, Susan and Leonard Feinstein IBD Clinical Center, Icahn School of Medicine at Mount Sinai, New York



Su1639

Dual Targeted Therapy With Vedolizumab and Tofacitinib in Patients With Ulcerative Colitis: Initial Results From the Phase 4 ExiGem Study

Andres Yarur,¹ Parakkal Deepak,² Edward Barnes,³ Christina Ha,⁴ David Hudesman,⁵ Vipul Jairath,⁶ Dana Lukin,⁷ David T Rubin,⁸ Stefan Schreiber,⁹ Megan Gower,¹⁰ Stephen Jones,¹¹ Ian Robinson,¹⁰ Marie Sanchirico,¹⁰ Vijay Yajnik¹⁰

¹Division of Gastroenterology and Hepatology, Cedars-Sinai Medical Center, Los Angeles, CA, USA; ²Division of Gastroenterology, Washington University School of Medicine in St. Louis, St. Louis, MO, USA; ³Division of Gastroenterology and Hepatology, UNC School of Medicine, University of North Carolina, Chapel Hill, NC, USA; ⁴Division of Gastroenterology and Hepatology, Mayo Clinic, Scottsdale, AZ, USA; ⁵Inflammatory Bowel Disease Centre, NYU Langone Health, NYU Langone, New York, NY, USA; ⁶Division of Gastroenterology, Schulich School of Medicine and Dentistry, Western University, London, ON, Canada; ⁷Jill Roberts Center for Inflammatory Bowel Disease, Weill Cornell Medicine, New York, NY, USA; ⁸University of Chicago Medicine Inflammatory Bowel Disease Center, Chicago, IL, USA; ⁹Kiel University Institute of Clinical Molecular Biology, Kiel, Germany; ¹⁰Takeda Pharmaceuticals U.S.A., Inc., Cambridge, MA, USA; ¹¹Synapse Medical Consultancy Ltd, London, UK

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COMBINAISON DE THÉRAPIES AVANCÉES (DAT)

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 Jairath⁸

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



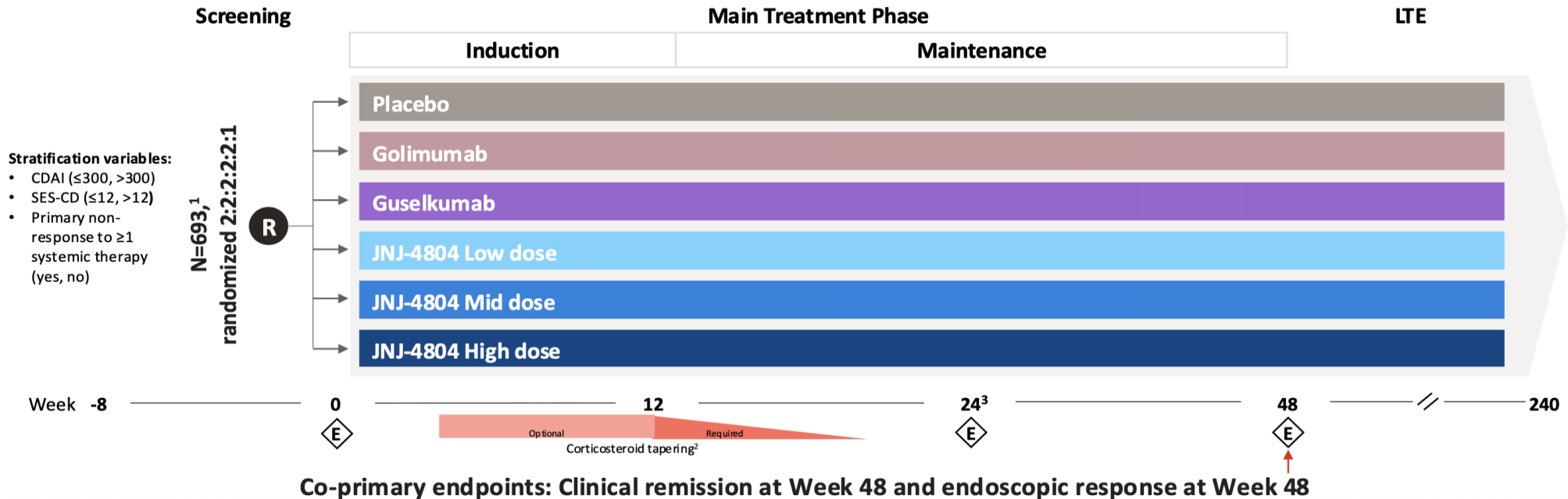
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EXHIBIT DATES: MAY 3-5, 2026

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PHASE 2B DUET CD

- 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



¹Full Analysis Set.

²All participants taking corticosteroids at Week 0 could begin tapering as early as Week 4 but no later than Week 12.

³Patients 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.

PHASE 2B DUET CD

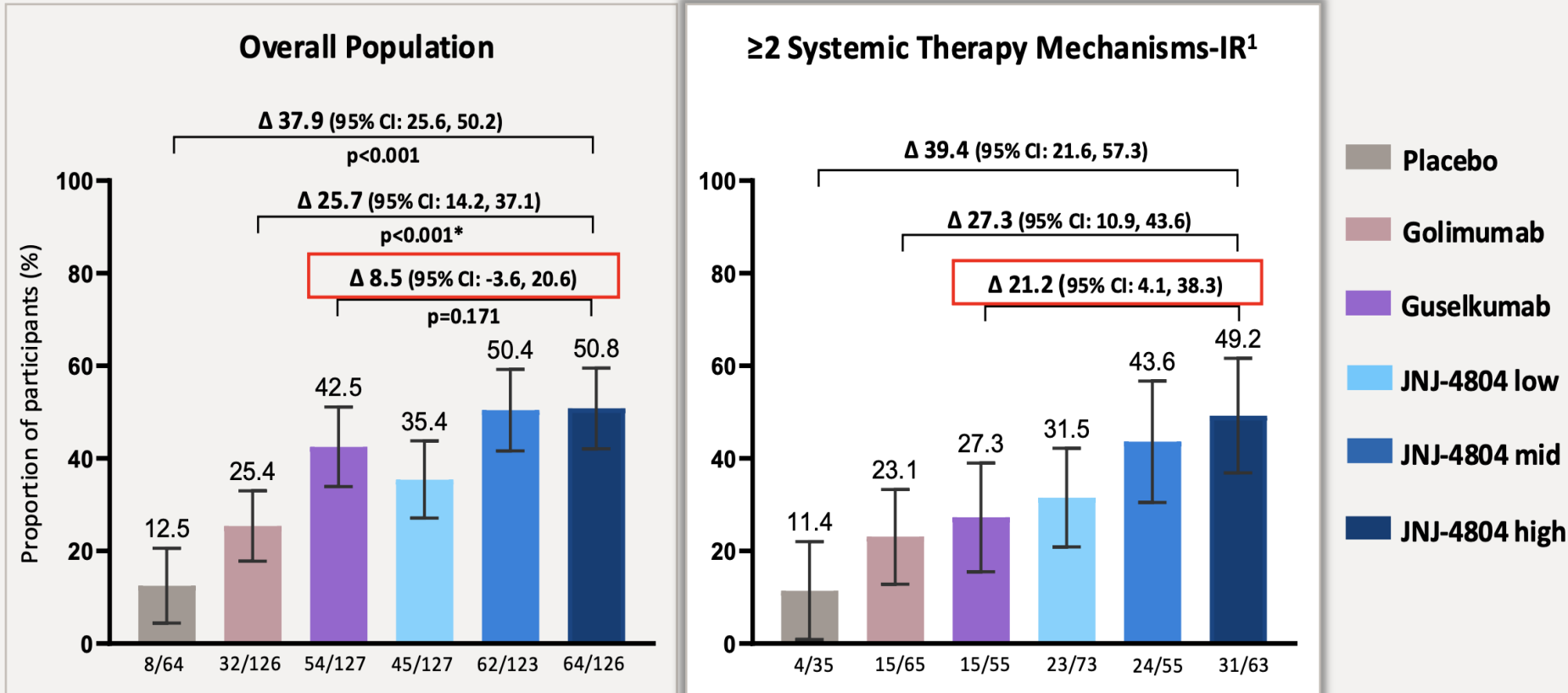
		Placebo	Golimumab	Guselkumab	JNJ-4804 Low dose	JNJ-4804 Mid dose	JNJ-4804 High dose	Total
Analysis set, n		64	126	127	127	123	126	693
Participants with inadequate response to 1 or more systemic therapy mechanisms ¹ , n (%)								
Number of systemic therapy mechanisms - inadequate responders, n (%) ²	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%)

