Obefazimod in Focus: Revolutionizing IBD Through a New Mechanism of Action

Thursday, February 19, 2026 | 14:00–14:20 | Stockholm, Sweden

This program is not affiliated with ECCO

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- This medical product theater is sponsored by Abivax and is not accredited for continuing education by any organization
- Obefazimod is an investigational agent not approved by any health regulatory agency
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Faculty

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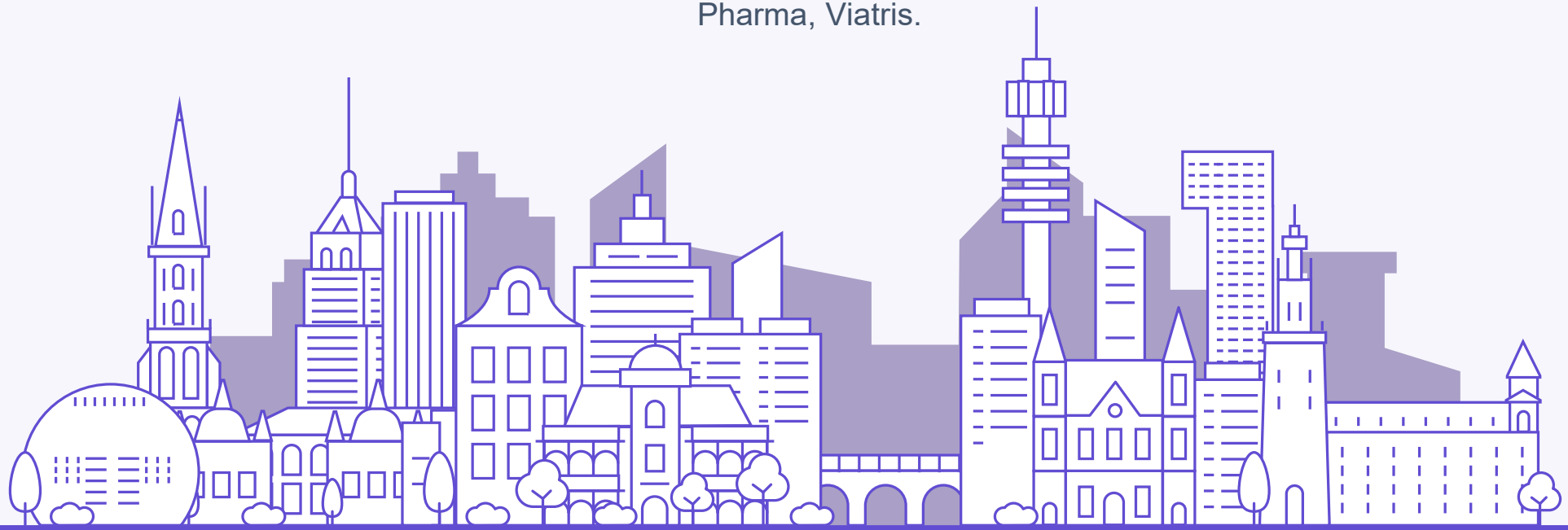
Disclosures

Prof Silvio Danese, MD, PhD received consultancy fees from AbbVie, Abivax, Alimentiv, Allergan, Amgen, Applied Molecular Transport, AstraZeneca, Athos Therapeutics, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Celltrion, Dr Falk Pharma, Eli Lilly, Enthera, Ferring, Gilead, Hospira, Inotrem, Janssen, Johnson & Johnson, Morphic, MSD, Mundipharma, Mylan, Pfizer, Roche, Sandoz, Sublimity Therapeutics, Takeda, Teladoc Health, TiGenix, UCB, Vial, and Vifor, and received lecture fees from AbbVie, Amgen, Ferring, Gilead, Janssen, Mylan, Pfizer, and Takeda.

Prof Raja Atreya, MD served as a speaker or consultant or received research grants from AbbVie, Abivax, Alfasigma, Amgen, AstraZeneca, Biogen, Boehringer Ingelheim, Bristol-Myers Squibb, CED Service GmbH, Celltrion Healthcare, Falk Foundation, Galapagos, Gilead, Index Pharmaceuticals, Johnson & Johnson, Lilly, MSD Sharp & Dohme, Pfizer, Pandion Therapeutics, Roche Pharma, Takeda Pharma, Viatris.



Agenda

Prof Raja Atreya, MD

University Hospital of Erlangen
Erlangen, Germany

Obefazimod Mechanism of Action

14:02–14:10

Prof Silvio Danese, MD

IRCCS San Raffaele Hospital
Milan, Italy

Overview of Phase 3 ABTECT Induction Results

14:10–14:18

All

Q&A

14:18–4:20

ABIVAX

Obefazimod Mechanism of Action

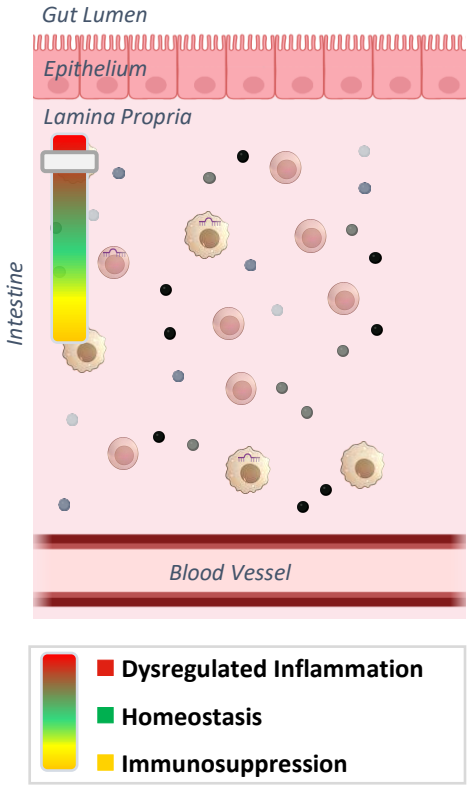
Raja Atreya, MD
University Hospital of Erlangen
Erlangen, Germany

Obefazimod Restores Mucosal Immune Balance in UC through Physiologic Immunoregulation

Obefazimod MoA addresses multiple hallmarks of IBD pathology & chronic inflammation

Active UC

Inflammatory Th17 cells & macrophages are elevated in the mucosa: key disease drivers



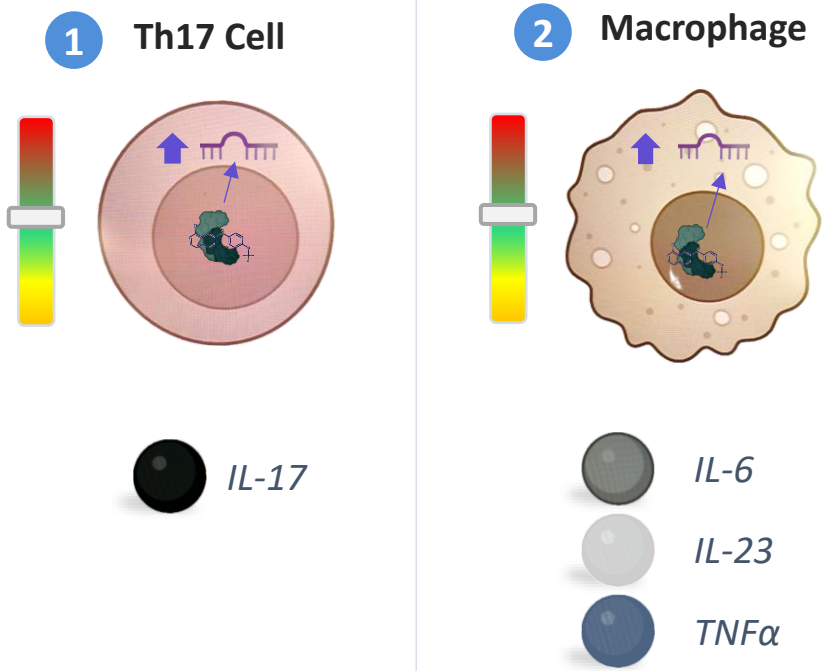
Obe ↑ miR-124

miR-124 is an endogenous regulator of cell behavior

↑ miR-124 normalizes the levels of inflammatory cells

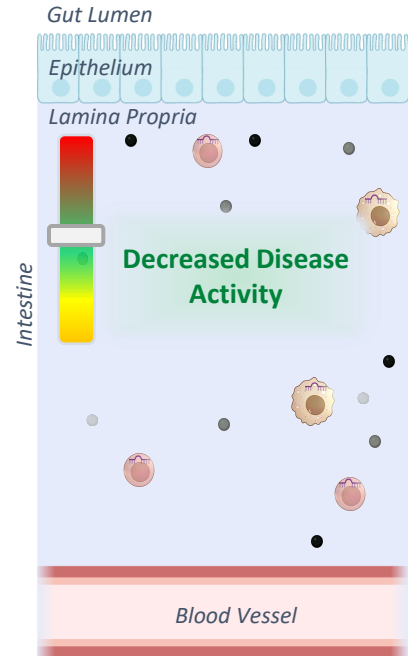
Normalizes Th17 T cells and IL-17 levels

