



Corporate Presentation  
ABTECT Phase 3 Maintenance Topline Results Webcast  
(including Appendix)

June 1, 2026

ABIVAX

# Agenda

**01 Welcome**

**Pat Malloy**

*Senior Vice President, Investor Relations*

**02 Opening Remarks**

**Marc de Garidel**

*Chief Executive Officer*

**03 ABTECT Maintenance Phase 3 Program Overview & Efficacy Results**

**Fabio Cataldi, M.D.**

*Chief Medical Officer*

**04 Topline ABTECT Phase 3 Maintenance Results – Safety**

**Chris Rabbat, PhD**

*Head of Global Medical Affairs*

**05 Summary & Next Steps**

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*Chief Executive Officer*

**06 Q&A**

**Abivax Leadership &**

**David Rubin, M.D.**



## David T. Rubin, MD

- Joseph B Kirsner Professor In Medicine
- Chief, Section of Gastroenterology, Hepatology and Nutrition
- Director, Inflammatory Bowel Disease Center
- Chair, International Organization for the Study of Inflammatory Bowel Disease

David T. Rubin, MD, is a renowned gastroenterologist whose work is focused on new clinical trial designs, novel measures and metrics for evaluating inflammation, prevention methods for poor outcomes and quality of life in IBD patients. He has published over 500 articles on managing IBD, including the 2025 American College of Gastroenterology (ACG) guidelines for ulcerative colitis.

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# Establishing a New Standard of Care for the Treatment of Ulcerative Colitis

Obefazimod 25 mg and 50 mg delivered transformational results in Phase 3 maintenance trial



## Transformational Efficacy Results

Both 25 mg and 50 mg doses met the primary endpoint, achieving >50% clinical remission at Week 44, and placebo-adjusted remission rates of  $\Delta$  39.3% and  $\Delta$  40.3% respectively ( $p < 0.0001$ )



## Consistent Clinical Benefit Across Both Doses

25 mg and 50 mg obefazimod both met all key secondary endpoints, demonstrating robust and clinically meaningful efficacy results across multiple measures of disease control



## Favorable Safety Results

Obefazimod demonstrated a favorable safety profile over the 44-week maintenance trial, with no new safety signals



## Strong Clinical Trial Execution

ABTECT maintenance randomized 580 obefazimod induction responders, achieving a 10% placebo remission rate, the lowest reported in a Phase 3 UC maintenance re-randomization trial

