Corporate Presentation

July 2026

ABIVAX

Forward Looking Statements

This presentation contains information pertaining to Abivax SA (“Abivax,” the “Company,” “we,” “our” or “us”).

Certain statements included in this presentation that are not historical facts are forward-looking statements for purposes of the safe harbor provisions under the United States Private Securities Litigation Reform Act of 1995. In some cases, you can identify forward-looking statements by the words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “future,” “goals,” “intend,” “likely,” “may,” “might,” “ongoing,” “objective,” “plan,” “potential,” “predict,” “project,” “seek,” “should,” “strategy,” “will” and “would” or the negative of these terms, or other comparable terminology intended to identify statements about the future. These statements are based on the Company’s current strategy, plans, objectives, assumptions, estimates and projections. These forward-looking statements include statements concerning the Company's expectations for 2026, including concerning the Company's anticipated timing for topline results of its ABTECT Phase 3 maintenance trial and timing of the Company's planned NDA filing, and results of its ENHANCE-CD Phase 2 induction clinical trials, and the potential therapeutic benefit and market opportunity of obefazimod, the availability and timing of preclinical data to support decision-making on therapy candidates for use in combination with obefazimod in UC, as well as the availability and timing of disclosure of preclinical data of any such combination therapy, the selection of an obefazimod follow-on drug candidate from Abivax’s miR-124 library, obefazimod’s potential to provide meaningful benefit to patients suffering from UC, CD, IBD or other indications, the potential commercial opportunity for obefazimod and projections of market share, expectations for potential patent term extensions for obefazimod, Abivax’s expected cash runway, and other statements that are not historical fact. Current results are not necessarily indicative of future results, including any clinical progress updates Abivax may provide from time to time. Readers are cautioned not to place undue reliance on these forward-looking statements.

Forward-looking statements are subject to inherent risks, contingencies and uncertainties beyond the Company’s control that could cause the Company’s actual results, performance or achievements to be materially different from the expected results, performance or achievements expressed or implied by such forward-looking statements. A description of the main risks, contingencies and uncertainties applicable to the Company can be found in the documents filed by the Company with the Autorité des marchés financiers (“AMF”) pursuant to its legal obligations, including the 2026 Universal Registration Document, as amended, available on the AMF website (www.amf-france.org/fr) and the Company’s Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission (the "SEC") on March 23, 2026 under the caption “Risk Factors” as well as other filings the Company makes with the SEC from time to time, available on the SEC’s website (www.sec.gov), as well as in the documents that may be published in the future by the Company. These documents are also available on Abivax’s website (www.abivax.com).

If any of these risks materialize or Abivax’s assumptions prove incorrect, actual results could differ materially from the results implied by these forward-looking statements. There may be additional risks that are presently unknown by the Company or that it currently believes are not material that could also cause actual results to differ from those contained in the forward-looking statements. In addition, forward-looking statements reflect Abivax’s expectations, plans, or forecasts of future events and views as of the date of this presentation and are qualified in their entirety by reference to the cautionary statements herein. Abivax anticipates that subsequent events and developments will cause the Company’s assessments to change. These forward-looking statements should not be relied upon as representing Abivax’s assessments as of any date subsequent to the date of this presentation. Accordingly, undue reliance should not be placed upon the forward-looking statements. Neither Abivax nor any of its affiliates undertakes any obligation to update these forward-looking statements, except as required by law.

This presentation also contains estimates and other statistical data made by independent third parties and by us relating to market size and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such data and estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk. Neither we nor our affiliates, advisors or representatives makes any representation as to the accuracy or completeness of that data or undertake to update such data after the date of this presentation.

Ongoing and future clinical development, including our Phase 3 UC and Phase 2b CD clinical programs, trial design and initiation, is subject to assessment of clinical data of obefazimod by European Medicines Agency ("EMA"), U.S. Food and Drug Administration ("FDA") and other regulatory authorities. These authorities could request important modifications to the design of the ongoing and future clinical trials and/or request that additional studies or trials be conducted prior to their initiation. The FDA, EMA or other regulatory authorities may take decisions that would result in a delay or a clinical hold of Abivax’s clinical programs (including in particular its Phase 3 clinical trials for obefazimod in moderately to severely active ulcerative colitis or Phase 2b clinical trial for obefazimod in Crohn’s disease.

Certain data in this presentation are based on cross-study comparisons and are not based on any head-to-head clinical trials. Cross-study comparisons are inherently limited and may suggest misleading similarities or differences and you are cautioned not to place undue emphasis on these comparisons. Actual results may differ from these comparisons.

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Abivax Pipeline

Drug Candidate	Regimen	Indication	Research	Preclinical	Phase 1	Phase 2	Phase 3	FDA Filing	Achieved & Anticipated Milestones
Obefazimod	Monotherapy	Moderately to Severely Active Ulcerative Colitis (UC)	Pivotal Phase 3 Program (ABTECT)						▪ Enrollment completed April 2025 ▪ Induction trial topline data readout on July 22, 2025 ▪ Maintenance trial topline data readout Part 1 & 2 in June 2026
	Monotherapy	Crohn's Disease (CD)	Phase 2b (ENHANCE)						▪ IND filed Q4 2023 ▪ First patient enrolled Phase 2b trial in October in 2024 ▪ Phase 2b induction topline results expected in mid-2027
	Combination Therapy	Moderately to Severely Active Ulcerative Colitis (UC)							▪ Encouraging preclinical combination data generated ▪ Decision on combination agent expected in 2026[1]
miR-124 Follow On	Monotherapy	To be disclosed							▪ Selection of follow-on compound in 2026

1. Under evaluation based on Induction and Maintenance Phase 3 clinical results

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Commercial Opportunity

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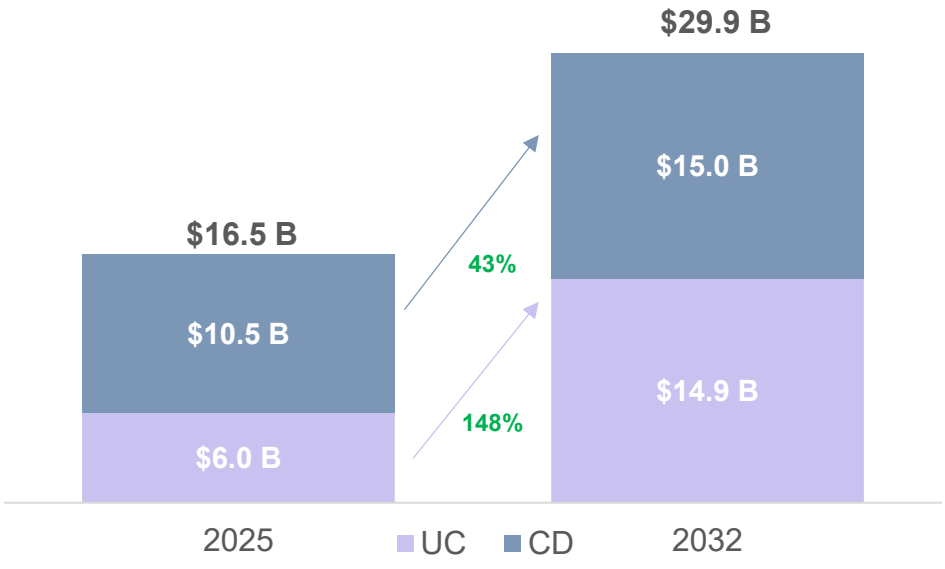
WW IBD Sales Expected to Increase, with Significant Growth Anticipated in UC

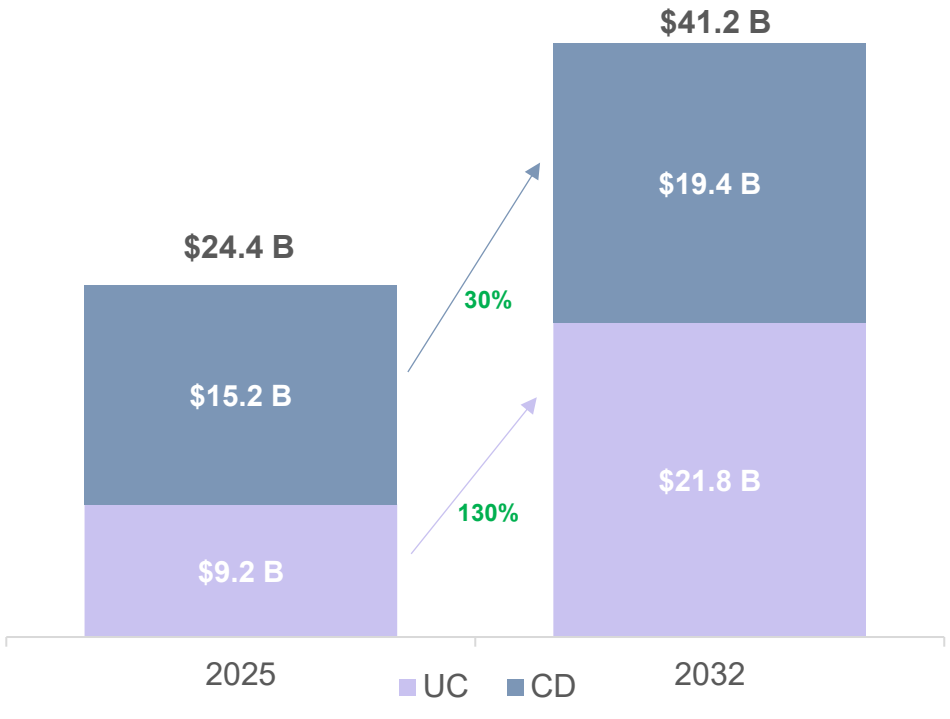
US and WW IBD annual sales forecasted to grow to ~$30B and ~$41B, respectively, by 2032[1]

Evaluate Pharma US IBD Sales ($B)[1]



~70% Of Expected US Growth from UC

Evaluate Pharma Worldwide IBD Sales ($B)[2]



~70% Of Sales from US

Source: 1. Evaluate Pharma pulled December 2025; WW= worldwide, which comprises the UK, EU, Japan and the US. Evaluate Pharma pulled January 2026

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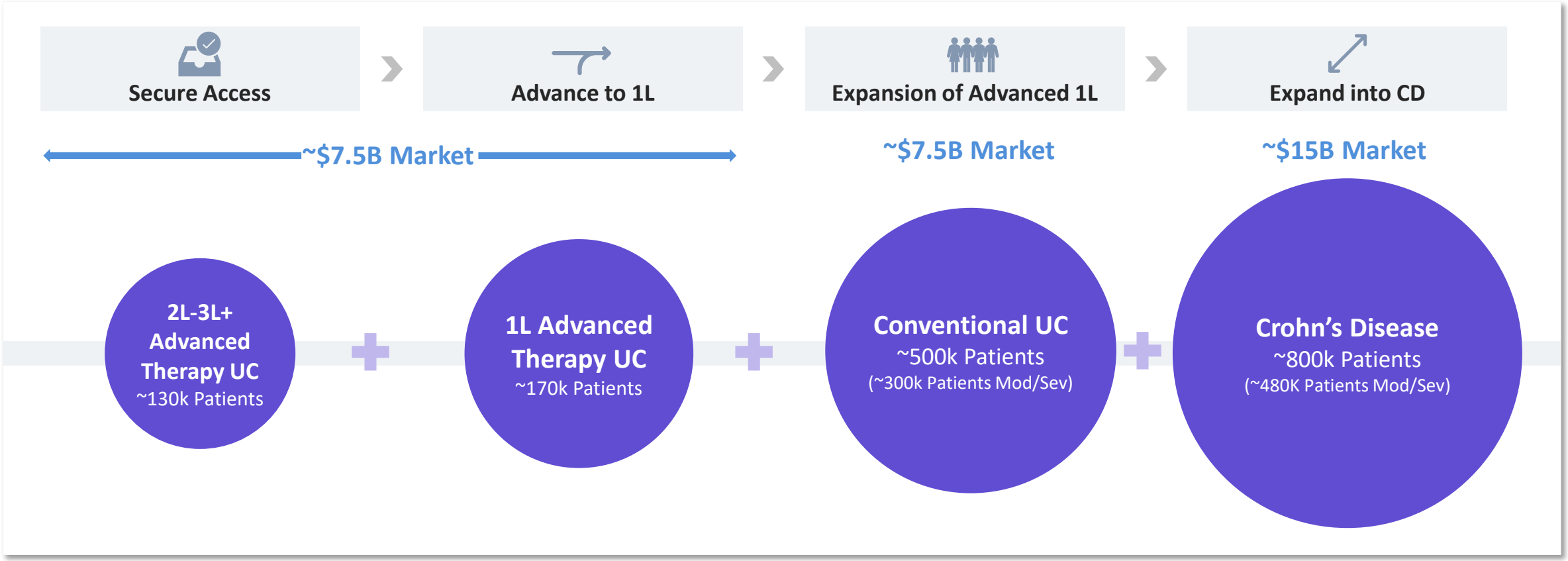
Obefazimod: Mega-Blockbuster Potential in US Alone Between UC and CD Indications

Evolution of Obefazimod Target Patient Population

Key Obefazimod Patient Populations in the US



Obefazimod has the potential to become the future standard of care in IBD

Source: Estimated revenue based on Evaluate Pharma's 2025-2032 UC and CD forecasts; Komodo PLAID claims data | Time period : Nov'15 to Oct'25.

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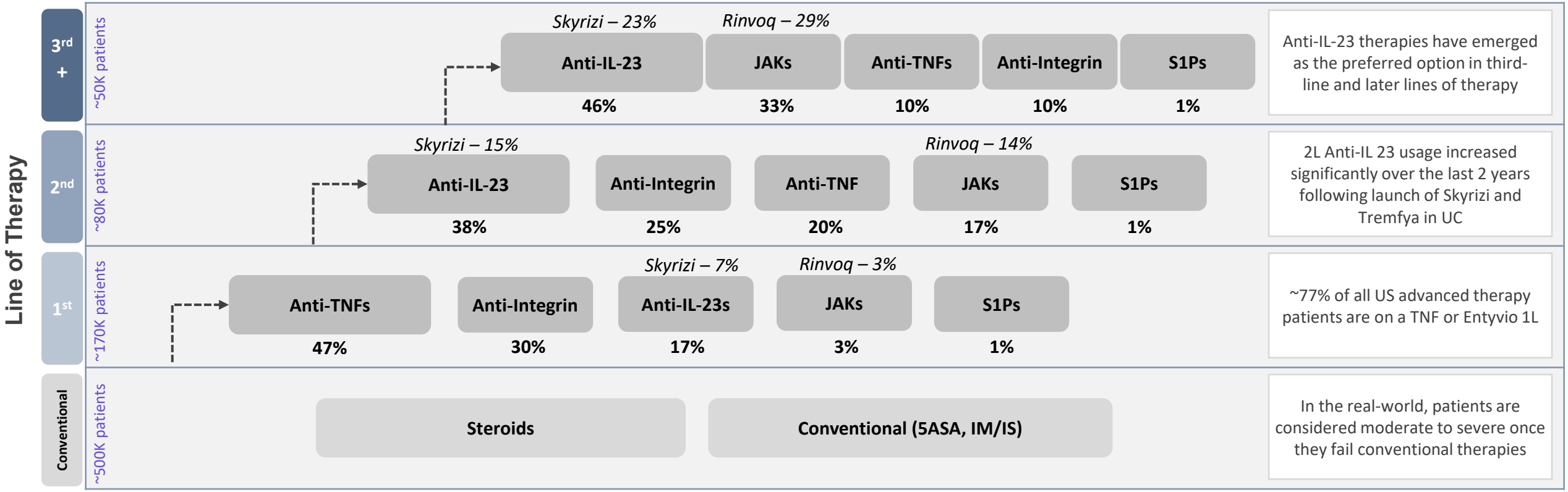
Approximately 80% of all first line patients remain on an anti-TNF or Entyvio

Estimated Market Share by Line of Therapy in 2025[1]

% of Patients by Line of Therapy



Recent market research confirmed obefazimod's profile has the potential to penetrate 1L and emerge as a market leader

1. Source: Komodo PLAID claims data | Time period : Nov'15 to Oct'25
~20% of moderate-severe conventional patients transition to 1L advanced therapy

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Mechanism of Action

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Obefazimod Development

An oral small molecule that enhances the expression of miR-124

Discovery | **Transition to Inflammation** | **Clinical Development**

2009 – 2015 | **2015 – 2017** | **2017 – Present**

Obefazimod Discovery

- Obefazimod was co-discovered with CNRS (French NIH) and Institut Curie

Initial Development in HIV

- Obefazimod was selected by functional screening on HIV replication from a chemical library of molecules designed to modulate RNA splicing
- Obefazimod was initially developed in HIV

miR-124 Selectivity

- Among >1000 microRNAs, obefazimod found to enhance expression of only miR-124, a physiological miRNA and known anti-inflammatory

Pre-Clinical POC

- Effective in DSS-induced colitis mouse model
- Consistent with known miR-124 profile, reduction of inflammatory cytokines and chemokines observed

MOA Evidence in Humans

- Enhanced expression of miR-124 in blood and colonic tissue of UC patients
- Reduction of inflammatory cytokines, including IL-23 & IL-17 in UC patients, and IL-6 in RA patients

Obefazimod Clinical Trial Programs

- Positive Phase 3 results from both ABTECT UC 8-week Induction Trials announced July 2025
- UC Maintenance Trial topline announced June 2026
- CD Induction Topline readout expected mid-2027

Abivax is using microRNA technology, a now Nobel Prize winning scientific discovery, to revolutionize the future treatment of IBD

Source: https://pubmed.ncbi.nlm.nih.gov/37129565/ ; Campos N, et al. *Retrovirology*. https://retrovirology.biomedcentral.com/articles/10.1186/s12977-015-0159-3. https://ard.bmj.com/content/81/8/1076.long

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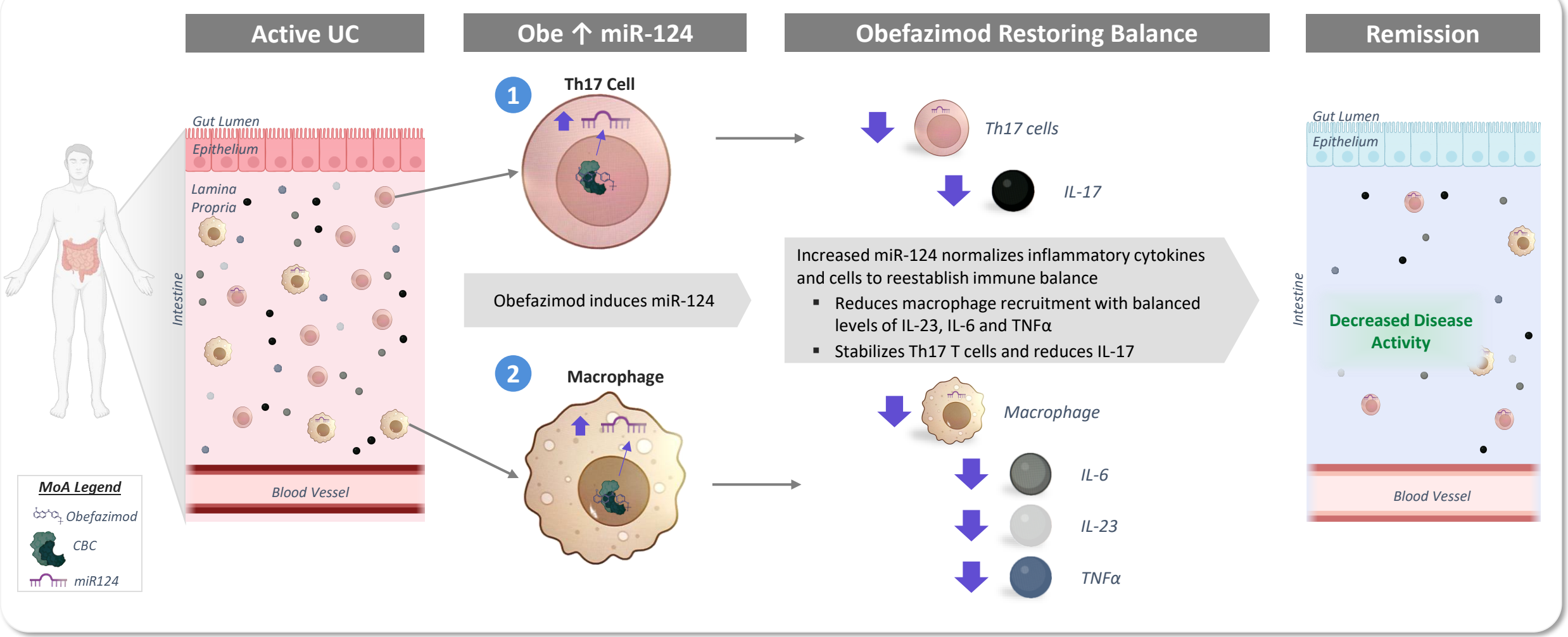
Obefazimod Restores Immune Balance in UC through Physiologic Immunoregulation

Obefazimod MoA addresses multiple hallmarks of IBD pathology & chronic inflammation

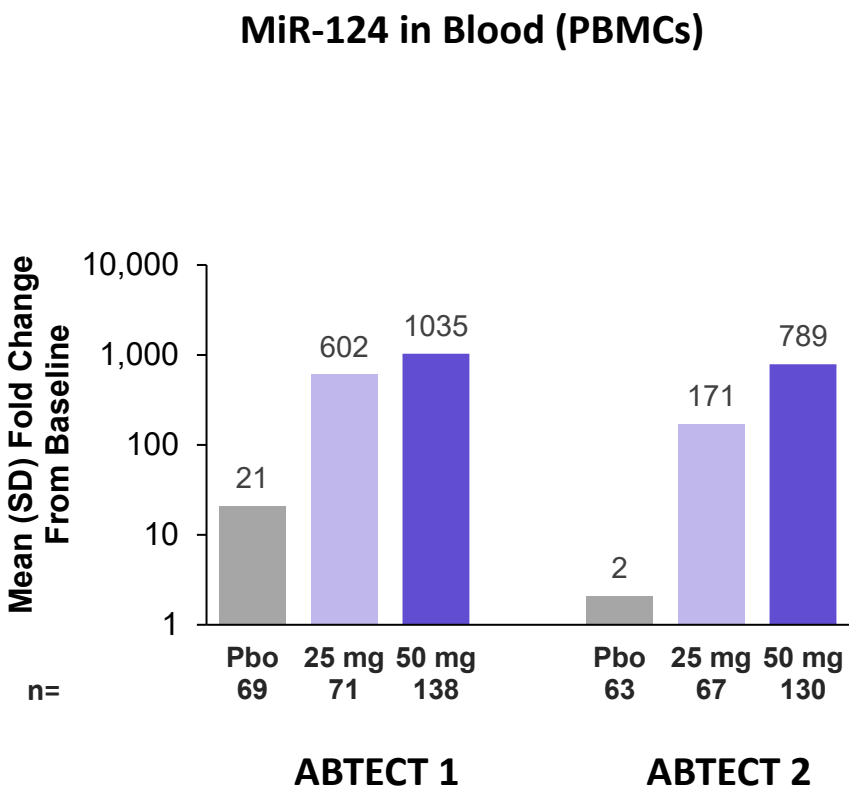


Apolit et al. Clin Transl Gastroenterol, 2023 | Vermeire et al., J Crohns Colitis, 2023 | Abivax Data on File | Images made with BioRender