Reduces macrophage recruitment while balancing levels of IL-23, IL-6 and TNFα



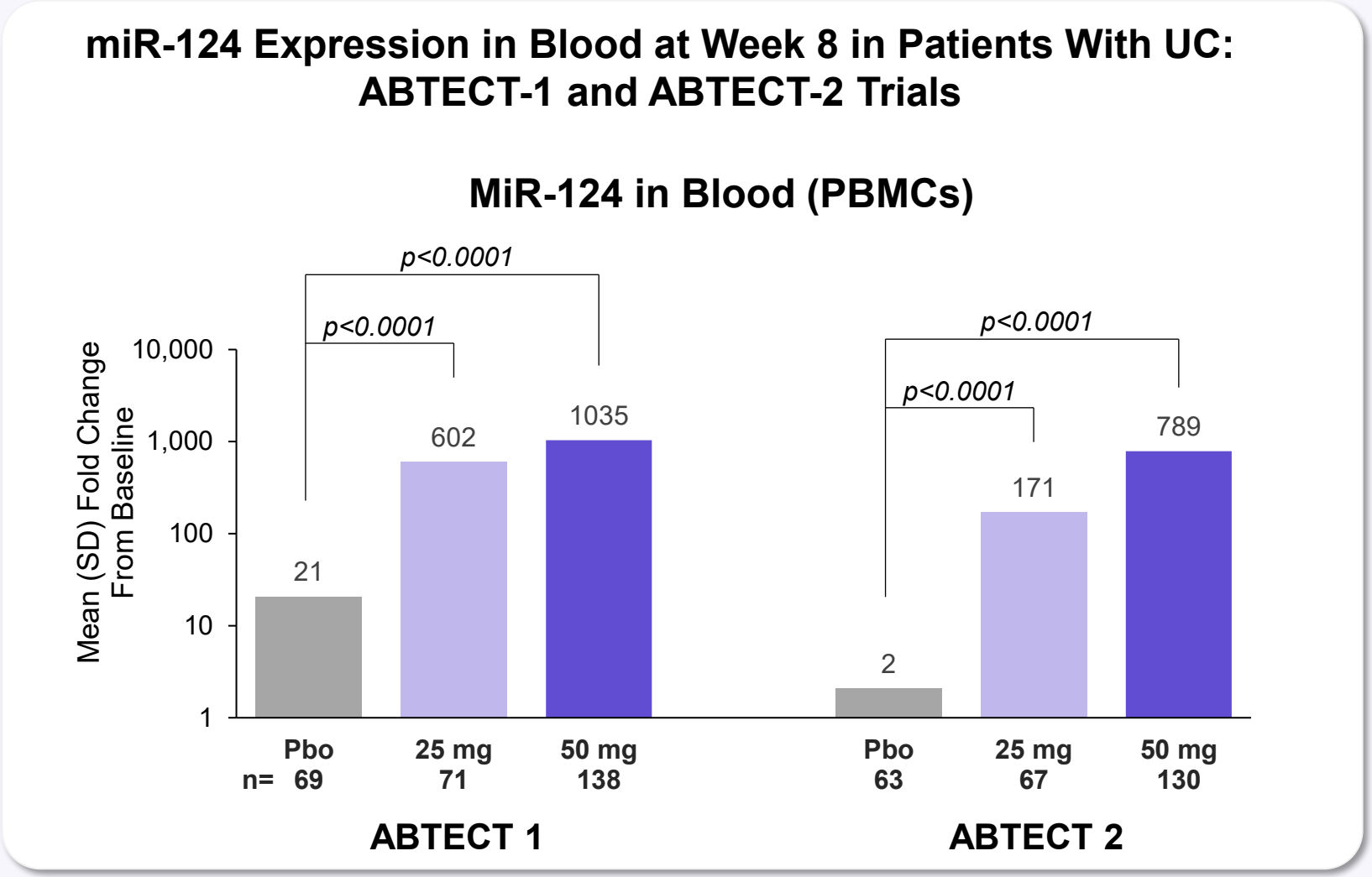
Balance restored

Restores mucosal immune balance



Apolit et al. Clin Transl Gastroenterol, 2023 | Vermeire et al., J Crohns Colitis, 2023 | Abivax Data on File | Images made with BioRender

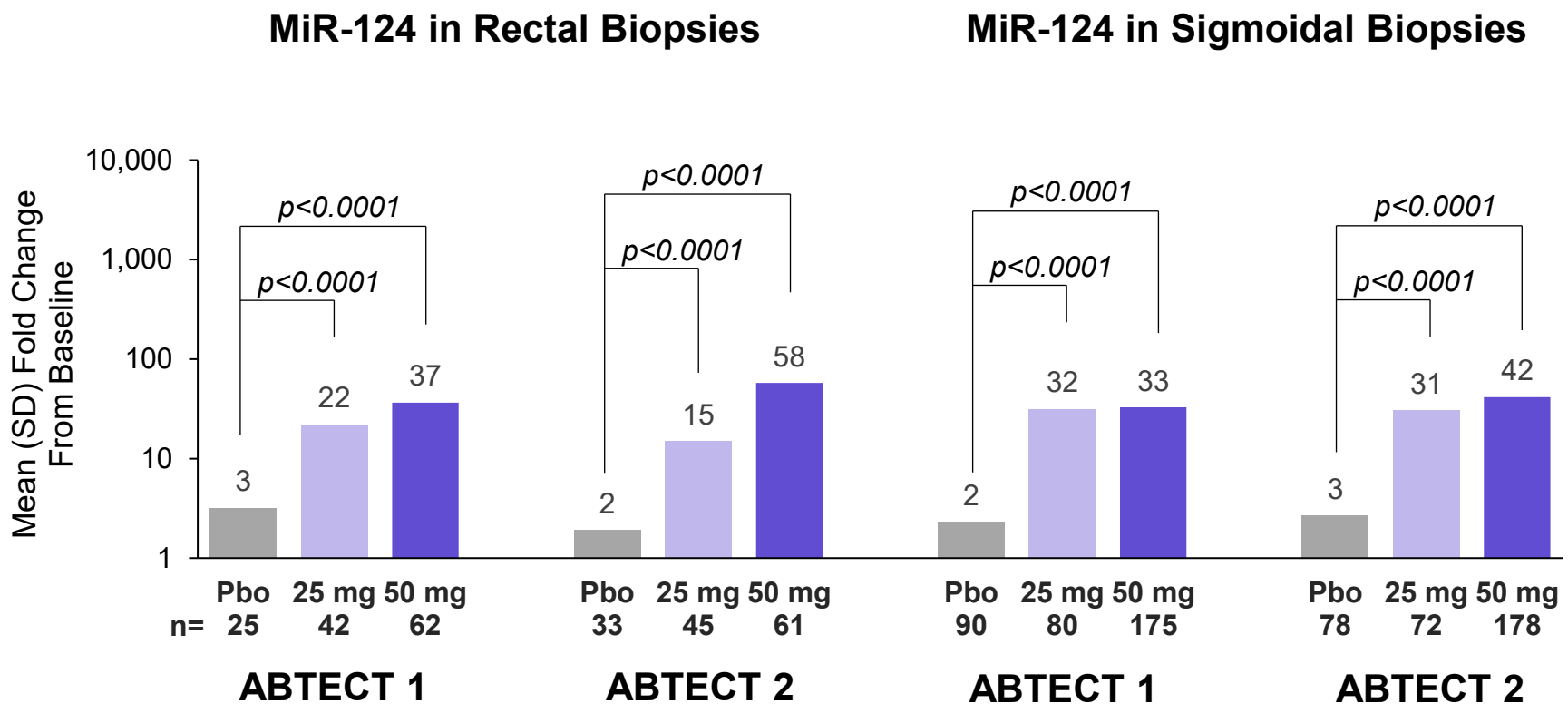
In Phase 3 Trials, Obefazimod Was Associated With Enhanced Expression of miR-124



Siegmund B et al. P0868. Poster presented at: the 21st Congress of ECCO, February 18–21, 2026, Stockholm, Sweden