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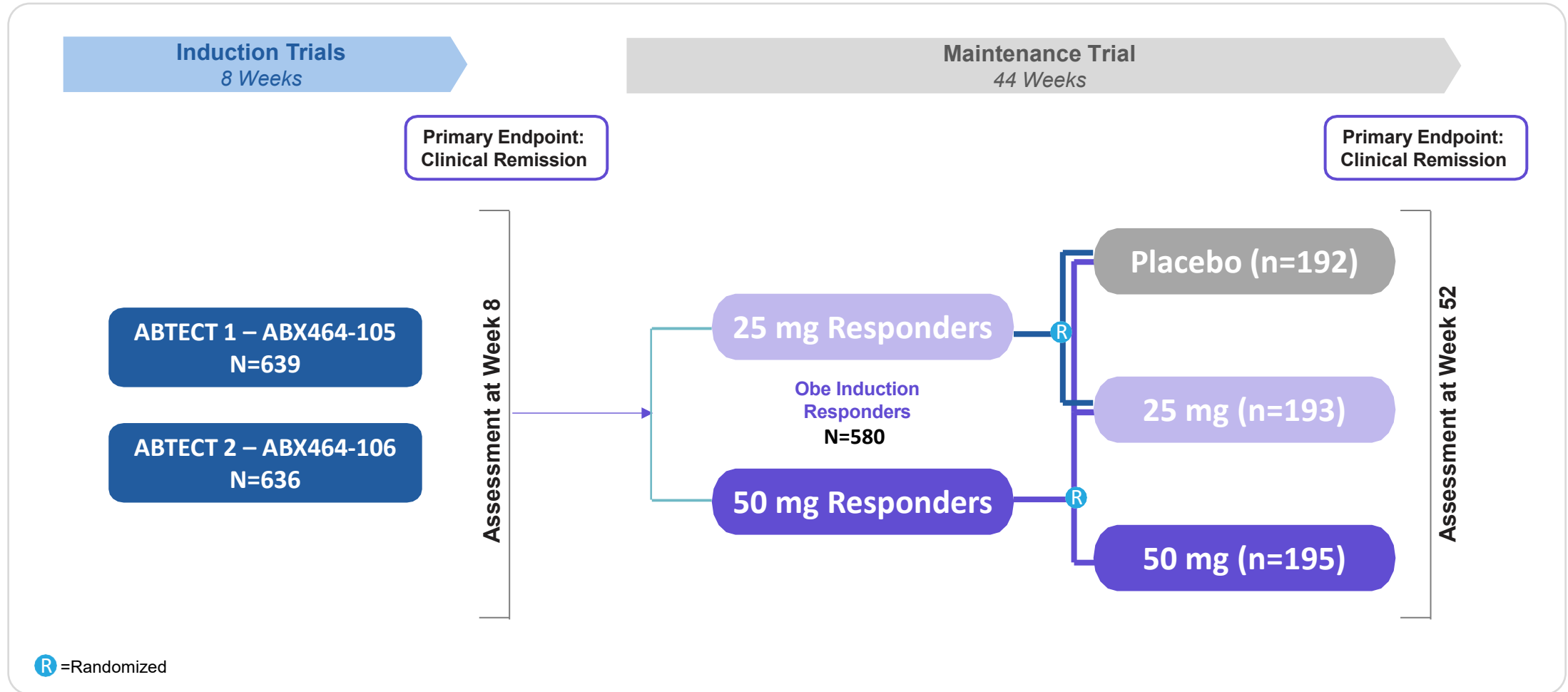
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# ABTECT Phase 3 Responder Re-Randomized Maintenance Trial Design