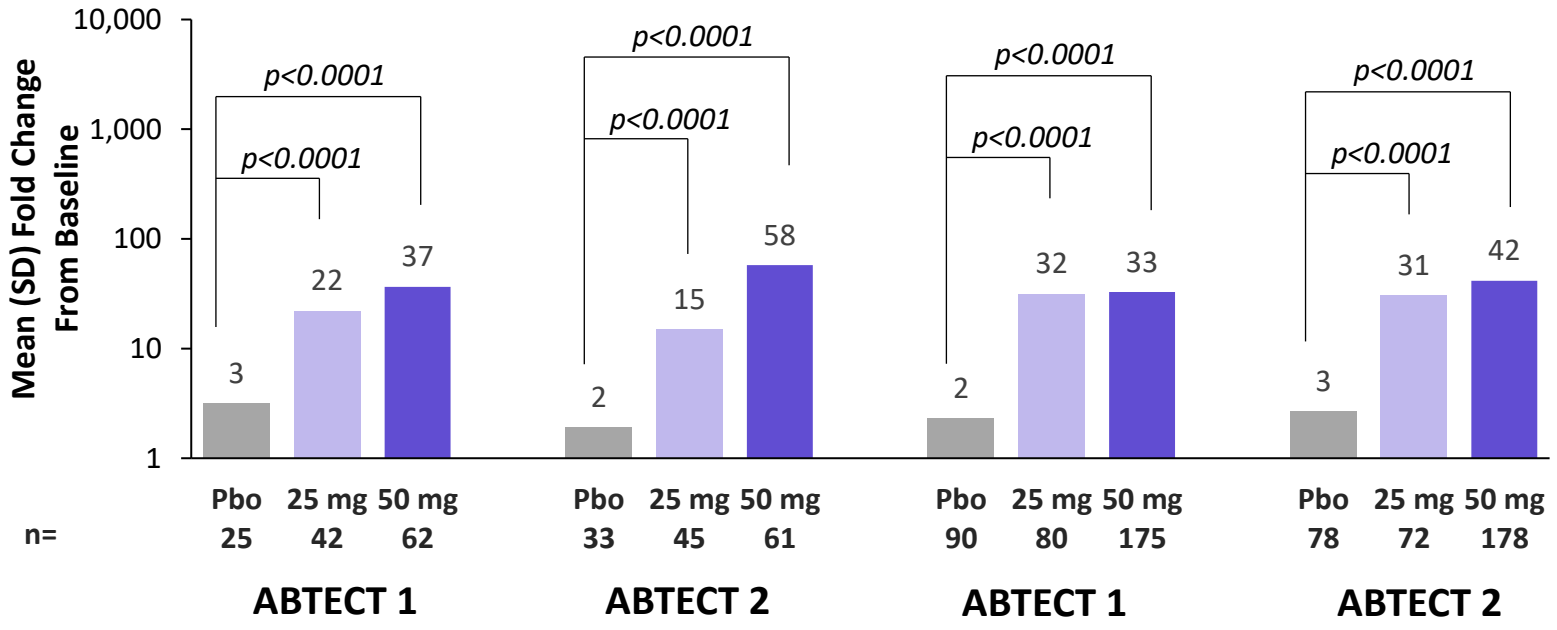
Obefazimod was associated with enhanced expression of miR-124

miR-124 expression in blood and colon tissues from Phase 3 induction trials

miR-124 Expression in Blood at Week 8 in Patients With UC



miR-124 Expression Colon Tissues at Week 8 in Patients With UC



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

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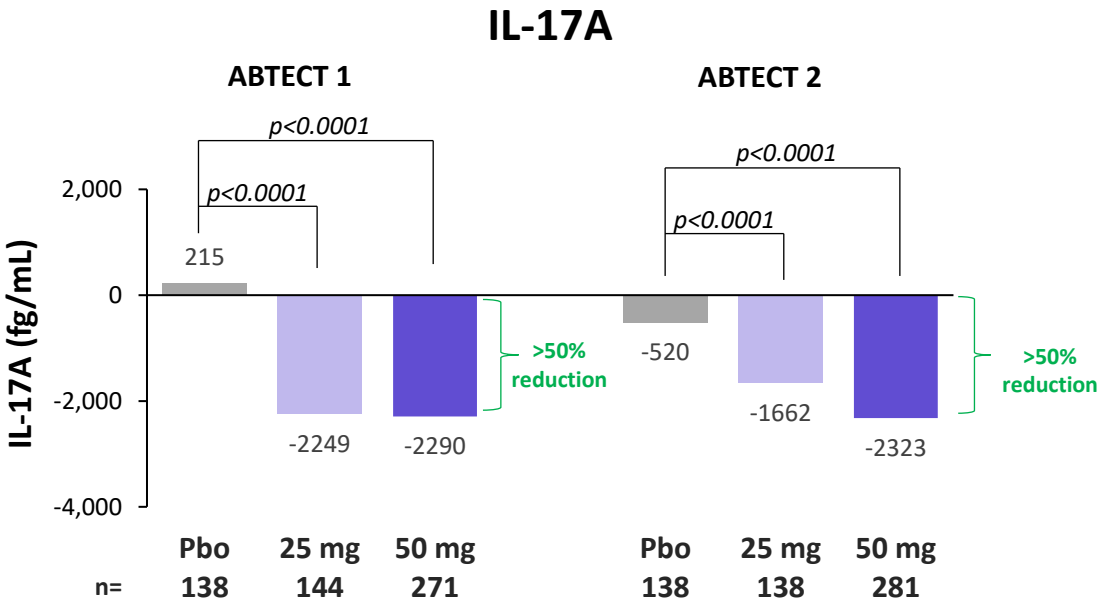
Obefazimod was also associated with reductions in proinflammatory cytokines IL-17A and IL-6

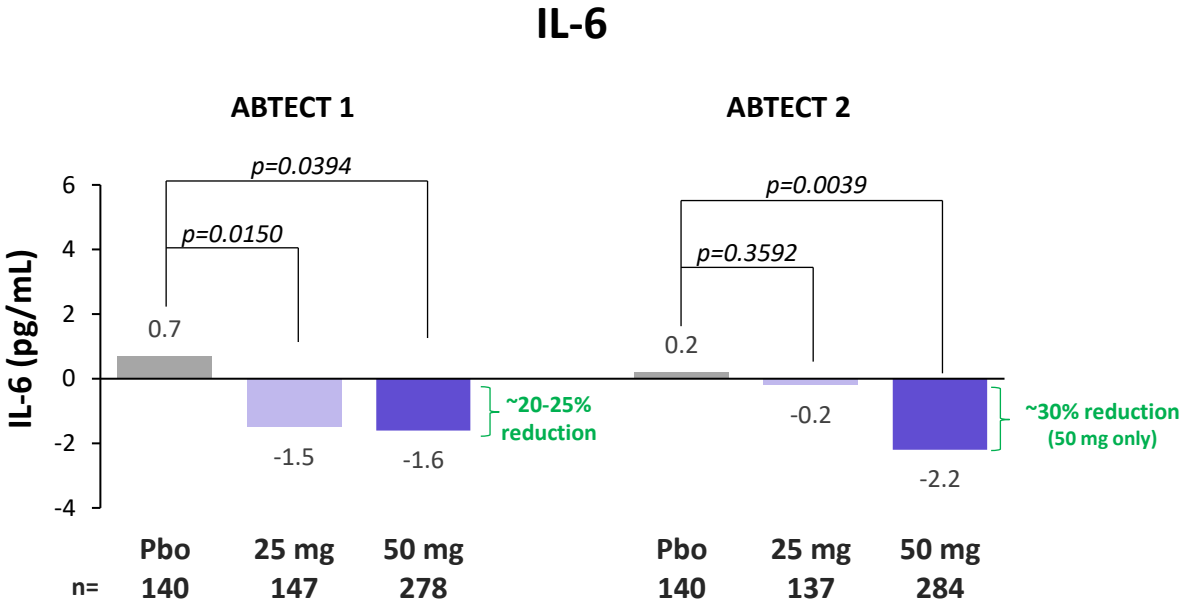
IL-17A Changes from Baseline to Week 8 in Serum from Patients with UC: ABTECT 1 and ABTECT 2 Trials



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

IL-6 Changes from Baseline to Week 8 in Serum 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

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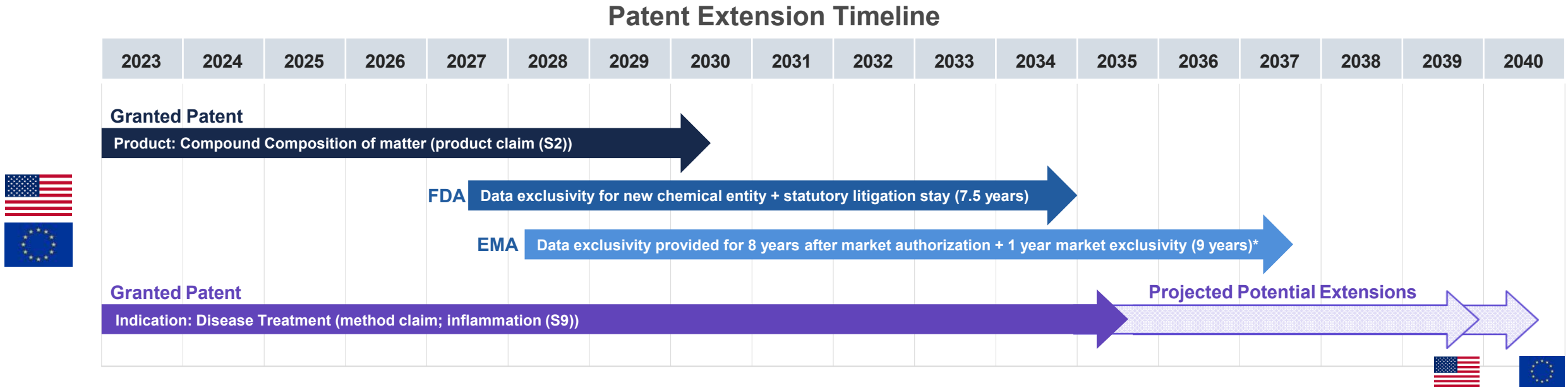
Strength of obefazimod Method of Use Patent Rigorously Assessed and Confirmed by Two Globally Renowned IP Law Firms



Exclusivity Considerations:

- **US: If obefazimod is approved by the FDA in 2H 2027, the FDA will grant an additional 7.5 years of exclusivity for a newly approved chemical entity (5 years of regulatory exclusivity plus 2.5 years of litigation stay against generic(s)), *taking obefazimod's US exclusivity, at a minimum, through 2034.* Pediatric extension would provide an additional 6 months of exclusivity**
- ***EU: If obefazimod is granted market authorization by the EMA in 2028, 8 years of data exclusivity + 2 additional years of market exclusivity would be granted (though legislation may decrease market exclusivity to only 1 additional year), *taking obefazimod's EU exclusivity, at a minimum, into 2037.* Pediatric extension would provide an additional 6 months exclusivity**
- **We have validated with multiple external experts our conviction in the eligibility and strength of our Method of Treatment patent, as well as our ability to extend and defend it through 2039 in the US and through 2040 in the EU**

Note: Applicable authorities in the US and EU may not agree with our assessment of whether such extensions to our Method of Treatment patents are available or may grant more limited extensions than we request.

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Phase 3 Topline Data Readout

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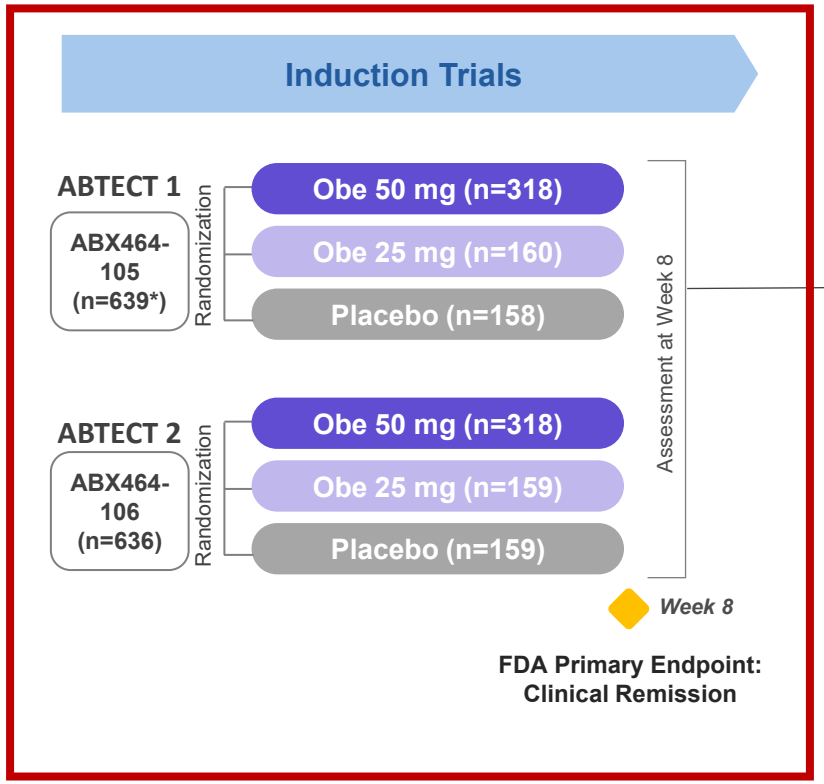
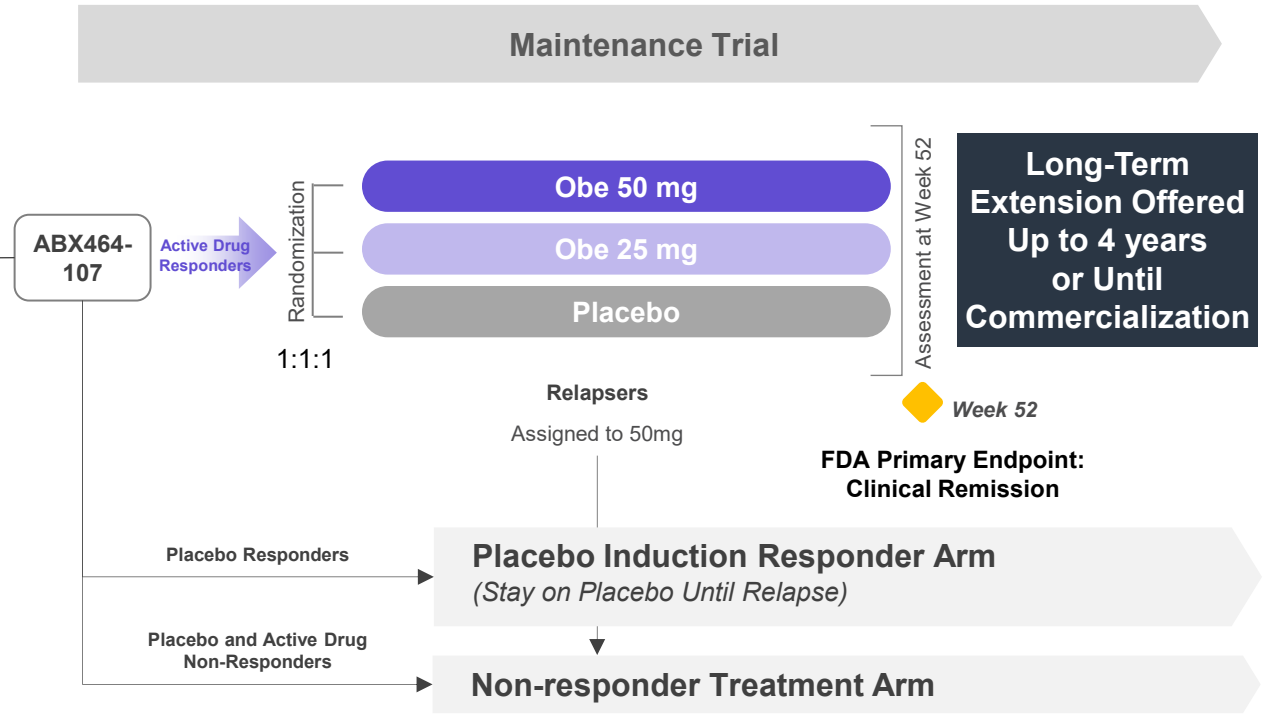
ABTECT Phase 3 Program in Ulcerative Colitis

2 Induction Trials and 1 Maintenance Trial

Screening

- ❑ Moderately to severely active UC defined by:
  - MMS 5-9, ES≥2, RB≥1
- ❑ Prior failure of conventional and/or biologic/JAKi/S1P
- ❑ No limit on number of prior treatment failures





There was no limit on the number of prior advanced treatment failures for inclusion into ABTECT 1 & 2

ABX464-105, ABX464-106, ABX464-107; Placebo responders from induction are not re-randomized and do not contribute to the primary endpoint in the maintenance study.*3 patients in ABTECT 1 were randomized but not treated.

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Baseline Characteristics: Generally Well Balanced

Slightly more severe and refractory population randomized 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

AT-IR=inadequate response, loss of response or intolerance to advanced therapies

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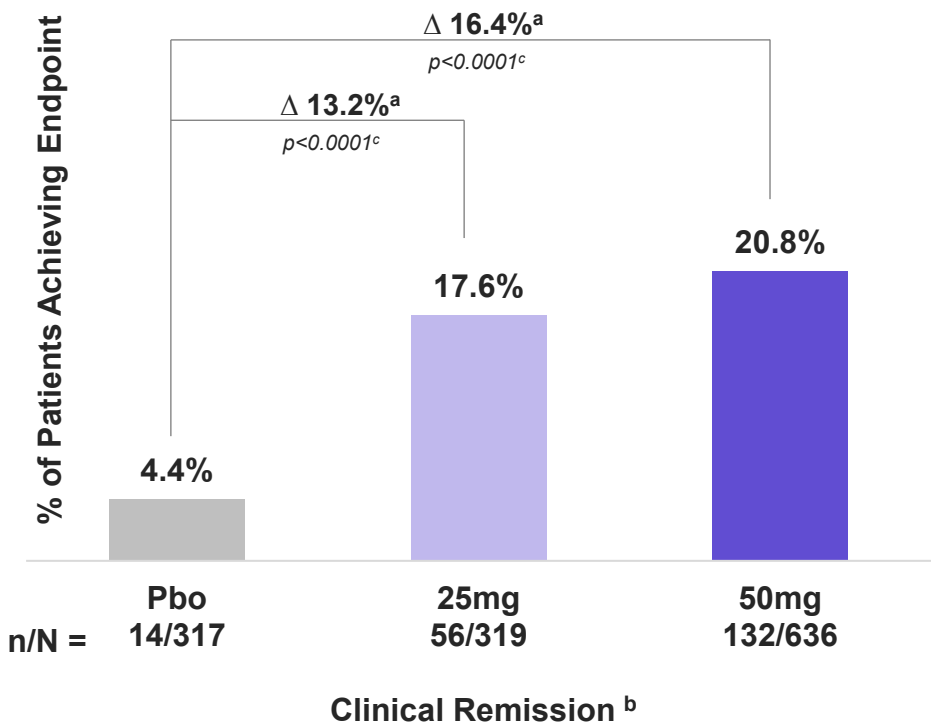
Obefazimod Met the FDA Primary Endpoint with Both Doses in a Pooled Analysis

50mg exceeded previous Phase 2b results; 25mg results were comparable to Phase 2b*

Pooled Clinical Remission – ABTECT 1 & ABTECT 2



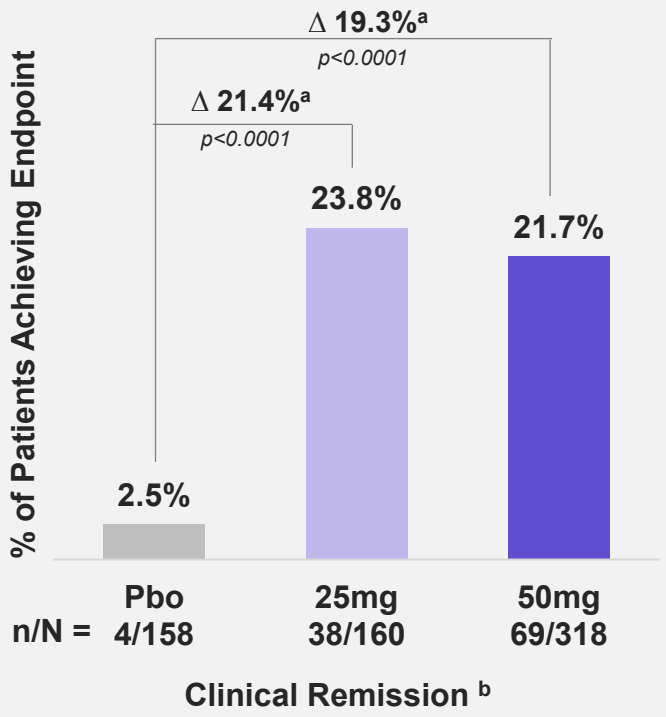
Sands BE et al. Oral presentation presented at: United European Gastroenterology Week, October 4–7 2025, Berlin, Germany.
[a] % Difference is for ABX464 minus placebo and is based on estimated common risk difference using the Mantel-Haenszel weights adjusting for the randomization stratification factors: 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).
*25mg showed a 13.7% delta vs placebo in Ph2b (26.2% vs 12.5%); 50mg dose showed a 5% delta vs placebo in Ph2B (17.5% vs 12.5%). However, clinical remission was not the primary endpoint in Ph2b and was not powered to show statistical significance. Both 25mg and 50mg met the primary endpoint in Ph2b (Change from Baseline in Modified Mayo Score at Week 8)
[c] Because this is a pooled analysis, all p-values are nominal

Obefazimod Achieved Statistical Significance with Both Doses in ABTECT 1

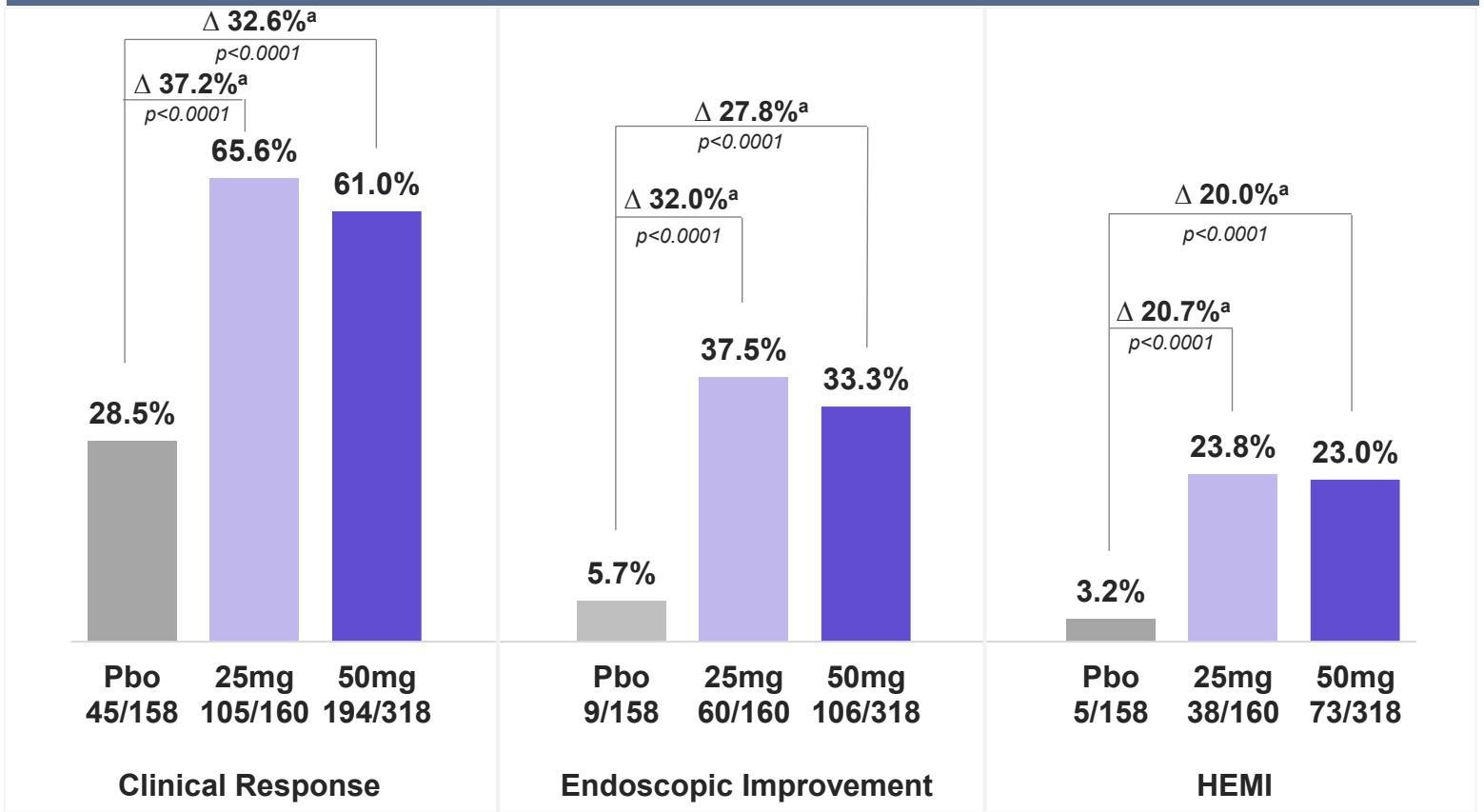
25mg and 50mg both statistically significant and clinically meaningful in all key secondary endpoints

Clinical Remission – ABTECT 1 (105)

FDA Primary Endpoint



FDA Key Secondary Endpoints – ABTECT 1 (105)



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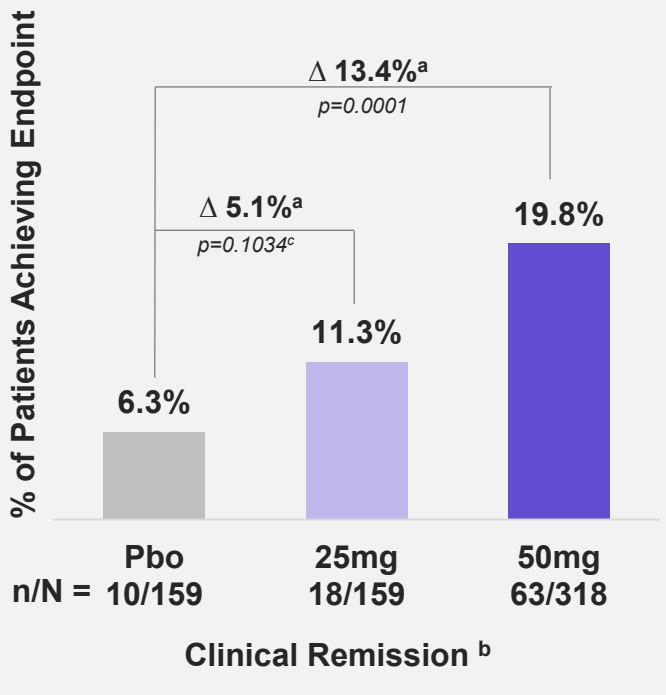
[b] Clinical remission is defined as SFS = 0 or 1, and RBS = 0 and MES = 0 or 1 (MES of 1 modified to exclude friability).
Endoscopic improvement is defined as MES = 0 or 1 (MES of 1 modified to exclude friability).
Clinical response is defined as a reduction from Baseline in MMS >= 2 points and a relative 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