In Phase 3 Trials, Obefazimod Was Associated With Enhanced Expression of miR-124

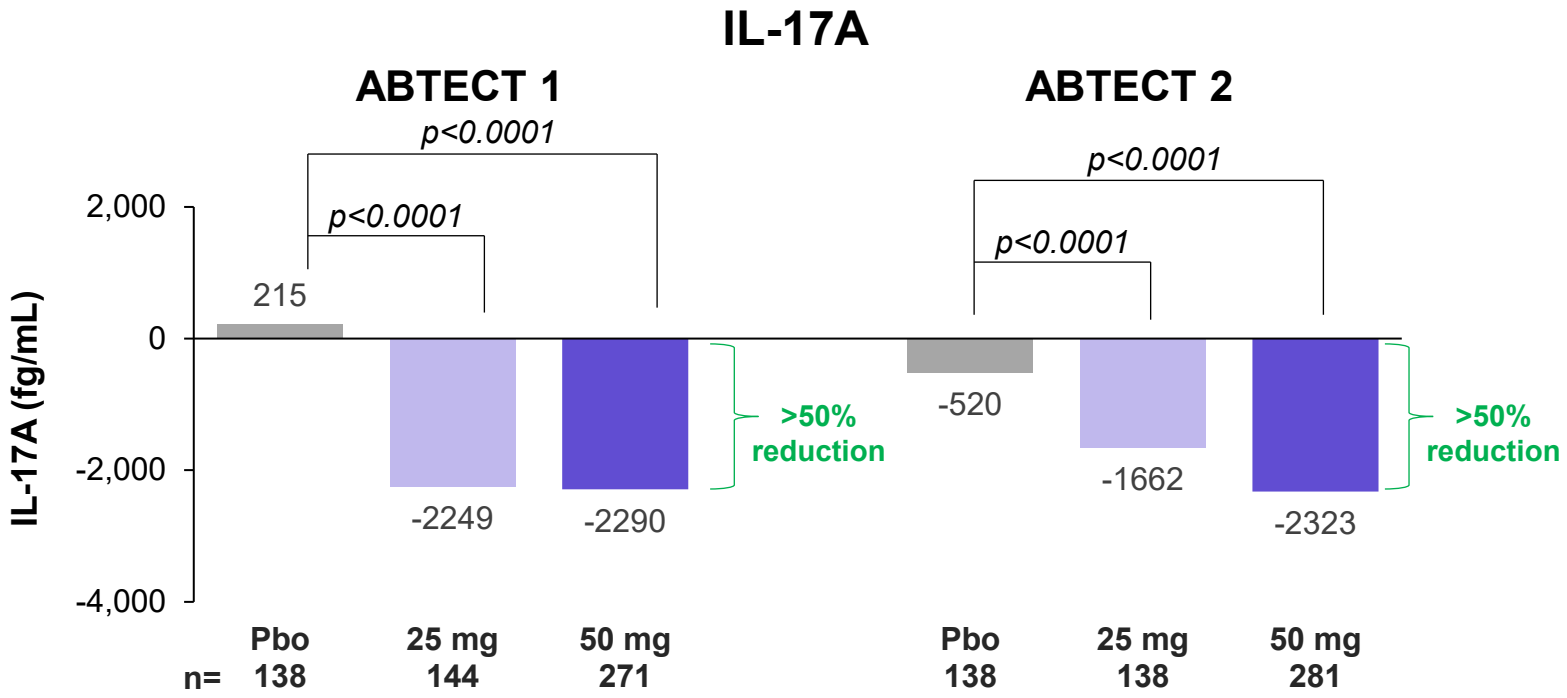
miR-124 Expression Colon Tissues at Week 8 in Patients With UC: ABTECT-1 and ABTECT-2 Trials



Siegmund B et al. P0868. Poster presented at: the 21st Congress of ECCO, February 18–21, 2026, Stockholm, Sweden

In Phase 3 Trials, Obefazimod Was Associated With Reductions in Proinflammatory Cytokines IL-17A

IL-17A Changes From Baseline to Week 8 in Blood From Patients With UC: ABTECT-1 and ABTECT-2 Trials



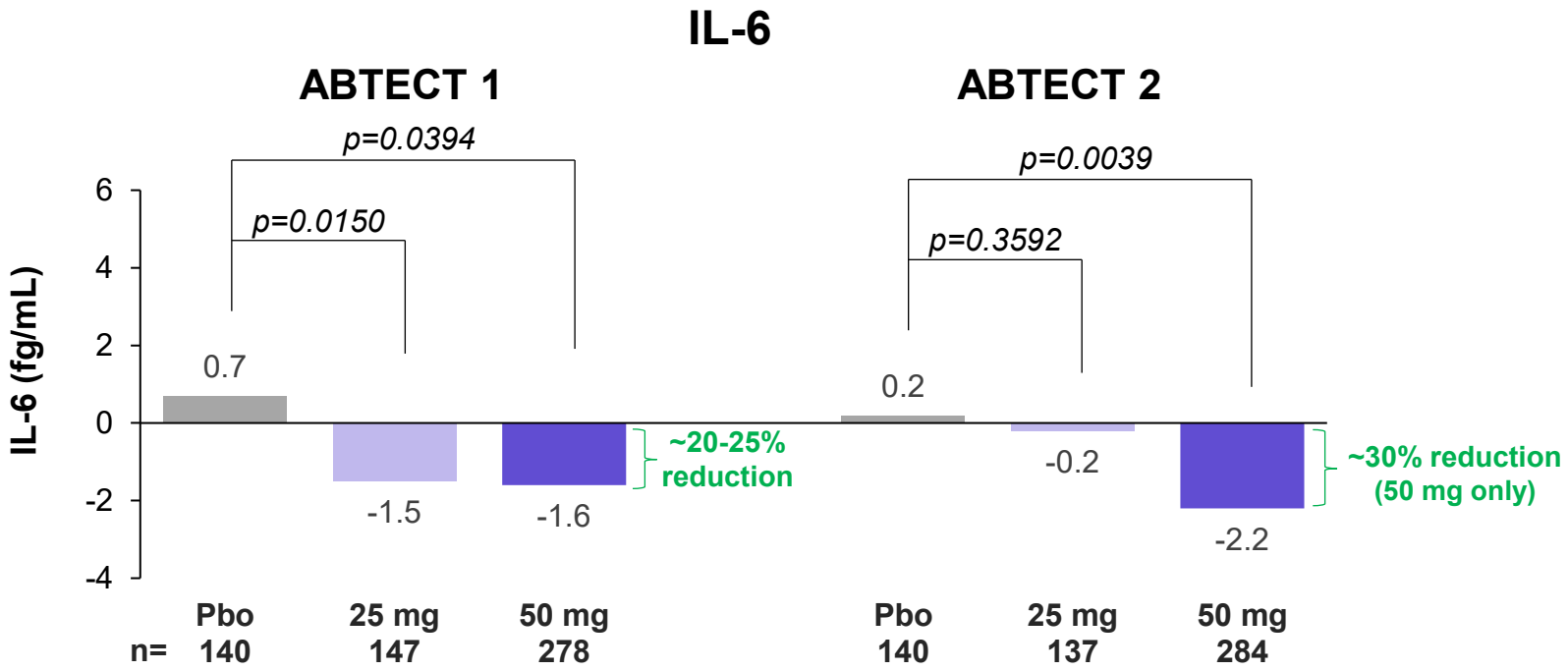
Baseline Levels (fg/mL)			
Dose	Pbo	25 mg	50 mg
Mean	4242	3684	3787
Median	2710	2462	2540

Baseline Levels (fg/mL)			
Dose	Pbo	25 mg	50 mg
Mean	3961	3297	3759
Median	2662	2428	2369

Siegmund B et al. P0868. Poster presented at: the 21st Congress of ECCO, February 18–21, 2026, Stockholm, Sweden

In Phase 3 Trials, Obefazimod Was Associated With Reductions in Proinflammatory Cytokines IL-6

IL-6 Changes From Baseline to Week 8 in Blood From Patients With UC: ABTECT-1 and ABTECT-2 Trials



Baseline Levels (pg/mL)			
Dose	Pbo	25 mg	50 mg
Mean	6.0	5.4	7.1
Median	4.2	3.5	3.7

Baseline Levels (pg/mL)			
Dose	Pbo	25 mg	50 mg
Mean	7.1	6.1	6.1
Median	4.0	3.8	4.0

Siegmund B et al. P0868. Poster presented at: the 21st Congress of ECCO, February 18–21, 2026, Stockholm, Sweden