## ABTECT Clinical Trial Design

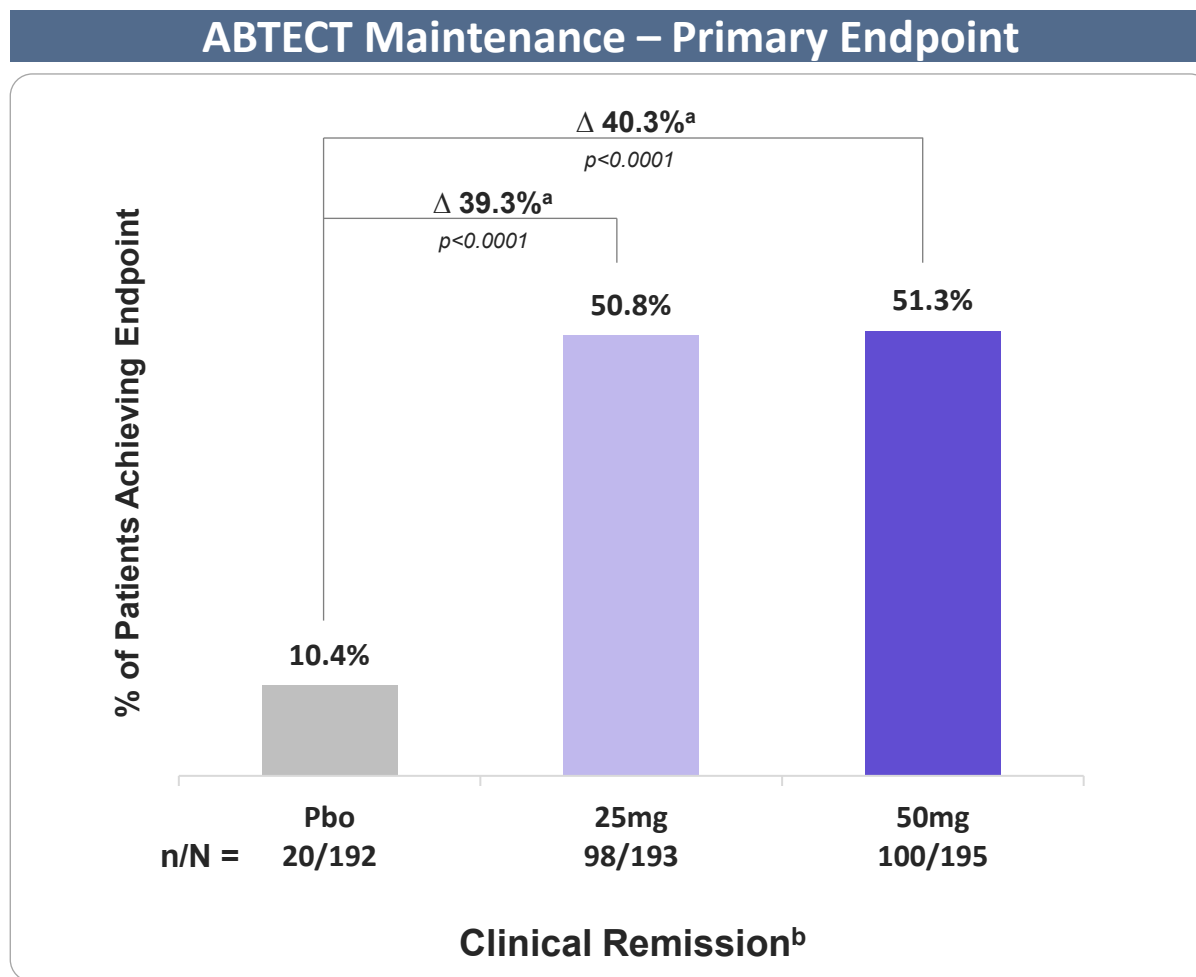


## ABTECT Maintenance Phase 3 Baseline Characteristics and Completion Rate

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

Obefazimod 25 mg & 50 mg delivered statistically significant, clinically meaningful efficacy results, with placebo-adjusted remission of  $\Delta 39.3\%$  and  $\Delta 40.3\%$ , respectively