Obefazimod Met the FDA Primary Endpoint with 50mg in ABTECT 2

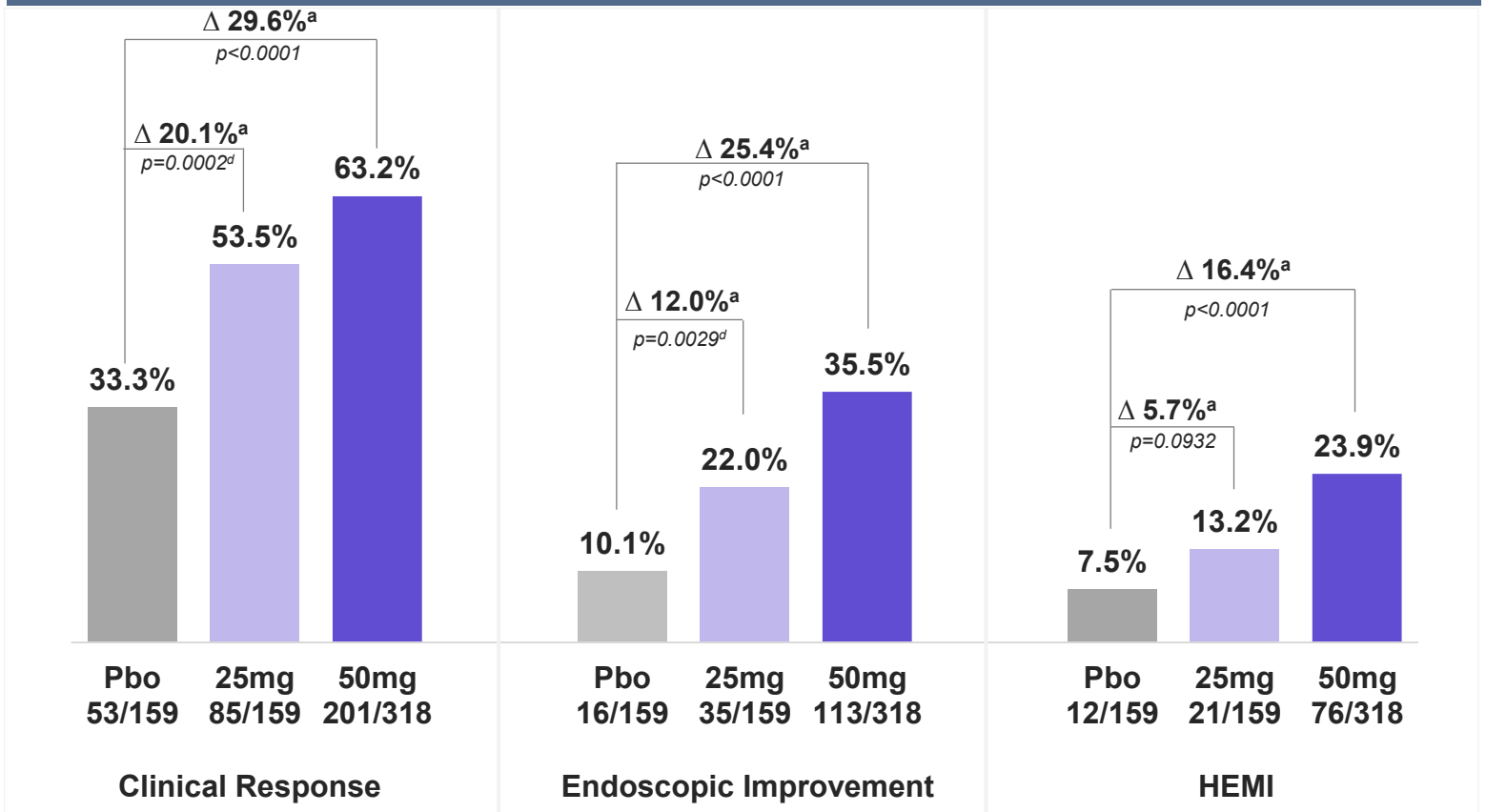
50mg achieved statistical significance on all key secondary endpoints in ABTECT 2

Clinical Remission – ABTECT 2 (106)

FDA Primary Endpoint



FDA Key Secondary Endpoints – ABTECT 2 (106)



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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

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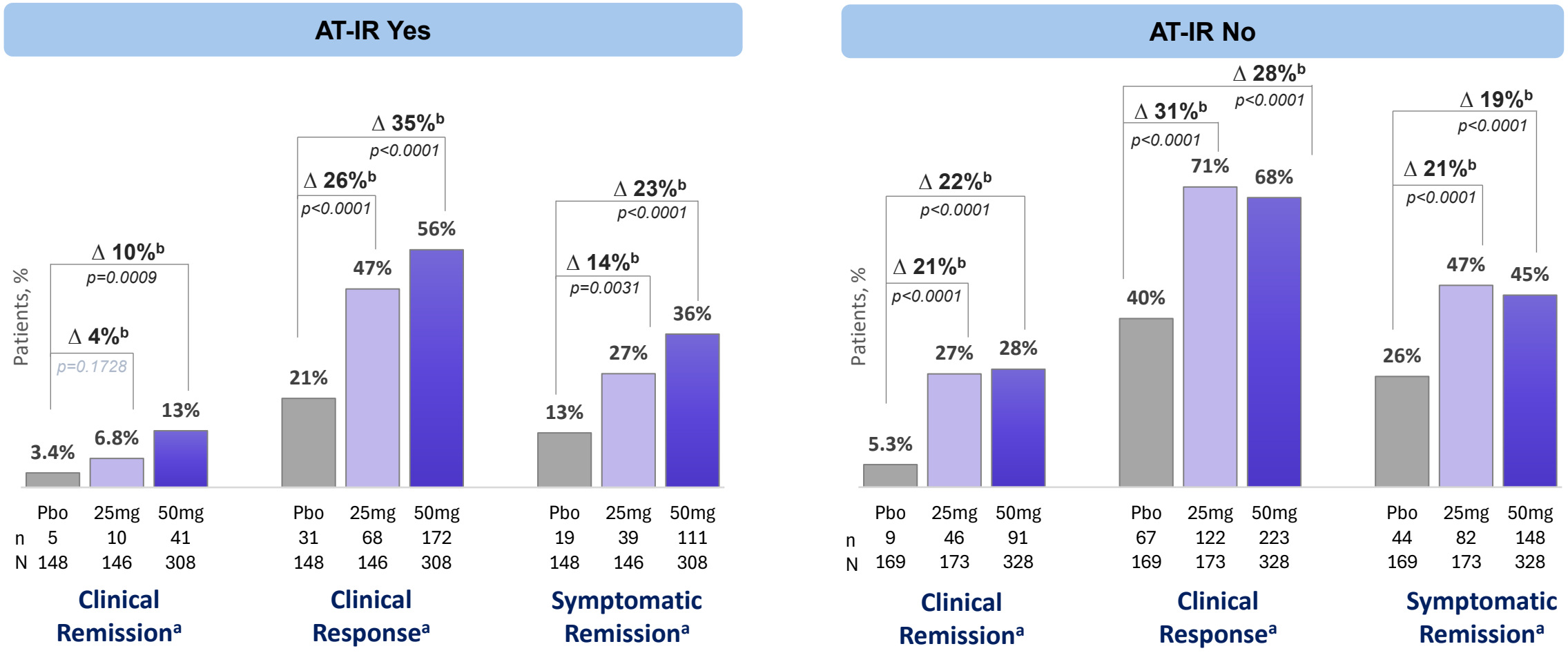
Pooled ABTECT 1 & 2: 50mg Dose Achieved Clinically Meaningful Improvements in all Clinical Endpoints Regardless of Prior AT-IR

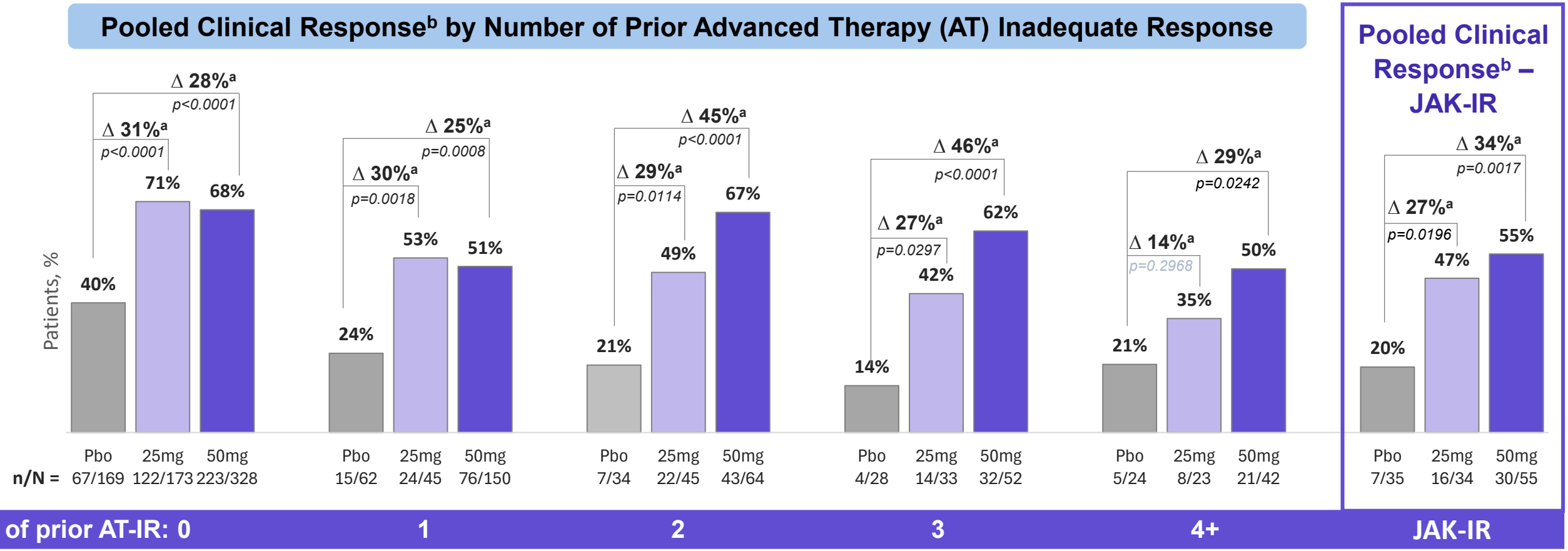
25mg and 50mg perform similarly in subgroup with no prior AT-IR in pooled data set



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.

Clinical Response by Number of Prior AT Inadequate Responses and Prior JAK Inhibitor

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



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[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

Safety Summary – ABTECT 1 & 2 – Pooled Full Data Set

Treatment Emergent Adverse Events (TEAE), n (%)	ABTECT 1 & 2 – Pooled Full Data Set		
	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)†
Serious/severe (grade ≥3) infections and opportunistic infections	1 (0.3)‡	1 (0.3)¥	4 (0.6)§

*No serious TEAE occurred in more than one subject except worsening of UC

Sands BE et al. Oral presentation presented at: United European Gastroenterology Week, October 4–7 2025, Berlin, Germany.
†Prostate cancer stage I
‡Bronchopulmonary aspergillosis; ¥Appendicitis; §Pneumonia (2), anal abscess, COVID-19

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ABTECT Maintenance – Part 1

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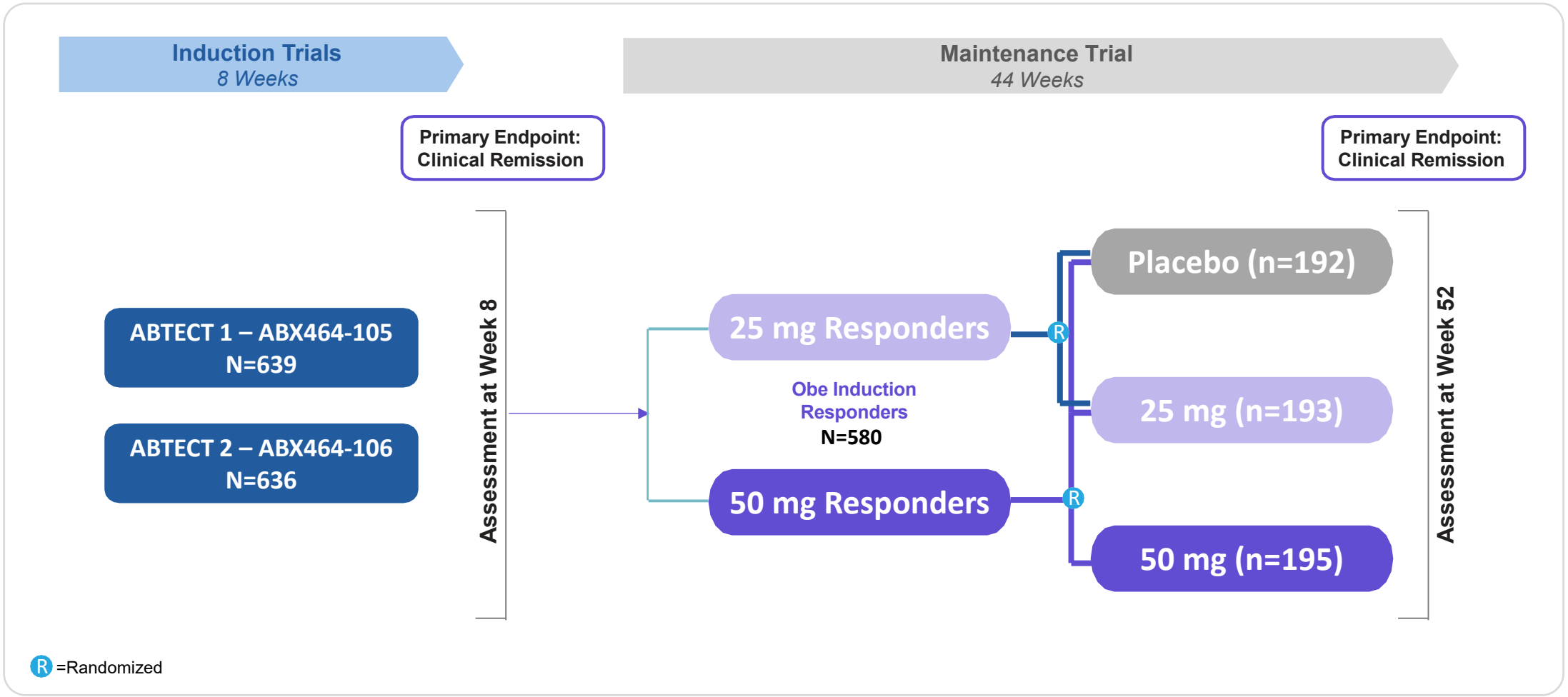
ABTECT Phase 3 Responder Re-Randomized Maintenance Trial Design

ABTECT Clinical Trial Design



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ABTECT Maintenance Phase 3 Baseline Characteristics and Completion Rate

	Placebo	Obe 25 mg	Obe 50 mg
Study Participants	192	193	195
Age (Years), Mean (SD)	41.3 (13.4)	43.0 (13.7)	42.3 (14.4)
Baseline Induction MMS, Mean (SD)	6.9 (1.1)	6.7 (1.1)	6.9 (1.2)
Duration of Disease (Years), Mean (SD)	8.1 (7.6)	8.1 (7.4)	7.8 (6.9)
Baseline Induction Fecal Calprotectin (μg/g), Median	1202	1585	1568
Corticosteroid Use at Maintenance Baseline (%)	35.9%	41.5%	40.5%
Prior Advanced Therapy Failure (%)	37.5%	39.4%	46.2%
44-Week Completion Rate	66 (34.3%)	152 (78.8%)	160 (82.1%)

50 mg cohort had a higher percentage of patients with prior advanced therapy failure relative to patients on 25 mg and placebo

Data on File ABX464-107; MMS = Modified Mayo Score

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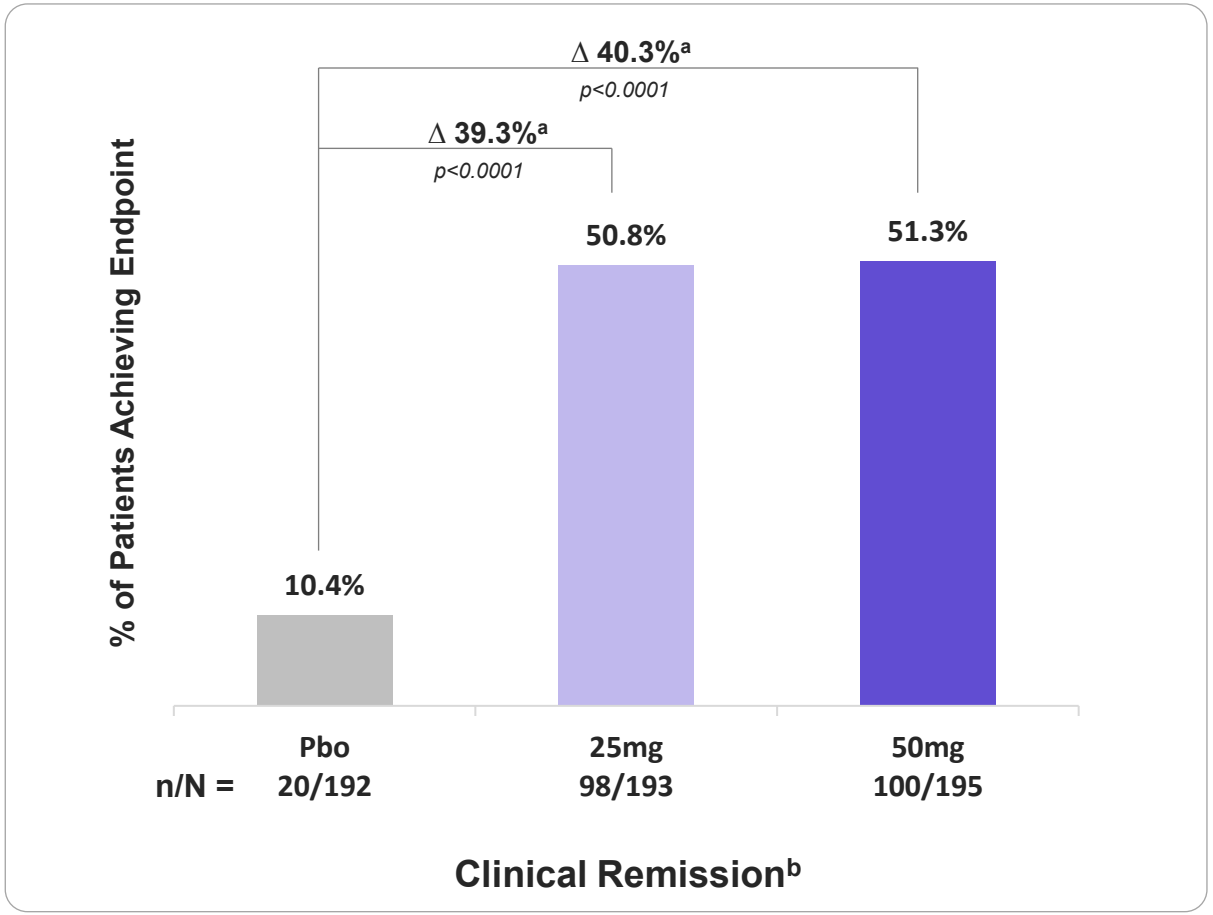
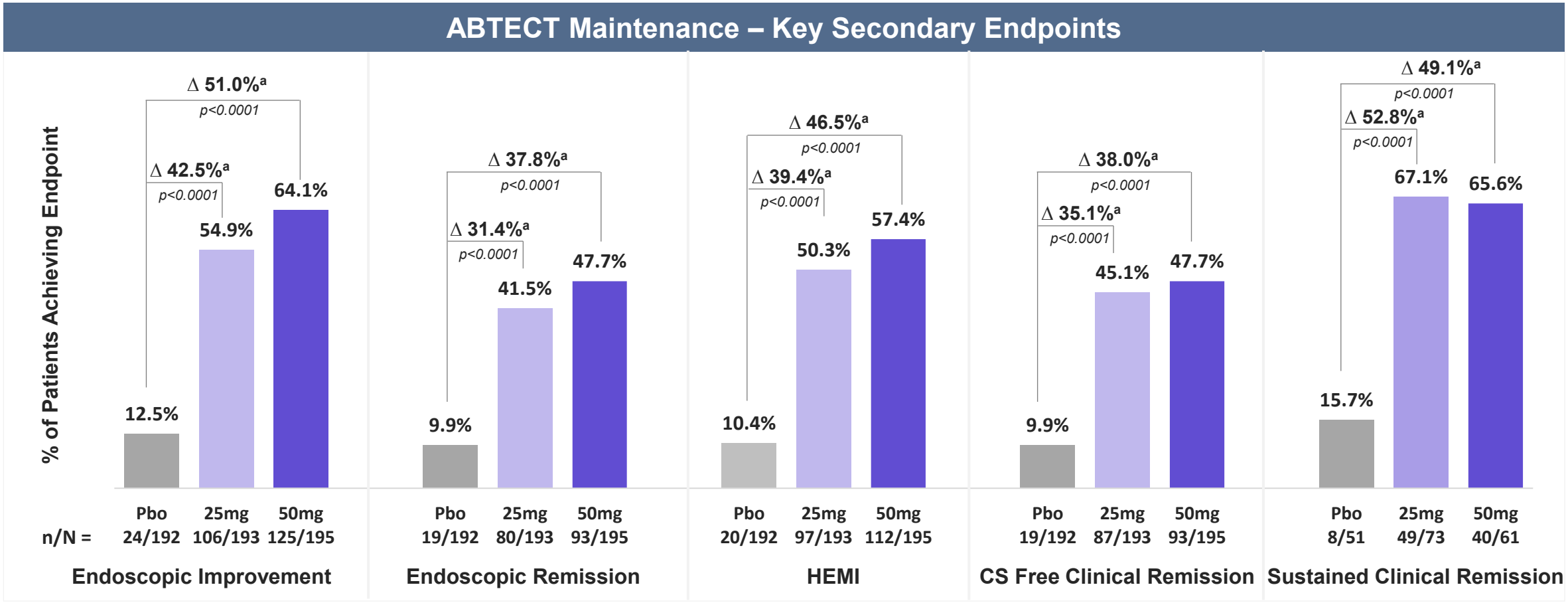
Obefazimod 25 mg & 50 mg delivered statistically significant, clinically meaningful efficacy results, with placebo-adjusted remission of Δ39.3% and Δ40.3%, respectively

ABTECT Maintenance – Primary Endpoint



Data on File ABX464-107
[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: clinical remission at maintenance baseline (yes/no), induction treatment (25 mg/50 mg), and maintenance baseline oral corticosteroids usage (yes/no)
[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)

Obefazimod achieved statistical significance on all key secondary endpoints



Data on File ABX464-107

[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: clinical remission at maintenance baseline (yes/no), induction treatment (25 mg/50 mg), and maintenance baseline oral corticosteroids usage (yes/no)

Endoscopic improvement is defined as MES = 0 or 1 (MES of 1 modified to exclude friability); Endoscopic remission is defined as MES = 0;

HEMI is defined as MES = 0 or 1 and Geboes Index score ≤3.1; CS-free clinical remission is defined as clinical remission (SFS = 0 or 1 and RBS = 0 and MES = 0 or 1 (MES of 1 modified to exclude friability)) at Week 44 and corticosteroid free for at least 12 weeks immediately prior to Week 44; Sustained clinical remission is defined as clinical remission at Week 44 in the sub-population of subjects in clinical remission at Week 8 of the induction trial; HEMI = Histologic Endoscopic Mucosal Improvement; CS Free = corticosteroid free

Safety Results Summary – ABTECT Maintenance Part 1

Summary Safety Events, n (%)	ABTECT Maintenance Part 1		
	Placebo (N=192)	Obe 25 mg (N=193)	Obe 50 mg (N=195)
Any TEAE	96 (50.0%)	112 (58.0%)	140 (71.8%)
TEAE leading to study drug discontinuation	13 (6.8%)	5 (2.6%)	9 (4.6%)
Serious TEAE	8 (4.2%)	5 (2.6%)	11 (5.6%)
Death	0	0	0
Pregnancy	0	0	2 (1.1%)
Serious/severe (grade ≥3) infections and opportunistic infections[1]	2 (1.0%)	2 (1.0%)	1 (0.5%)
Malignancies other than Non-melanoma Skin Cancer (non-NMSC)[2]			
Breast cancer	0	0	1 (0.5%)
Prostate cancer	0	0	1 (0.5%)
Non-melanoma Skin Cancer (NMSC)			
Basal cell carcinoma	1 (0.5%)	0	2 (1.1%)
Squamous cell carcinoma	0	1 (0.5%)	2 (1.1%)
Acute Pancreatitis	0	0	0

1. Serious/Severe Infections and Opportunistic Infections: Placebo = Anal abscess, bronchitis & gastroenteritis, 25 mg = 1 Lymph node tuberculosis, 1 tonsillitis, 50 mg = 1 Appendicitis, focal peritonitis; TEAE = Treatment-Emergent Adverse Event. 2. One case of colonic dysplasia was reported in the obefazimod 50mg arm.

Data on File ABX464-107

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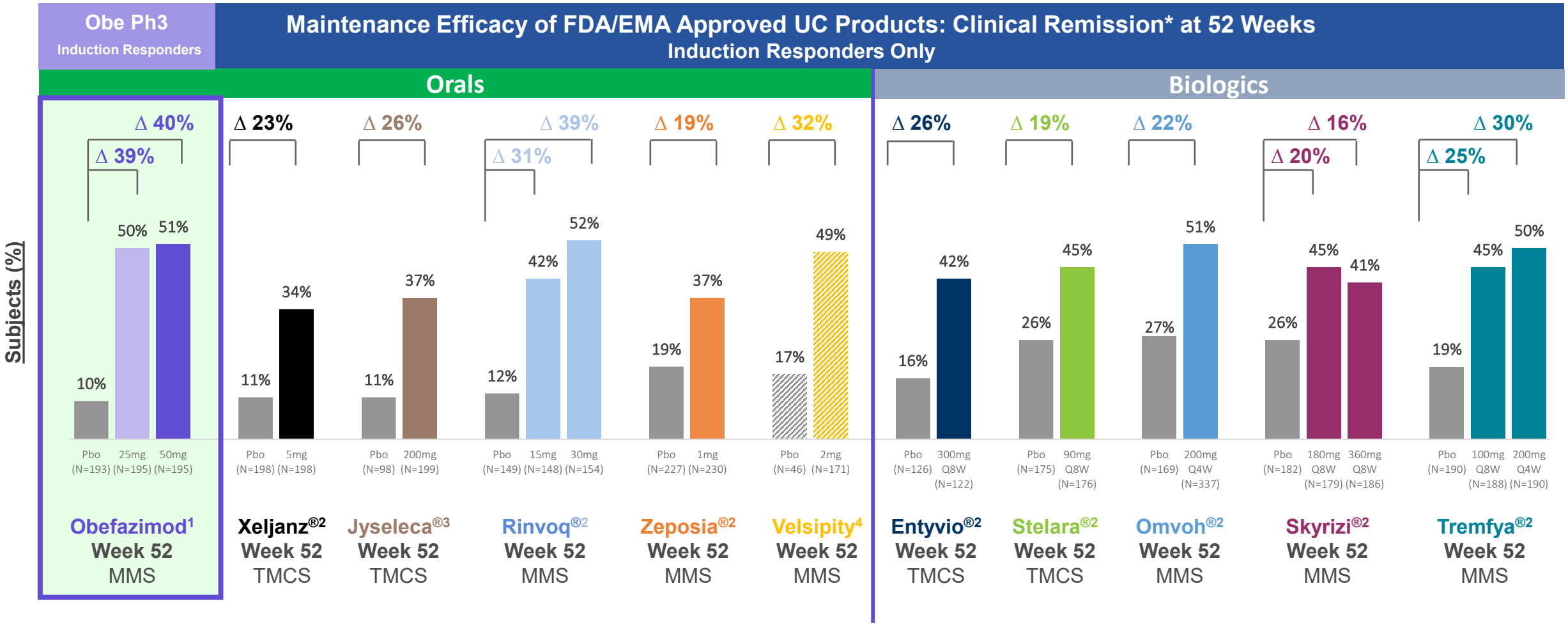
Clinical Remission Maintenance Data

Obefazimod 50 mg and 25 mg delivered the highest placebo-adjusted clinical remission reported to date



For illustrative purposes only. Not a head-to-head comparison. Differences exist between trial designs and subject characteristics, and caution should be exercised when comparing data across trials.