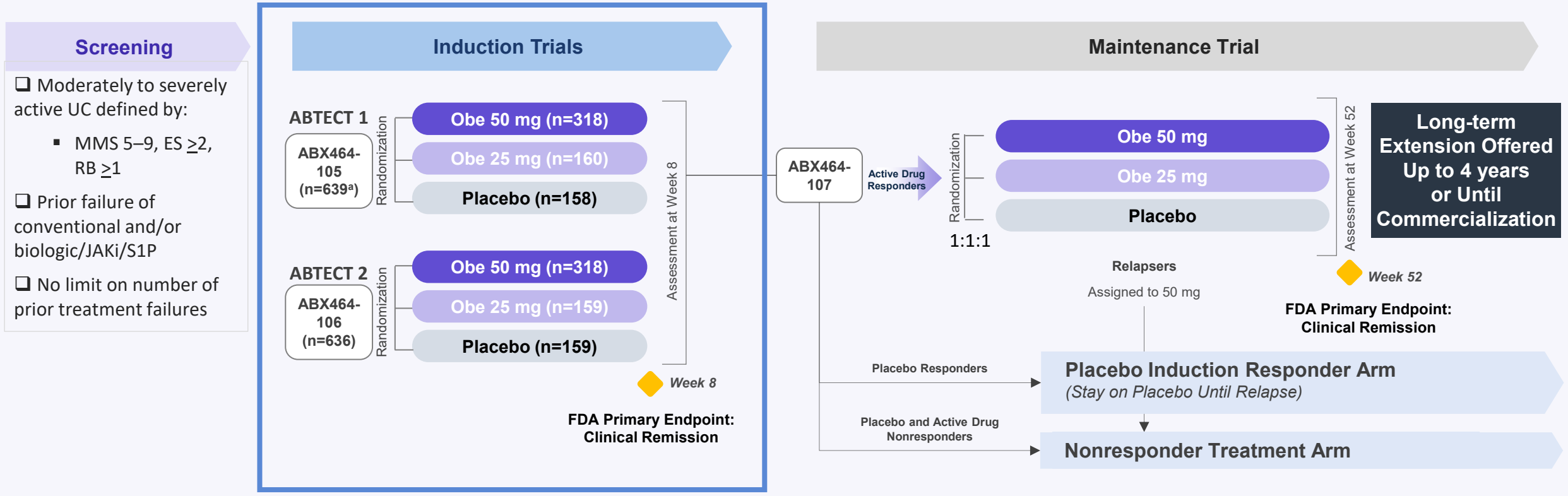
ABIVAX

Overview of Phase 3 ABTECT Induction Results

Silvio Danese, MD, PhD
IRCCS San Raffaele Hospital
Milan, Italy

ABTECT Phase 3 Program: Obefazimod in Ulcerative Colitis

2 Induction Trials and 1 Maintenance Trial



This presentation will focus on the safety and efficacy results of patients from ABTECT 1 and 2 induction trials

Sands BE et al. Oral presentation presented at: United European Gastroenterology Week, October 4–7 2025, Berlin, Germany.
Placebo responders from induction are not re-randomized and do not contribute to the primary endpoint in the maintenance study. Clinical remission is defined as SFS=0 or 1, and RBS=0 and MES=0 or 1 (MES of 1 modified to exclude friability).
[a]Three patients in ABTECT 1 were randomized but not treated.

Baseline Characteristics: Generally Well Balanced

Slightly more severe and refractory population randomised to 25mg group in ABTECT 2 vs. ABTECT 1

	Pooled ABTECT 1 & 2			ABTECT 1 (105)			ABTECT 2 (106)		
	Placebo (N=317)	Obe 25 mg (N=319)	Obe 50 mg (N=636)	Placebo (N=158)	Obe 25 mg (N=160)	Obe 50 mg (N=318)	Placebo (N=159)	Obe 25 mg (N=159)	Obe 50 mg (N=318)
Age (years), mean (SD)	42.3 (14.1)	41.4 (13.2)	42.1 (14.0)	43.1 (13.6)	41.5 (13.5)	42.7 (14.3)	41.6 (14.7)	41.3 (12.8)	41.4 (13.6)
Baseline MMS, mean (SD)	6.9 (1.0)	6.9 (1.0)	6.9 (1.1)	6.9 (1.0)	6.8 (1.0)	6.9 (1.1)	6.8 (1.0)	7.0 (1.0)	6.9 (1.1)
Endoscopic subscore 3, n (%)	189 (59.6)	194 (60.8)	378 (59.4)	94 (59.5)	91 (56.9)	190 (59.7)	95 (59.7)	103 (64.8)	188 (59.1)
Extensive Colitis	130 (41.0)	131 (41.1)	236 (37.1)	59 (37.3)	63 (39.4)	110 (34.6)	71 (44.7)	68 (42.8)	126 (39.6)
Fecal Calprotectin (μg/g), median	1902	1762	1564	1969	1499	1581	1792	2041	1499
Concomitant Corticosteroids	126 (39.7)	120 (37.6)	262 (41.2)	61 (38.6)	61 (38.1)	132 (41.5)	65 (40.9)	59 (37.1)	130 (40.9)
AT-IR Yes	148 (46.7)	146 (45.8)	308 (48.4)	69 (43.7)	70 (43.8)	149 (46.9)	79 (49.7)	76 (47.8)	159 (50.0)
Number of prior JAK-IR (% of AT-IR Yes Patients)	35 (23.6)	34 (23.3)	55 (17.9)	15 (21.7)	15 (21.4)	22 (14.8)	20 (25.3)	19 (25.0)	33 (20.8)
Number of prior AT-IR by medication name†, n (%)									
1	62 (19.6)	45 (14.1)	150 (23.6)	31 (19.6)	23 (14.4)	70 (22.0)	31 (19.5)	22 (13.8)	80 (25.2)
2	34 (10.7)	45 (14.1)	64 (10.1)	16 (10.1)	20 (12.5)	35 (11.0)	18 (11.3)	25 (15.7)	29 (9.1)
3	28 (8.8)	33 (10.3)	52 (8.2)	12 (7.6)	18 (11.3)	25 (7.9)	16 (10.1)	15 (9.4)	27 (8.5)
4+	24 (7.6)	23 (7.2)	42 (6.6)	10 (6.3)	9 (5.6)	19 (6.0)	14 (8.8)	14 (8.8)	23 (7.2)

Highly refractory population with ~21% of AT-IR failing a JAK inhibitor

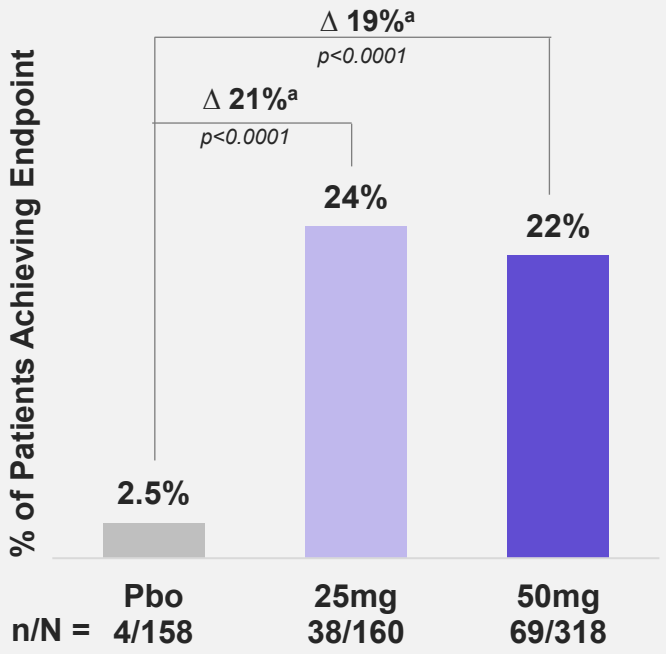
Sands BE et al. Oral presentation presented at: United European Gastroenterology Week, October 4–7 2025, Berlin, Germany.

† Medication name results in each individual advanced therapy being counted as a unique medication; e.g. infliximab + adalimumab would be counted as 2

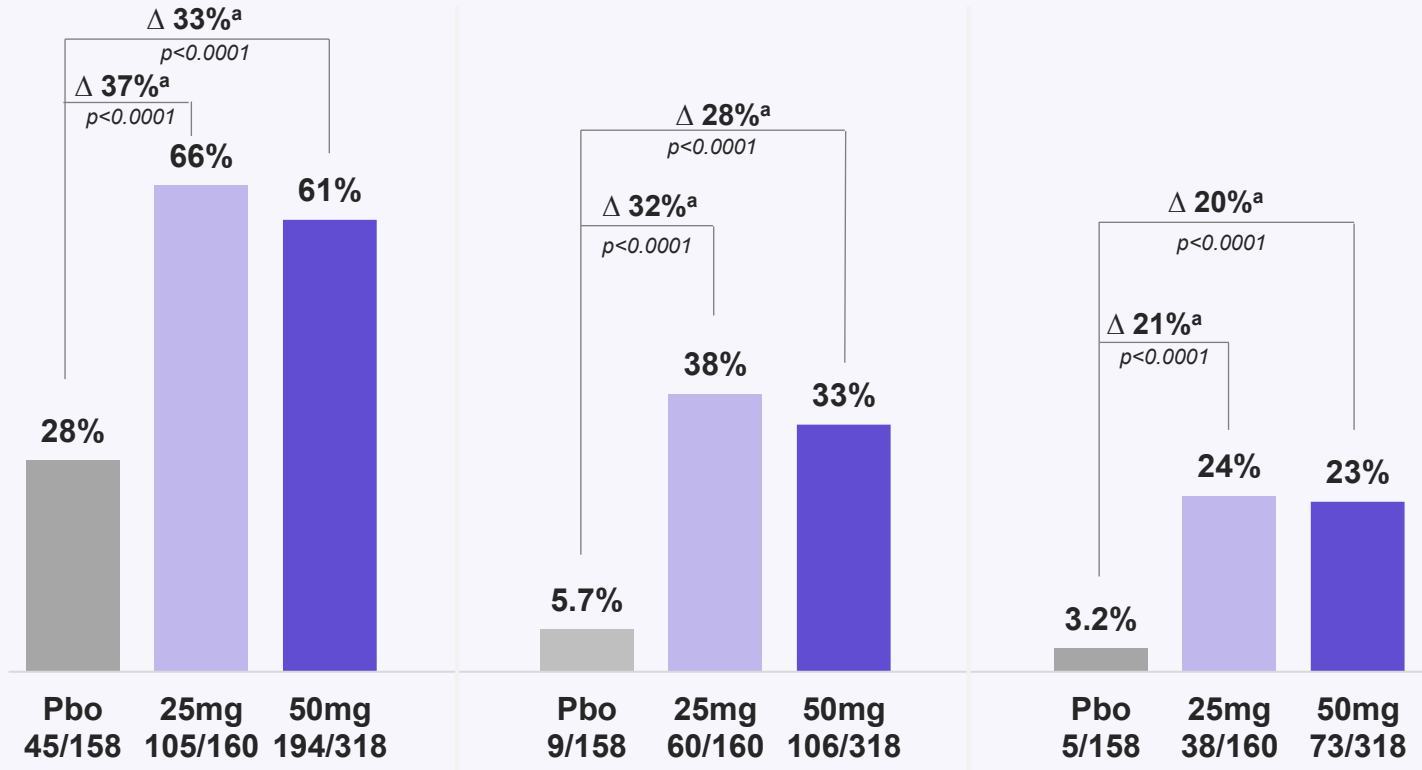
ABTECT-1: Both doses met primary and all key secondary endpoints