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%

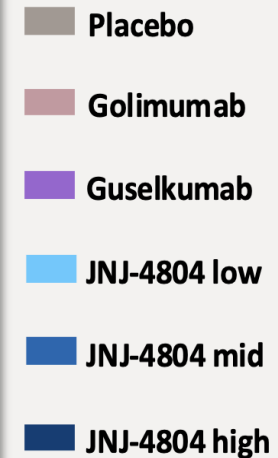
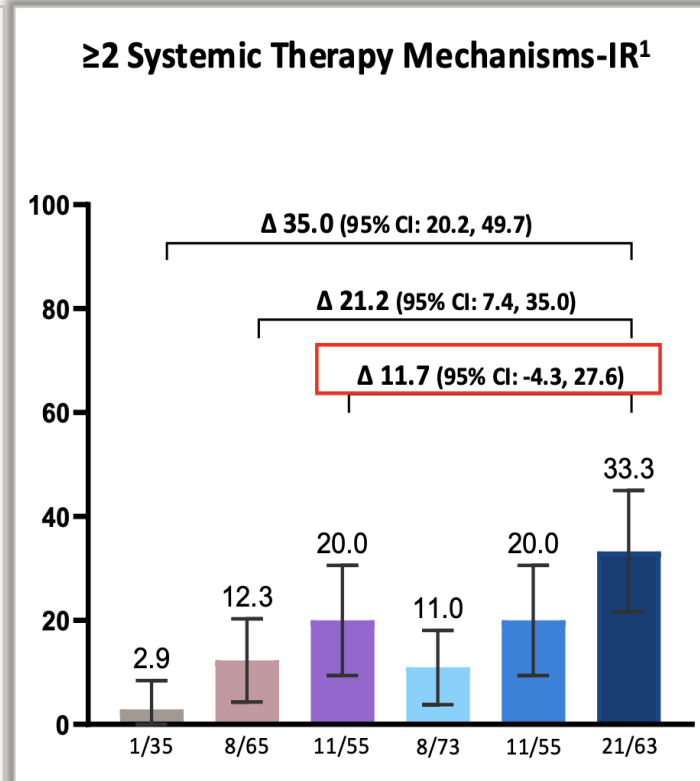
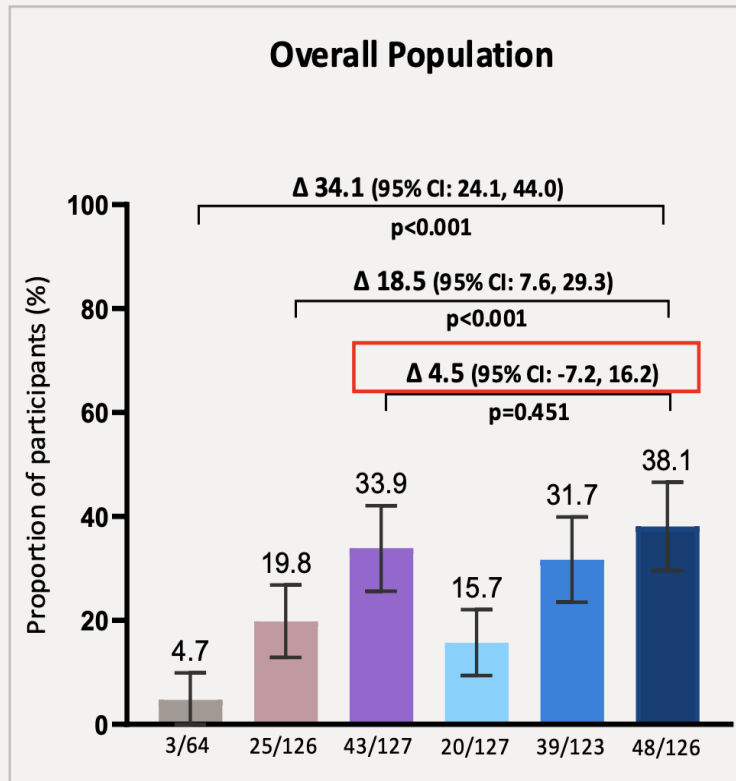
50% were refractory to
2 or more systemic therapy mechanisms

DUET CD – RÉMISSION CLINIQUE SEM 48



Clinical remission: CDAI score of <150

DUET CD – RÉPONSE ENDOSCOPIQUE SEM 48



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

DUET CD

Conclusions

- ❖ Première co-thérapie en développement qui démontre une efficacité supérieure vs monothérapies chez les patients avec un Crohn réfractaire
- ❖ Supérieur au golimumab et numériquement vs guselkumab dans la population globale
- ❖ Chez les pts réfractaires à 2 ou plus thérapies : supérieur au golimumab et guselkumab
- ❖ Pas de nouveau signal d'innocuité vs profil de chacune des thérapies

COMBINAISON DE THÉRAPIES AVANCÉES (DAT)

EFFICACY AND SAFETY OF THE FIRST CO-ANTIBODY THERAPY, JNJ-78934804, IN PATIENTS WITH MODERATELY TO SEVERELY ACTIVE ULCERATIVE COLITIS REFRACTORY TO SYSTEMIC THERAPIES

Maria T. Abreu,¹ Bruce E. Sands,² Séverine Vermeire,³ Remo Panaccione,⁴ Gregory T Moore,⁵ Raja Atreya,⁶ John Lynch,⁷ Melissa G. Marko,⁷ Eun Suk Jung,⁷ Siyka Alexandrova,⁷ Hayley Perry,⁸ Marion L. Vetter,⁷ Julián Panés⁹

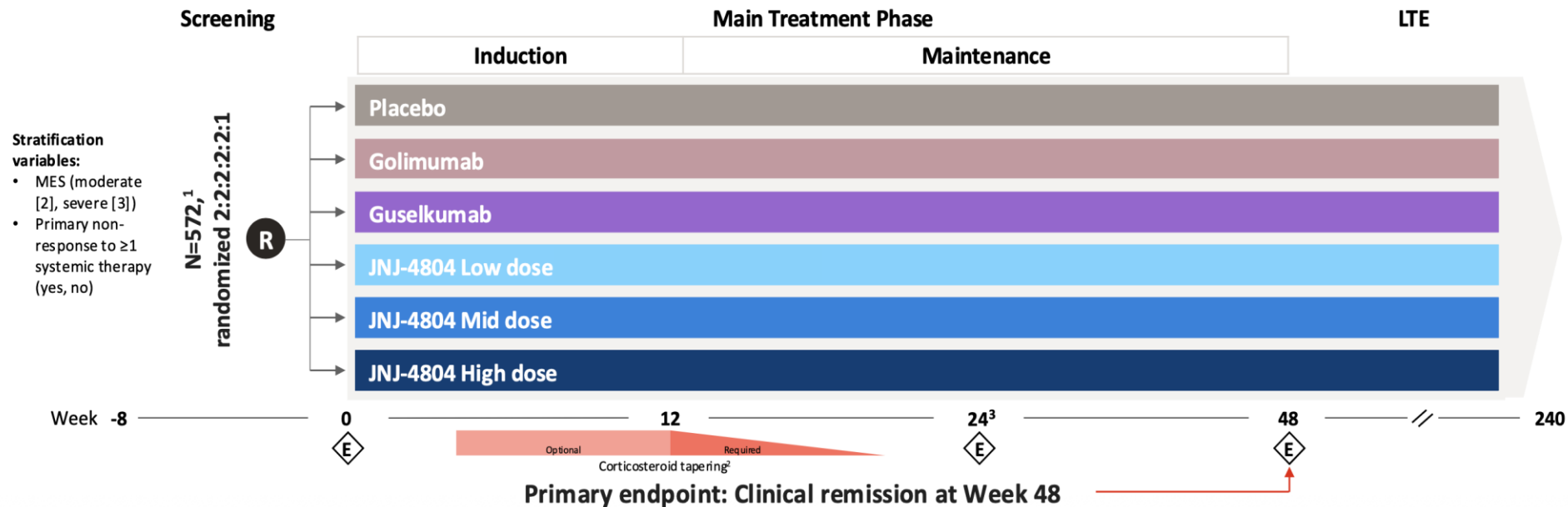
¹Cedars-Sinai, Los Angeles, CA, USA; ²Dr. Henry D Janowitz Division of Gastroenterology, Icahn School of Medicine at Mount Sinai, New York, NY, USA; ³University Hospitals Leuven, Leuven, Belgium; ⁴Inflammatory Bowel Disease Unit, Division of Gastroenterology and Hepatology, University of Calgary, Calgary,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



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PHASE 2B DUET UC

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



¹Full Analysis Set; 559 were included in the modified Full Analysis Set (13 did not meet mMayo inclusion criteria at baseline).

²Participants taking corticosteroids at Week 0 could begin tapering as early as Week 4 but no later than Week 12.

³Participants who met inadequate response criteria at Week 24 received a JNJ-4804 regimen (regardless of treatment assignment).

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

PHASE 2B DUET UC

		Placebo	Golimumab	Guselkumab	JNJ-4804 Low dose	JNJ-4804 Mid dose	JNJ-4804 High dose	Total
Full analysis set		52	104	103	103	105	105	572
Participants with inadequate response to 1 or more systemic therapy mechanisms ¹								
Number of systemic therapy mechanisms - inadequate responders, n (%) ²	1	30 (58.8%)	56 (53.8%)	51 (49.5%)	63 (61.2%)	58 (55.2%)	58 (55.8%)	316 (55.4%)
	≥2	21 (41.2%)	48 (46.2%)	52 (50.5%)	40 (38.8%)	47 (44.8%)	46 (44.2%)	254 (44.6%)

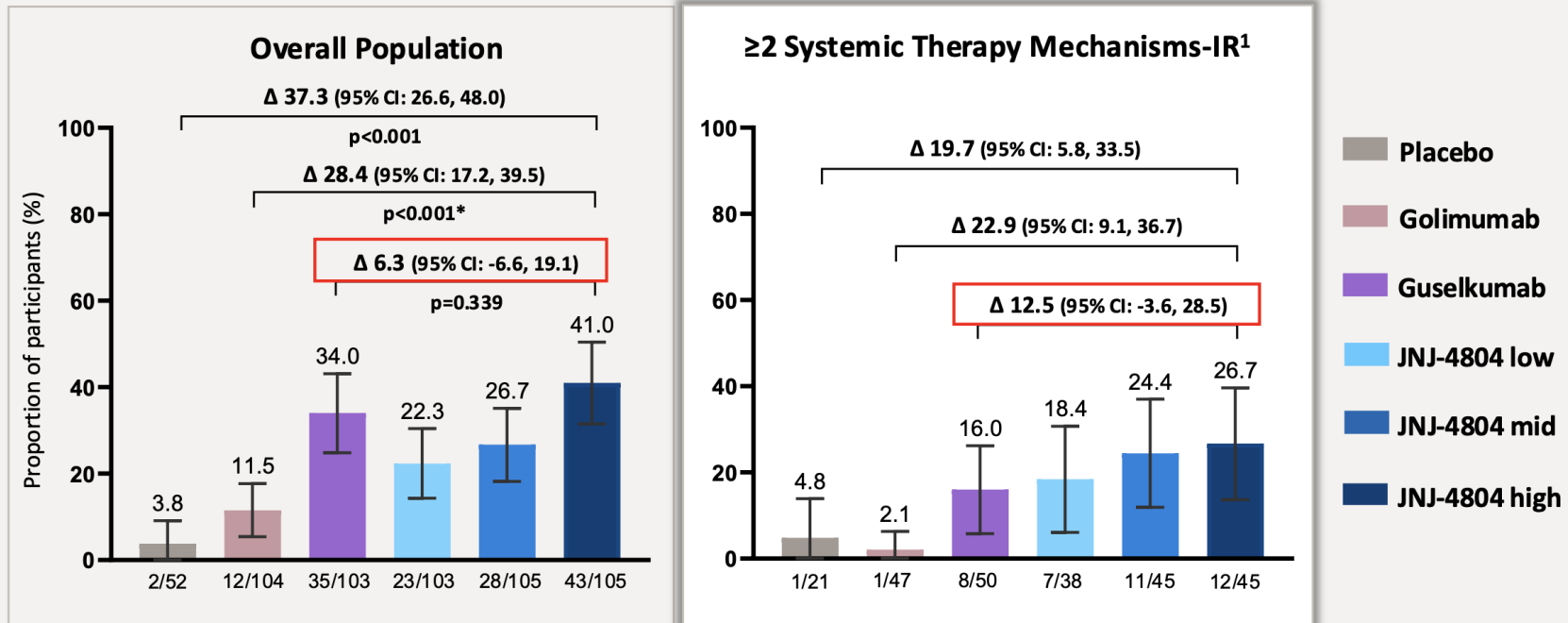
History of inadequate response or intolerance by system therapy mechanism in the overall population

