



# Corporate Presentation

November 2024

ABIVAX

# Forward Looking Statements

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Ongoing and future clinical development, including our Phase 3 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).

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# Overview

# Developing oral small molecule therapies that harness the body's natural regulatory mechanisms



## Advance Obefazimod

### Establish obefazimod as a potential 1<sup>st</sup> line advanced therapy for Inflammatory Bowel Disease (IBD)

- Obefazimod, an oral small molecule that enhances the expression of miR-124 to stabilize the immune response, has generated robust data in Phase 2 clinical trials for the treatment of moderately to severely active ulcerative colitis, resulting in the initiation of Phase 3 clinical trials in October 2022
- Clinical data to date demonstrate that obefazimod is well-tolerated (>1,000 patients treated to date)
- A Phase 2b clinical trial in Crohn's Disease is ongoing with the first patient enrolled in October 2024, and exploration of potential combination therapy opportunities in UC is ongoing



## Disrupt the IBD Landscape

### Disrupt the IBD landscape in the near term with Phase 3 data in early Q2 2025

- Currently available therapies are limited by black box safety warnings, extensive pre-initiation requirements, and efficacy that lacks durability and wanes over time. Many broadly target patients' immune systems, which can result in a range of systemic side effects such as increased susceptibility to infection and higher risk of malignancies
- Obefazimod's novel mechanism of action that modulates multiple inflammatory pathways simultaneously to stabilize the immune response offers a potentially differentiated oral treatment option that may lead to more durability of efficacy results over the long-term.



## Leverage Library of miR-124 Enhancers

### Leverage proprietary small molecule library of miR-124 enhancers to expand our pipeline

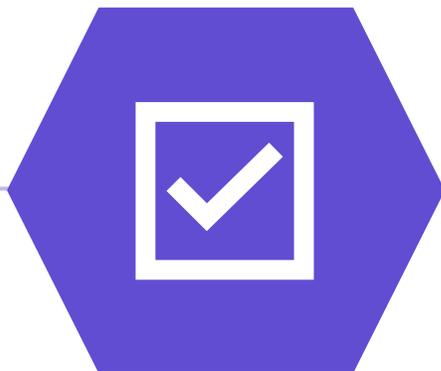
- Based on the mechanistic concept of obefazimod, we have launched an R&D program to generate new potential drug candidates to strengthen our intellectual property portfolio on the miR-124 platform
- The first follow-on drug candidate is expected to be selected in Q4 2024

# Abivax Pipeline

Phase 2b Crohn's Disease Trial Enrolled 1<sup>st</sup> Patient in October 2024

Drug Candidate	Regimen	Indication	Research	Nonclinical	Phase 1	Phase 2	Phase 3	Achieved & Anticipated Milestones
Obefazimod	Monotherapy	Moderately to Severely Active Ulcerative Colitis (UC)	Pivotal Phase 3 Program (ABTECT) Initiated First Patient Enrolled in the US on Oct. 11, 2022					<ul style="list-style-type: none"> <li>Induction trial topline data readout in early Q2 2025</li> <li>Maintenance trial topline data readout in Q1 2026</li> </ul>
	Monotherapy	Crohn's Disease (CD)	Phase 2b					<ul style="list-style-type: none"> <li>IND filed Q4 2023</li> <li>First patient enrolled Phase 2b trial in October in 2024</li> <li>Phase 2b induction topline results expected in 2H 2026</li> </ul>
	Combination Therapy	Moderately to Severely Active Ulcerative Colitis (UC)						<ul style="list-style-type: none"> <li>Preclinical data to support decision-making on combination agent expected in Q4 2024</li> <li>Encouraging preclinical combination data generated</li> <li>Decision on combination agent expected in 2025<sup>1</sup></li> </ul>
miR-124 Follow On	Monotherapy	To be disclosed						<ul style="list-style-type: none"> <li>Selection of follow-on compound Q4 2024</li> </ul>

Provider and payer research indicates significant need for a novel oral agent that provides the potential for both durable efficacy and safety<sup>1,2</sup>



## SIMPLE

Once-Daily Oral  
Without Pre-Initiation Burden

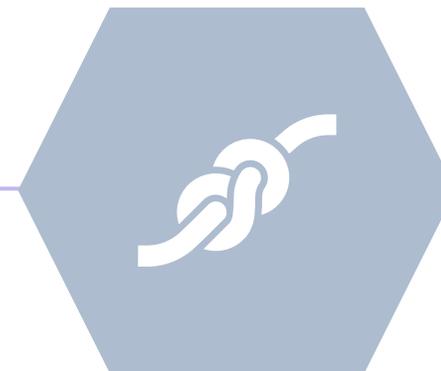
*“Route of Administration plays a very important role in young patients, which is the majority...to them it means a greater degree of freedom and flexibility.”*  
– German Gastroenterologist<sup>1</sup>



## SAFE

The Potential of an  
Improved Safety Profile

*“Nothing is perfectly safe. We need highly effective, very safe, and oral. We don't have this now.”*  
– US Gastroenterologist<sup>1</sup>