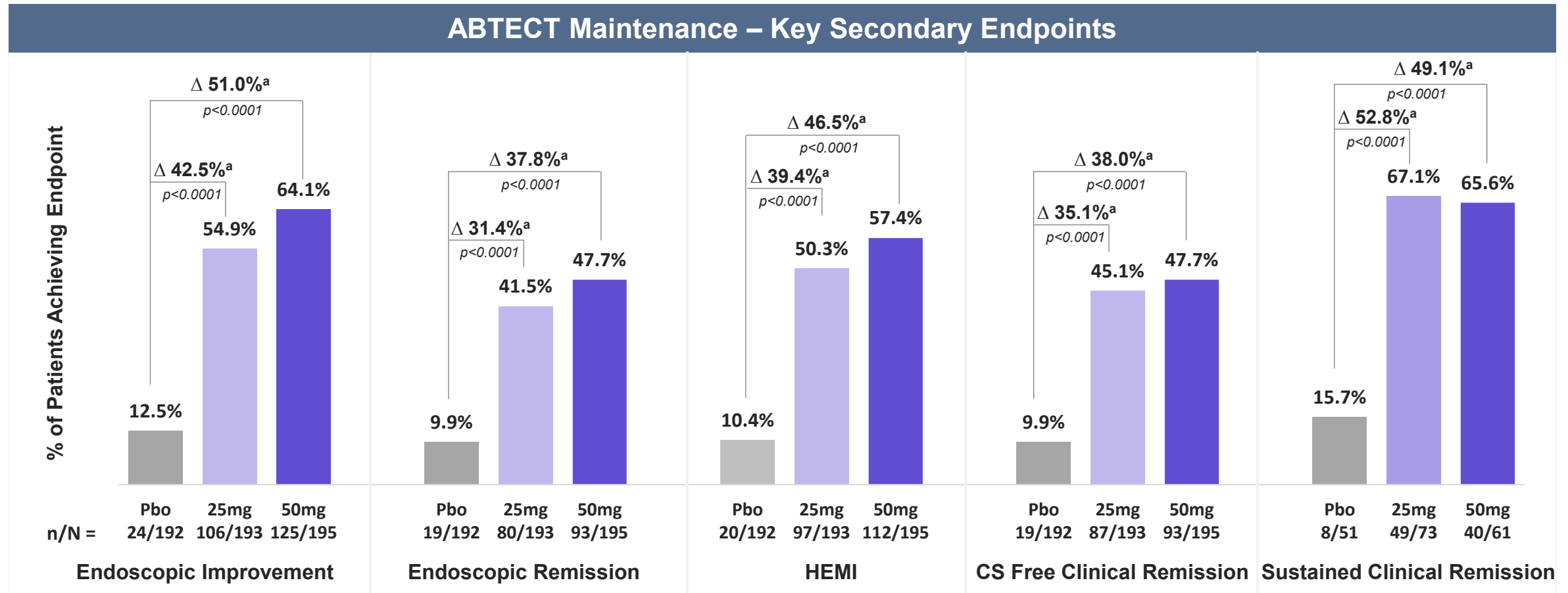


Data on File ABX464-107

[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  $\leq 3.1$ ; 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



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## Safety Results Summary – ABTECT Maintenance

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

## Headache incidence during maintenance was similar across treatment groups

Time to onset in maintenance not associated with drug exposure

	ABTECT Maintenance		
	Placebo (N=192)	Obe 25 mg (N=193)	Obe 50 mg (N=195)
<b>Headache, n (%) [incidence rate per 100 PY]</b>	8 (4.2%) [8.7]	12 (6.2%) [8.9]	16 (8.2%) [11.3]
Headache leading to study <b>discontinuation</b> (per subject), n (%)	1 (0.5%)	0	0
<b>Time to onset</b> of first TE headache per subject (days), median	109.0	100.5	66.5
<b>Duration of headache</b> for all TE headaches (days), median	10.5	1.0	1.0

Headache did not lead to study discontinuation in either obefazimod group

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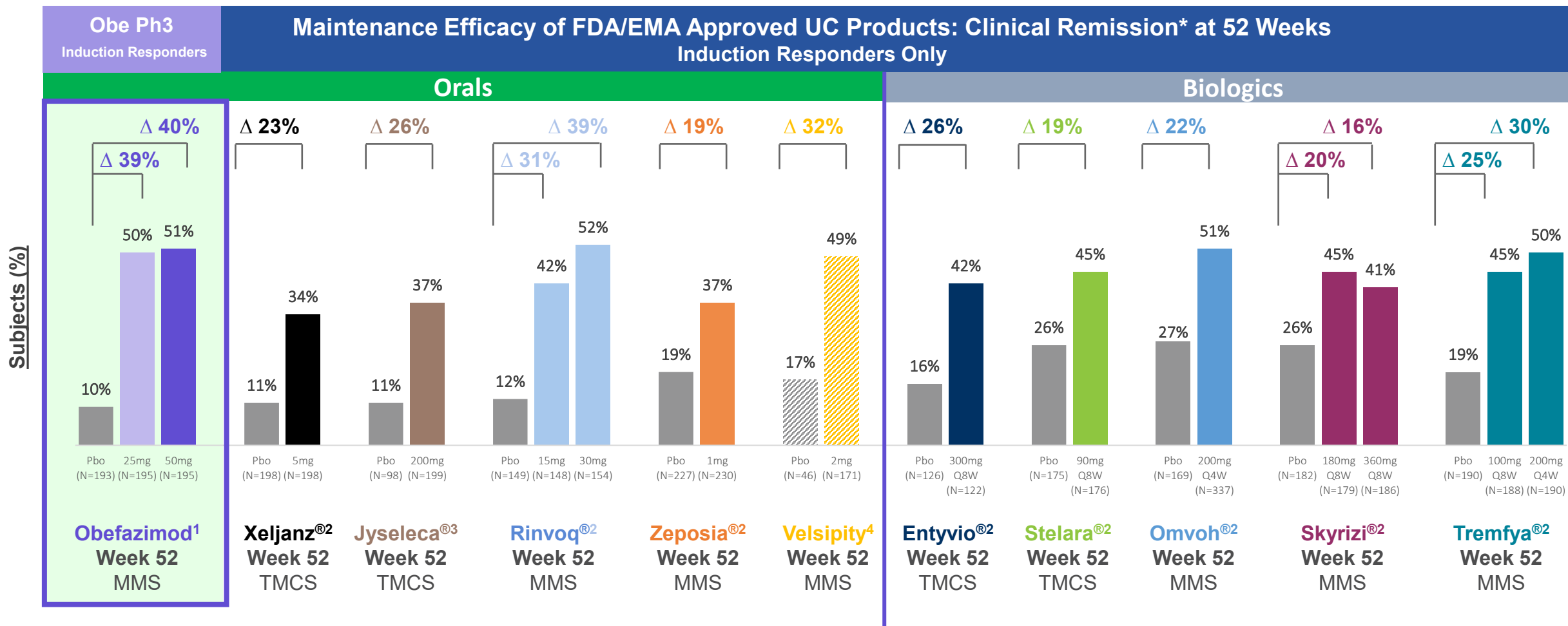
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# Clinical Remission Maintenance Data