1. Data on File ABX464-107. 2. FDA package inserts. 3. EMA Product Summary Characteristics. 4. Clinical remission among week 12 clinical responders; Vermeire et. al., ECCO 2023 Poster #582. Velsipity Phase 3 was a treat-through design. *All clinical remission numbers are rounded to the nearest whole number as reported in FDA prescribing information in package inserts. TMCS = Total Mayo Clinic Score; MMS = Modified Mayo Score

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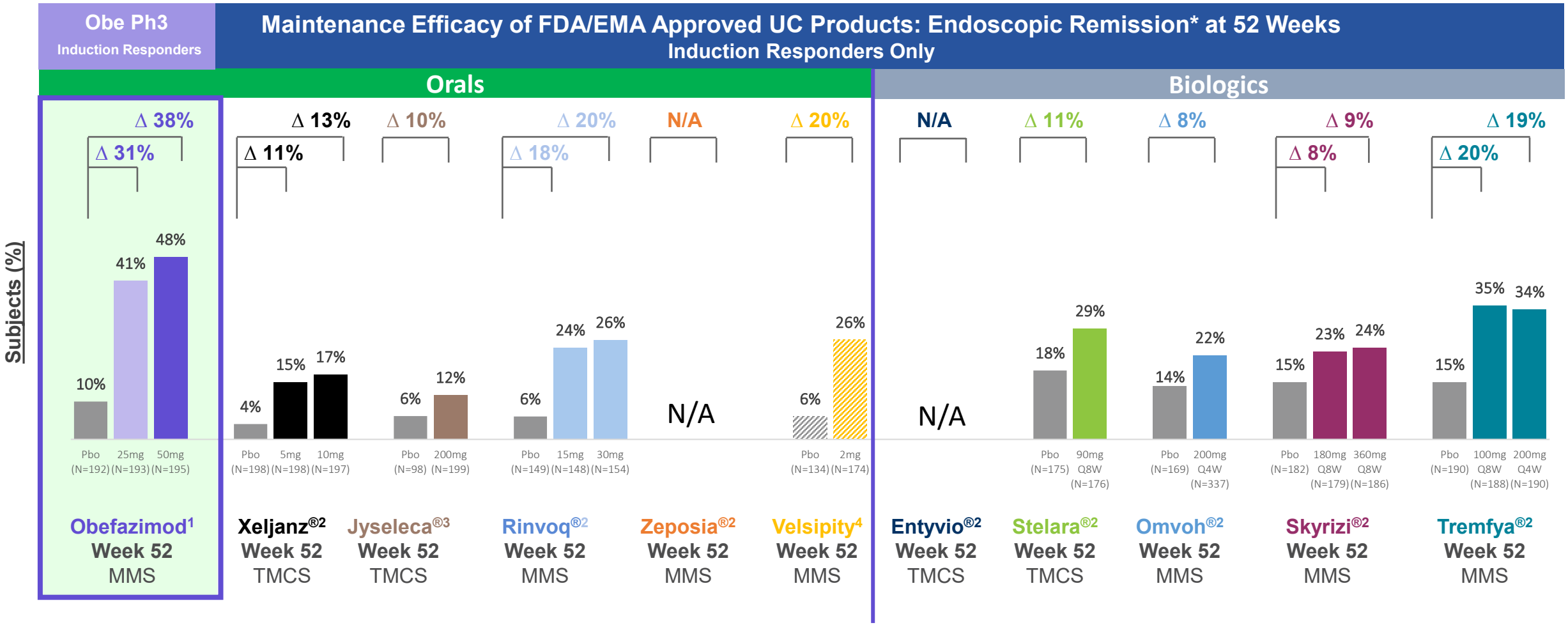
Endoscopic Remission Maintenance Data

Obefazimod 50 mg and 25 mg delivered potential best-in-disease endoscopic remission reported to date



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1. Data on File ABX464-107. 2. FDA package inserts. 3. EMA Product Summary Characteristics. 4. Clinical remission among week 12 clinical responders; Vermeire et. al., ECCO 2023 Poster #582. Velsipity Phase 3 was a treat-through design. *All endoscopic remission numbers are rounded to the nearest whole number as reported in FDA prescribing information in package inserts. TMCS = Total Mayo Clinic Score; MMS = Modified Mayo Score

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ABTECT Maintenance – Part 2

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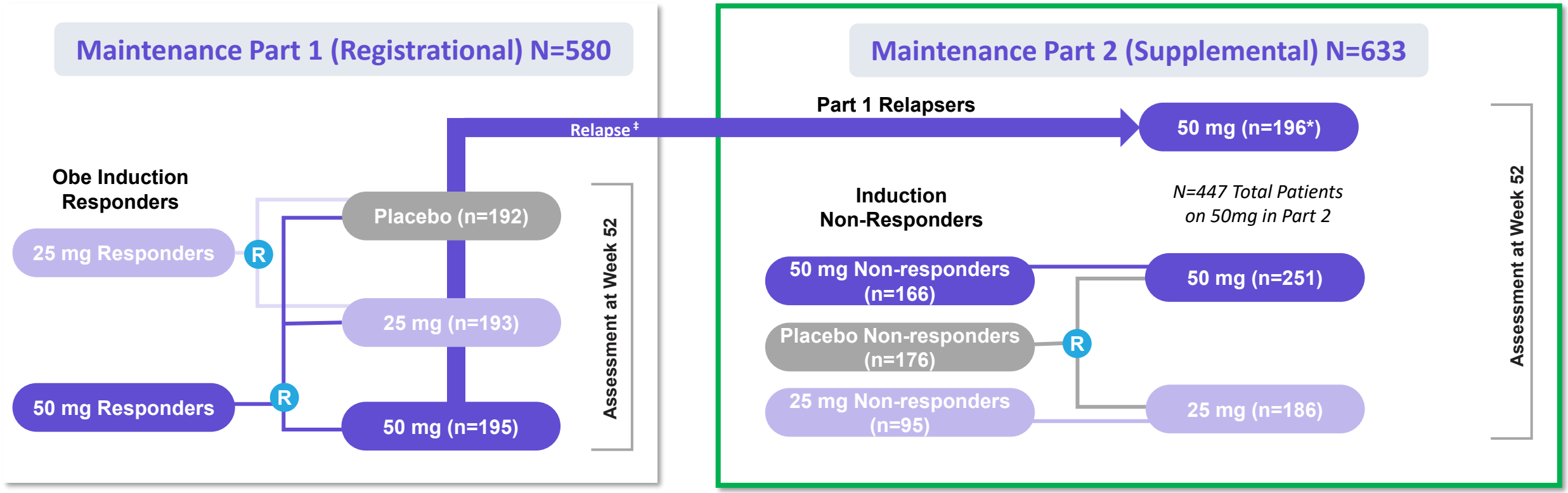
Part 2 Study Design: Difficult-to-Treat Population

Part 1 Relapsers and Induction Non-Responders

1. **Part 2 serves as a supplemental dataset to Part 1**
2. **Part 2 includes two distinct patient populations**
3. **Part 2 patients are more refractory and difficult to treat**
4. **All patients receive obefazimod**



R=Randomized

ABX464-107 Protocol

†Induction placebo responders will not be a part of the registrational efficacy dataset.

‡**Relapse is assessed in two steps: symptomatic relapse** during maintenance, followed by confirmation of a Mayo Endoscopic Subscore ≥2 at the **Relapse Confirmation Visit endoscopy**. Symptomatic relapse requires a ≥2-point increase from maintenance baseline in the partial Modified Mayo Score, including a ≥1-point increase in the Rectal Bleeding Score, at two timepoints 7–14 days apart.

*Includes Part 1 Relapsers who were originally randomized to Placebo (N=109), 25 mg (N=33), 50 mg (N=17) in Part 1 and Placebo Responders (N=37)

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Part 2 Patients Entered Maintenance With A Greater Inflammatory Burden Than Part 1 Patients

Baseline Characteristics at Start of Maintenance

Post-Induction

		Focus of Today
	Part 1 **Induction Responders*** (N=678)	**Part 2** **Induction Non-responders** (N=437)
Measure	**Maintenance Baseline**	**Maintenance Baseline**
MMS, mean (SD)	**2.7 (1.4)**	**6.2 (1.2)**
Fecal Calprotectin (%) >150µg/g	**49.7%**	**82.4%**
Prior Advanced Therapy Failure (%)	**39.8%**	**57.0%**
JAK Failure **(% of Prior Advanced Therapy Failures)**	**18.9%**	**22.1%**
	Clinical Responders **Less Disease Activity**	**Clinical Non-Responders** **High Inflammatory Burden**

Data on File ABX464-107; *Includes N=98 placebo induction responders
MMS = Modified Mayo Score

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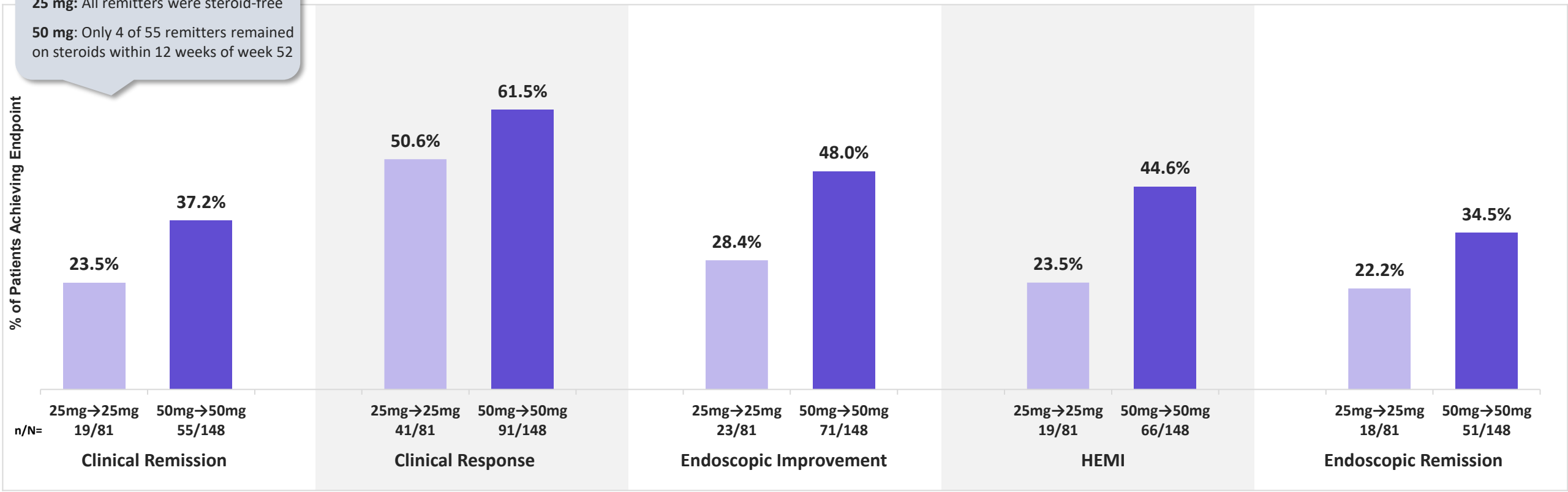
Continued Obefazimod Treatment Delivered Unprecedented Efficacy Results for Patients who Failed to Respond After 8 Weeks

Part 2: Induction Non-Responders – Exploratory Efficacy Endpoints

At Week 44 of Maintenance

25 mg: All remitters were steroid-free

50 mg: Only 4 of 55 remitters remained on steroids within 12 weeks of week 52



Compelling efficacy results were consistently observed across all key exploratory endpoints, with numerically stronger efficacy results observed in the 50 mg arm

Data on File ABX464-107; Clinical remission is defined as SFS = 0 or 1, and RBS = 0 and MES = 0 or 1; 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; Endoscopic improvement is defined as MES = 0 or 1; HEMI is defined as MES = 0 or 1 and Geboes Index score ≤3.1; Endoscopic remission is defined as MES = 0; HEMI = Histologic Endoscopic Mucosal Improvement

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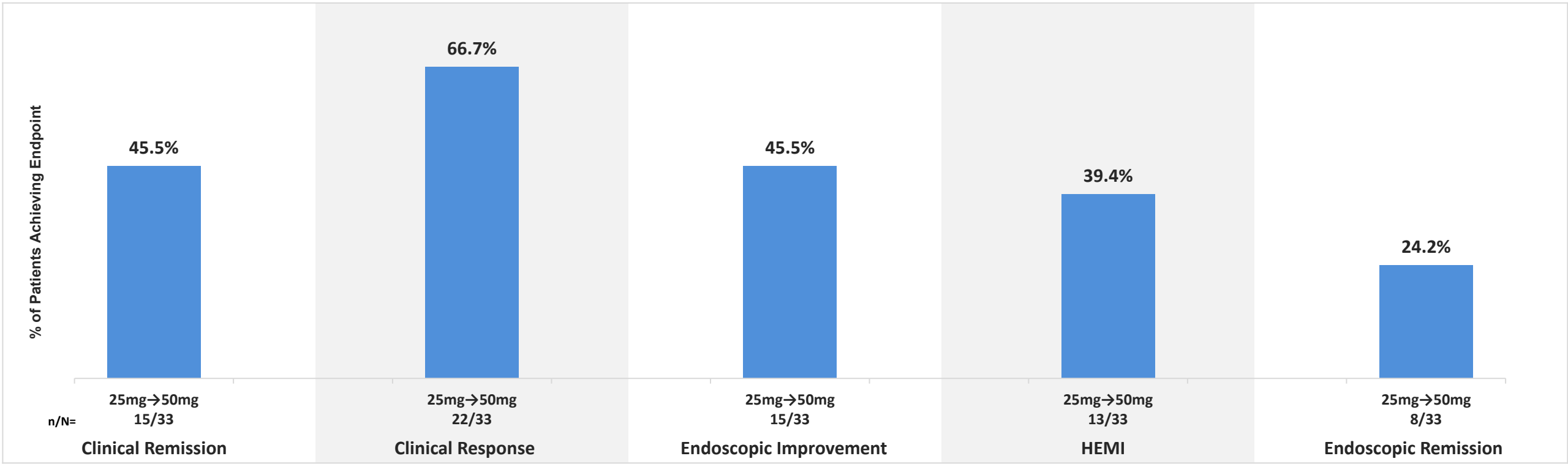
Dose Escalation From 25 mg to 50 mg Restored Disease Control in Patients Who Relapsed in Part 1, Supporting a Practical, Real-World Treatment Approach

Part 1 Relapsers: Dose Escalation After Relapse on 25mg

25/50 mg (Induction) → 25 mg (Part 1) → Relapse → 50 mg (Part 2)
N=33, Week 44 of Maintenance



Data on File ABX464-107; Clinical remission is defined as SFS = 0 or 1, and RBS = 0 and MES = 0 or 1; 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; Endoscopic improvement is defined as MES = 0 or 1; HEMI is defined as MES = 0 or 1 and Geboes Index score ≤3.1; Endoscopic remission is defined as MES = 0; HEMI = Histologic Endoscopic Mucosal Improvement; Part 1 Relapsers are patients who were originally randomized to Placebo (N=109), 25 mg (N=33), 50 mg (N=17) in Part 1

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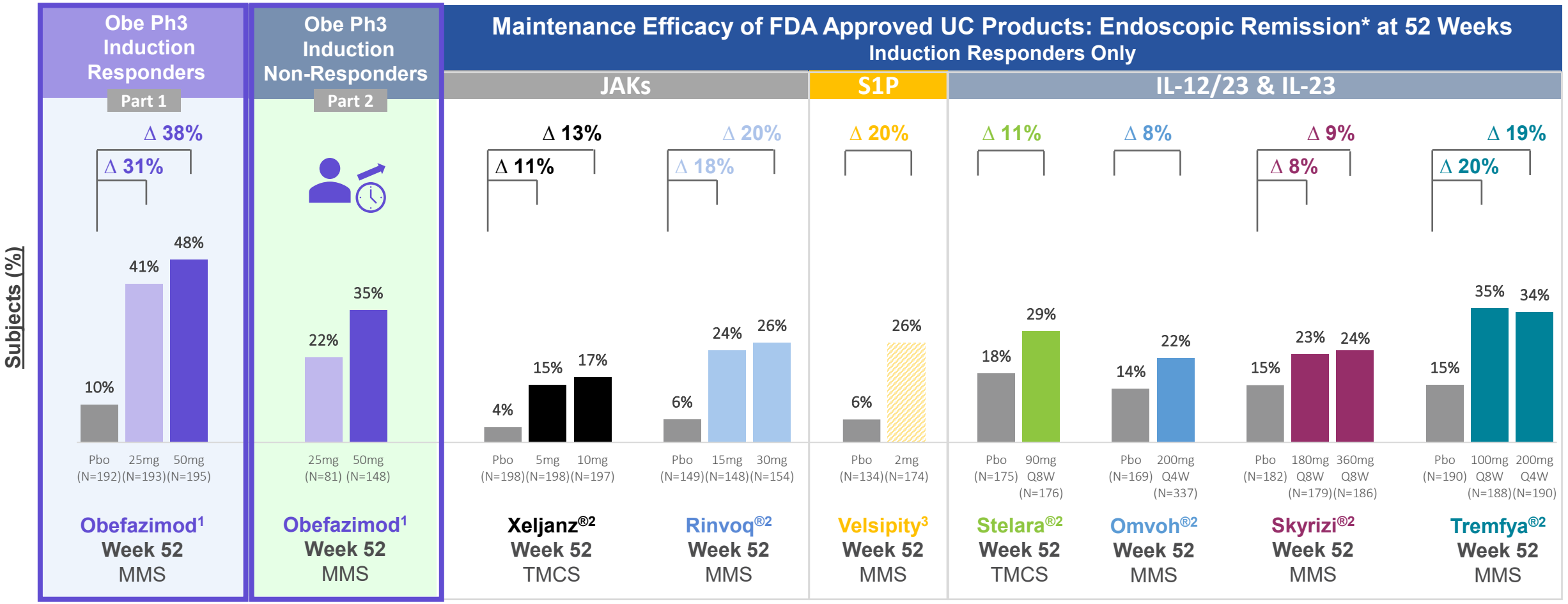
Obefazimod Achieved the Highest Endoscopic Remission Rate Among All UC Therapies

Obefazimod delivered transformational endoscopic remission, even in induction non-responders



For illustrative purposes only. Not a head-to-head comparison. Differences exist between trial designs and subject characteristics, and caution should be exercised when comparing data across trials.

= Induction Non-Responders: Patients who did not achieve clinical response following 8-week induction with obefazimod

1. Data on File ABX464-107. 2. FDA package inserts. 3. Vermeire et. al., ECCO 2023 Poster #582. Velsipity Phase 3 was a treat-through design. Endoscopic remission is defined as MES = 0. All endoscopic remission numbers are rounded to the nearest whole number as reported in FDA prescribing information in package inserts. TMCS = Total Mayo Clinic Score; MMS = Modified Mayo Score

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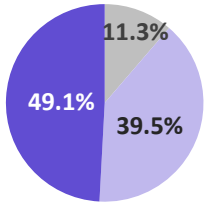
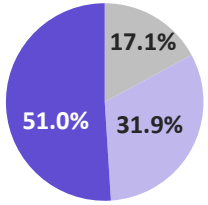
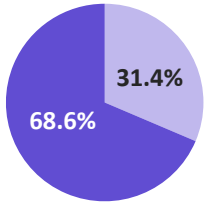
Obe 50 mg Accounts for 49% of Patient Year Exposure in Integrated UC Clinical Program

Placebo accounts for a small minority of patient-year exposure

Patient Years Overview for Exposure-Adjusted Incidence Rates

Analysis Set	Treatment Arm	Patient Years	Exposure Distribution
Integrated UC Clinical Program Phase 2 + Phase 3 Induction and Maintenance Part 1 & 2	Placebo	218	
	25 mg	760	
	50 mg	944	
	All Active	1,704	
Maintenance Part 1 + Part 2	Placebo	147	
	25 mg	274	
	50 mg	438	
	All Active	712	
Maintenance Part 2 Only	25 mg	132	
	50 mg	288	
	All Active	420	

Exposure-adjusted incidence rates provide a **meaningful comparison** across treatment groups with unequal exposure

$$\text{Incidence Rate per 100 Patient-Years} = \frac{\text{\# of events}}{\text{PYs of Exposure}} \times 100$$

Data on File ABX464-104, ABX464-105, ABX464-106, ABX464-107 and ABX464-108
All Active = 25 mg & 50 mg doses only, excluding placebo; Phase 2 included 838 Patient Years of Obefazimod Exposure (50mg = 404 PY, 25mg = 434 PY) with an additional 20 PY of placebo

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Favorable Safety Profile Observed in Part 2, Consistent with the Overall Obefazimod Safety Experience

ABTECT Maintenance Part 2 Safety Results

Summary Safety Events, n (%)	Obe 25 mg N=186	Obe 50 mg N=447*
Any TEAE	132 (71.0%)	307 (68.7%)
TEAE leading to study drug discontinuation	21 (11.3%)	27 (6.0%)
Serious TEAE	16 (8.6%)	23 (5.1%)
Death (Non-Treatment Related)[1]	1 (0.5%)	0
Pregnancy[2]	1 (0.5%)	1 (0.2%)
Serious/severe (Grade ≥3) infections and opportunistic infections[3]	5 (2.7%)	5 (1.1%)
Malignancies (excluding NMSC)[4]	0	2 (0.4%)
Non-melanoma Skin Cancer (NMSC)[5]	2 (1.1%)	2 (0.4%)
Acute Pancreatitis	1 (0.5%)	1 (0.2%)
Cardiac Abnormalities suggestive of cardiac fibrosis	0	0

Data on File ABX464-107; 1. One death occurred in the 25 mg arm and was assessed by the investigator as unrelated to obefazimod. The suspected cause was pulmonary embolism in a 65+ patient with multiple pre-existing thromboembolic risk factors, including prior pulmonary embolism, and recent prolonged immobility. 2. Both pregnancies are currently ongoing 3. Serious/severe (grade ≥3) infections and opportunistic infections: 25 mg = Appendicitis, Bartonellosis, Cytomegalovirus gastrointestinal infection, Peritonsillar abscess, Sepsis; 50 mg (induction non-responder) = Clostridium difficile infection, pilonidal disease, Urethritis gonococcal; 50 mg Open Label (part 1 relapsers = Appendicitis (Part 1 50mg), Septic arthritis staphylococcal (Part 1 Pbo) 4. Part 1 Relapsers previous on placebo: One Case of Myoproliferative Neoplasm and one Prostate Cancer 5. Two Cases of Basal Cell Carcinoma (25mg | 50 mg) and two Cases of Squamous Cell Carcinoma (25mg | 50 mg); TEAE = Treatment-Emergent Adverse Event; *Includes combined Induction non-responders on 50mg in Part 2 (N=251) and Part 1 Relapsers (N=196) who entered Part 2

Abivax Conducted Regulatory Assessments with Multiple Former FDA Senior Leaders Following the ABTECT Maintenance Part 1 and 2 Readouts

Feedback from Four Regulatory Consultants Regarding Part 1 and 2 Data

1 Safety & Labeling

Safety profile well within expectations

- Boxed warning considered highly unlikely
- Limited expectation for additional testing or referral requirements
- Potential warnings can likely be managed through established clinical practice guidelines (e.g. annual skin exam, sun protection)

2 Dose Strategy

Strong support for advancing both 25 mg and 50 mg

- Consensus recommendation to pursue both maintenance doses (25 mg & 50 mg)
- Preserves flexibility for patients and prescribers

3 Totality of Evidence

Maintenance strengthens the overall package

- Strong consensus that obefazimod offers a “compelling” profile in UC based on totality of evidence from Phase 2 + Phase 3
- Maintenance data strengthens the overall assessment of adverse events and provides context that rates observed are well within expected ranges

Multiple former FDA senior leaders consistently concluded that obefazimod has a favorable benefit-risk profile, that a boxed warning is highly unlikely, and that both the 25 mg and 50 mg maintenance doses should advance

Source: June 2026 regulatory consultant feedback meetings on ABTECT maintenance data

Regulatory Filing Strategy: Pursue Both 25 mg and 50 mg Doses for Maintenance

GOAL: File for BOTH 25 mg and 50 mg as maintenance treatment doses

Top Priority

Induction

8 weeks

50 mg

Maintenance

25 mg

Best-in-disease endoscopic remission results

Safety results compare favorably with approved UC therapies

50 mg

Best-in-disease endoscopic remission results

Favorable overall benefit-risk profile supported by the totality of the evidence

Flexible dosing could enable treatment optimization based on individual patient needs

Consistent feedback from former FDA senior leaders reinforces pursuing both 25 mg and 50 mg as the preferred strategy

Source: *June 2026 regulatory consultant feedback meetings on ABTECT maintenance data

Obefazimod Demonstrates Best-in-Disease Opportunity for Ulcerative Colitis

Differentiated value proposition supports blockbuster commercial opportunity

Best-In-Disease Efficacy

Obefazimod demonstrated **best-in-disease efficacy** in both treatment-naïve and highly refractory ulcerative colitis patients, including **unmatched endoscopic remission rates**

Compelling Benefit-Risk Profile

>1,700 patient-years of exposure across Phase 2 + Phase 3 studies, with no evidence of broad immunosuppression, and NMSC/malignancy rates consistent with expected IBD background risk

Clear Regulatory Pathway

Four former FDA senior leaders* expressed **confidence in the overall safety profile**, viewed a **boxed warning as highly unlikely**, and **supported advancement of both 25 mg and 50 mg doses**

Data on File ABX464-107. *Regulatory consultant feedback meetings on ABTECT maintenance data on June 2026.