Clinical Remission – ABTECT 1

Primary Endpoint



Key Secondary Endpoints – ABTECT 1

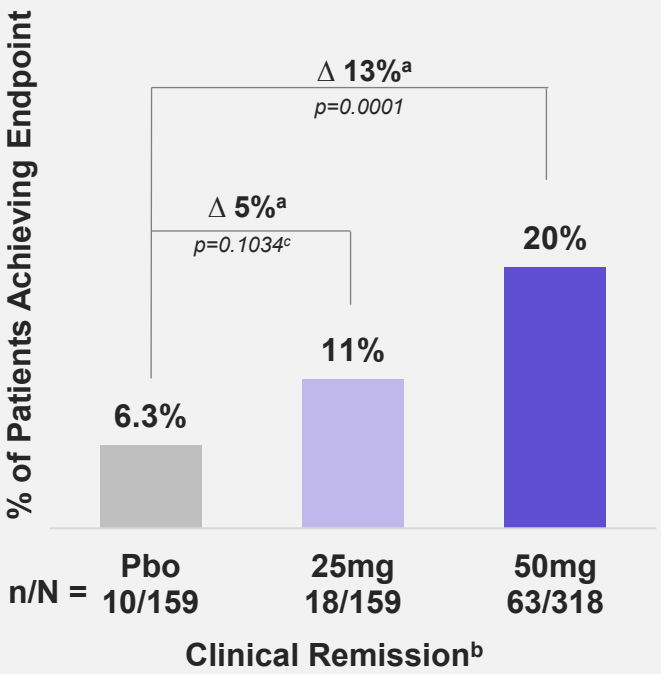


Sands BE et al. Oral presentation presented at: United European Gastroenterology Week, October 4–7 2025, Berlin, Germany.
[a] % Difference is for ABX464 minus placebo and is based on estimated common risk difference using the Mantel-Haenszel weights adjusting for the randomization stratification factors: 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.
[b] Clinical remission is defined as SFS = 0 or 1, and RBS = 0 and MES = 0 or 1 (MES of 1 modified to exclude friability).
Endoscopic improvement is defined as MES = 0 or 1 (MES of 1 modified to exclude friability).
Clinical response is defined as a reduction from Baseline in MMS >= 2 points and a relative reduction from Baseline in MMS >= 30%, and a reduction from Baseline in RBS >= 1 point and/or RBS = 0 or 1. HEMI is defined as MES = 0 or 1 and Geboes Index score <3.1

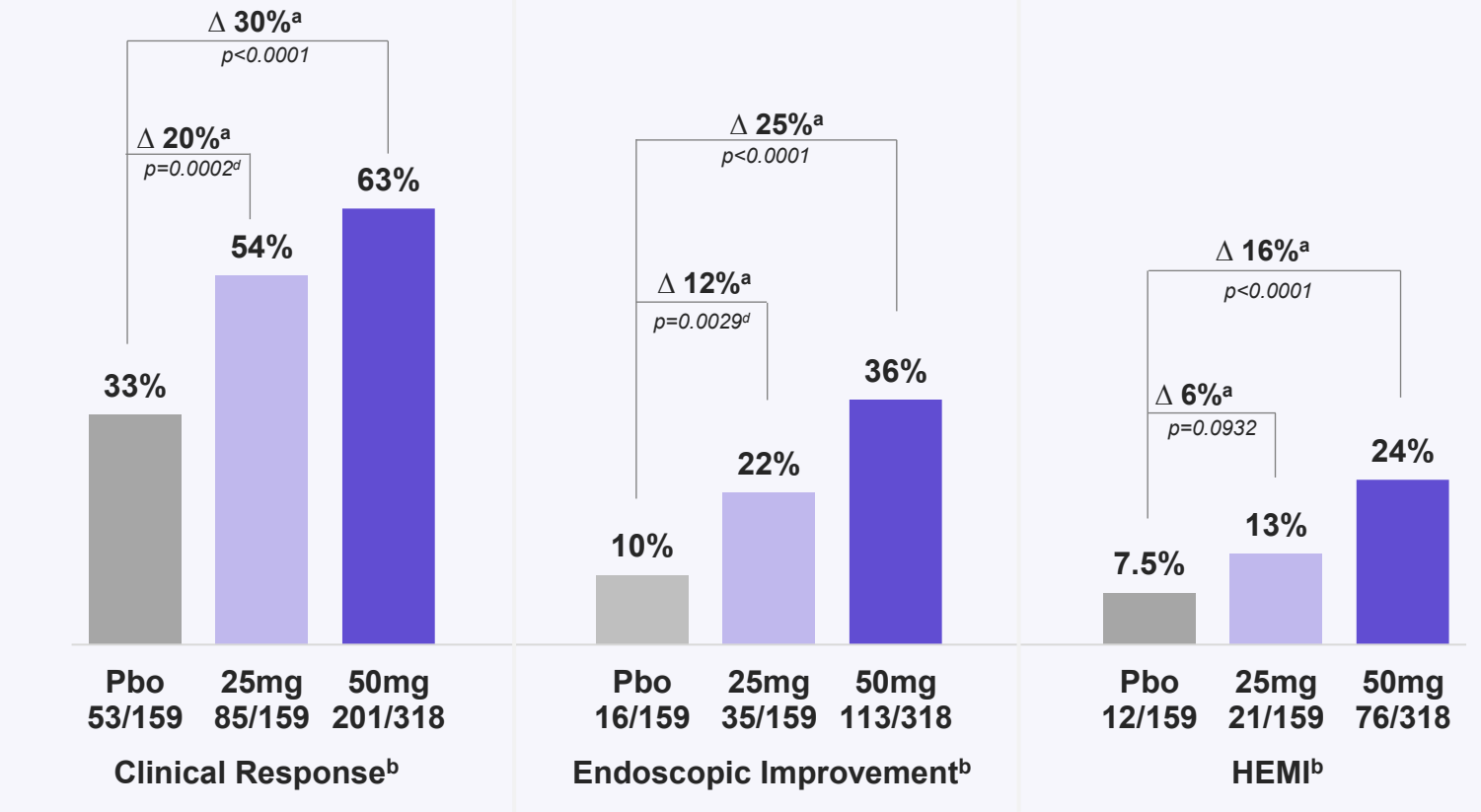
ABTECT-2: Obefazimod 50mg met primary and all key secondary endpoints