- Anti-TNF: 74%
- Anti-integrin: 44%
- JAK inhibitor: 26%
- Ustekinumab: 19%
- S1PR modulator: 4%
- Anti-IL-23: 1%

60% of participants with disease refractory to 1 systemic therapy had inadequate response to an anti-TNF only

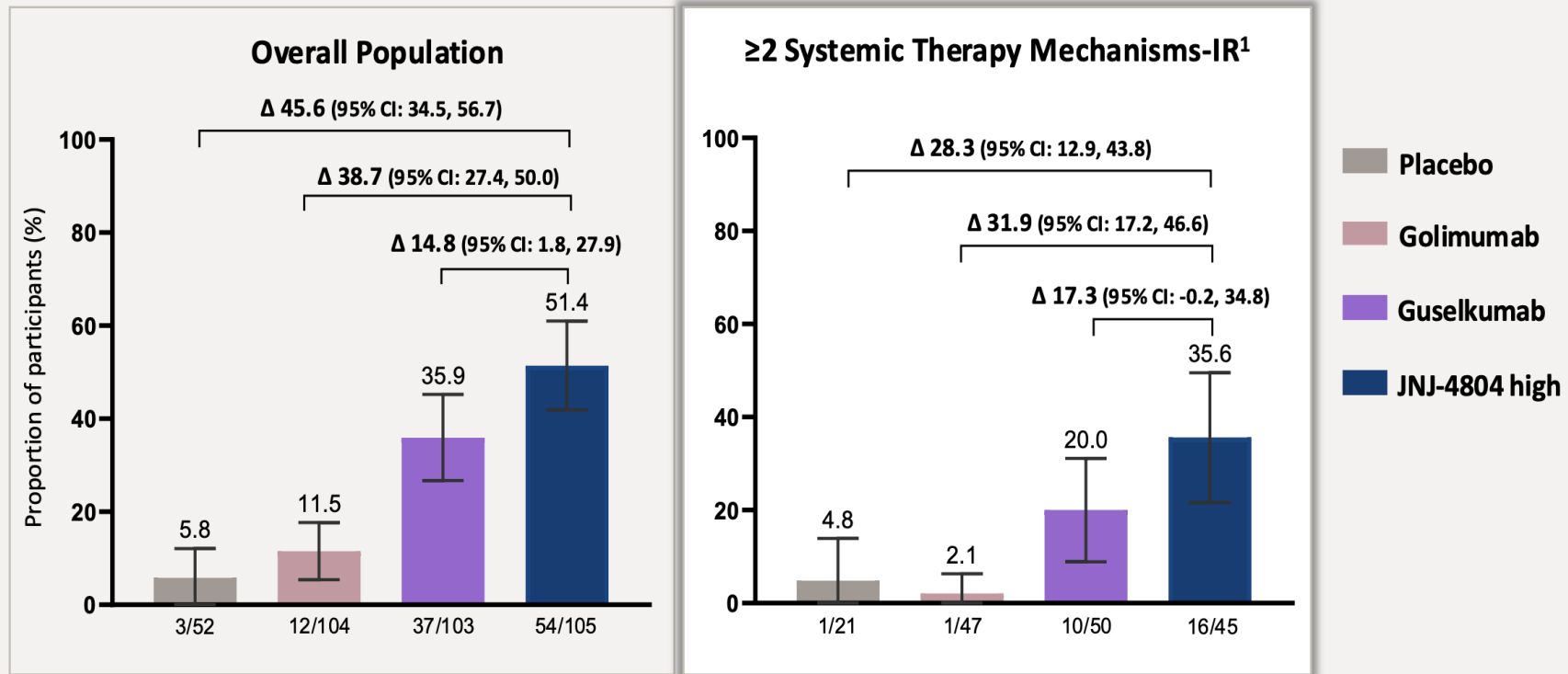
44.6% were refractory to 2 or more systemic therapy mechanisms

PHASE 2B DUET UC — RÉMISSION CLINIQUE SEM48



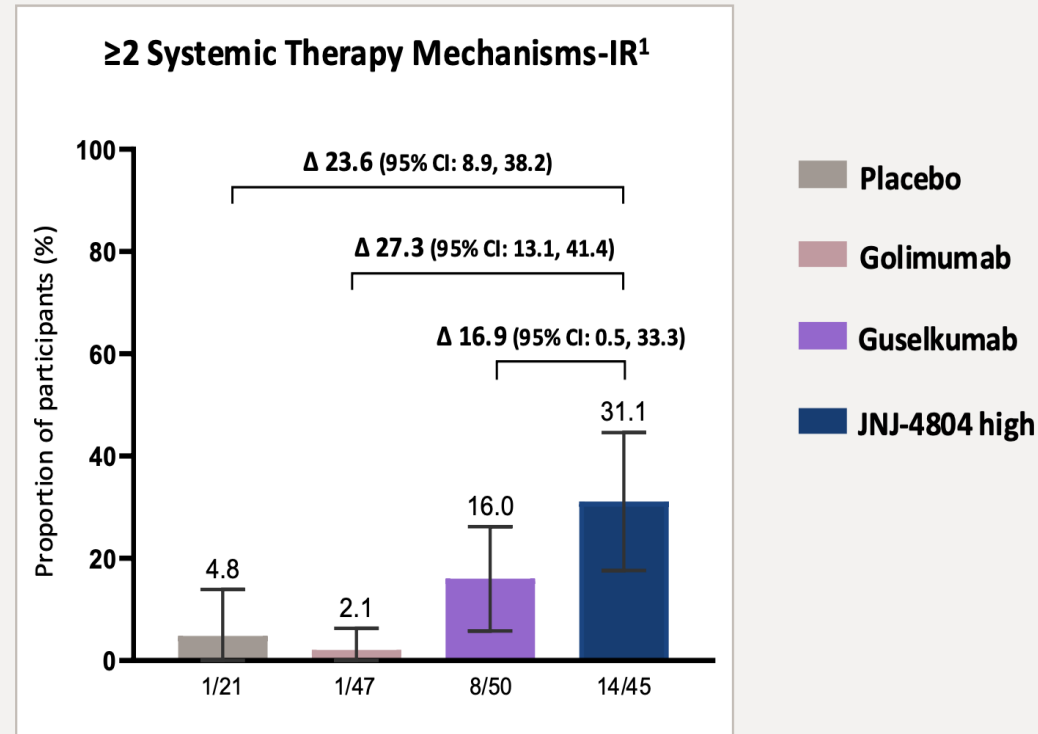
Clinical remission: stool frequency subscore of 0 or 1, rectal bleeding subscore of 0, and endoscopy subscore of 0 or 1 per central review of the video endoscopy

PHASE 2B DUET UC — AMÉLIORATION ENDO SEM48



Endoscopic improvement: endoscopy subscore of 0 or 1 per central review of the video endoscopy

PHASE 2B DUET UC — RÉMISSION HISTO ET AMÉLIORATION ENDO SEM 48



Histologic remission AND endoscopic improvement: absence of neutrophils from the mucosa (both lamina propria and epithelium), no crypt destruction, and no erosions, ulcerations, or granulation tissue according to the Geboes grading system, and an endoscopy subscore of 0 or 1 per central review of the video endoscopy

NOUVEAUTÉS – INH IL23 ORAL

ICOTROKINRA, THE FIRST TARGETED ORAL PEPTIDE THAT SELECTIVELY BLOCKS THE INTERLEUKIN-23 RECEPTOR, REDUCES SYSTEMIC AND TISSUE INFLAMMATORY BURDEN IN ULCERATIVE COLITIS: RESULTS FROM THE ANTHEM-UC STUDY

Edward V. Loftus, Jr., Vipul Jairath, Britta Siegmund, Arun K. Kannan, Martha Zeeman, Amy Hart, David Strawn, Swati Venkat, Lynn Tomsho, Bradford Mcrae, Darren Ruane, Lindsey Surace, Ngozi Erundu, Joyce Zhan, Minhu Chen, Karen Chachu, Katsuyoshi Matsuoka, Jimmy Limdi, Grazyna Rydzewska, Maria T. Abreu, Edouard Louis