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Obefazimod in Crohn’s Disease – Phase 2b

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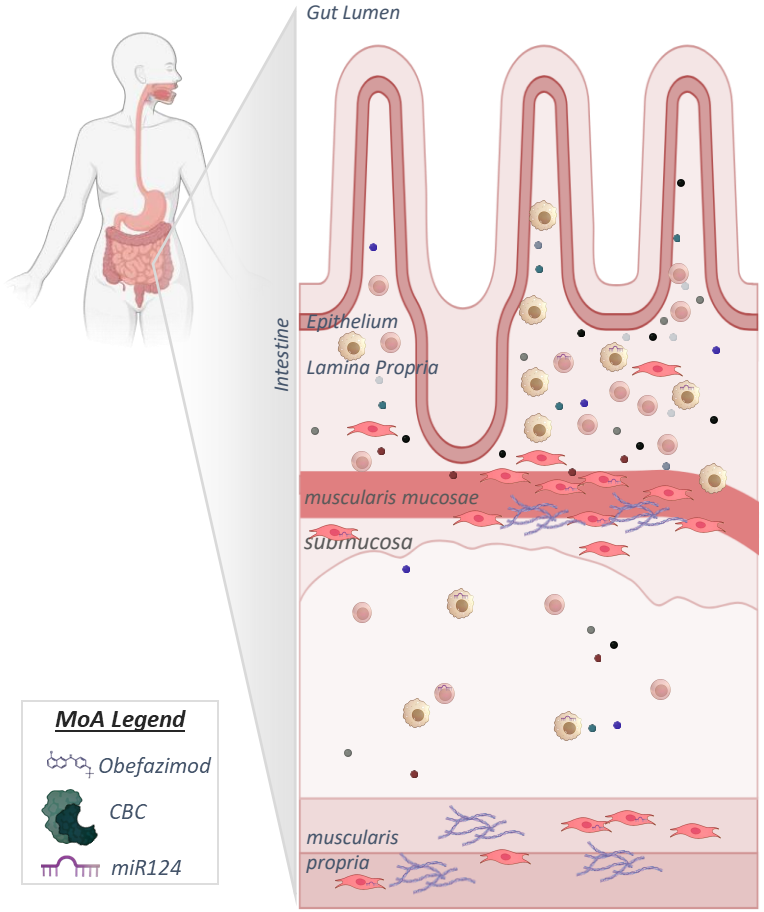
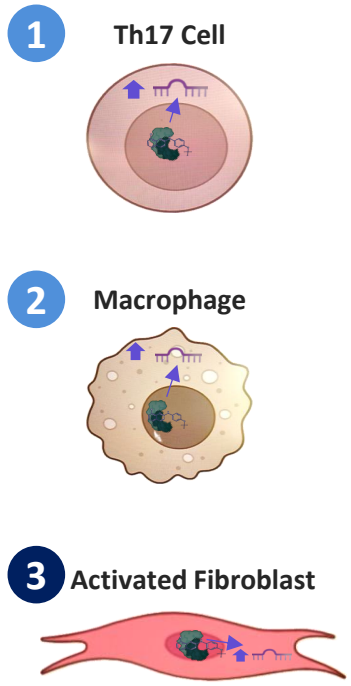
Obefazimod MoA Addresses Multiple Mediators of Crohn's Disease Progression

Modulation of Th17 cells, macrophages and fibroblasts attenuates inflammatory and fibrotic pathways

Active CD

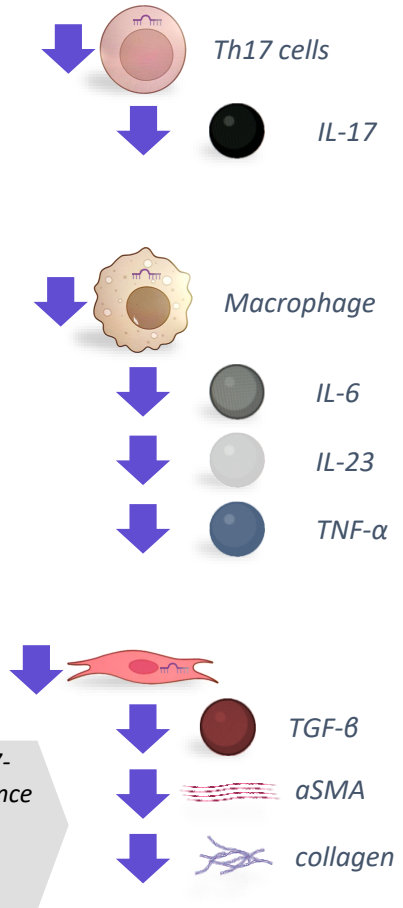


Obe ↑ miR-124

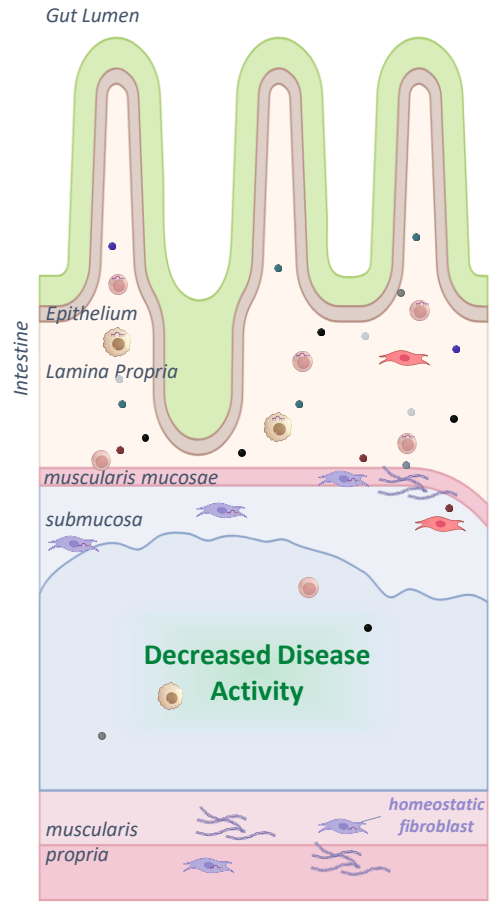


In addition to miR-124 stabilizing macrophages and Th17-mediated inflammation, in Crohn's disease there is evidence that miR-124 also targets TGF-β signaling to reduce fibroblast activation, αSMA expression, & collagen deposition

Obefazimod Restoring Balance



Remission



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

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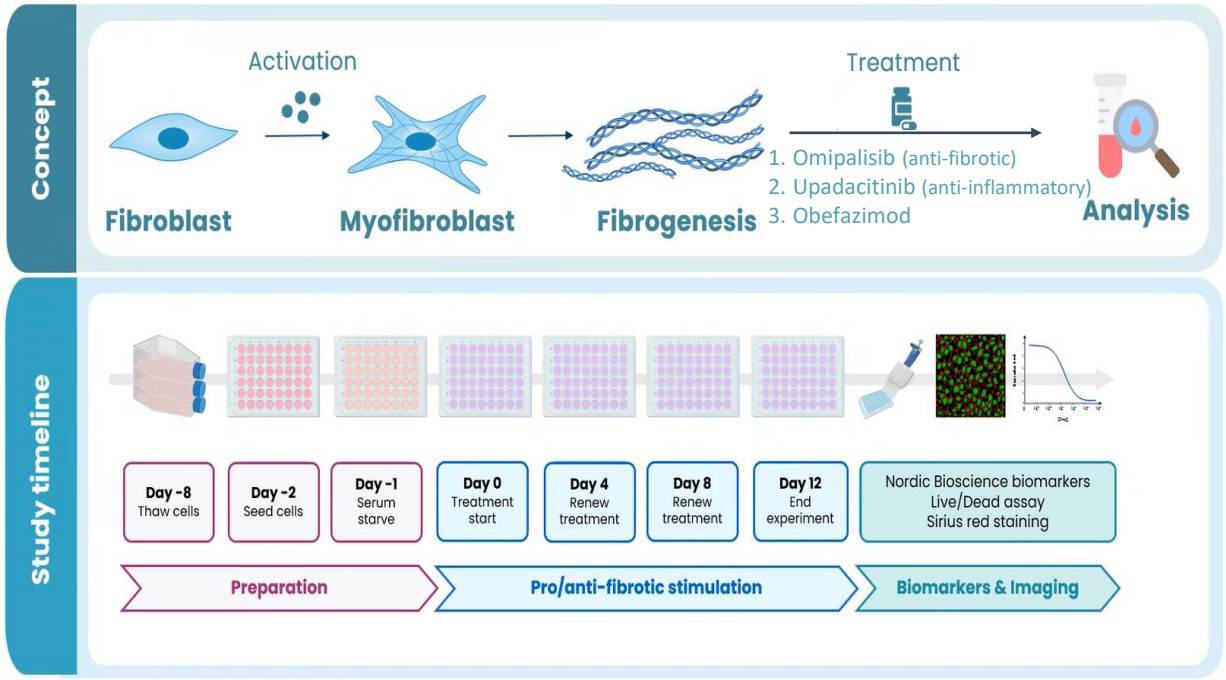
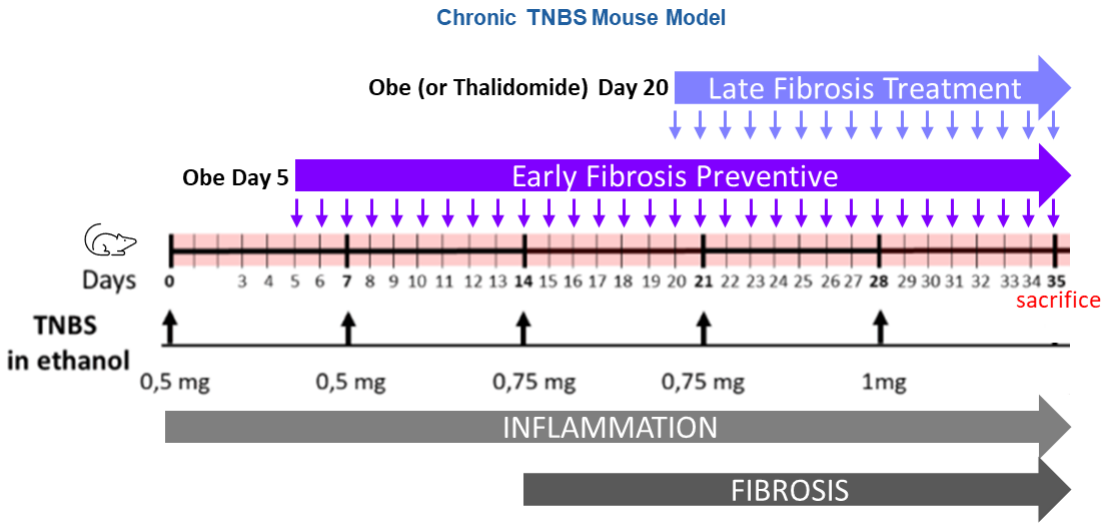
Two well-established models were used to assess obefazimod's anti-fibrotic effects

Model 1
In Vitro Scar-in-a-Jar Assay



Scar-in-a-Jar is an in vitro assay that forms a 3D extracellular matrix in a dish, mimicking fibrotic scarring in tissues, and can be used to explore whether compounds show anti-fibrotic activity by assessing collagen formation and maturation

Model 2
In Vivo Chronic TNBS Colitis Mouse Model

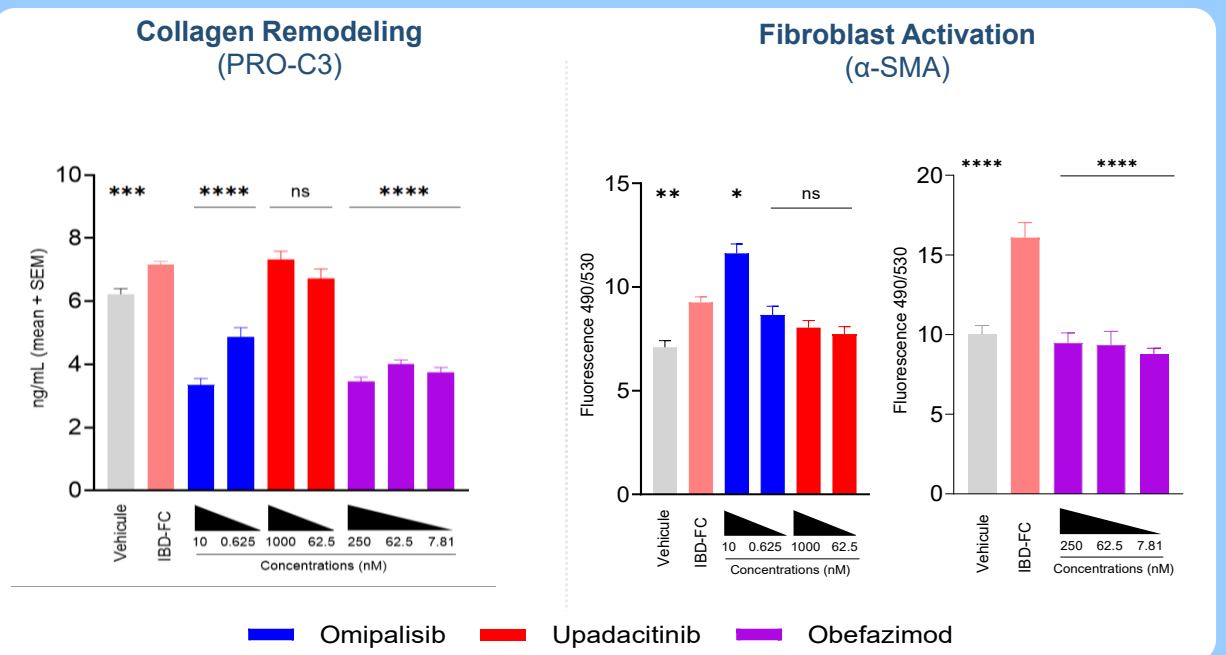


The chronic TNBS colitis mouse is a standard model used to study Crohn's disease. It causes long-lasting intestinal inflammation in mice that mimics key features of Crohn's disease in humans, including tissue damage and scarring (fibrosis).

Danese S et al. Oral presentation presented at: the 21st Congress of ECCO, February 18–21, 2026, Stockholm, Sweden

Model 1: Obefazimod showed an anti-fibrotic effect on human small intestine fibroblasts in the scar-in-a-jar model

Results



Conclusions

Obefazimod reduced human fibroblast populations and activation status

- **~50% reduction in Pro-C3** (fibrogenesis marker)
- **~30% reduction in αSMA** (fibroblast activation marker)

Profound effect of obefazimod *suggests* ***dual anti-inflammatory and anti-fibrotic effects***
which are greater than singular anti-fibrotics (omipalisib) or anti-inflammatories (upadacitinib)

Danese S et al. Oral presentation presented at: the 21st Congress of ECCO, February 18–21, 2026, Stockholm, Sweden; *p<0.05, ** p<0.01, *** p<0.001, **** p<0.0001 one-way ANOVA with Dunnet's for multiple comparison testing used | Upadacitinib marketed as Rinvoq for UC, CD, & other inflammatory disorders; Omipalisib (GSK2126458) in development for IPF & oncology indications. | Pro-C3: proprietary marker of Collagen III cleavage by Nordic Biosciences; α-SMA: alpha-smooth muscle actin

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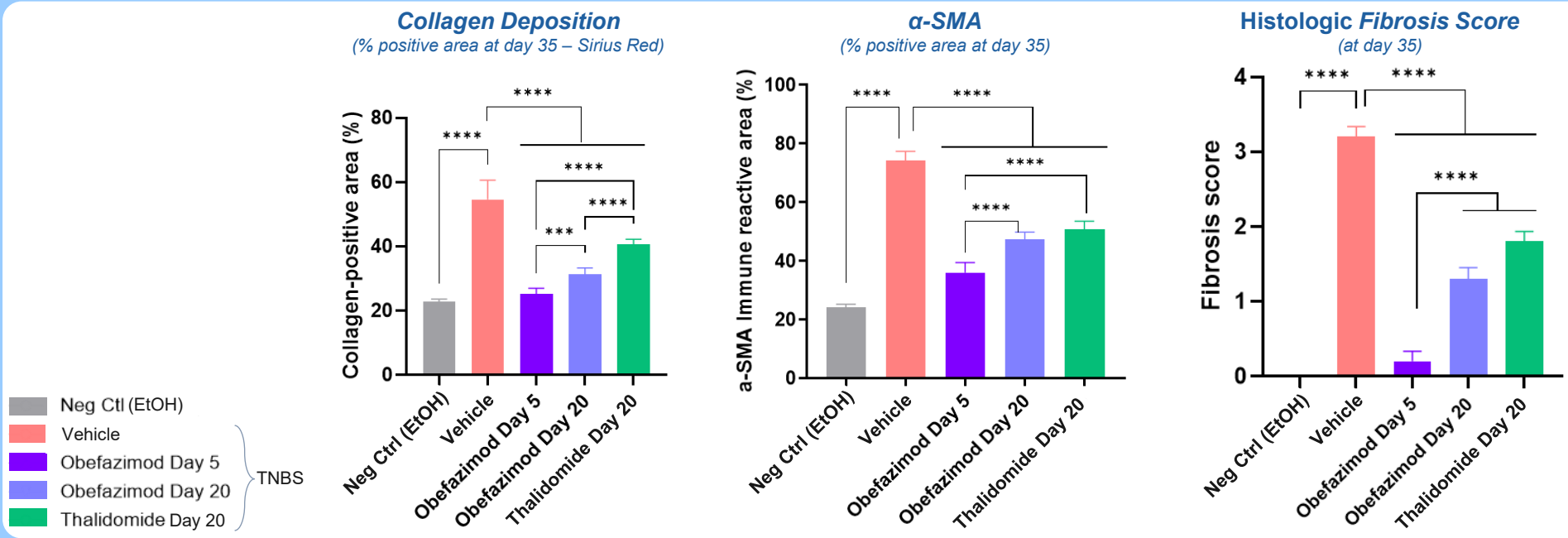
Model 2: Obefazimod led to reduced fibrosis in the chronic TNBS mouse model

Results: Day 35



Conclusions

Obefazimod showed anti-fibrotic effects when initiated as a **fibrosis preventative** or **fibrosis treatment:**

- **~45% & ~55% reduction** in **Collagen Deposition** (fibrogenesis marker) with late and early treatment, respectively
- **~40% & ~50% reduction** in **αSMA** (fibroblast activation marker) with late and early treatment, respectively
- **~60% & ~90% reduction** in histologic **Fibrosis Score** with late and early treatment, respectively

***Obefazimod effects** were **more profound** than **dual anti-inflammatory/anti-fibrotic** thalidomide positive control*

Danese S et al. Oral presentation presented at: the 21st Congress of ECCO, February 18–21, 2026, Stockholm, Sweden; ***p<0.001, ****p<0.0001 one-way ANOVA with Tukey's multiple comparisons test

Obefazimod in Crohn's Disease

Mechanistic Rationale

1 Direct action on tissue-resident effectors (Th17/macrophages)

- Obefazimod boosts miR-124 (via a CBC-dependent increase from the miR-124-1 locus)[1]
- miR-124 dampens STAT3 in T cells and macrophages → fewer pro-inflammatory outputs inside the tissue[2]

2 Attenuation of the IL-6/STAT3–Th17 axis

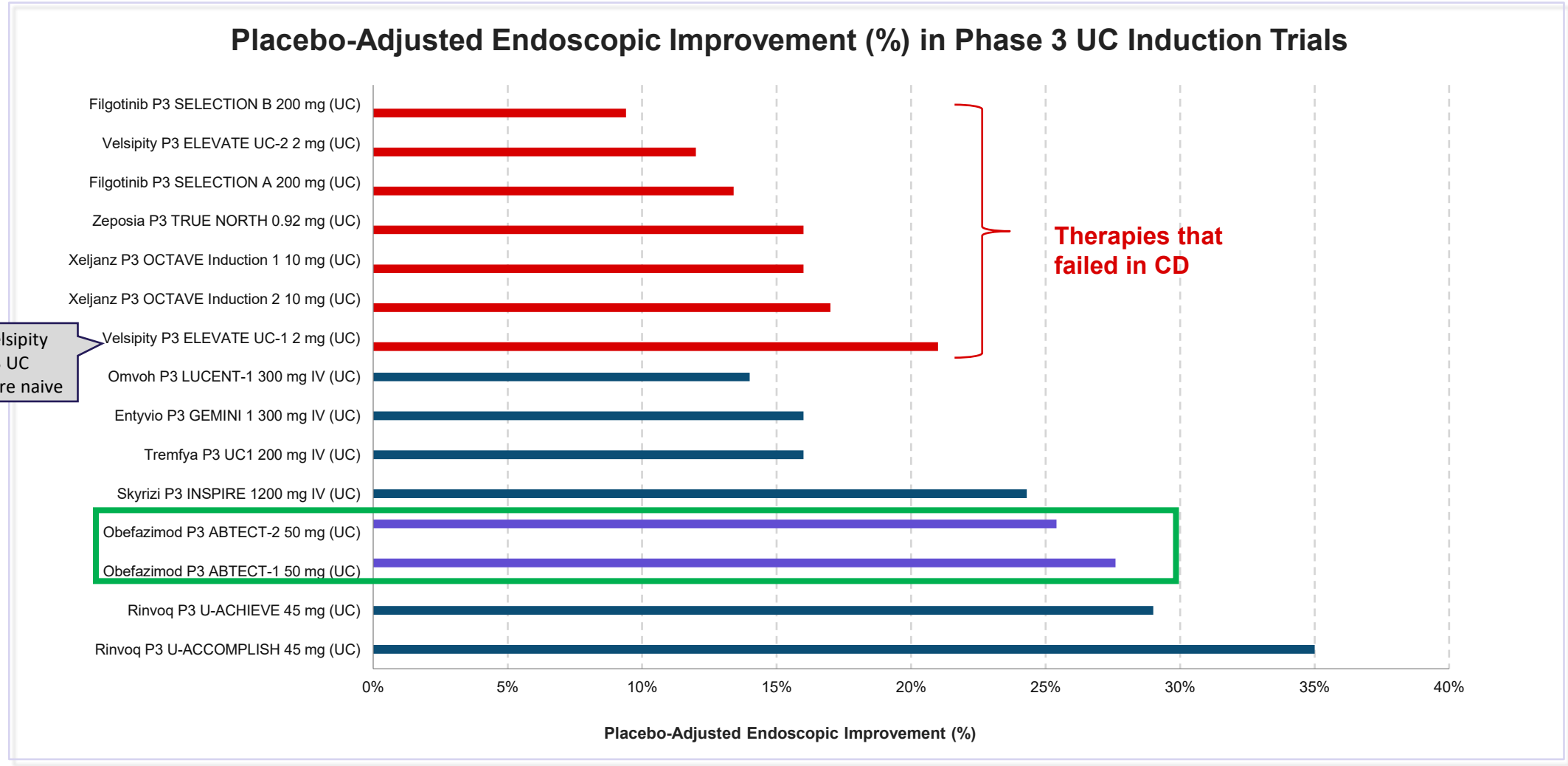
- IL-6/STAT3–Th17 axis is a driver of Crohn's Disease[3]
- By lowering STAT3 signaling and IL-6R, obefazimod may reduce Th17 survival/pathogenicity[4]

3 Macrophage "De-Fueling"

- miR-124 upregulation in myeloid cells reduces CCL2/MCP-1[5]
- Reduction of CCL2/MCP-1 calms resident macrophages and reduces fresh monocyte influx, addressing both "entrenched" and "incoming" inflammatory drivers[6]

1. Apolit C, et al. Clin Transl Gastroenterol. 2023;14(4):e00632.; 2. Bron P, et al. J Crohns Colitis. 2024 (ECCO abstract); 3.Cheng Y, et al. BMC Cancer. 2015;15:536. 4. Shahini A, et al. Front Pharmacol. 2022;13:913785; 5.Wang D, et al. Circ Res. 2014;114:79-88. 6. Aschenbrenner D, et al. Nat Commun. 2021;12:5824.

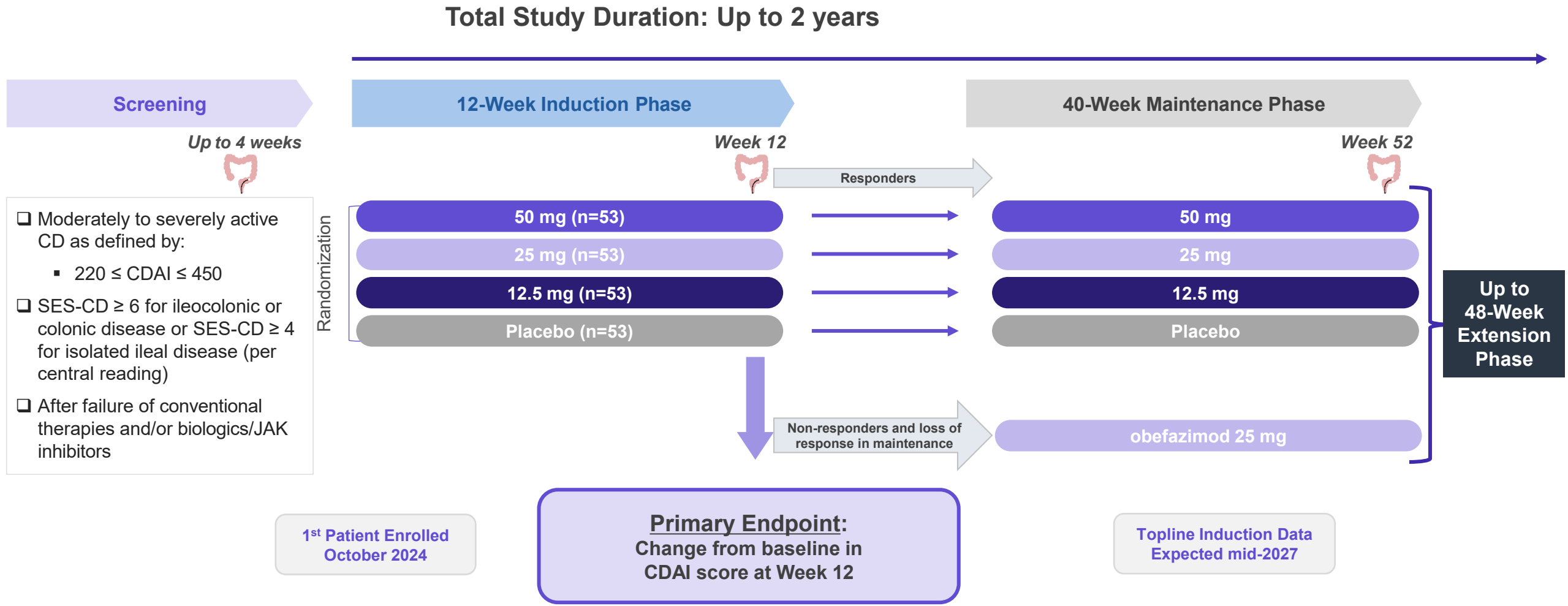
Phase 3 UC Induction Trials: Therapies That Later Failed in CD Generally, Did Not Achieve Placebo-Adjusted Endoscopic Improvement Above ~20%



Despite being studied in a heavily pre-treated UC population, including prior JAK failures, obefazimod delivered robust endoscopic efficacy, exceeding the ~20% threshold that many CD-failed agents did not reach.