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

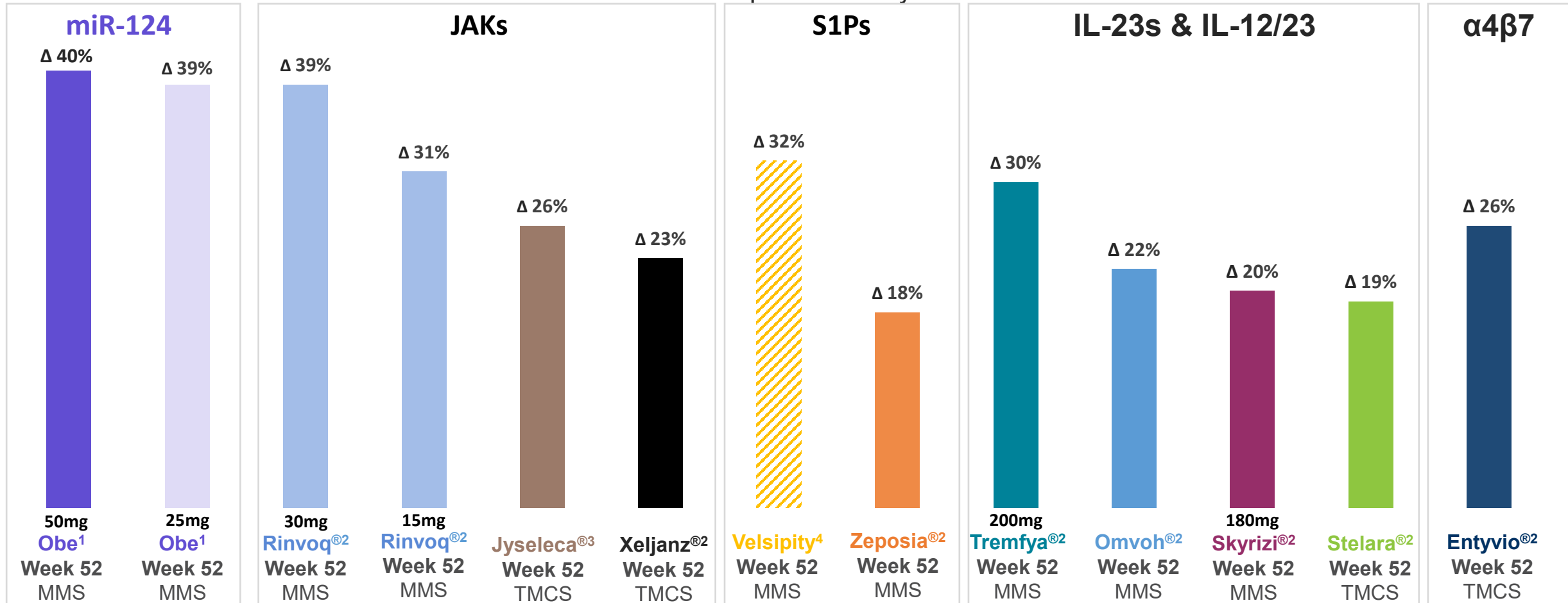


For illustrative purposes only. Not a head-to-head comparison. Differences exist between trial designs and subject characteristics, and caution should be exercised when comparing data across trials.