Clinical Remission – ABTECT 2

Primary Endpoint



Key Secondary Endpoints – ABTECT 2

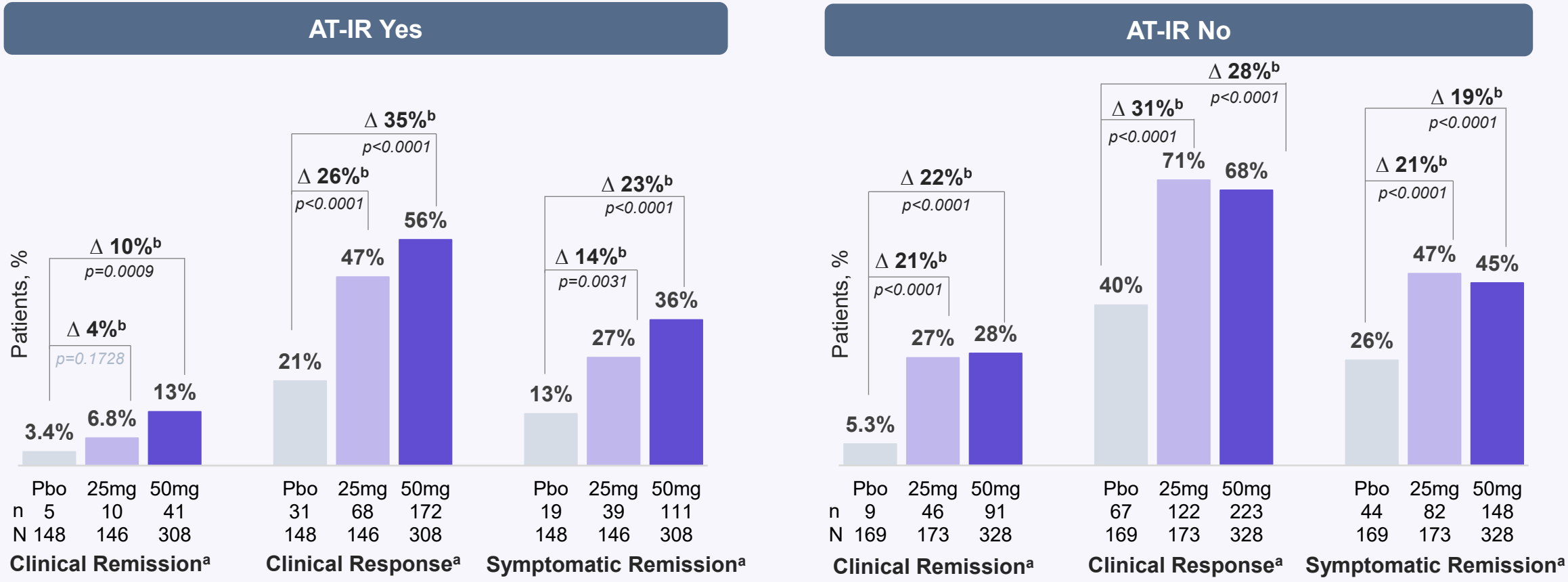


Sands BE et al. Oral presentation presented at: United European Gastroenterology Week, October 4–7 2025, Berlin, Germany.
[a] % Difference is for ABX464 minus placebo and is based on estimated common risk difference using the Mantel-Haenszel weights adjusting for the randomization stratification factors: 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.
[b] Clinical remission is defined as SFS = 0 or 1, and RBS = 0 and MES = 0 or 1 (MES of 1 modified to exclude friability).
Endoscopic improvement is defined as MES = 0 or 1 (MES of 1 modified to exclude friability).
[c] 25mg did not show statistical significance at 8 weeks [d] p values for 25mg are nominal on key FDA secondary endpoints of HEMI and Clinical Response
Clinical response is defined as a reduction from Baseline in MMS >= 2 points and a relative reduction from Baseline in MMS >= 30%, and a reduction from Baseline in RBS >= 1 point and/or RBS = 0 or 1. HEMI is defined as MES = 0 or 1 and Geboes Index score ≤3.1

ABTECT-1
ABTECT-2

Pooled ABTECT 1 & 2: Obefazimod 50mg achieved clinically meaningful improvements in all clinical endpoints regardless of prior AT-IR

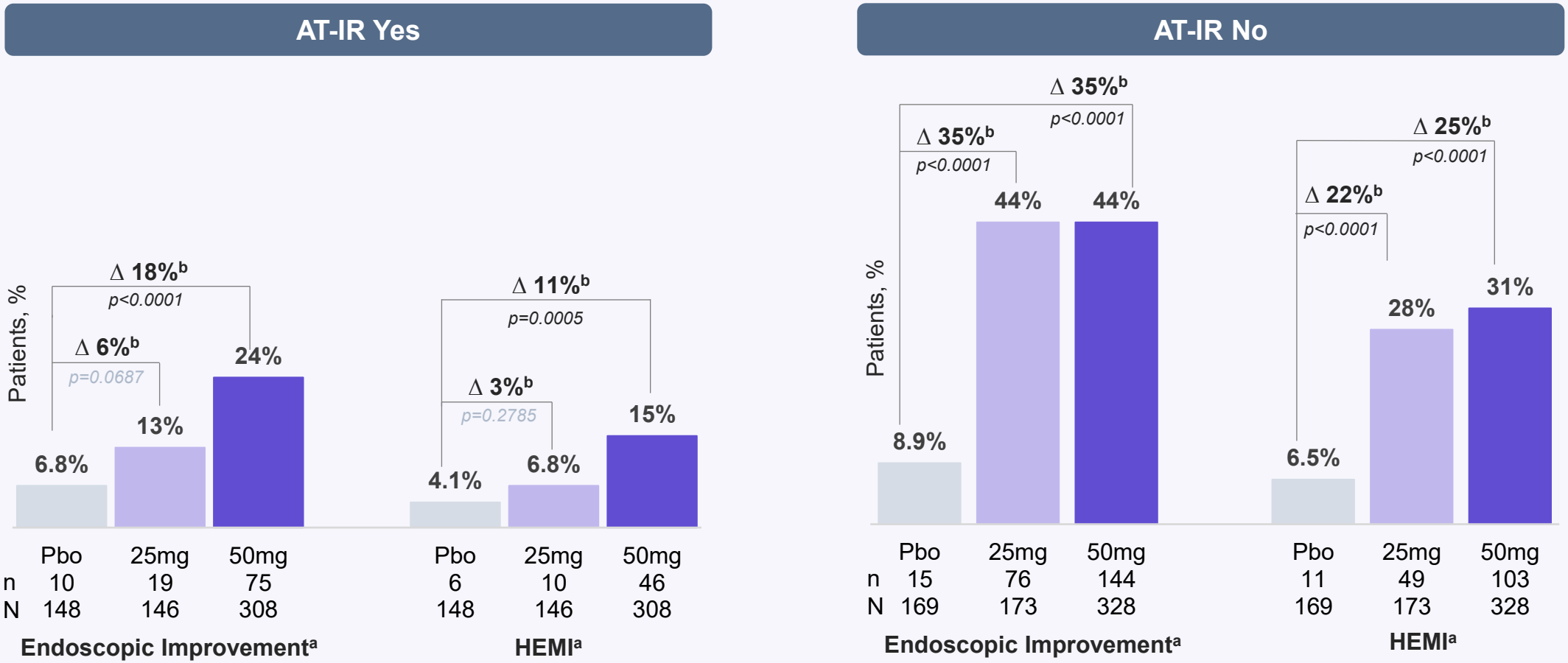
- 25mg and 50mg perform similarly in subgroup with no prior AT-IR in pooled data set



Danese S et al. Oral presentation presented at: United European Gastroenterology Week, October 4–7 2025, Berlin, Germany.
All p-values are nominal
[a] **Clinical remission** is defined as SFS = 0 or 1, and RBS = 0 and MES = 0 or 1 (MES of 1 modified to exclude friability). **Clinical response** is defined as a reduction from Baseline in MMS >= 2 points and a relative reduction from Baseline in MMS >= 30%, and a reduction from Baseline in RBS >= 1 point and/or RBS = 0 or 1. **Symptomatic remission** is defined as RBS=0 and SFS= 0 or 1
[b] % Difference is for ABX464 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.

Pooled ABTECT 1 & 2: Obefazimod 50mg achieved clinically meaningful improvements in endoscopic & histologic endpoints regardless of prior AT-IR

- 50mg outperformed 25mg in subjects with prior AT-IR; 25mg and 50mg performed similarly with no prior AT-IR