ENHANCE CD: Phase 2b Trial Design

Obefazimod in Crohn's Disease



Source: ABX464-202

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Multiple MOAs are being assessed to identify candidate that will have the greatest synergistic effect with obefazimod, without compromising on safety

Criteria For Combination Therapy Candidate

Synergistic Pathways

- Enable broader disease control and more durable clinical response by targeting complementary pathways

Safe

- No pre-initiation requirements
- No black box warnings
- Reduce complexity and minimize patient risk

Oral

- Improves convenience and adherence by simplifying co-administration
- Supports real world usability

MOAs Currently Under Evaluation

α4β7 | IL-23 | PDE-4 | AHR

Strong Phase 3 induction results prompted a careful evaluation of additional mechanisms of action for combination therapy, with a combination candidate to be selected by year end 2026

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Upcoming Catalysts

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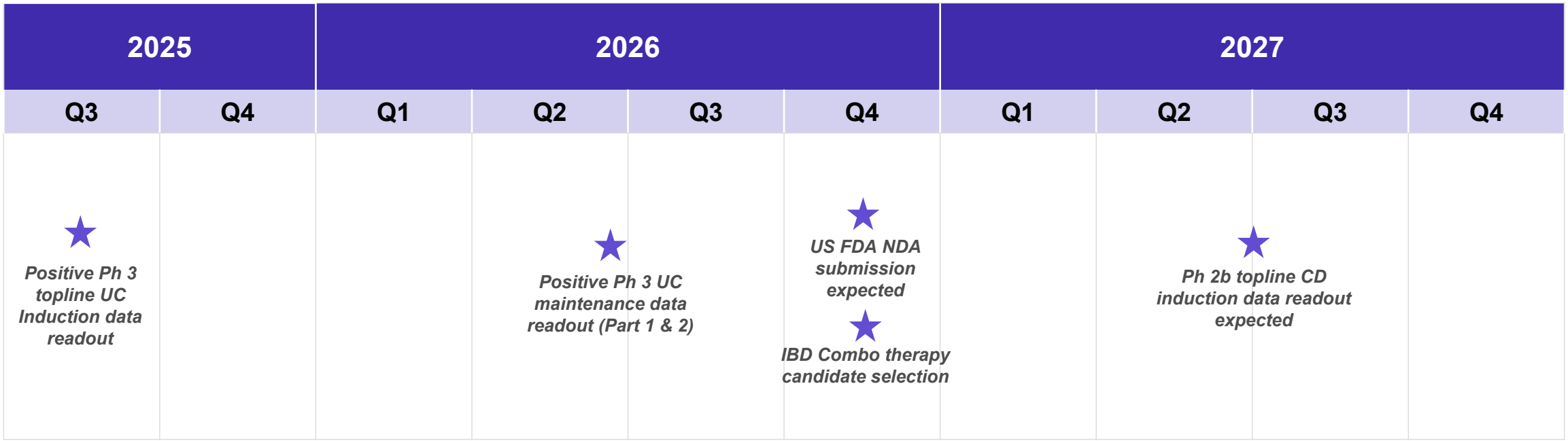
Key Milestones Through Mid-2027

- [x] **Q3 2025** — **Phase 3 Topline UC Induction Data**
- [x] **Late Q2, 2026** — **Phase 3 Topline UC Maintenance Data**
- [ ] **Late 2026** — **Expected Obefazimod US FDA NDA Submission**
- [ ] **Year end 2026** — **IBD Combo Therapy Candidate Selection**
- [ ] **Mid-2027** — **Phase 2b Topline CD Induction Data**



Thank You

Nasdaq: ABVX / Euronext Paris: ABVX

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Appendix

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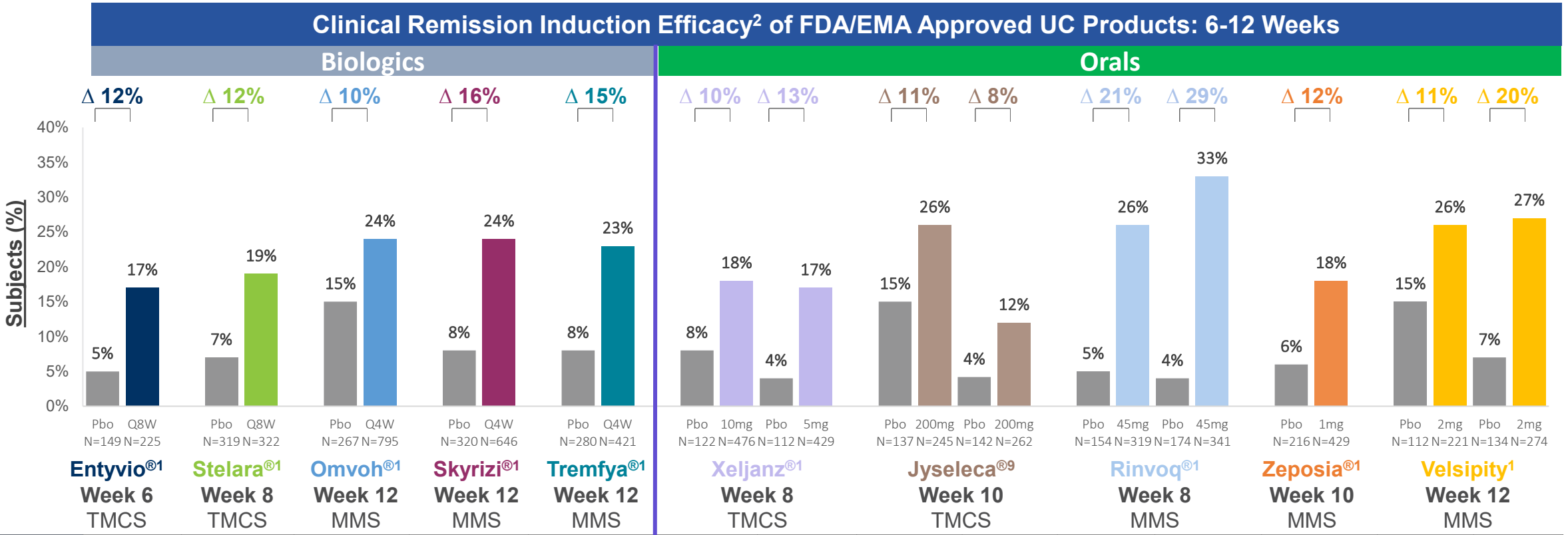
Clinical Remission Induction Data of FDA/EMA Approved UC Products



	Entyvio®[1] Week 6 TMCS	Stelara®[1] Week 8 TMCS	Omvoh®[1] Week 12 MMS	Skyrizi®[1] Week 12 MMS	Tremfya®[1] Week 12 MMS	Xeljanz®[1] Week 8 TMCS	Jyseleca®[9] Week 10 TMCS		Rinvoq®[1] Week 8 MMS		Zeposia®[1] Week 10 MMS	Velsipity[1] Week 12 MMS	
Prior Adv Treat.	39%[1]	51%[1]	41%[1]	52%[1]	52%[1]	51%[1]	52%[1]	0%[9]	100%[9]	53%[4]	51%[4]	33%[1,5]	34%[1]	30%[1]
≥2[3] Prior Adv Treat.	Not reported	32%[1]	49%[8]	54%[10]	54%[11]	Not Reported	Not Reported	0%[9]	43%[9]	66%[4]	62%[4]	63%[1]	50%[1,6]	47%[1,6]

For illustrative purposes only. Not a head-to-head comparison. Differences exist between trial designs and subject characteristics, and caution should be exercised when comparing data across trials.

1. FDA package inserts. TCMS = Clinical Remission on 4-Component Mayo Score (TCMS ≤2 with no individual score >1). MMS = Clinical Remission on 3-Component Mayo Score* (RB=0, SF≤1 with Improvement ≥1, Endo ≤1), MMS*Current FDA Required Endpoint. 2. All clinical remission efficacy numbers are rounded to the nearest whole number as reported in FDA prescribing information in package inserts. 3. Reflects percentage of prior advanced tx population, not total population 4. Lancet 2022; 399: 2113-28; 5. Applies to TNF blockers; 6. Converted from percentage of total population reported in US PI; 7. Mean of 25 mg and placebo dose arms; Lancet Gastroenterol Hepatol 2022; 11, 1024-1035. 8. https://www.nejm.org/doi/full/10.1056/NEJMoa2207940#supplementary-materials. 9. EMA Product Characteristics. 10. Journal of Crohn's and Colitis, 2025, 19(1), jjaf005. 11. Lancet 2024; 405: 10472, P33-49.

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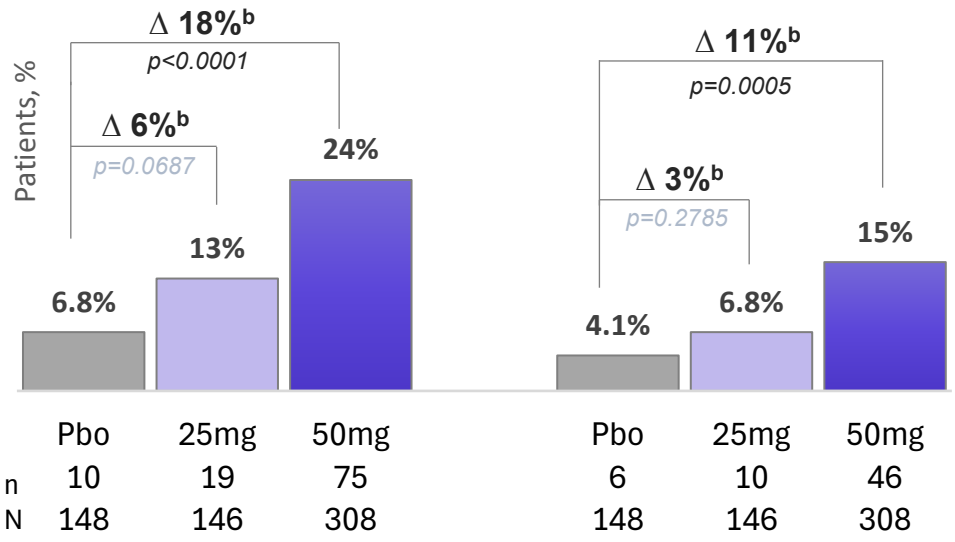
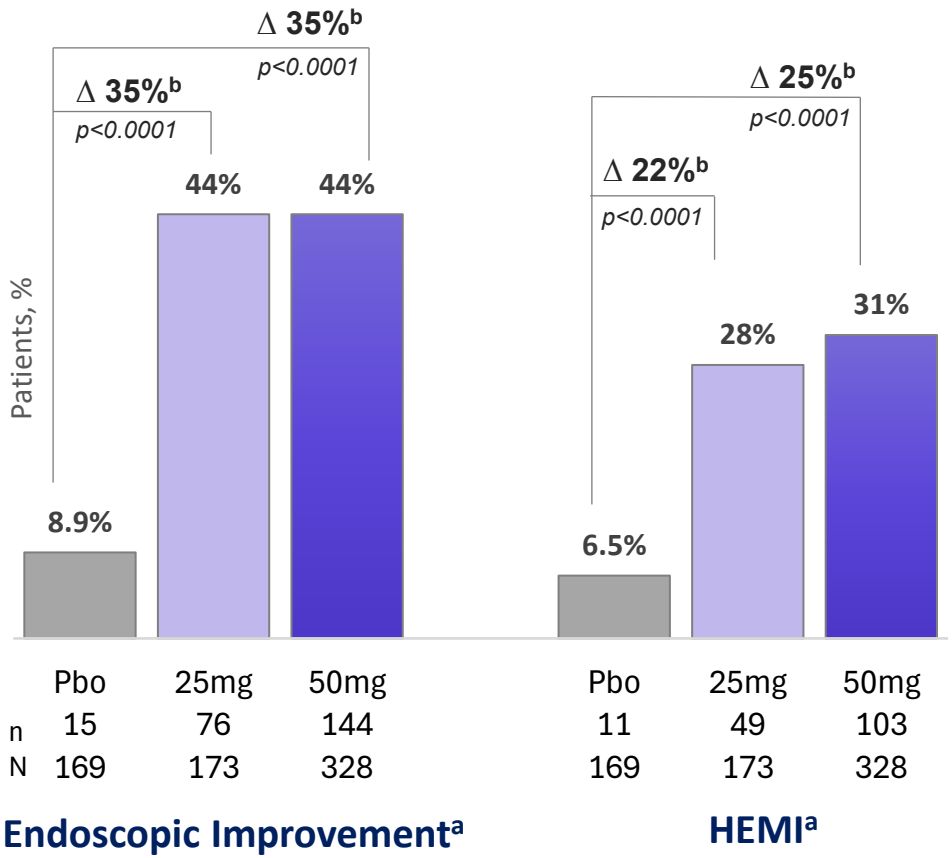
Pooled ABTECT 1 & 2: 50mg Dose Achieved Clinically Meaningful Improvements in Endoscopic & Histologic Endpoints Regardless of Prior AT-IR

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

AT-IR Yes



AT-IR No



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.

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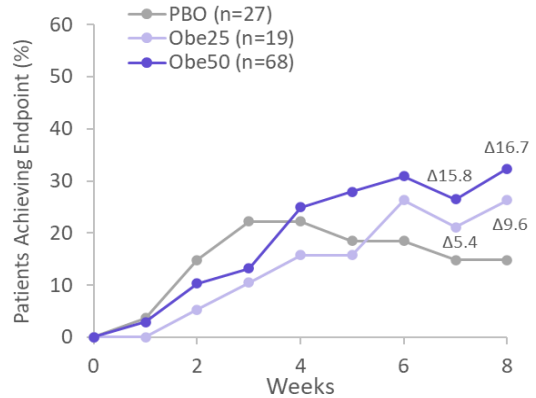
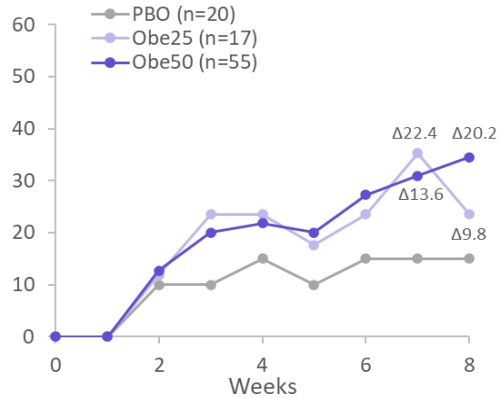
Rates of symptomatic remission across subgroups of AT-IR patients

1 TNFi Only (N=114)



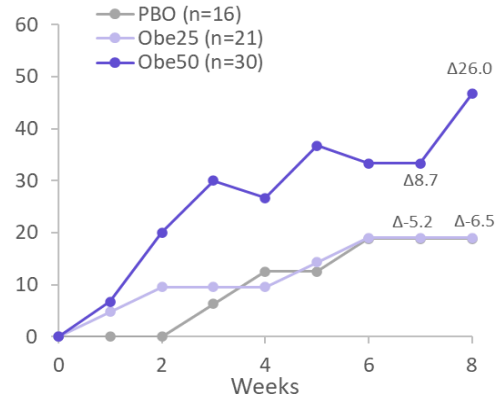
PBO, n/N	0/27	1/27	4/27	6/27	6/27	8/27	8/27	4/27	4/27
Obe25, n/N	0/19	0/19	1/19	2/19	3/19	3/19	5/19	4/19	5/19
PBO adjusted Δ %	0	-5.3	-8.9	-16.5	-6.9	-6.9	4.3	5.4	9.6
Obe50, n/N	0/68	2/68	7/68	9/68	17/68	19/68	21/68	18/68	22/68
PBO adjusted Δ %	0	-3.3	-4.2	-10.4	3.1	11.8	14.6	15.8	16.7

Vedolizumab Only (N=92)



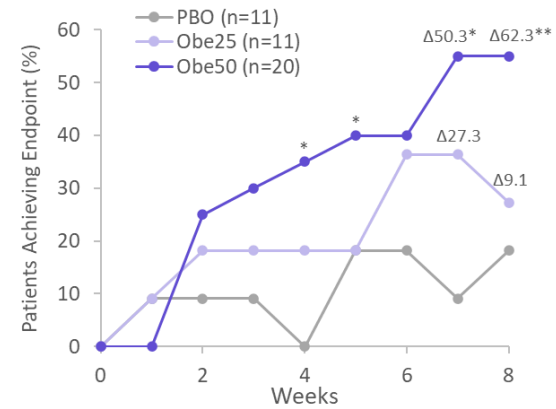
	0/20	0/20	2/20	2/20	3/20	2/20	3/20	3/20	3/20
	0/17	0/17	2/17	4/17	4/17	3/17	4/17	6/17	4/17
	0	0	2.6	15.6	9.8	9.2	9.8	22.4	9.8
	0/55	0/55	7/55	11/55	12/55	11/55	15/55	17/55	19/55
	0	0	4.1	7.7	3.9	6.9	9.7	13.6	20.2

1 TNFi + Vedolizumab Only (N=67)



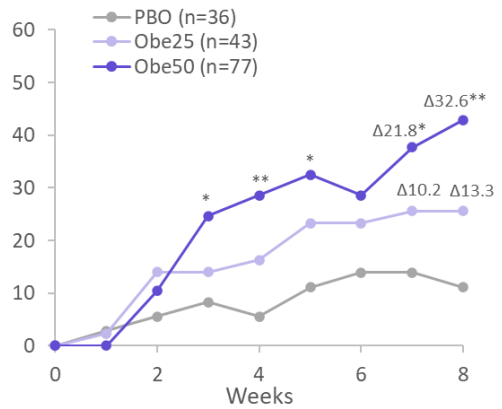
	0/16	0/16	0/16	1/16	2/16	2/16	3/16	3/16	3/16
	0/21	1/21	2/21	2/21	2/21	3/21	4/21	4/21	4/21
	0	3.9	7.8	1.3	-6.5	-2.6	-5.2	-5.2	-6.5
	0/30	2/30	6/30	9/30	8/30	11/30	10/30	10/30	14/30
	0	7.1	21.4	25.5	12.9	20.1	10.5	8.7	26.0

1 TNFi + Vedolizumab + Ustekinumab Only (N=42)



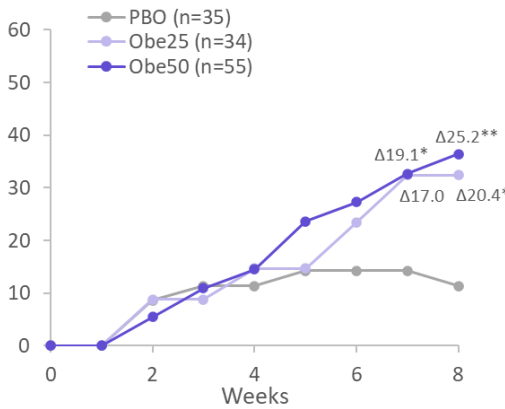
PBO, n/N	0/11	1/11	1/11	1/11	0/11	2/11	2/11	1/11	2/11
Obe25, n/N	0/11	1/11	2/11	2/11	2/11	2/11	4/11	4/11	3/11
PBO adjusted Δ %	0	0	9.1	9.1	18.2	0	18.2	27.3	9.1
Obe50, n/N	0/20	0/20	5/20	6/20	7/20	8/20	8/20	11/20	11/20
PBO adjusted Δ %	0	-14.3	33.3	36.7	47.1*	44.3*	36.5	50.3*	62.3**

Ustekinumab in Any Line of Therapy (N=156)



	0/36	1/36	2/36	3/36	2/36	4/36	5/36	5/36	4/36
	0/43	1/43	6/43	6/43	7/43	10/43	10/43	11/43	11/43
	0	-0.3	5.9	2.8	8	10.4	8.2	10.2	13.3
	0/77	0/77	8/77	19/77	22/77	25/77	22/77	29/77	33/77
	0	-2.9	5.9	16.7*	22.3**	21.9*	14.2	21.8*	32.6**

JAKi in Any Line of Therapy (N=124)



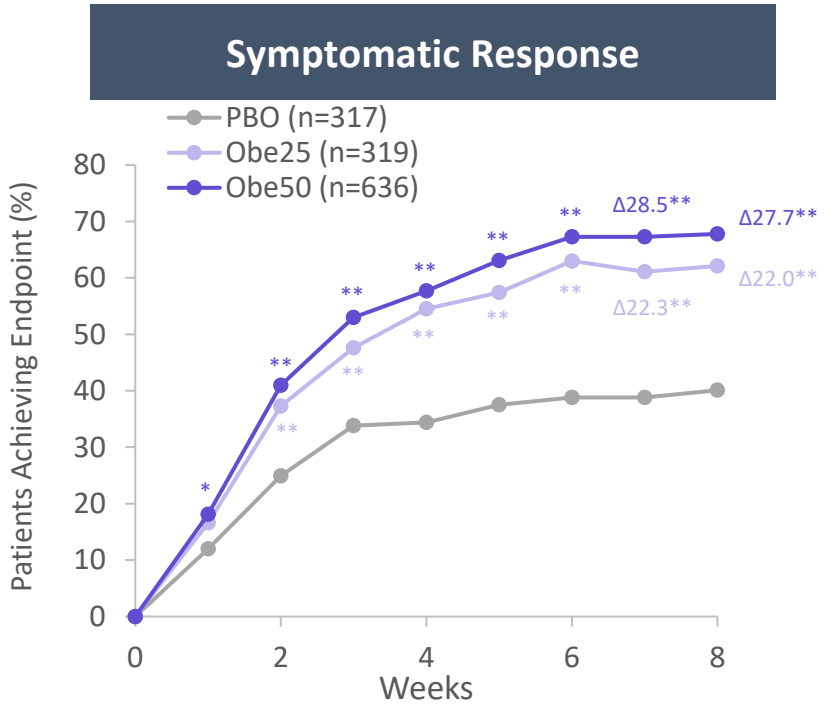
	0/35	0/35	3/35	4/35	4/35	5/35	5/35	5/35	4/35
	0/34	0/34	3/34	3/34	5/34	5/34	8/34	11/34	11/34
	0	0	-0.1	-3.5	2.2	-0.6	7.9	17	20.4*
	0/55	0/55	3/55	6/55	8/55	13/55	15/55	18/55	20/55
	0	0	-3.1	-0.3	3.7	9.5	13.1	19.1*	25.2**

Danese S et al. P0894. Poster presented at: the 21st Congress of ECCO, February 18–21, 2026, Stockholm, Sweden

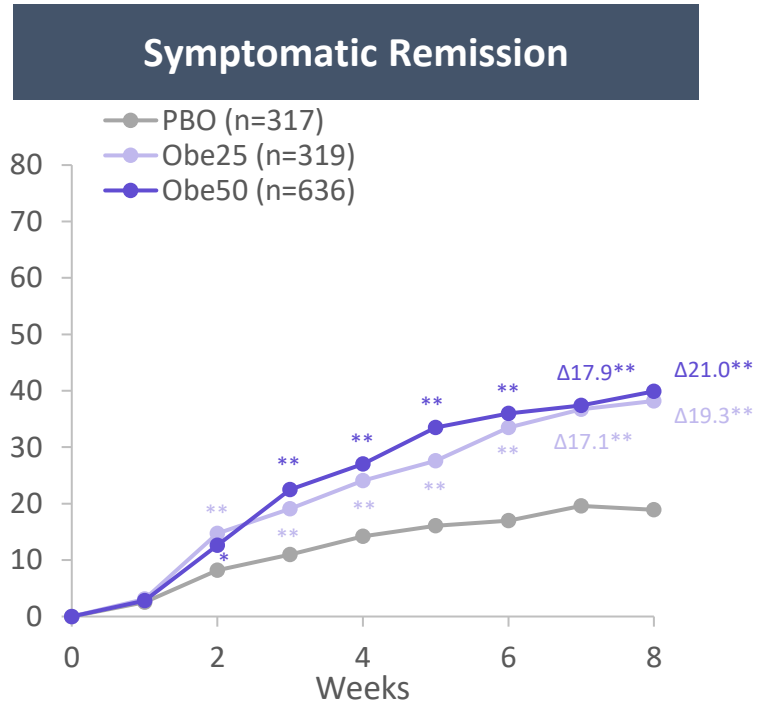
Analyses not powered for statistical significance in small subgroups; results are exploratory and directional. Nominal *P* values are provided for descriptive purposes only. NRI is used for subjects with missing outcome at W8 and subjects reporting any IE prior to W8; % Difference is for Obe minus OBO and is based on estimated common risk difference using the Mantel-Haenszel weights adjusting for the randomization stratification factors: ATIR (yes/no), baseline oral corticosteroids usage (yes/no). *P* values are 2-sided. Symptomatic remission: RBS=0, SFS <1.