# Both 25 mg and 50 mg doses achieved best-in-disease placebo-adjusted clinical remission in maintenance

## Placebo-Adjusted Clinical Remission\* Maintenance Rates

Induction Responders Only



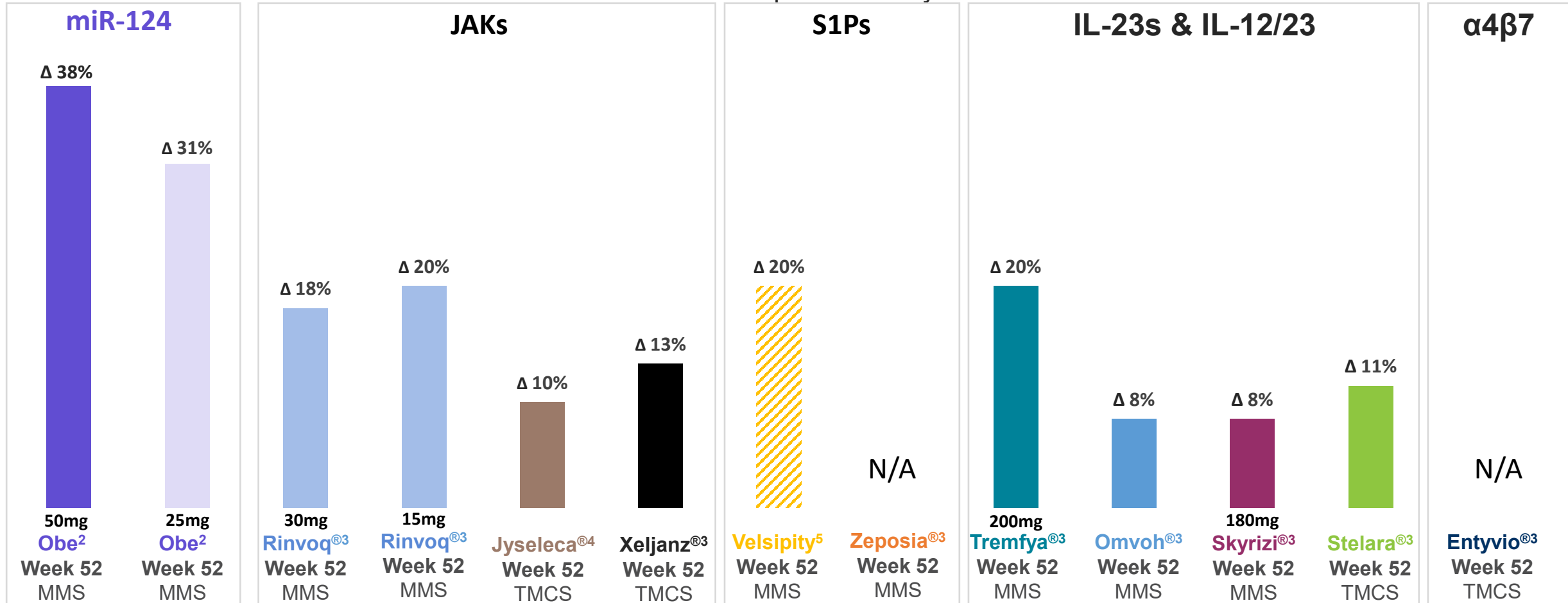
For illustrative purposes only. Not a head-to-head comparison. Differences exist between trial designs and subject characteristics, and caution should be exercised when comparing data across trials.