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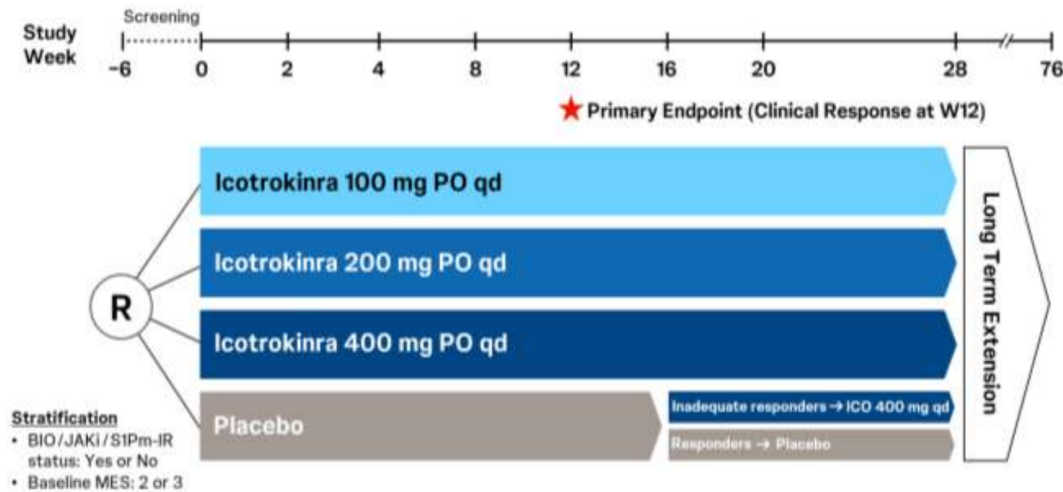


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ANTHEM-UC



Key Eligibility Criteria

- Diagnosed UC of ≥ 12 weeks duration
- Modified Mayo score of 5–9, inclusive
- Mayo endoscopic subscore (MES) ≥ 2 per central review
- Inadequate response/intolerance (IR) to CS, 6-MP, or AZA **OR** CS dependence **OR** IR to TNF α antagonists, ustekinumab, vedolizumab, JAK inhibitors, or S1P receptor modulators (BIO/JAKi/S1Pm-IR)

Clinical inflammatory biomarkers: C-reactive protein and fecal calprotectin

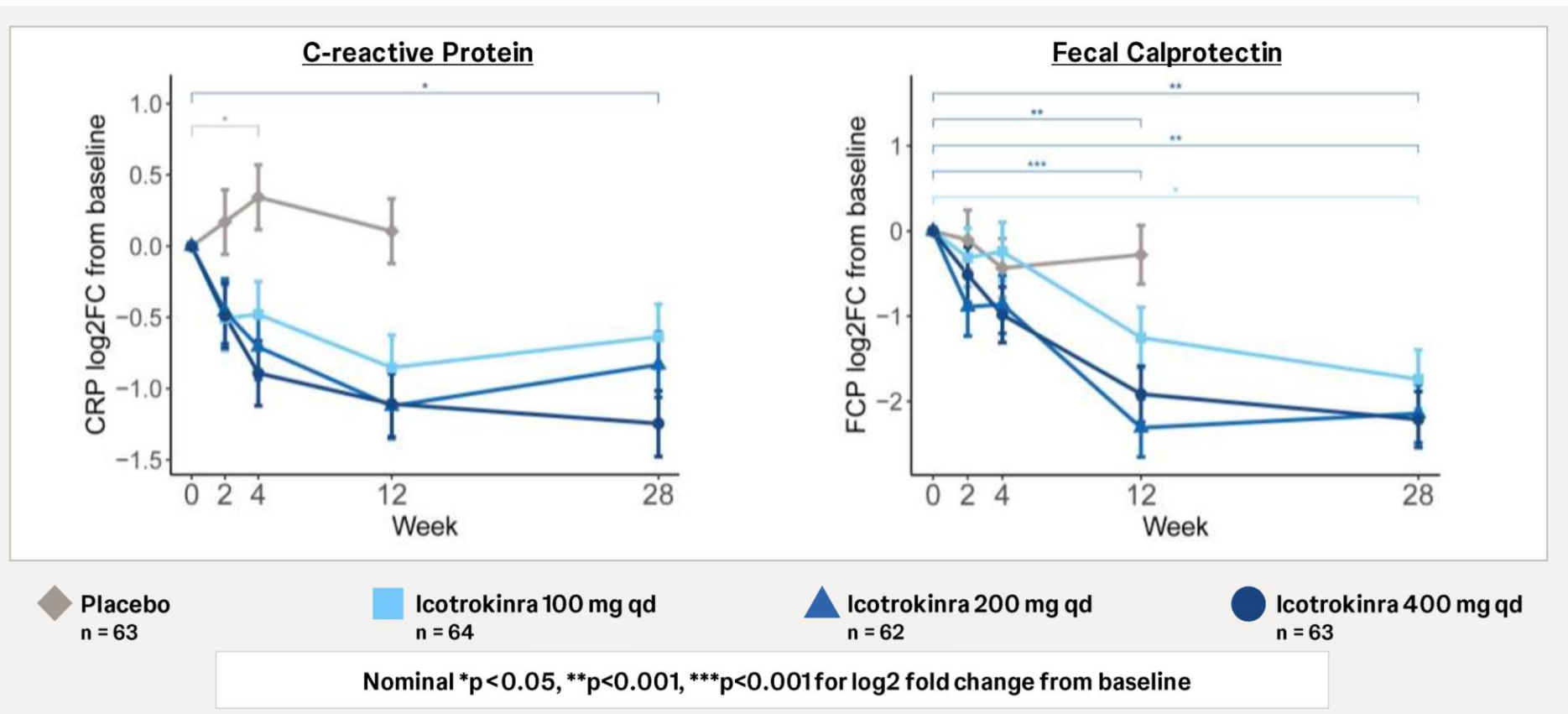
Systemic IL-23 pathway biomarkers: IL-22, IL-17A, and IL-17F

Tissue biomarkers: IL-23 pathway gene expression changes in colonic biopsies

- At screening, biopsies were collected from the colon/rectum (at least 15–20 cm from the anal verge) in a representative area that was consistent with the severity of inflammation
- Subsequent biopsies from the same location were collected at Weeks 12 and 28

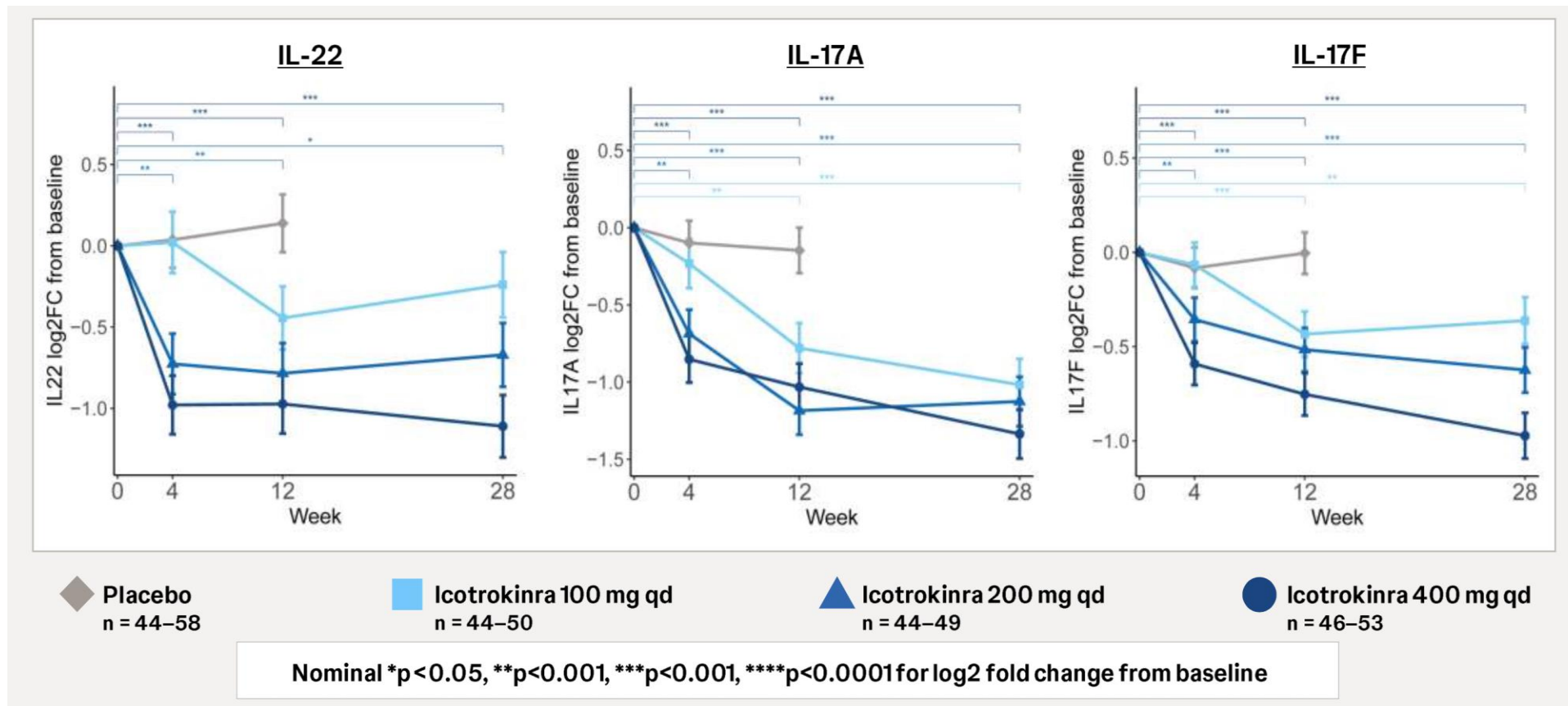
Statistical analyses of these biomarkers were not controlled for multiple comparisons