Greater proportions of patients receiving obefazimod achieved symptomatic response from W1 and symptomatic remission from W2 increasing through W8 with no evidence of a plateau

Proportion of Patients Achieving Symptomatic Response, Symptomatic Remission
Pooled ABTECT-1 and ABTECT-2 Studies



PBO, n/N	0/317	38/317	79/317	107/317	109/317	119/317	123/317	123/317	127/317
Obe25, n/N	0/319	53/319	119/319	152/319	174/319	183/319	201/319	195/319	198/319
PBO adjusted Δ %	0	4.6	12.4**	13.9**	20.1**	19.8**	24.2**	22.3**	22.0**
Obe50, n/N	0/636	115/636	261/636	337/636	367/636	401/636	428/636	428/636	431/636
PBO adjusted Δ %	0	6.1*	16.2**	19.3**	23.4**	25.5**	28.6**	28.5**	27.7**



	0/317	8/317	26/317	35/317	45/317	51/317	54/317	62/317	60/317
	0/319	10/319	47/319	61/319	77/319	88/319	107/319	117/319	122/319
	0	0.6	6.5**	8.1**	10.0**	11.5**	16.5**	17.1**	19.3**
	0/636	18/636	80/636	143/636	172/636	213/636	229/636	238/636	254/636
	0	0.3	4.4*	11.5**	12.9**	17.4**	19.0**	17.9**	21.0**

Armuzzi A et al. P0923. Poster presented at: the 21st Congress of ECCO, February 18–21, 2026, Stockholm, Sweden
Obe, obefazimod; PBO, placebo
*P<0.05; **P<0.01; Statistical inferences are exploratory, and all P values are nominal and 2-sided

Malignancy Exposure-Adjusted Incidence Rate Summary Tables

Phase 3 Maintenance

Maintenance (Part 2 Only)	Placebo	25 mg	50 mg	All Active Combined	Expected UC Background
Total PYs of Exposure	N/A	~132	~288	~420	-
Observed Malignancies	N/A	0	2	2	-
Observed IR per 100 PY	N/A	0.00	0.69	**0.48**	**0.30 - 0.70**

Maintenance (Part 1 + Part 2)	Placebo	25 mg	50 mg	All Active Combined	Expected UC Background
Total PYs of Exposure	~147	~274	~438	~712	-
Observed Malignancies	0	0	4	4	-
Observed IR per 100 PY	0.00	0.00	0.91	**0.56**	**0.30 - 0.70**

Integrated UC Clinical Program

(Phase 3 + Phase 2)

Phase 3 (Ind, Part 1 & 2) + Phase 2 Program	Placebo	25 mg	50 mg	All Active Combined	Expected UC Background
Total PYs of Exposure	~218	~760	~944	~1,704	-
Observed Malignancies	0	0	6	6	-
Observed IR per 100 PY	0.00	0.00	0.64	**0.35**	**0.30 - 0.70**

Phase 3 (Ind, Part 1 &2) + Phase 2 Program	UC Phase 2 (25 mg + 50 mg)	Phase 3 (Ind,1 & 2) (25 mg + 50 mg)	All Active Combined	Expected UC Background
Total PYs of Exposure	~838	~866	~1,704	-
Observed Malignancies*	1	5	6	-
Observed IR per 100 PY	0.12	0.58	**0.35**	**0.30 - 0.70**

Data on File ABX464-103, ABX464-104, ABX464-105, ABX464-106, ABX464-107 and ABX464-108
~54 placebo patient-years reflect placebo induction responders in Phase 3 who remained on placebo through maintenance without transitioning to Part 2 and switching to 50 mg obefazimod. Phase 3 induction patient years were: placebo = ~51 patient years, 25 mg = ~52 patient years, 50 mg = ~102 patient years. Patient years rounded to the largest whole number; Patient years rounded to the largest whole number; IR = Incidence Rate; Sources: The composite malignancy benchmark range (0.3–0.7 per 100 patient-years) was derived from published ulcerative colitis (UC) and inflammatory bowel disease (IBD)-specific malignancy epidemiology, supplemented by National Cancer Institute SEER incidence data for common malignancies where disease-specific estimates were limited. The benchmark incorporates malignancies commonly observed in UC/IBD populations, while excluding non-melanoma skin cancer (NMSC). Key references include Long et al. *Gastroenterology* 2012; Bencardino et al, *Cancers (Basel)* 2025; Carli E et al. *Medicina* 2020 meta-analysis; Kaneko et al. *J Clin Med* 2024; National Cancer Institute SEER Statistics; Beaugerie et al. *Lancet* 2009 (CESAME cohort); Lemaitre et al. *JAMA* 2017; and Scandinavian population-based registry studies evaluating malignancy risk in IBD. The benchmark range is intended for contextual comparison of observed malignancy rates and does not represent a single published incidence estimate.
*Phase 2b: malignant meningioma; Phase 3 induction: prostate; Phase 3 Maintenance Part 1: breast, prostate; Phase 3 Maintenance Part 2: myeloproliferative neoplasm, prostate.

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NMSC Exposure-Adjusted Incidence Rate Summary Tables

Phase 3 Maintenance

Maintenance (Part 2 Only)	Placebo	25 mg	50 mg	All Active Combined	Expected UC Background
Total PYs of Exposure	N/A	~132	~288	~420	-
Observed NMSCs	N/A	2	2	4	-
Observed IR per 100 PY	N/A	1.52	0.69	**0.95**	**0.70 - 1.40**

Maintenance (Part 1 + Part 2)	Placebo	25 mg	50 mg	All Active Combined	Expected UC Background
Total PYs of Exposure	~147	~274	~438	~712	-
Observed NMSCs	1	3	6	9	-
Observed IR per 100 PY	0.68	1.09	1.37	**1.26**	**0.70 - 1.40**

Integrated UC Clinical Program

(Phase 3 + Phase 2)

Phase 3 (Ind, Part 1 & 2) + Phase 2 Program	Placebo	25 mg	50 mg	All Active Combined	Expected UC Background
Total PYs of Exposure	~218	~760	~944	~1,704	-
Observed NMSCs	1	4	6	10	-
Observed IR per 100 PY	0.46	0.53	0.64	**0.59**	**0.70 - 1.40**

Phase 3 (Ind, Part 1 &2) + Phase 2 Program	UC Phase 2 (25 mg + 50 mg)	Phase 3 (Ind,1 & 2) (25 mg + 50 mg)	All Active Combined	Expected UC Background
Total PYs of Exposure	~838	~866	~1,704	-
Observed NMSCs*	1	9	10	-
Observed IR per 100 PY	0.12	1.04	**0.59**	**0.70 - 1.40**

Data on File ABX464-103, ABX464-104, ABX464-105, ABX464-106, ABX464-107 and ABX464-108
~54 placebo patient-years reflect placebo induction responders in Phase 3 who remained on placebo through maintenance without transitioning to Part 2 and switching to 50 mg obefazimod. Phase 3 induction patient years were: placebo = ~51 patient years, 25 mg = ~52 patient years, 50 mg = ~102 patient years. Patient years rounded to the largest whole number; Patient years rounded to the largest whole number; IR = Incidence Rate; NMSC incidence rates were benchmarked against published IBD and UC literature. Long et al. reported an overall NMSC incidence of 912 per 100,000 patient-years in patients with IBD (0.91 per 100 patient-years). Bencardino et al. reviewed evidence demonstrating increased NMSC risk in IBD and reported an annual NMSC incidence of 733 per 100,000 patients (~0.73 per 100 patient-years). Abbas et al. reported UC-specific NMSC incidence rates ranging from 3.7 to 13.6 per 1,000 patient-years (0.37–1.36 per 100 patient-years) across thiopurine exposure strata. Based on these published estimates, a benchmark NMSC incidence range of 0.7–1.4 per 100 patient-years was used for contextual comparison. Expected cases were calculated as: (incidence rate per 100 patient-years × cumulative patient-years of exposure) ÷ 100. *Phase 2b: squamous cell carcinoma (n=1); Phase 3 Maintenance Part 1: basal cell carcinoma (n=2), squamous cell carcinoma (n=3); Phase 3 Maintenance Part 2: basal cell carcinoma (n=2), squamous cell carcinoma (n=2)

ABIVAX

All Active Combined NMSC Rates Were Consistent With the Reference Range Across All Three Datasets

Increasing Size and Relevance of Dataset

Integrated UC Clinical Program (Phase 2 + Phase 3 Induction and Maintenance)	Placebo	25 mg	50 mg	All Active Combined	Reference Range Based on Published UC Studies
Total PYs of Exposure	~218	~760	~944	~1,704	-
Observed IR per 100 PY	0.46	0.53	0.64	0.59	0.70 – 1.40

Maintenance (Part 1 + Part 2)	Placebo	25 mg	50 mg	All Active Combined	Reference Range Based on Published UC Studies
Total PYs of Exposure	~147	~274	~438	~712	-
Observed IR per 100 PY	0.68	1.09	1.37	1.26	0.70 - 1.40

Maintenance (Part 2 Only)	Placebo	25 mg	50 mg	All Active Combined	Reference Range Based on Published UC Studies
Total PYs of Exposure	N/A	~132	~288	~420	-
Observed IR per 100 PY	N/A	1.52	0.69	0.95	0.70 - 1.40

Data on File ABX464-103, ABX464-104, ABX464-105, ABX464-106, ABX464-107 and ABX464-108; Patient years rounded to the largest whole number; IR = Incidence Rate; NMSC incidence rates were benchmarked against published IBD and UC literature. Long et al. reported an overall NMSC incidence of 912 per 100,000 patient-years in patients with IBD (0.91 per 100 patient-years). Bencardino et al. reviewed evidence demonstrating increased NMSC risk in IBD and reported an annual NMSC incidence of 733 per 100,000 patients (~0.73 per 100 patient-years). Abbas et al. reported UC-specific NMSC incidence rates ranging from 3.7 to 13.6 per 1,000 patient-years (0.37–1.36 per 100 patient-years) across thiopurine exposure strata. Based on these published estimates, a benchmark NMSC incidence range of 0.7–1.4 per 100 patient-years was used for contextual comparison. Expected cases were calculated as: (incidence rate per 100 patient-years × cumulative patient-years of exposure) ÷ 100.

All Active Combined Malignancy Other Than NMSC Rates were Consistent with the Reference Range Across All Three Datasets

Increasing Size and Relevance of Dataset

Integrated UC Clinical Program (Phase 2 + Phase 3 Induction and Maintenance)	Placebo	25 mg	50 mg	All Active Combined	Reference Range Based on Published UC Studies
Total PYs of Exposure	~218	~760	~944	~1,704	-
Observed IR per 100 PY	0.00	0.00	0.64	0.35	0.30 - 0.70

Maintenance (Part 1 + Part 2)	Placebo	25 mg	50 mg	All Active Combined	Reference Range Based on Published UC Studies
Total PYs of Exposure	~147	~274	~438	~712	-
Observed IR per 100 PY	0.00	0.00	0.91	0.56	0.30 - 0.70

Maintenance (Part 2 Only)	Placebo	25 mg	50 mg	All Active Combined	Reference Range Based on Published UC Studies
Total PYs of Exposure	N/A	~132	~288	~420	-
Observed IR per 100 PY	N/A	0.00	0.69	0.48	0.30 - 0.70

Data on File ABX464-103, ABX464-104, ABX464-105, ABX464-106, ABX464-107 and ABX464-108; Patient years rounded to the largest whole number; IR = Incidence Rate; Sources: The composite malignancy benchmark range (0.3–0.7 per 100 patient-years) was derived from published ulcerative colitis (UC)- and inflammatory bowel disease (IBD)-specific malignancy epidemiology, supplemented by National Cancer Institute SEER incidence data for common malignancies where disease-specific estimates were limited. The benchmark incorporates malignancies commonly observed in UC/IBD populations, while excluding non-melanoma skin cancer (NMSC). Key references include Long et al. *Gastroenterology* 2012; Bencardino et al, *Cancers (Basel)* 2025; Carli E et al. *Medicina* 2020 meta-analysis; Kaneko et al. *J Clin Med* 2024; National Cancer Institute SEER Statistics; Beaugerie et al. *Lancet* 2009 (CESAME cohort); Lemaitre et al. *JAMA* 2017; and Scandinavian population-based registry studies evaluating malignancy risk in IBD. The benchmark range is intended for contextual comparison of observed malignancy rates and does not represent a single published incidence estimate.

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Treatment-Emergent Adverse Events (≥1% and greater than placebo)

	ABTECT 1 & 2 – Pooled Full Data Set		
	Placebo (N=317)	Obefazimod 25 mg (N=319)	Obefazimod 50 mg (N=636)
Headache*	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)
Hypertriglyceridaemia	0	3 (0.9)	12 (1.9)
Dyslipidaemia	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)
Hyperlipidaemia	1 (0.3)	0	7 (1.1)
Hypertension	2 (0.6)	1 (0.3)	7 (1.1)

Headache was not a barrier to treatment, as evidenced by the low discontinuation rate

Sands BE et al. Oral presentation presented at: United European Gastroenterology Week, October 4–7 2025, Berlin, Germany
*Headache Custom MedDRA Query includes the following Preferred Terms (PT): headache, tension headache, procedural headache, cluster headache, cervicogenic headache, migraine. All other TEAEs are shown by individual Preferred Term.

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No clustering of serious TEAEs was observed; only worsening of UC and pneumonia were reported more than once in any individual treatment arm

Serious TEAEs in ABTECT Induction Trials

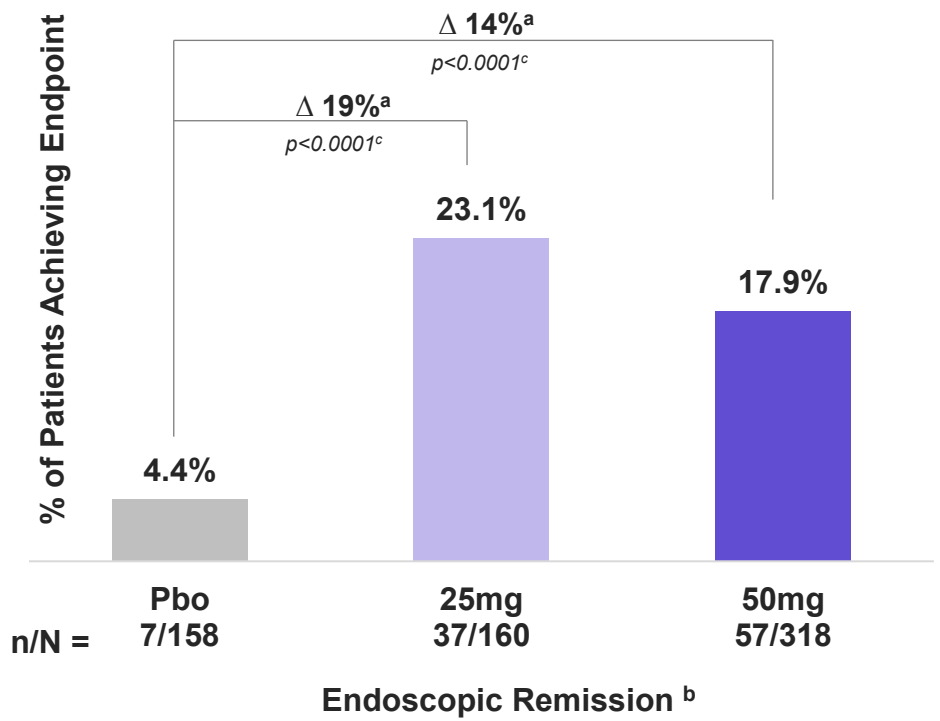
	Obe-50 (n=636)	Obe-25 (n=319)	PBO (n=317)
Serious TEAE, n (%)	**20 (3.1)**	**7 (2.2)**	**10 (3.2)**
Colitis ulcerative	5 (0.8)	2 (0.6)	5 (1.6)
Gastritis	1 (0.2)	0	0
Pancreatitis	1 (0.2)	0	0
Pancreatitis acute	1 (0.2)	1 (0.3)	1 (0.3)
Vomiting	1 (0.2)	0	0
Anal inflammation	0	0	1 (0.3)
Pneumonia	2 (0.3)	0	0
Anal abscess	1 (0.2)	0	0
Appendicitis	0	1 (0.3)	0
Clavicle fracture	1 (0.2)	0	0
Procedural dizziness	1 (0.2)	0	0
Anaemia	1 (0.2)	0	0
Blood loss anaemia	0	0	1 (0.3)
Myocardial infarction	1 (0.2)	0	0
Acute coronary syndrome	0	0	1 (0.3)
Type 2 diabetes mellitus	1 (0.2)	0	0
Prostate cancer stage I	1 (0.2)	0	0
Migraine	1 (0.2)	0	0
Calculus bladder	1 (0.2)	0	0
Pyrexia	0	0	1 (0.3)
Lipase increased	0	1 (0.3)	0
Pleurisy	0	1 (0.3)	0
Vasculitis	0	0	1 (0.3)

Seidler U et al. P0712 Poster presented at: the 21st Congress of ECCO, February 18–21, 2026, Stockholm, Sweden
Obe, obefazimod; PBO, placebo; TEAE, treatment-emergent adverse event.

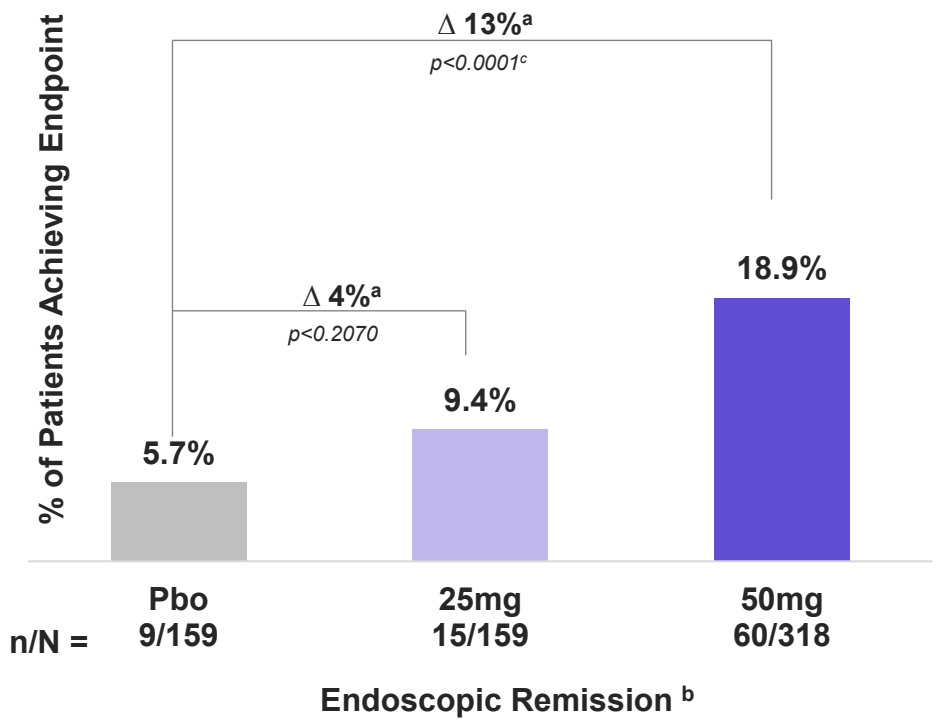
ABTECT 1&2: Obefazimod 50mg Achieves Endoscopic Remission by Week 8

In ABTECT 1 both 25mg and 50mg achieved endoscopic remission

Endoscopic Remission – ABTECT 1



Endoscopic Remission – ABTECT 2



Sands BE et al. Poster presented at the Advances in Inflammatory Bowel Diseases (AIBD) Conference December 8-10, 2025, Orlando, Florida
[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] Endoscopic Remission is defined as MES = 0
[c] Because this was a non-multiplicity controlled secondary endpoint, all p-values are nominal

Over 55% of Part 2 Participants Previously Failed 1 or More Advanced Therapies

Comparing Maintenance Part 1 and Part 2 Patient Populations

	Part 1			Part 2		
	Induction Responders – Part 1			Induction Non-Responders‡ – Part 2		Part 1 Relapsers* – Switch to Part 2
Part of Phase 3 Program	Double-Blind Placebo Controlled Trial Part 1			Double-Blind Uncontrolled Trial Part 2		Open-Label Part 2
Arm	**PBO**	**Obe 25 mg**	**Obe 50 mg**	**Obe 25 mg**	**Obe 50 mg**	**Relapsers (Pooled), Obe 50 mg**
Study Participants (N)	192	193	195	81	148	159
Age (Years), Mean (SD)	41.3 (13.4)	43.0 (13.7)	42.3 (14.4)	42.3 (11.7)	43.5 (14.3)	40.1 (13.6)
Baseline Induction MMS, Mean (SD)	6.9 (1.1)	6.7 (1.1)	6.9 (1.2)	7.1 (0.9)	7.0 (1.0)	7.1 (1.1)
Duration of Disease (Years), Mean (SD)	8.1 (7.6)	8.1 (7.4)	7.8 (6.9)	6.9 (5.3)	7.9 (6.6)	7.9 (7.3)
Baseline Induction Fecal Calprotectin (µg/g), Median	1202	1585	1568	2102	1806	1625
Corticosteroid Use at Maintenance Baseline (%)	35.9%	41.5%	40.5%	40.7%	33.8%	42.1%
Prior Advanced Therapy Failure (%)	**37.5%**	**39.4%**	**46.2%**	**59.3%**	**58.1%**	**55.3%**
44-Week Completion Rate, n (%)	66 (34.3%)	152 (78.8%)	160 (82.1%)	57 (70.4%)	115 (77.7%)	137 (86.2%)

Despite being a more difficult-to-treat population, Part 2 patients achieved completion rates comparable to Part 1 induction responders

Data on File ABX464-107; *Includes Part 1 Relapsers who were originally randomized to Placebo (N=109), 25 mg (N=33), 50 mg (N=17) in Part 1 and excludes placebo responders (N=37); ‡Excludes placebo non-responders who were randomized to 25 mg or 50 mg. Excludes N=32 patients who switched doses due to an early version of the ABTECT protocol and are not included in this analysis

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Two Malignancies Excluding NMSCs Observed in Part 2 Maintenance Trial

Multiple confounding pre-existing risk factors for both malignancy cases

Part 2 Malignancy Cases in Context

Preferred Term	Obefazimod 25 mg N=186, n	Obefazimod 50 mg N=447, n	Total in Part 2 N=633, n
Part 2 : Malignancies other than NMSC	**0**	**2**	**2**
Myeloproliferative neoplasm (MPN)	0	1	1
Prostate cancer	0	1	1

Both cases deemed unrelated to obefazimod by the study investigators

	Malignancy (Excluding NMSC)	Obefazimod Treatment Duration	Exposure to obefazimod	Pre-Existing Risk Factors for Malignancy: Age	Thiopurine History	Prior Advanced Therapies	Other Prior UC Treatment	Medical History of Cancer	Summary
50 mg	**Myeloproliferative Neoplasm (MPN)**	**Induction:** 50mg (9 wks) **Maint-Part 1:** PBO (20.1 wks) **Maint-Part 2:** 50mg (23.3 wks)	7.4 Months	40+	No	2 (adalimumab, infliximab)	mesalazine	N	**Thrombocythemia since 2023.** Had **elevated platelets at baseline** (909,000 per microliter)
	Prostate Cancer	**Induction:** PBO (8.7 wks) **Maint-Part 1**: PBO (6.9 wks) **Maint-Part 2:** 50mg (14.7 wks)	3.4 Months	55+	Yes azathioprine	2 (infliximab, vedolizumab)	prednisolone, mesalazine, budesonide	N	Limited adenocarcinoma of the prostate CT2 CN0 M0; Gleason score 7B

Both cases had multiple confounding factors: the MPN patient had pre-existing thrombocythemia with elevated platelets at baseline, while the prostate cancer patient was 55+, had failed two advanced therapies, and was exposed to obe for only 3.4 months

 Data on File ABX464-107; **Blue** = Pre-Existing Risk Factor

ABIVAX

A Nonclinical Photosensitivity Finding Led to Enhanced Skin Surveillance in the ABTECT Phase 3 and Phase 2 OLE Protocols

Photosensitivity in Context

Nonclinical Photosensitivity Findings

Photosensitivity findings were observed in a nonclinical animal model

At the request of regulatory agencies, photosensitivity was incorporated into the existing skin lesion AESI

All skin lesion AESI forms, including supplementary photos, were **reviewed by a central dermatologist**

Rigorous Skin Lesion Monitoring in ABTECT and Phase 2 OLE

Phase 2 initially did not include a photosensitivity skin lesion AESI and reported no NMSCs; NMSC detection increased only after enhanced skin surveillance was added to the protocols

Most comprehensive skin lesion surveillance among historical UC Phase 3 programs

	Obefazimod ABTECT/108	Other Ph3 UC Programs*
AESI classification	✓	×
Dedicated reporting form	✓	×
Central dermatologist review	✓	×
Lesion photograph encouraged	✓	×
Lesion-specific adjudication	✓	×

*Other programs include ozanimod, etrasimod, tofacitinib, upadacitinib, risankizumab, guselkumab, and mirikizumab

Skin Lesion: No difference between obefazimod and placebo

The exposure-adjusted incidence rates (EAIR) were similar across treatment groups for ABTECT maintenance Part 1 & 2

NMSCs: Enhanced Skin Surveillance Increased Detection of NMSCs in Phase 3

NMSCs remained rare despite intensive protocol-driven surveillance

60% of NMSCs identified in Phase 3 were within the first 6 months of obefazimod exposure

No increase in NMSC detection was observed with longer treatment exposure

Clinical Study Protocols: ABX464-104, ABX464-105, ABX464-106, ABX464-107 and ABX464-108
AESI = adverse event of special interest; OLE = open-label extension; NMSC = non-melanoma skin cancer; EAIR = exposure-adjusted incidence rates

No Increase in Skin Lesion Occurrence Between Placebo and Obefazimod Despite Robust Surveillance

Skin Lesion Summary – Phase 3 Maintenance Program

	Maintenance Part 1 & Part 2 Combined		
Patient Years of Exposure	**~147**	**~274**	**~438**
	Placebo	**Obe 25 mg**	**Obe 50 mg**
	n (IR per 100 PY)	n (IR per 100 PY)	N (IR per 100 PY)
Skin Lesions, All Types, *Externally Adjudicated*	**15 (10.2)**	**24 (8.8)**	**44 (10.0)**