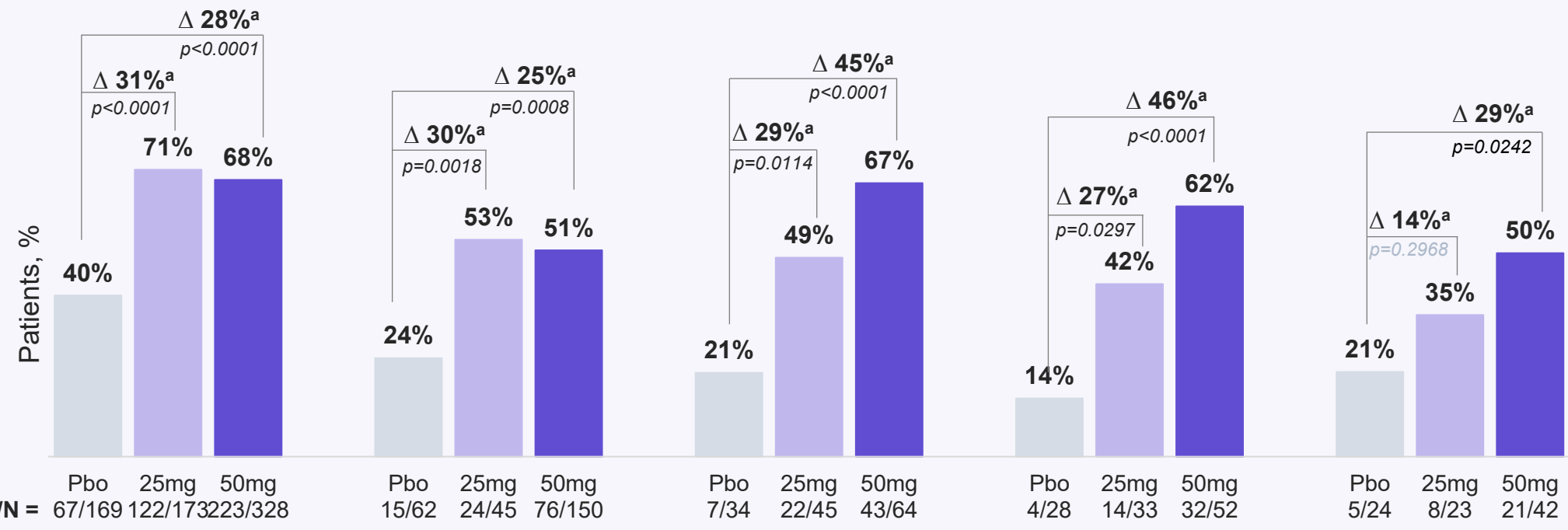


Danese S et al. Oral presentation presented at: United European Gastroenterology Week, October 4–7 2025, Berlin, Germany. All p-values are nominal
[a] Endoscopic improvement is defined as MES = 0 or 1 (MES of 1 modified to exclude friability). HEMI is defined as MES = 0 or 1 and Geboes Index score ≤3.1
[b] % Difference is for ABX464 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.

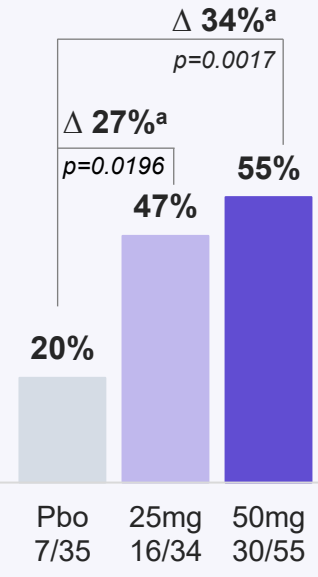
Clinical Response by Number of Prior AT Inadequate Responses and Prior JAKi

50mg clinical response consistent in subgroups with no prior AT-IR through 4+ AT-IR or JAK-IR

Pooled Clinical Response[b] by Number of Prior Advanced Therapy (AT) Inadequate Response



Pooled Clinical Response[b] – JAK-IR



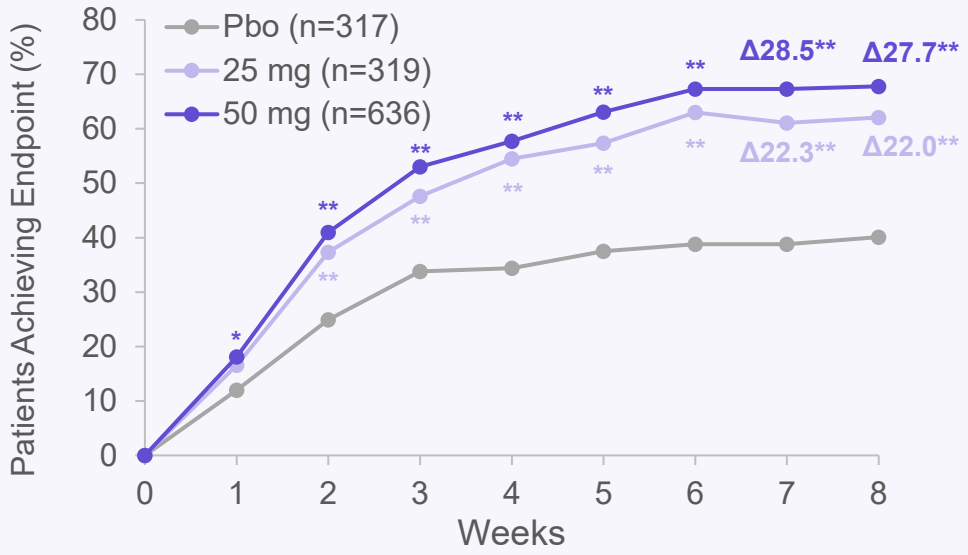
~21% of AT-IR population had JAK-IR

Danese S et al. Oral presentation presented at: United European Gastroenterology Week, October 4–7 2025, Berlin, Germany.
All p-values are nominal
[a] % Difference is for ABX464 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.
[b] Clinical response is defined as a reduction from Baseline in MMS >= 2 points and a relative reduction from Baseline in MMS >= 30%, and a reduction from Baseline in RBS >= 1 point and/or RBS = 0 or 1.

ABTECT-1
ABTECT-2

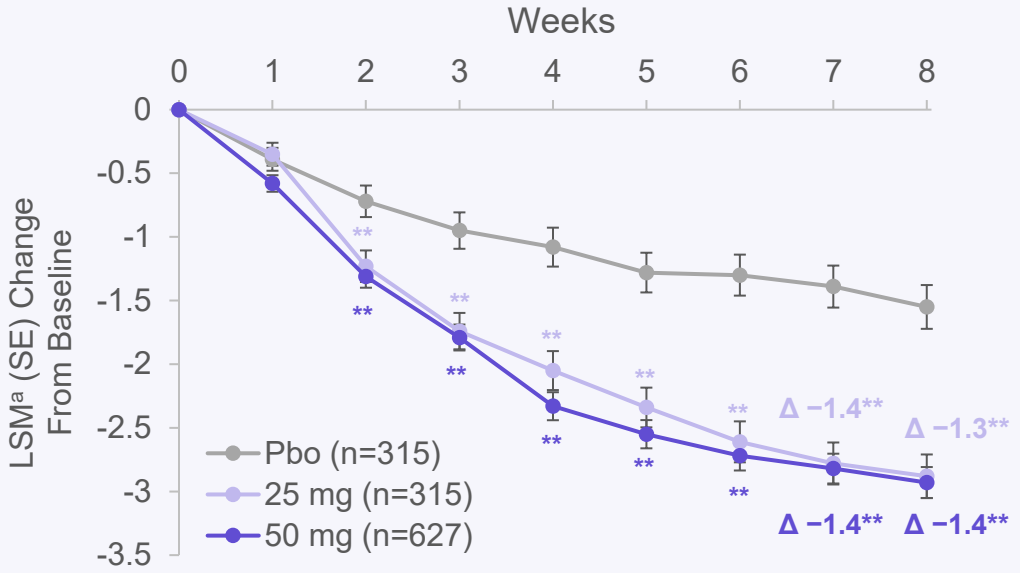
Pooled ABTECT 1 & 2: Early Separation from Placebo: Symptomatic Response (Week 1) and Urgency (Week 2)

Symptomatic Response



Pbo, n/N	0/317	38/317	79/317	107/317	109/317	119/317	123/317	123/317	127/317
25 mg, n/N	0/319	53/319	119/319	152/319	174/319	183/319	201/319	195/319	198/319
Pbo adjusted Δ[c]		4.6	12.4**	13.9**	20.1**	19.8**	24.2**	22.3**	22.0**
50 mg, n/N	0/636	115/636	261/636	337/636	367/636	401/636	428/636	428/636	431/636
Pbo adjusted Δ[c]		6.1*	16.2**	**19.3	23.4**	25.5**	28.6**	28.5**	27.7**

Change in Bowel Urgency



Pbo, n	315	313	309	303	303	295	293	290	276
25 mg, n	315	312	304	302	301	291	294	289	286
Pbo adjusted Δ[b]		0	−0.5**	−0.8**	−1.0**	−1.1**	−1.3**	−1.4**	−1.3**
50 mg, n	627	615	603	593	590	583	581	578	564
Pbo adjusted Δ[b]		−0.2	−0.6**	−0.8**	−1.3**	−1.3**	−1.4**	−1.4**	−1.4**

Armuzzi A et al. P0923. Poster presented at: the 21st Congress of ECCO, February 18–21, 2026, Stockholm, Sweden; Dubinsky MC et al. P0713. Poster presented at: the 21st Congress of ECCO, February 18–21, 2026, Stockholm, Sweden
Symptomatic response: a reduction from baseline in pMMS of ≥1 point and a relative reduction from baseline in pMMS of ≥30%, and a reduction from baseline in RBS of ≥1 point and/or RBS ≤1. Analyses not powered for statistical significance in subgroups; statistical inferences are exploratory, and all *P* values are nominal and 2-sided. NRI is used for subjects with missing outcome at week 8 and subjects reporting any IE prior to week 8.
[a]Least squares means were calculated with mixed model for repeated measures with fixed categorical effects for treatment, week, treatment-by-week interaction and randomization stratification factors (inadequate response to advanced therapies [yes/no] and baseline oral corticosteroids usage [yes/no]), and a fixed continuous effect for the baseline value of the outcome of interest.
[b]The least squares mean difference is for Obe minus placebo.
[c]% 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). *P<0.05, **P<0.01.