# Obefazimod delivered potential best-in-disease endoscopic remission

Endoscopic remission is associated with a lower risk of clinical relapse<sup>1</sup>

## Placebo-Adjusted Endoscopic Remission\* Maintenance Rates

Induction Responders Only



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. Yoon H, Jangi S, Dulai PS, et al. *Gastroenterology*. 2020;159:1262–1275. 2 Data on File ABX464-107 3. FDA package inserts 4. EMA Product Summary Characteristics. 5. Endoscopic remission among week 12 clinical responders; Vermeire et al., ECCO 2023 Poster #582; Velsipity Phase 3 was a treat-through design. Obefazimod and all other products used re-randomization Phase 3 design. \*All endoscopic remission numbers are rounded to the nearest whole number as reported in FDA prescribing information in package inserts

# ABTECT Topline Maintenance Results Summary

Today's Phase 3 results reinforce the transformational potential of obefazimod in ulcerative colitis



## Strong Clinical Trial Execution

- **580 induction responders re-randomized** 1:1:1 across placebo, 25mg obefazimod and 50mg obefazimod in the Phase 3 ABTECT Maintenance trial
- **Historically low placebo remission rate of 10%**, the lowest reported placebo rate across all Phase 3 UC maintenance re-randomization trials



## Differentiated Clinical Results

- Both **25 mg and 50 mg doses met the primary endpoint**, achieving >50% clinical remission at Week 44 and placebo-adjusted remission rates of  **$\Delta 39.3\%$  and  $\Delta 40.3\%$** , respectively ( $p < 0.0001$ ), with **favorable safety results** with no new signals observed across 44 weeks
- Recently reported Phase 2a/2b open-label extension data (Study 108) demonstrated durable clinical remission and a favorable safety profile with **up to seven years of exposure**



## Looking Ahead

- **NDA submission** in UC targeted **for late Q4 2026**
- These results, plus **additional subgroup analyses**, will be submitted for presentation at **upcoming medical congresses**



# Appendix

# UC is associated with increased risk for non-melanoma skin cancers and malignancies

Cancer Type	General Population	IBD / UC Population
<b>Non-Melanoma Skin Cancers (NMSCs)</b>	Common age-related skin cancer in men and women	<ul style="list-style-type: none"> <li>Ulcerative Colitis associated with increased relative risk for NMSCs (Basal Cell Carcinoma and Squamous Cell Carcinoma), with advanced age and thiopurines contributing to risk</li> <li>American Gastroenterology and Hepatology (AGA) guidelines recommend annual skin cancer screenings for IBD patients</li> </ul>
<b>Prostate Cancer</b>	Common age-related malignancy in men	<ul style="list-style-type: none"> <li>Multiple studies and meta-analyses suggest modestly increased risk of prostate cancer in patients with IBD, particularly UC.</li> <li>In one study, men with IBD were nearly 5x more likely to be diagnosed with prostate cancer than those without IBD</li> </ul>
<b>Breast Cancer</b>	Common age-related malignancy in women	<ul style="list-style-type: none"> <li>Large-scale study reported a breast cancer prevalence of 2.3% in individuals with UC, compared with 1.1% in individuals without IBD</li> <li>However, other studies have found no significant difference in breast cancer rates between patients with UC and the general population</li> </ul>

**Published epidemiology data supports increased rates of NMSC in IBD populations, with emerging evidence suggesting elevated risks of breast cancer and prostate cancer**

**Sources:** Long M et al *Gastroenterology* 2012: Risk of melanoma and nonmelanoma skin cancer among patients with inflammatory bowel disease; Breast and prostate cancer incidence generally not substantially different from the general population, although elevated prostate cancer risk has been reported in some cohorts; Carli E et al. *Medicina* 2020 meta-analysis: IBD associated with increased prostate cancer risk (RR 1.71; 95% CI 1.16–2.51); UC RR 1.22.; Kaneko M et al. *J Clin Med* 2024: Supports accumulating evidence linking UC and elevated prostate cancer risk; Mansoor E, Abou-Saleh M, Sarmini M *Gastroenterology*, 158, S39-S40 P126 Epidemiology and risk factors of breast cancer in inflammatory bowel disease in the united states between 2014 and 2019: a population-based study