Data on File ABX464-107; IR = Incidence Rate; PY = Patient Years

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All Four Part 2 NMSC Cases Occurred in Patients with Established NMSC Risk Factors

Advanced age (3/4), thiopurine use (3/4), prior skin cancer history (2/4), failure of multiple advanced therapies (3/4)

Part 2 NMSC Cases in Context

Preferred Term	Obefazimod 25 mg N=186, n	Obefazimod 50 mg N=447, n	Total in Part 2 N=633, n
NMSC	**2**	**2**	**4**
Basal cell carcinoma	1	1	2
Squamous cell carcinoma of skin	1	1	2

Pre-Existing Risk Factors for Malignancy

	NMSC	Months of obefazimod Exposure	Age	Thiopurine History	Prior Advanced Therapies	Other Prior UC Treatment	Medical History of Skin Cancer	Summary
50 mg	**Basal Cell Carcinoma**	10.4 months	40+	**Yes azathioprine**	**3 vedolizumab, infliximab, ustekinumab**	mesalazine, **prednisone**	N	Thiopurine use and failure of 3 prior advanced therapies
	Squamous Cell Carcinoma	4.6 months	**55+**	**Yes azathioprine**	**2 adalimumab, vedolizumab**	budesonide	**Y**	Prior history of squamous cell carcinoma and history of multiple skin lesions
25 mg	**Basal Cell Carcinoma**	8.1 months	**50+**	**Yes azathioprine**	None	budesonide, sulfasalazine, mesalazine, **prednisone**, metronidazole, sodium butyrate	N	Age 50+, prior thiopurine history
	Squamous Cell Carcinoma	8.3 months	**75+**	No	**2 adalimumab, vedolizumab**	**prednisone**, mesalamine	**Y**	Age 75+ and prior history of 2x Basal cell carcinoma

Data on File ABX464-107; **Blue** = Pre-Existing Risk Factor; NMSC = non-melanoma skin cancer

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Safety Database Now Includes >1,700 Patient-Years of Exposure

Key safety observations from the expanded maintenance dataset

Safety Analysis Summary

1	**Favorable Safety Profile Maintained**	With the addition of Part 2 maintenance data, the obefazimod safety database now includes **>1,700 patient-years of exposure**, supporting a continued favorable overall safety profile
2	**Lack of Immunosuppressive Signal Consistent with MOA**	The low incidence of immunosuppression-associated AEs is consistent with obefazimod's MOA of restoring mucosal immune balance without evidence of broader immunosuppression **(no lymphomas, no melanomas, no signal of serious opportunistic infection**)
3	**Malignancy Rates Consistent with UC Background**	Exposure adjusted incidence rates for **NMSCs and malignancies excluding NMSCs** were consistent with the expected background incidence in a UC population

Data on File ABX464-107
MOA = mechanism of action; AE = adverse event; UC = ulcerative colitis; NMSC = non-melanoma skin cancer

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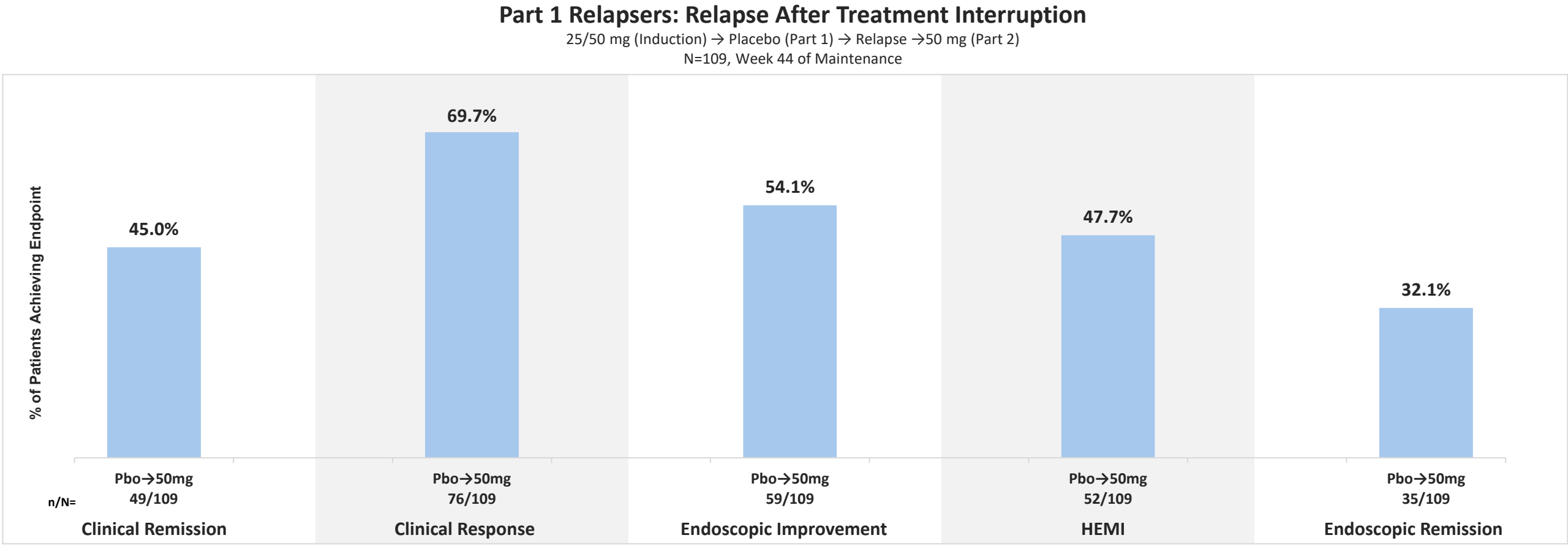
ADDITIONAL EFFICACY

Obefazimod Also Recaptured Response in Patients who Relapsed After Being Randomized to Placebo in Part 1 and Switched to 50 mg in Part 2



Data on File ABX464-107; Clinical remission is defined as SFS = 0 or 1, and RBS = 0 and MES = 0 or 1; 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; Endoscopic improvement is defined as MES = 0 or 1; HEMI is defined as MES = 0 or 1 and Geboes Index score ≤3.1; Endoscopic remission is defined as MES = 0; HEMI = Histologic Endoscopic Mucosal Improvement; Part 1 Relapsers are patients who were originally randomized to Placebo (N=109), 25 mg (N=33), 50 mg (N=17) in Part 1

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PHASE 3 INDUCTION AND PHASE 3 PART 2 PATIENT CASES

Malignancy in Phase 3 Induction

	Preferred Term	Gender/ Age	Obefazimod Treatment Duration	Months of Obe Exposure	Location	Prior UC Treatment	Investigator Assessment*	Medical History of Cancer	Medical History & Summary
50 mg	**Prostate Cancer**	60+	**Induction:** 50mg (2.1 wks)	0.5 months	Eastern Europe	Mesalazine, budesonide, prednisolone	Not Related	N	Prostatic hyperplasia (benign prostatic hyperplasia) the year prior to enrolling in ABTECT Elevated PSA (4.52 ng/mL) was identified; early-stage, acinar adenocarcinoma of the prostate, Stage I, Grade Group 2 was reported

Data on File ABX464-105; *Investigator Assessment: Study investigators were asked to indicate whether the adverse event of special interest was "Related (to the drug)", “Probably Related”, "Possibly Related", "Unlikely Related", or "Not Related"

Part 2: Malignancies other than non-melanoma skin cancers (non-NMSC)

	Preferred Term	Gender/ Age	Obefazimod Treatment Duration	Months of Obe Exposure	Location	Prior UC Treatment	Investigator Assessment*	Medical History of Cancer	Medical History & Summary
50 mg	**Myeloproliferative Neoplasm (MPN)**	40+	**Induction:** 50mg (9 wks) **Maint-Part 1**: PBO (20.1 wks) **Maint-Part 2:** 50mg (23.3 wks)	7.4 months	Eastern Europe	Adalimumab, infliximab, mesalazine	Not Related	N	MH of thrombocythemia since 2023. Had elevated platelets (909,000 per microliter; N: 140-450) at screening. The subject started treatment with hydroxycarbamide and ruxolitinib after diagnosis
	Prostate Cancer	55+	**Induction:** PBO (8.7 wks) **Maint-Part 1**: PBO (6.9 wks) **Maint-Part 2:** 50mg (14.7 wks)	3.4 months	Western Europe	Prednisolone, mesalazine, budesonide, azathioprine, infliximab, vedolizumab	Not Related	N	Limited adenocarcinoma of the prostate CT2 CN0 M0; Gleason score 7B

The MPN patient had pre-existing thrombocythemia and elevated platelets at baseline, while the prostate cancer case emerged after only 3.4 months of exposure

Data on File ABX464-107; *Investigator Assessment: Study investigators were asked to indicate whether the adverse event of special interest was "Related (to the drug)", “Probably Related”, "Possibly Related", "Unlikely Related", or "Not Related"

All four Part 2 NMSC cases occurred in patients with established NMSC risk factors

Advanced age (3/4), thiopurine use (3/4), prior skin cancer history (2/4), failure of multiple advanced therapies (3/4)

	Preferred Term	Gender/ Age	Obefazimod Treatment Duration	Months of Obe Exposure	Location	Prior UC Treatment	Investigator Assessment*	Medical History of Skin Cancer	Medical History & Summary
50 mg	**Basal Cell Carcinoma**	40+	**Induction:** 50mg (8.7 wks) **Maint-Part 1**: PBO (5.0 wks) **Maint-Part 2:** 50mg (36.7 wks)	10.4 months	Western Europe	Mesalazine, prednisone, azathioprine, vedolizumab, infliximab, ustekinumab	Probably Related	N	None reported
	Squamous Cell Carcinoma	55+	**Induction:** 50mg (8.7 wks) **Maint-Part 1**: N/A **Maint-Part 2:** 50mg (11.4 wks)	4.6 months	North America	adalimumab, budesonide, vedolizumab, azathioprine for 5 years	Not Related	Y	Squamous cell carcinoma and history of multiple skin lesions
25 mg	**Basal Cell Carcinoma**	50+	**Induction:** 25mg (8.9 wks) **Maint-Part 1**: N/A **Maint-Part 2:** 25mg (26.3 wks)	8.1 months	Eastern Europe	Budesonide, sulfasalazine, mesalazine, prednisone, azathioprine, metranidazole, sodium butyrate	Unlikely Related	N	None reported
	Squamous Cell Carcinoma	75+	**Induction:** PBO (9.0 wks) **Maint-Part 1**: N/A **Maint-Part 2:** 25mg (36.0 wks)	8.3 months	North America	Prednisone, adalimumab, vedolizumab, mesalamine	Probably Related	Y	2x Basal cell carcinoma

All four Part 2 NMSC cases occurred in patients with established NMSC risk factors, including prior azathioprine exposure (3/4), prior skin cancer history (2/4), and exposure to multiple advanced therapies including TNF inhibitors, Entyvio, and Stelara

Data on File ABX464-107; *Investigator Assessment: Study investigators were asked to indicate whether the adverse event of special interest was "Related (to the drug)", “Probably Related”, "Possibly Related", "Unlikely Related", or "Not Related"

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Reported Part 2 acute pancreatitis events occurred in patients with medical history and relevant clinical context

Case 1: 25 mg

Age: 50+

Location: Central Europe

Induction: PBO (8 wks)
Maint Part 2: 25 mg (6.9 wks)

Treatment duration: 1.6 months

Prior UC treatment:
Azathioprine, adalimumab, etrolizumab (investigational), tofacitinib

Medical History of Pancreatitis: Yes

- **Prior acute pancreatitis in 2007** attributed to azathioprine
- Immunosuppressant and steroid exposure
- **Pancreatic enzyme elevations first noted at maintenance baseline prior to any obefazimod exposure** (Placebo Induction Non-Responder)

Prior history of acute pancreatitis; pancreatic enzyme elevations first noted at maintenance baseline prior to obefazimod exposure

Case 2: 50 mg

Age: 35+

Location: Eastern Europe

Induction: 50 mg (8 wks)
Maint Part 2: 50 mg (12 wks)

Treatment duration: 4.6 months

Prior UC treatment:
Methylprednisolone, azathioprine, vedolizumab, mesalazine

Medical History of Pancreatitis: No

- Prior history of gastritis and arthralgia
- Multiple prior immunosuppressant exposures
- Abdominal pain was associated with **transient elevations in amylase (120 U/L) and lipase (130 U/L)** and CT-confirmed pancreatic edema; enzymes normalized a couple months later

Mild/transient enzyme elevations below the typical acute pancreatitis threshold

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Deaths Reported in Competitor Phase 3 Trials for Context

Obefazimod: One Non-Treatment Related Death in ABTECT Maintenance Part 2

Drug (Brand)	Phase 3 UC Program (Induction + Maintenance) Active Drug – *52 weeks*
	Death (n)
Risankizumab (Skyrizi)	2
Ustekinumab (Stelara)	2
Guselkumab (Tremfya)	1
Tofacitinib (Xeljanz)	1
Vedolizumab (Entyvio)	1
Mirikizumab (Omvoh)	1
Ozanimod (Zeposia)	1
Obefazimod	**1**
Upadacitinib (Rinvoq)	0
Etrasimod (Velsipity)	0

Details of Non-Treatment Related Death in ABTECT Part 2

Treatment Arm	**25 mg**
Age	65+
Obefazimod Treatment Duration	**Induction:** 25 mg (8 wks) **Maintenance Part 2**: 25 mg (28.6 wks)
Months of Obefazimod Exposure	8.5 months
Location	Eastern Europe
Prior UC Treatment	Mesalazine, methylprednisolone
Investigator Assessment	**Not Related**
Suspected Cause of Death	Pulmonary Embolism (Prior History)

Relevant Medical History

Prior history of pulmonary embolism in 2021

- Recent hospitalization with prolonged immobility
- Atrial fibrillation
- Type 2 diabetes
- Hypertension
- Hyperlipidemia

Other Comorbidities

- Osteoporosis
- Hepatic steatosis
- Iron deficiency anemia
- GERD
- Prostatic hyperplasia
- Recent/recurrent pneumonia
- Active UC history

Incident Details

- Fatal pulmonary embolism was suspected but unconfirmed
- Patient had substantial baseline thromboembolic and cardiometabolic risk factors plus recent infection and prolonged immobility

Sources: Data on File ABX464-107; INSPIRE/COMMAND—Louis *JAMA* 2024; UNIFI—Sands *NEJM* 2019; QUASAR—Rubin *Lancet* 2025; OCTAVE—Sandborn *NEJM* 2017; GEMINI—Feagan *NEJM* 2013; LUCENT-1/2—D'Haens *NEJM* 2023; Data on File ABX464-107. U-ACHIEVE/U-ACCOMPLISH—Danese *Lancet* 2022; TRUE NORTH—Sandborn *NEJM* 2021; ELEVATE—Sandborn *Lancet* 2023.

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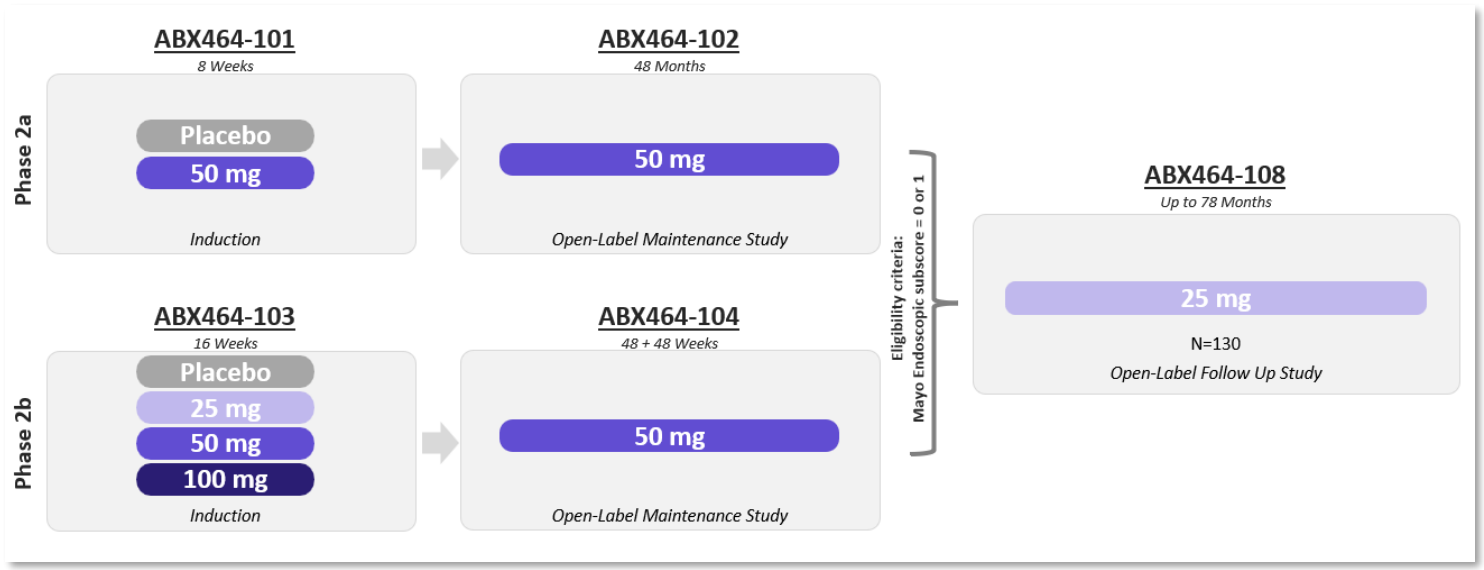
PHASE 2 PATIENT YEARS AND CASES

Long-term Phase 2 experience included ~858 patient years of exposure

TOTAL PHASE 2 PATIENT YEARS (PYs)*

~858 PY of Obe Exposure

50 mg = ~404 PY, 25 mg = ~434 PY, PBO = ~20PY



MH = Medical History; Patient Years for this analysis included obefazimod exposure only; *As of May 2026
Data on File ABX464-104 and ABX464-108. Vermeire et al. *JCC* May 2025.

Malignancy / NMSC in Phase 2 Studies

	Preferred Term	Gender/ Age	Obefazimod Treatment Duration	Months of Obe Exposure	Location	Prior UC Treatment	Investigator Assessment*	Medical History of Cancer	Medical History & Summary
50 mg	**Meningioma Malignant**	65+	**ABX464-104:** 50mg (60.7 wks)	14.0 months	Eastern Europe	Budesonide, mesalazine	Not Related	N	Approximately 14 months after treatment initiation, the subject was hospitalized for neurological symptoms and treated with carbamazepine and sulpiride; MRI subsequently identified a Grade III malignant meningioma
	Squamous Cell Carcinoma	55+	**ABX464-103:** 100mg (15.6 wks) **ABX464-104:** 50mg (96.1 wks) **ABX464-108:** 25mg (14.0 wks)	28.9 months	Eastern Europe	Infliximab, vedolizumab, prednisolone	Unlikely Related	Y	Basal cell carcinoma

Data on File ABX464-103, ABX464-104, ABX464-108; *Investigator Assessment: Study investigators were asked to indicate whether the adverse event of special interest was "Related (to the drug)", “Probably Related”, "Possibly Related", "Unlikely Related", or "Not Related"

PROTOCOL

ABTECT Phase 3 and Phase 2b OLE protocols incorporated enhanced skin lesion surveillance following pre-clinical photosensitivity findings

Initial Protocol

ABX464-108 CSP, v1.0, released 01-Sep-2021

9.1.2. Adverse Events of Special Interest

The following events will be considered AESI and must be reported to (same procedure as SAE).

Skin Lesions (regardless of its severity)

A dermatologist consultation should be scheduled to evaluate the type of lesion, its severity and etiology. An anonymized medical report shall be provided.

Updated Protocol

ABX464-108 CSP, v3.0, released 13-Jul-2022

9.1.2. Adverse Events of Special Interest (AESIs)

The following events will be considered AESI and must be reported to (same procedure as SAE).

Skin Lesions (regardless of its severity)

The AESI "skin lesion" should be broadly captured by the site physician. Subjects are informed via the ICF that oral administration of ABX464-N-Glu was phototoxic in a nonclinical model at clinically relevant exposure levels. To mitigate this risk, subjects must comply with usual public recommendations for sun protection, such as: use shade wisely, wear protective clothing (hat, sunglasses), use sunscreen (with a sun protective factor [SPF] of 15 or higher), and limit time spent in mid-day sun or strong sunlight. Subjects experiencing skin lesion(s) will be instructed to contact the site study coordinator or investigator and to take a picture of the skin lesion for medical assessment. The site investigator will complete a specific skin lesion form as provided in Appendix 14.4. Additionally, the skin lesion form may be supplemented by pictures of the affected skin region(s) taken by the subject, at their discretion. The pseudonymized skin lesion form will be reviewed by a central dermatologist, to investigate a potential for photosensitivity. A pseudonymized medical report will be provided by the central dermatologist. In addition, the site should report the skin lesion to using the standard AESI/SAE form.

Protocol Feature	Obefazimod Initial (ABX-484-108 v1.0)	Obefazimod Updated (ABTECT/108 v3.0)
Skin lesions specifically classified as AESIs	✓	✓
Dedicated skin-lesion reporting form	✗	✓
Lesion photography permitted/encouraged	✗	✓
Central dermatologist review	✗	✓
Skin lesion adjudication pathway	✗	✓
NMSC reported through lesion-specific pathway	✗	✓
All NMSCs treated as AESIs	✗	✓
Explicit protocol for skin-lesion surveillance	✓	✓
Routine Scheduled Skin Examination	✗	✗
Dermatologist consultation if skin effect identified	✓	✓

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INCIDENCE RATES CALCULATIONS

How Malignancy Incidence Rates (per 100 Patient-Years) Were Derived

1 Published Sources

- **Long MD, Martin CF, Pipkin CA, et al.** Risk of melanoma and nonmelanoma skin cancer among patients with inflammatory bowel disease. *Gastroenterology*. 2012;143(2):390–399.e1
- **Bencardino S, Bernardi F, Allocca M, et al**. Advanced Therapies for Inflammatory Bowel Disease and Risk of Skin Cancer: What's New? *Cancers (Basel).* 2025;17(10):1710
- **Beaugerie L, Brousse N, Bouvier AM, et al**. Lymphoproliferative Disorders in Patients Receiving Thiopurines for Inflammatory Bowel Disease: A Prospective Observational Cohort Study. *Lancet*. 2009;374(9701):1617-1625
- **Kaneko M, Kantani Y, Sato H, et al**. Prognostic Factors in Prostate Cancer Associated with Ulcerative Colitis. *Journal of Clinical Medicine*. 2024;13(5):1392
- **Lemaitre M, Kirchgesner J, Rudnichi A, et al.** Association Between Use of Thiopurines or Tumor Necrosis Factor Antagonists Alone or in Combination and Risk of Lymphoma in Patients With Inflammatory Bowel Disease. *JAMA*. 2017;318(17):1679-1686
- **National Cancer Institute SEER Statistics** - Population-based U.S. cancer incidence data used to contextualize expected rates of common malignancies where UC/IBD-specific incidence estimates were limited

2 Converted to 100 Patient Years

Common UC Malignancies

Includes malignancies most commonly reported in a UC/IBD population:

- ✓ Prostate cancer
- ✓ Breast Cancer
- ✓ Other malignancies associated with IBD

3 Derived Benchmark Range

Published malignancy incidence in IBD/UC population is generally on the order of:

0.3 – 0.7

per 100 patient years

Lower bound reflects conservative estimates from population-based IBD cohorts

Upper bound reflects higher estimate observed in older, longer disease duration and more heavily treated UC populations

Key Assumptions

- Published malignancy incidence in IBD/UC varies by patient demographics, disease characteristics, treatment history, and surveillance intensity
- A composite benchmark range of 0.3 – 0.7 cases per 100 patient-years was derived from published IBD/UC epidemiology and population-based cancer incidence data
- The range is intended for contextual comparison of observed malignancy rates and does not represent a single published incidence estimate

Note: Common UC Malignancies excludes non-melanoma skin cancers (NMSCs)

How NMSC Incidence Rates (per 100 Patient-Years) Were Derived

1 Published Sources

Source	Population	NMSC Incidence (as reported)
Long et al., Gastroenterolgy 2012[1]	IBD (UC & Crohn's Disease)	912 per 100,000 patient years
Bencardino et al., Cancers 2025[2]	IBD (Overall)	733 per 100,000 patient years
Abbas et al., Am J Gastroenterol 2014[3]	UC (thiopurine exposure strata)	3.7 to 13.6 per 1,000 patient years

NMSC = non-melanoma skin cancer, IBD = inflammatory bowel disease, UC = ulcerative colitis

2 Converted to 100 Patient Years

Calculation	Incidence (per 100 patient years)
912 per 100,000 PY ÷ 1,000	0.91
733 per 100,000 ÷ 1,000	0.73
(3.7 to 13.6 per 1,000 PY) ÷ 10	0.37 to 1.36

Note = Incidence rates are expressed per person-year in the original publications and converted above to cases per 100 patient years for comparability

3 Derived Benchmark Range

Published NMSC incidence in IBD/UC population is generally on the order of:

0.7 – 1.4

NMSC Cases per 100 patient years

Lower bound anchored by Bencardino et al. (0.73)
Upper bound anchored by Abbas et al. (1.36)
Long et al. (0.91) supports the mid range

Sources

1. Long MD, Martin CF, Pipkin CA, et al. Risk of melanoma and nonmelanoma skin cancer among patients with inflammatory bowel disease. *Gastroenterology*. 2012;143(2):390–399.e1
2. Bencardino S, Bernardi F, Allocca M, et al. Advanced Therapies for Inflammatory Bowel Disease and Risk of Skin Cancer: What's New? *Cancers (Basel)*. 2025;17(10):1710
3. Abbas AM, Almukhtar RM, Loftus EV, et al. Risk of melanoma and non-melanoma skin cancer in patients treated with thiopurines: a nationwide retrospective cohort. *Am J Gastroenterol* 2014;109(3):390–399

Key Assumption

Published NMSC incidence estimates vary by patient characteristics, immunosuppressive exposure, age, and surveillance intensity; therefore, a benchmark range of 0.7–1.4 cases per 100 patient-years was selected to bracket published IBD/UC incidence estimates and provide context for safety comparisons

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