Safety Summary—ABTECT 1 and 2: Pooled Full Data Set

	ABTECT 1 and 2: Pooled Full Data Set		
Treatment-Emergent Adverse Events (TEAE), n (%)	**Placebo (n=317)**	**Obefazimod 25 mg (n=319)**	**Obefazimod 50 mg (n=636)**
Any TEAE	161 (50.8)	156 (48.9)	383 (60.2)
TEAE leading to study drug discontinuation	15 (4.7)	8 (2.5)	32 (5.0)
Serious TEAE	10 (3.2)	7 (2.2)	20 (3.1)
Death	0	0	0
Malignancy	0	0	1 (0.2)[a]
Serious/severe (grade ≥3) infections and opportunistic infections	1 (0.3)[b]	1 (0.3)[c]	4 (0.6)[d]

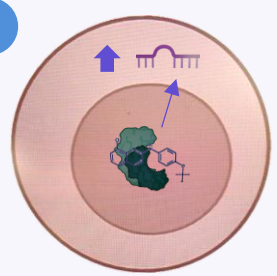
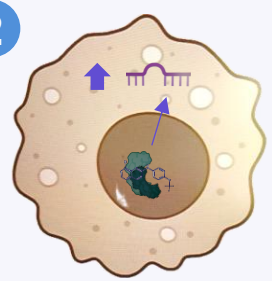
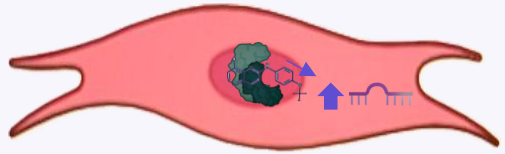
Sands BE et al. Oral presentation presented at: United European Gastroenterology Week, October 4–7 2025, Berlin, Germany.
[a]Prostate cancer stage I. [b]Bronchopulmonary aspergillosis. [c]Appendicitis. [d]Pneumonia (2), anal abscess, COVID-19.

Treatment-Emergent Adverse Events (≥1% and Greater Than Placebo)

	ABTECT 1 and 2: Pooled Full Data Set		
	Placebo (n=317)	**Obefazimod 25 mg (n=319)**	**Obefazimod 50 mg (n=636)**
Headache[a]	19 (6.0)	51 (16.0)	153 (24.1)
Headache leading to study **discontinuation** (per subject), n (%)	0	1 (0.3)	7 (1.1)
Time to onset of first TE headache per subject (days), median	7.0	1.0	1.0
Duration of headache for all TE headaches, days, median	2.0	3.0	2.0
Nausea	4 (1.3)	16 (5.0)	46 (7.2)
Lipase increased	7 (2.2)	9 (2.8)	27 (4.2)
Abdominal pain	2 (0.6)	2 (0.6)	24 (3.8)
Vomiting	1 (0.3)	7 (2.2)	18 (2.8)
Upper abdominal pain	2 (0.6)	5 (1.6)	18 (2.8)
Back pain	0	4 (1.3)	13 (2.0)
Alanine aminotransferase increased	2 (0.6)	5 (1.6)	10 (1.6)
Hypertriglyceridemia	0	3 (0.9)	12 (1.9)
Dyslipidemia	2 (0.6)	1 (0.3)	9 (1.4)
Pyrexia	1 (0.3)	3 (0.9)	8 (1.3)
Amylase increased	1 (0.3)	4 (1.3)	7 (1.1)
Hyperlipidemia	1 (0.3)	0	7 (1.1)
Hypertension	2 (0.6)	1 (0.3)	7 (1.1)

Sands BE et al. Oral presentation presented at: United European Gastroenterology Week, October 4–7 2025, Berlin, Germany.
[a]Headache Custom MedDRA Query includes the following preferred terms: headache, tension headache, procedural headache, cluster headache, cervicogenic headache, and migraine. All other TEAEs are shown by individual preferred term.
Data on File: ABX464-105 and ABX464-106.

Obefazimod and miR-124 Enhancement Restores Function Across Key Cell Types in Crohn's Disease

Cell Type:	Th17 Cell	Macrophage	Fibroblast
	1	2	3
			
Targets:	STAT3, IL-6R	CCL2	TGFβ, MMPs
Effects:	• Reduce Th17 differentiation • Reduce IL-17 expression	• Reduce IL-6 expression • Reduce IL-23 expression • Reduce TNFα expression • Reduce macrophage recruitment	• Reduce collagen deposition • Reduce αSMA expression • Reduce proliferation
	Inflammation		Fibrosis[a]

Oral Presentation

OP30 Obefazimod shows first evidence of anti-fibrotic activity in preclinical models of inflammatory bowel disease

- Date: Saturday, Feb 21st
- Time: 8:40 - 8:50 AM CET
- Location: Plenary Hall

MoA Legend

Obefazimod

CBC

miR124

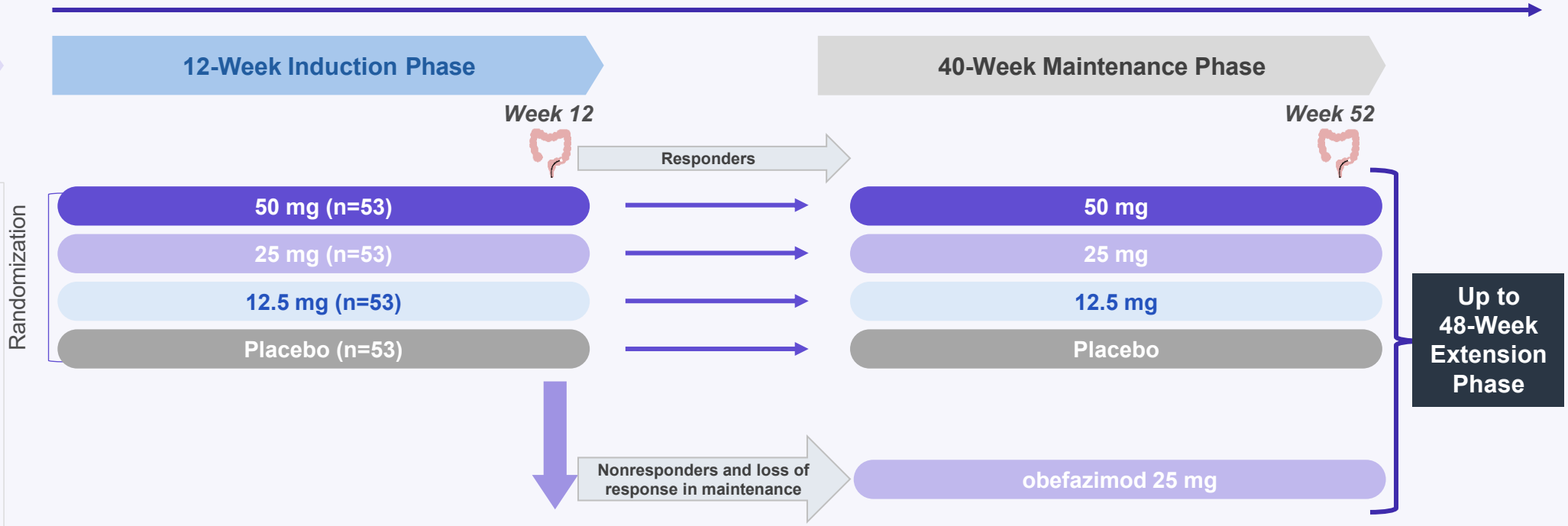
IL, interleukin; miR, microRNA; TGF, transforming growth factor; Th, T helper; TNF, tumor necrosis factor.
[a]Additional cell types beyond fibroblasts can also play a role in fibrosis.
Apolit et al. *Clin Transl Gastroenterol.* 2023. Vermeire et al. *J Crohns Colitis.* 2023. Abivax Data on File. Images made with BioRender.

ENHANCE CD: Phase 2b Trial Design

Obefazimod in Crohn's Disease

Total Study Duration: Up to 2 Years

- ❑ Moderately to severely active CD as defined by:
  - 220 ≤ CDAI ≤ 450
- ❑ SES-CD ≥6 for ileocolonic or colonic disease or SES-CD ≥4 for isolated ileal disease (per central reading)
- ❑ After failure of conventional therapies and/or biologics/JAK inhibitors



Primary Endpoint:
Change from baseline in CDAI score at week 12

Scan QR code to access clinical trial locations

https://clinicaltrials.gov/study/NCT06456593

Thank You!

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speaker bios, presentation slides, recording, and post-symposium evaluation

This program is not affiliated with ECCO

Q&A

Silvio Danese, MD, PhD
IRCCS San Raffaele Hospital
Milan, Italy

Raja Atreya, MD
University Hospital of Erlangen
Erlangen, Germany

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