ANTHEM-UC - BIOMARQUEURS



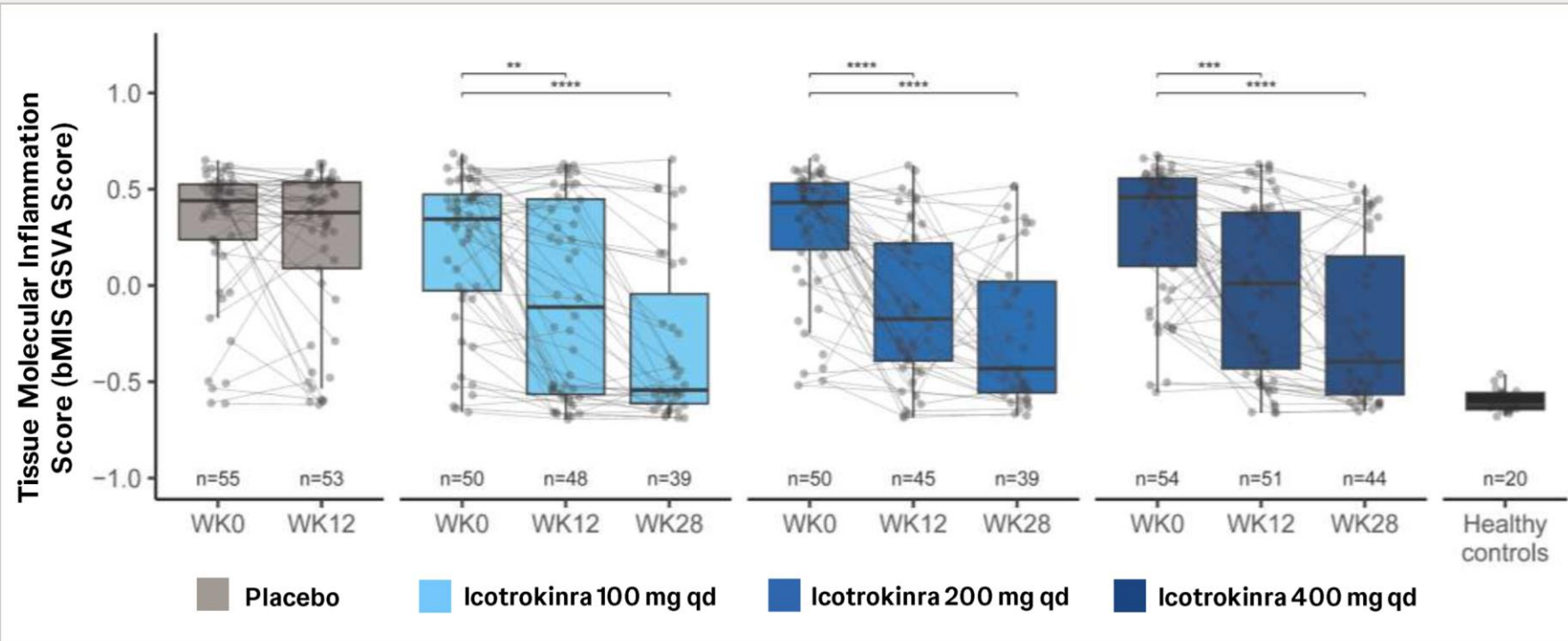
Plots track mean values (estimated marginal means) using a linear mixed effect model that accounts for treatment*time interaction, age, and sex, with subject as a random effect. Error bars are model-based standard errors.

ANTHEM-UC BIOMARQUEURS SYSTÉMIQUES VOIE IL23



Plots track mean values (estimated marginal means) using a linear mixed effect model that accounts for treatment*time interaction, age, and sex, with subject as a random effect. Error bars are model-based standard errors.

ANTHEM-UC CHARGE INFLAMMATOIRE TISSULAIRE



Nominal **p<0.01, ***p<0.001, ****p<0.0001

Quantification of biopsy molecular inflammation score (bMIS) using gene set variation analysis (GSVA) at the indicated time points after placebo or icotrokinra treatment. GSVA scores are depicted and compared at Week 0 and Week 12 or Week 28 with a t-test. Error bars are 95% confidence intervals. Data from healthy controls were generated from commercially obtained colonic biopsies.

NOUVEAUTÉS — TL1A...AU-DELÀ DE L'INFLAMMATION !

The Anti-TL1A Monoclonal Antibody Tulisokibart Inhibits Inflammatory and Fibrosis Pathways: Results From a Phase 2 Ulcerative Colitis Study

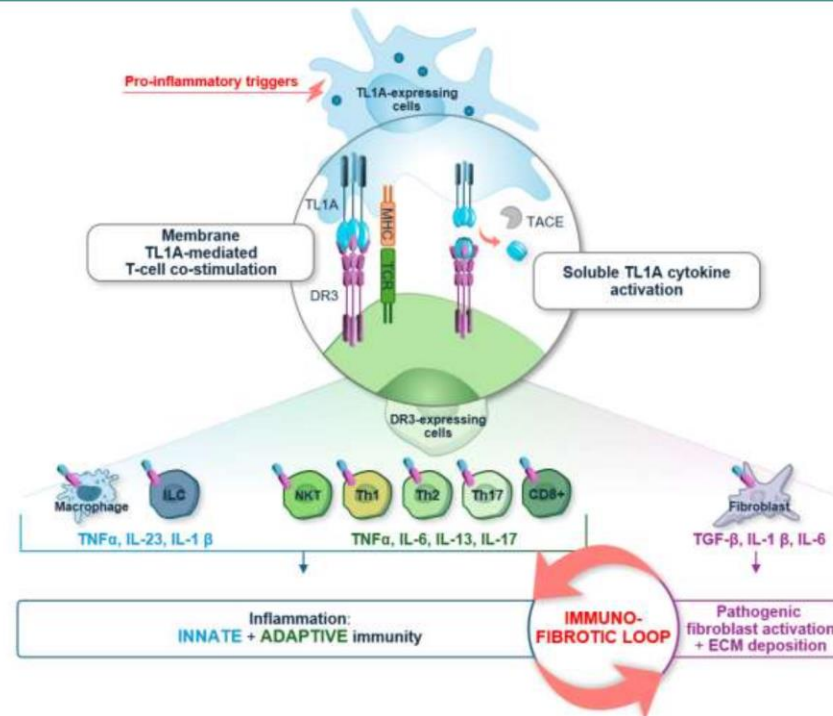
¹Florian Rieder, ²Richard Wnek, ²Shiuli Agarwal, ²Heather Llewellyn, ²John Kang, ²Peining Tao, ²Wen Zhou, ²Justin Klaff, ²In Sock Jang, ²Ernesto J. Muñoz-Elias, ³Jean-Frederic Colombel

¹Department of Gastroenterology, Hepatology and Nutrition, Digestive Diseases Institute, Cleveland Clinic Foundation, Cleveland, Ohio, USA; ²Merck & Co., Inc., Rahway, New Jersey, USA; ³Department of Gastroenterology, Icahn School of Medicine at Mount Sinai, New York, NY, USA

CONTEXTE

Tulisokibart Inhibits TL1A, a Central Amplifier of Inflammatory and Fibrotic Pathways in IBD Pathogenesis

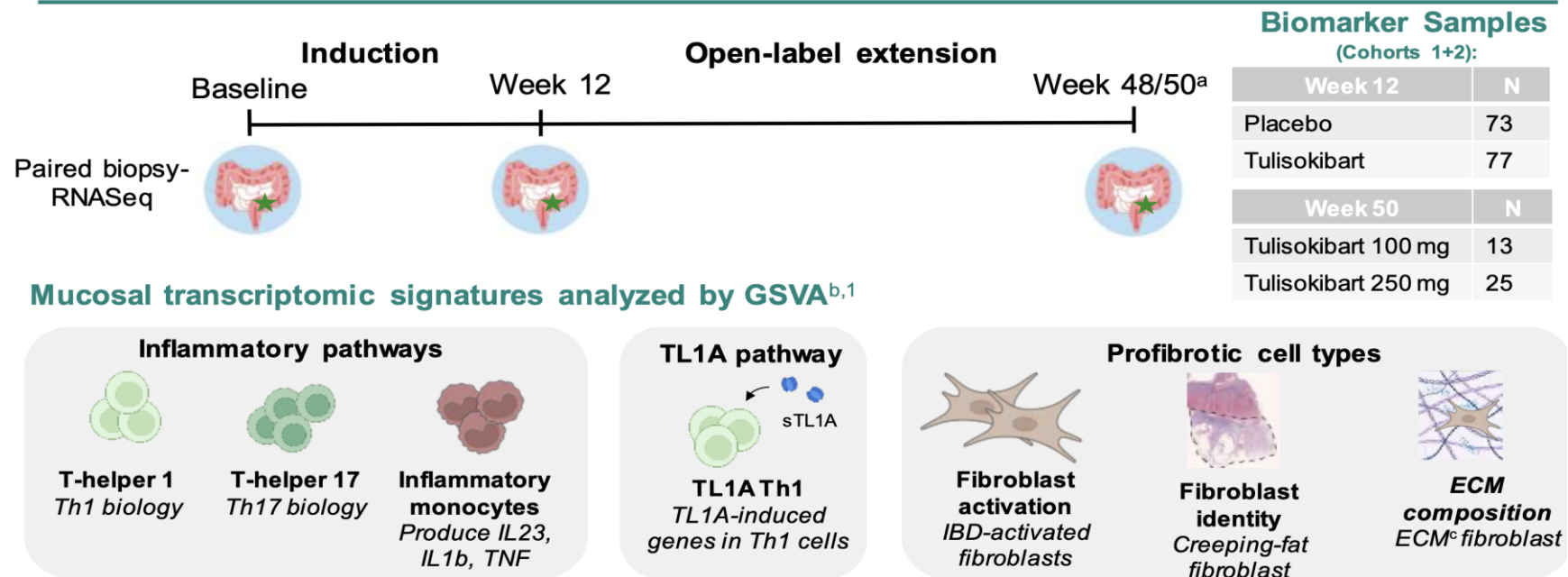
- Preclinical and translational data supported targeting TL1A for the treatment of IBD¹⁻⁷
- Tulisokibart is a humanized monoclonal antibody that binds membrane and soluble TL1A and inhibits signaling through DR3 leading to reduction of inflammatory and fibrosis pathways^{8,9,10}
- Phase 2 ARTEMIS-UC in moderately to severely active ulcerative colitis: tulisokibart induction treatment significantly improved clinical, endoscopic, and patient-reported outcomes vs placebo at week 12¹¹; responses were maintained through week 50¹²



1. Bamias G, et al. *Gut*. 2025;74(4):652-668. 2. Lusetti F, et al. *Expert Rev Gastroenterol Hepatol*. 2025;19(1):15-25. 3. Solitano V, et al. *BioDrugs*. 2025;39(2):171-183. 4. Siakavellas SI, et al. *Inflamm Bowel Dis*. 2015;21(10):2441-2452. 5. Bamias G, et al. *Clin Immunol*. 2010;137(2):242-249. 6. Yamazaki K, et al. *Hum Mol Genet*. 2005;14(22):3499-3506. 7. Jostins L, et al. *Nature*. 2012;491(7422):119-124. 8. Feagan BG, et al. *Lancet Gastroenterol Hepatol*. 2025;10(8):715-725. 9. Fransson J, et al. Protein & Antibody Engineering Summit (PEGS) Europe; Lisbon, Portugal; 2023. 10. Danese S, et al. United European Gastroenterology (UEG) Week; Copenhagen, Denmark; 2023. 11. Sands B, et al. *N Engl J Med*. 2024;391:1119-1129. 12. Ma C, et al. United European Gastroenterology (UEG) Week; Vienna, Austria; 2024.