# Non-Melanoma Skin Cancers

## ABTECT Maintenance Trial

	Preferred Term	Age	Obefazimod Treatment Duration	Months of Obe Exposure	Location	Prior UC Treatment	Investigator Assessment*	Medical History of Skin Cancer	Medical History
50 mg	Basal Cell Carcinoma	70+	Induction: 50mg (8 wks) Maint-Part 1: 50mg (18.0 wks) Maint-Part 2: N/A	6.1 months	Australia	Hydrocortisone, prednisone	Unlikely Related	Yes	Basal cell carcinoma
	Basal Cell Carcinoma	45+	Induction: 50mg (8 wks) Maint-Part 1: 50mg (15.6 wks) Maint-Part 2: N/A	5.5 months	Eastern Europe	Methylprednisolone, budesonide, sulfasalazine, mesalamine	Not Related	No	Reportedly no family history of melanoma or other skin cancers.
	Squamous Cell Carcinoma	70+	Induction: 50mg (8 wks) Maint-Part 1: 50mg (7.0 wks) Maint-Part 2: N/A	3.5 months	Southern US	Prednisone, tofacitinib citrate, infliximab, adalimumab, vedolizumab, mesalamine	Possibly Related	Yes	Single squamous cell carcinoma
	Squamous Cell Carcinoma	60+	Induction: 50mg (8 wks) Maint-Part 1: 50mg (4.0 wks) Maint-Part 2: N/A	2.8 months	Western Europe	Prednisolone, mesalamine, budesonide	Possibly Related	No	Confounders per investigator: sun exposure, age, smoking, and others
25 mg	Squamous Cell Carcinoma	60+	Induction: 25mg (8 wks) Maint-Part 1: 25mg (29.0 wks) Maint-Part 2: N/A	8.7 months	Southern US	Mesalazine, azathioprine, prednisone methylprednisolone deucravacitinib (investigational)	Not Related	Yes	Melanoma
Placebo	Basal Cell Carcinoma	70+	Induction: 50mg (8 wks) Maint-Part 1: PBO (18.6wks) Maint-Part 2: N/A	1.9 months	Eastern Europe	Vedolizumab, infliximab, corticosteroids	Not Related	No	Reportedly no past medical history of basal cell carcinoma or pre-cancerous skin lesions. Pre-existing skin lesion at the site of the carcinoma.

5/6 NMSC cases had one or more established risk factors, including advanced age (5/6 ≥60 years), prior skin cancer history (3/6), and prior exposure to therapies associated with increased NMSC risk (5/6); 5/6 cases occurred within the first ~6 months of obefazimod exposure

# Malignancies Other Than Non-Melanoma Skin Cancers

## ABTECT Maintenance Trial

	Preferred Term	Age	Obefazimod Treatment Duration	Months of Obe Exposure	Location	Prior UC Treatment	Investigator Assessment*	Medical History of Cancer	Medical History
50 mg	Prostate Cancer	50+	<b>Induction:</b> 50mg (8.9 wks) <b>Maint-Part 1:</b> 50mg (28.0 wks) <b>Maint-Part 2:</b> N/A	8.5 months	Western Europe	Mesalazine, budesonide, beclomethasone dipropionate, dexamethasone, beclomethasone, Adalimumab, vedolizumab, infliximab, upadacitinib, ustekinumab	Unlikely Related	No	Relevant history included monoclonal gammopathy of undetermined significance (MGUS), vitamin D deficiency, and sideropenic anemia  Elevated PSA was identified, leading to diagnosis of Grade 2 (Gleason 7) intermediate-risk prostate adenocarcinoma
	Breast Cancer	65+	<b>Induction:</b> 50mg (8.0 wks) <b>Maint-Part 1:</b> 50mg (21.4 wks) <b>Maint-Part 2:</b> N/A	6.8 months	Eastern Europe	Methylprednisolone	Unlikely Related	No	No reported family history of breast cancer or other identified breast cancer risk factors  Breast cancer was detected on routine screening mammography and confirmed by core needle biopsy as a moderately differentiated Grade 2 invasive non-specific NST (ductal) carcinoma

**Both malignancies occurred in patients with demographic and clinical characteristics consistent with background cancer risk, with no shared pattern suggestive of a treatment-related signal**