ANALYSE POST-HOC

Gene Expression Analysis of Mucosal Inflammatory and Fibrosis Pathways

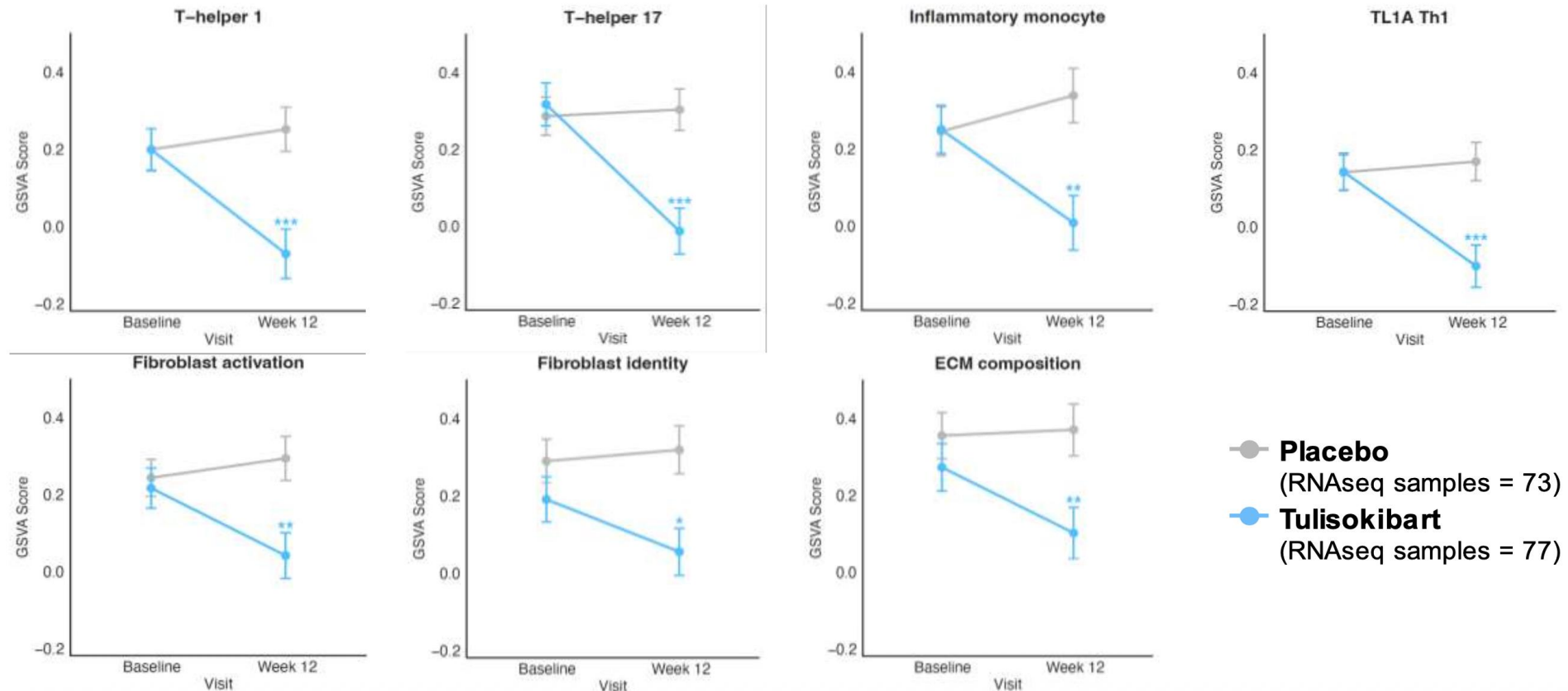


^aPatients had either a week 48 or week 50 biopsy collection. ^bGSVA estimates pathway or gene-set activity at the sample level by summarizing coordinated expression of predefined gene sets in an unsupervised manner. ^cECM composition: the overlap of genes between the fibroblast activation signature and the Core matrisome signature for ECM as identified in The Matrisome Project [The Matrisome Project \(mtrproject.org\)](https://www.mtrproject.org/).

SEMAINE 12

Molecular pathways modulated by tulisokibart treatment in intestinal mucosal biopsies of UC patients support a pleiotropic role for TL1A dysregulation in driving inflammatory and fibrotic pathways

- Tulisokibart suppressed Th1, Th17, TL1A-Th1, and fibrosis gene expression pathways
- Tulisokibart also suppressed gene expression pathways associated with inflammatory monocytes, which are known to produce $\text{TNF}\alpha$, IL-1b, and IL-23



P values are for week 12 versus baseline; one-sided significance levels: * $P < 0.05$; ** $P < 0.01$; *** $P < 0.001$. Paired analysis. ECM, extracellular matrix; GSVA, gene set variation analysis; RNAseq, RNA sequencing; Th1, T-helper 1.

NOUVEAUTÉS - OBEFAZIMOD

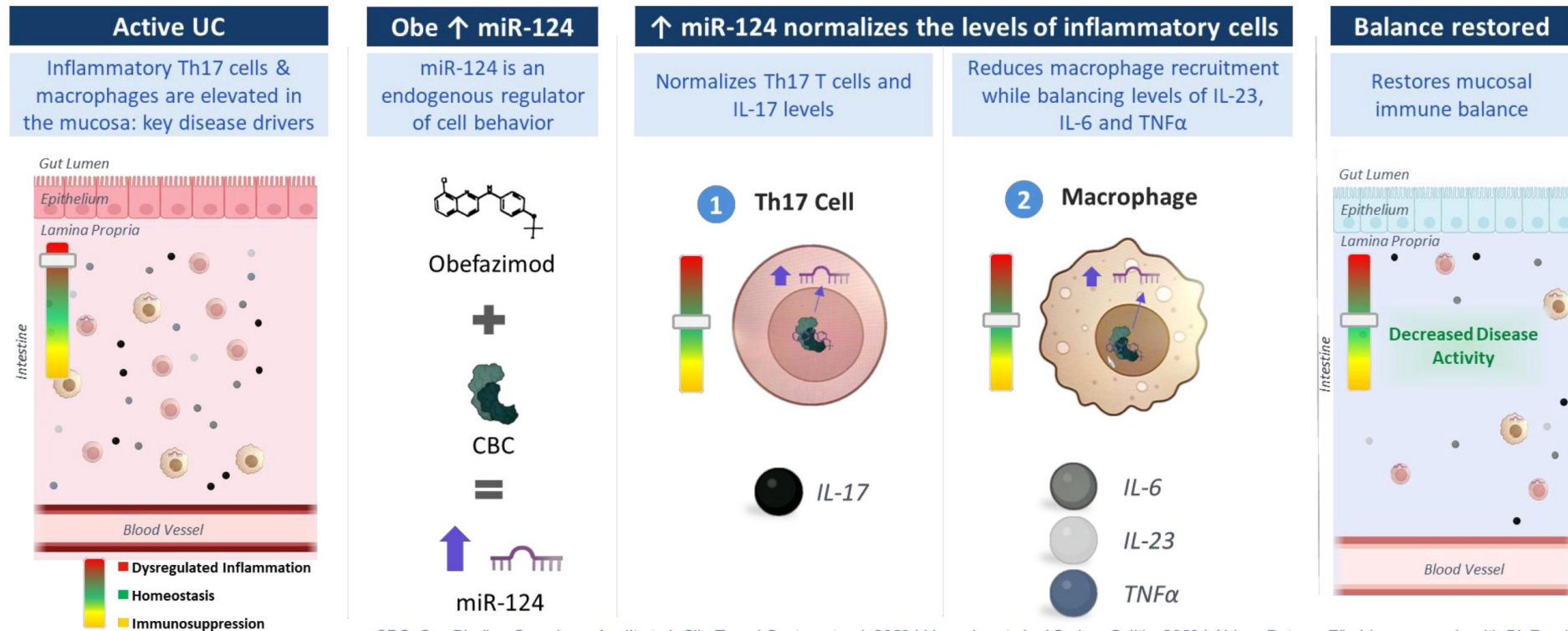
Impact of obefazimod treatment on histologic and combined histologic-endoscopic outcomes in patients with moderately to severely active ulcerative colitis: results from the ABTECT-1 and ABTECT-2 Phase 3, double-blind, placebo-controlled induction trials

Fernando Magro, Bruce E Sands, Silvio Danese, Marla Dubinsky, Fabio Cataldi, Doug Jacobstein, Christopher J Rabbat, Kevin Shan, Luciana Harlacher, Franco Scaldaferri, Geert D'Haens, Luc Biedermann, Laurent Peyrin-Biroulet



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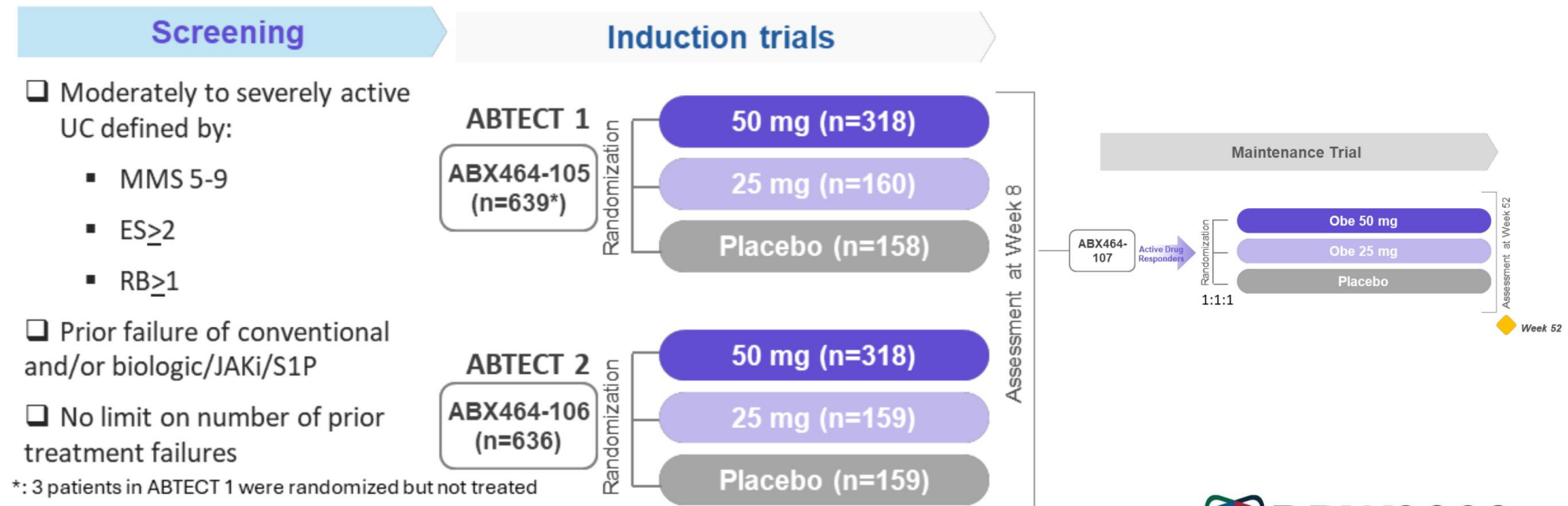
OBEFAZIMOD



CBC: Cap Binding Complex - Apolit et al. Clin Transl Gastroenterol, 2023 | Vermeire et al., J Crohns Colitis, 2023 | Abivax Data on File | Images made with BioRender

Obefazimod restores mucosal immune balance in ulcerative colitis through regulation of Th17 cells and macrophages

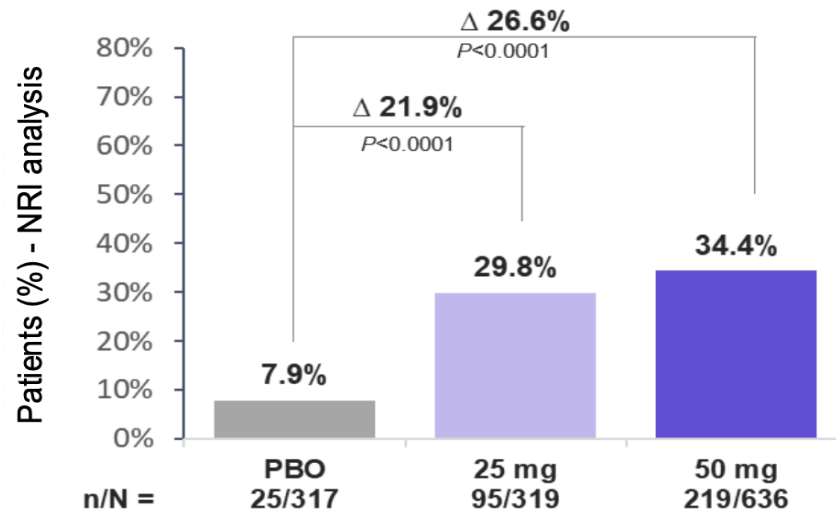
ABTECT 1&2



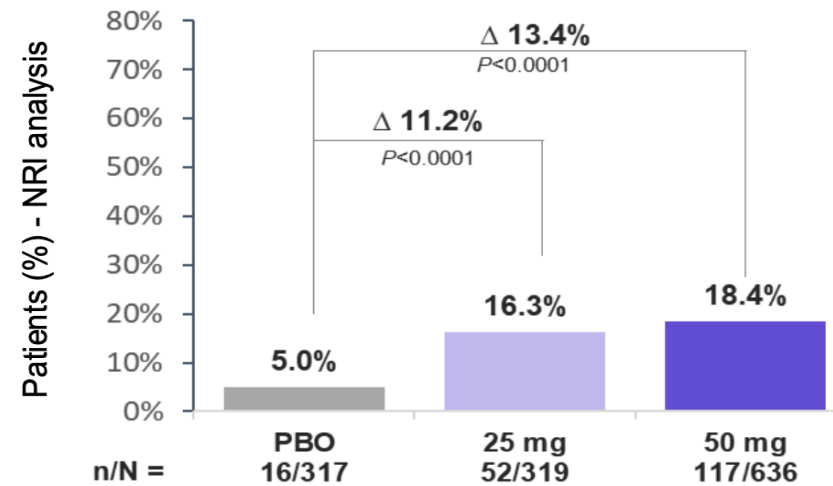
Rectal or sigmoidal biopsies from the most affected segment were collected during endoscopy at screening and Week 8

SEMAINE 8 — ISSUES ENDOSCOPIQUES

Endoscopic improvement



Endoscopic remission

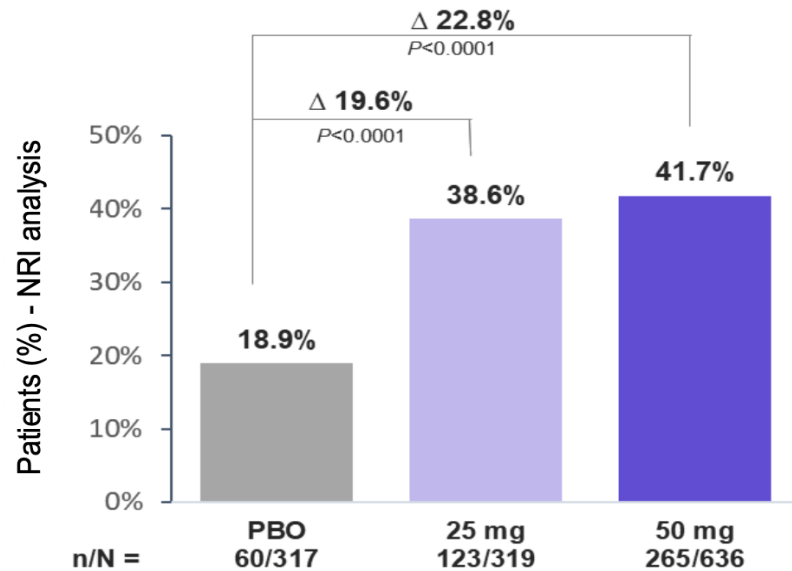


* All p-values are nominal

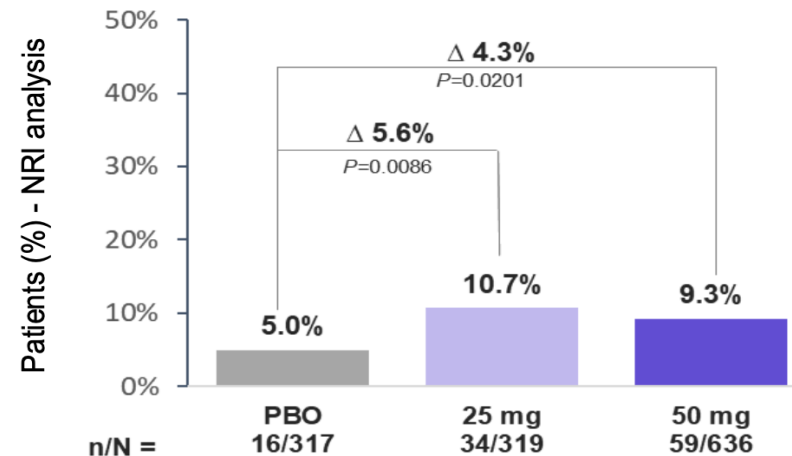
NRI is used for subjects with missing outcome at week 8 and subjects reporting any IE prior to week 8; % Difference is for Obe minus placebo and is based on estimated common risk difference using the Mantel-Haenszel weights adjusting for the randomization stratification factors: inadequate response to advanced therapies (yes/no), baseline oral corticosteroids usage (yes/no), and pivotal study (ABX464-105/ABX464-106). All P values are 2-sided. Endoscopic improvement: endoscopic subscore ≤ 1 . Endoscopic remission: endoscopic subscore = 0. IE, intercurrent event; MES, Mayo Endoscopic Subscore; NRI, non-responder imputation; Obe, obefazimod; PBO, placebo.

SEMAINE 8 - HISTOLOGIE

Histologic improvement (Geboes histologic score ≤ 3.1)

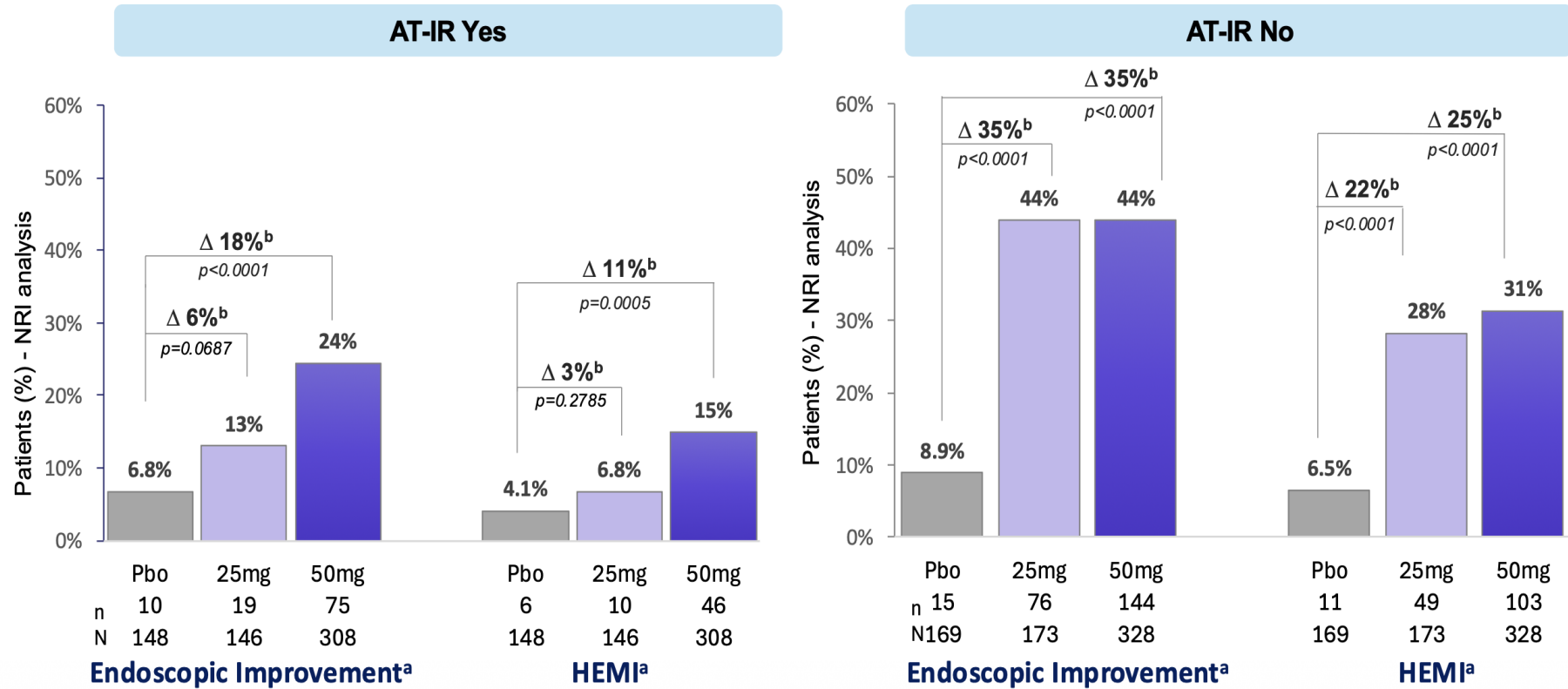


Histologic remission (Geboes histologic score $< 2A.0$)



*: All p-values are nominal; NRI is used for subjects with missing outcome at week 8 and subjects reporting any IE prior to week 8; % Difference is for Obe minus placebo and is based on estimated common risk difference using the Mantel-Haenszel weights adjusting for the randomization stratification factors: inadequate response to advanced therapies (yes/no), baseline oral corticosteroids usage (yes/no), and pivotal study (ABX464-105/ABX464-106). All P values are 2-sided. Histological improvement: neutrophil infiltration in $< 5\%$ of crypts, no crypt destruction, and no erosions, ulcerations, or granulation tissue according to the Geboes grading system (ie, Geboes histologic score ≤ 3.1). Histological remission: absence of neutrophils in the epithelial crypts or lamina propria and no increase in eosinophils, no crypt destruction, and no erosions, ulcerations, or granulation tissue, according to the Geboes grading system (ie, Geboes histologic score $< 2A.0$). IE, intercurrent event; MES, Mayo Endoscopic Subscore; NRI, non-responder imputation; Obe, obefazimod; PBO, placebo.

SEMAINE 8



AT-IR: inadequate response to advanced therapies

All p-values are nominal; [a] Endoscopic improvement is defined as MES = 0 or 1 (MES of 1 modified to exclude friability). HEMI is defined as MES = 0 or 1 and Geboes Index score ≤ 3.1 ; [b] % Difference is for obefazimod minus placebo and is based on estimated common risk difference using the Mantel-Haenszel weights adjusting for the randomization stratification factors: inadequate response to advanced therapies (yes/no), Baseline oral corticosteroids usage (yes/no). P-values are two sided. NRI is used for subjects with missing outcome at Week 8 and subjects reporting any IE prior to Week 8.

AUTRE ALLIÉ CONTRE LA FIBROSE!

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Obefazimod shows first evidence of dual anti-inflammatory and anti-fibrotic activity in murine *in vivo* and human *in vitro* models

S. DANESE¹, F. MAGRO², B. SIEGMUND³, R. ATREYA⁴, J. SANTO⁵, A. GARCEL⁶, S. D'ALESSIO⁷, M. PEHRSSON⁸, JH MORTENSEN⁹, M SOROKINA ALEXDOTTIR⁷, A-C. BAY-JENSEN⁷, M. ASSER KARSDAL⁷, D. JACOBSTEIN⁸, R. MOSIG⁸, C. J. RABBAT⁸, M. DE LA ROSA⁸, F. CATALDI⁸, B. VERSTOCKT⁸

¹UCD Ospedale San Raffaele, Italy; ²São João University Hospital, a Porto, Portugal; ³Charité - Universitätsmedizin, Berlin, Germany; ⁴University Hospital, Erlangen, Germany; ⁵University Hospital, Hamburg, Germany; ⁶Novartis, Basel and Virology, Basel, Switzerland; ⁷Novartis, Boston, MA; ⁸Novartis, Basel, Switzerland; ⁹Novartis, Copenhagen, Denmark; ¹⁰Novartis, Department of Gastroenterology & Hepatology, Leuven, Belgium

Tu1433



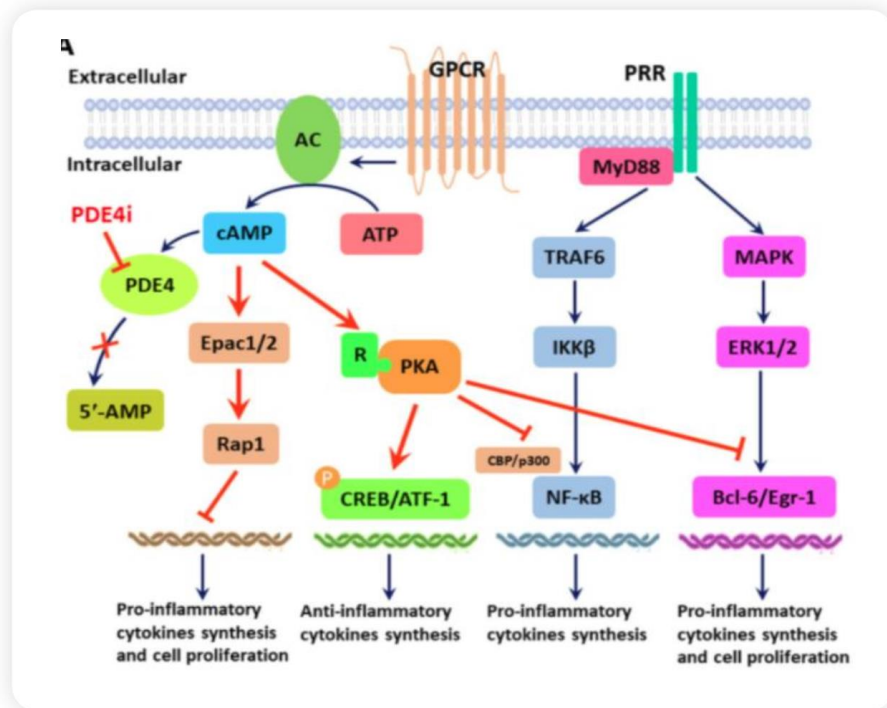
NOUVEAUTÉS - MUFEMILAST

MUFEMILAST (ORAL PDE4 INHIBITOR) FOR ULCERATIVE COLITIS: OPEN-LABEL EXTENSION RESULTS AT 24 WEEKS FROM A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED PARALLEL GROUP INDUCTION PHASE II CLINICAL TRIAL

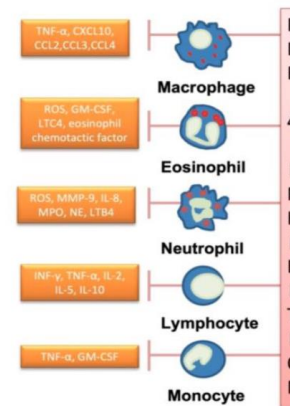
L. Peyrin-Biroulet, C.R. Jones, S. T. Zhang, C.Q. Zheng, B.R. Liu, X.L. Zuo, S.G. Ding, X.Y. Ding, L. P. Li, Y.X. Chen, X. Ren, C.X. Liu, X.W. Liu, B.M. Wang, C. D. Wang, H. Guo, B.H. Xu, R.M. Yu, F. Tian, X.H. Hou, H. Yang, Z. H. Yu, X.P. Hu, Z.H. Wang, Y.Y. Zhen, H. Hai, A.H. Huo, H.S. Zhang

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MUFEMILAST



Mufemilast works beyond the axis of specific cytokines blocked by biologics (IL12/23; IL17) without additional safety concerns. This includes targeting NF-κB, MAPK, neutrophil trafficking, and PDE4b expression inhibition



Multiple target cells

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DOI:10.3389/fphar.2018.01048 Corpus ID: 53167673
Phosphodiesterase-4 Inhibitors for the Treatment of Inflammatory Diseases

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CE QUI A RETENU MON ATTENTION!

- ❖ IL23i – emphase sur la durabilité et l'innocuité à long-terme
- ❖ Innovation liée à la commodité module la compétition dans la classe des IL23i
 - ❖ Icotrokinra (oral)
 - ❖ Induction sous-cutanée
 - ❖ SPY003 (liaison FcRn qui permet une extension de la demi-vie)
 - ❖ XmAb412 (dual IL23i/TL1Ai avec extension de la demi-vie)
- ❖ TL1Ai font déplacer la conversation au-delà de l'inflammation : fibrose!
- ❖ Nouveaux MoA :
 - ❖ Obefazimod (upreg miR-124)
 - ❖ Mufemilast (PDE4i)
- ❖ Combinaison de thérapies avancées – préparez-vous!

A scenic view of a city, likely Montreal, featuring a large, ornate cathedral with a dark roof and multiple spires on the left. To the right is a large, multi-story brick building with many windows. In the background, a large, forested hill rises, topped with several communication towers. The sky is clear and blue. The text "Merci de votre attention!" and the email address "joannie.ruel@usherbrooke.ca" are overlaid in the center of the image.

Merci de votre attention!
joannie.ruel@usherbrooke.ca