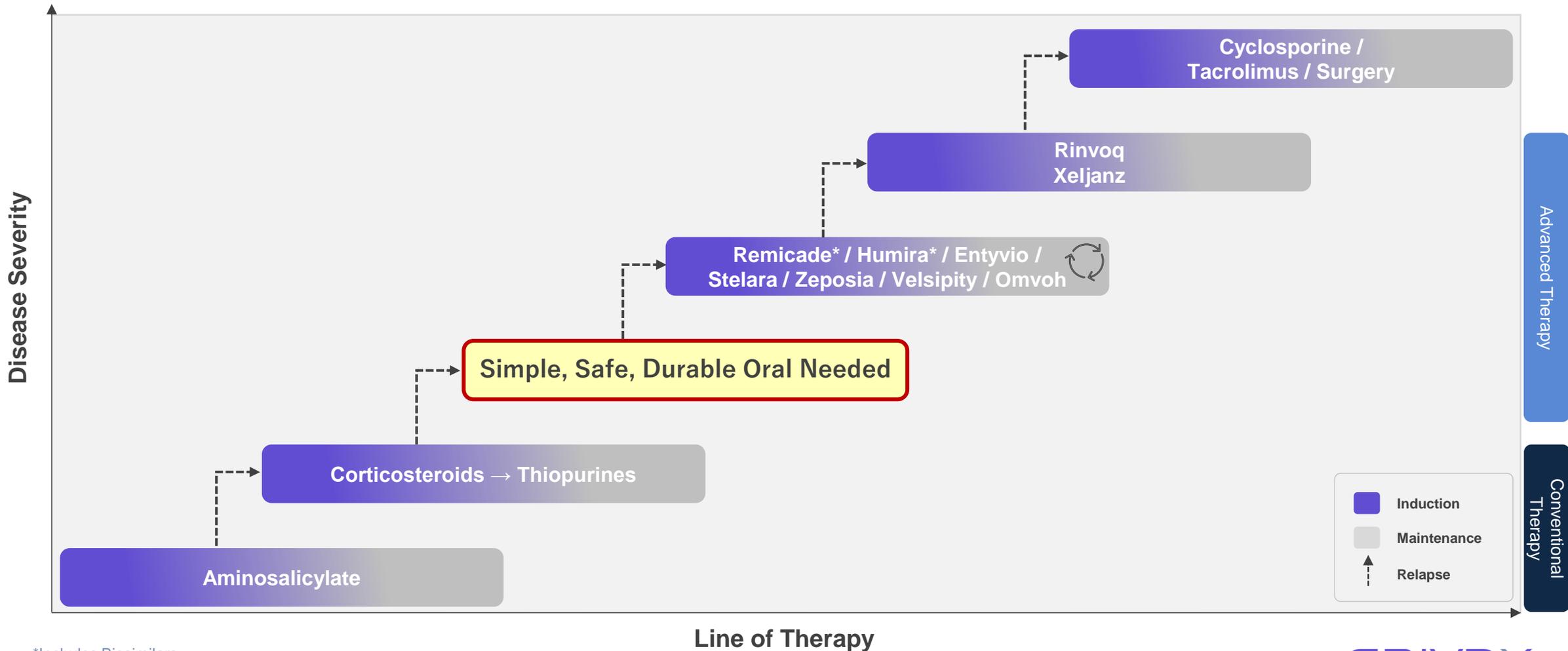
## DURABLE

Clinical Remission That Has  
Demonstrated Potential to Last

*“Currently available agents are ineffective in long-term clinical remission.”*  
– US National Health Plan<sup>2</sup>

A simple, safe, and durable oral option would help shorten the gap between conventional and advanced therapies

### UC Treatment Paradigm with Disease Progression



7 | \*Includes Biosimilars  
 Patients often cycle through these advanced therapies

# Sizable opportunity exists for a simple, safe, and durable therapy that alleviates patients' concerns about stepping up to advanced therapy

776K UC Patients Treated in the US in 12 Months Ended May 2023<sup>1</sup>

**Conventional Therapy**  
77% (594K)

**Advanced Therapy**  
23% (182K)

**\$5.3B**  
In US UC  
Sales<sup>2</sup>

37% (285k)  
Maintained on  
Conventional  
Therapies

25% (193k)  
Steroids Only

15% (116k)  
Uncontrolled on  
Conventional  
Therapies

5% (43k)  
New to  
Advanced  
Therapy

7% (51k)  
Sub-Optimal  
(4%) or  
Recently  
Switched  
(1%)

11% (88k)  
Maintained  
on Advanced  
Therapy

**Significant Unmet Need**

**Additional Unmet Need**

**Intervention Opportunities For New Advanced Therapy**

27% (210K) Patients

A significant number of patients whose UC is uncontrolled on conventional therapies are not stepping up to advanced therapies due to limitations of available agents, leading to suboptimal disease management.

Worldwide IBD sales are expected to grow by 45% by 2030, and Evaluate Pharma forecasts obefazimod to be the 4<sup>th</sup> most successful advanced therapy by that time if approved.



Multiple new therapies are expected to significantly grow the already competitive UC and CD markets

**Annual Estimated Worldwide UC Sales Based on 2030 Projections – Evaluate Pharma**

Rank	Product	MOA	Company	2023 (\$M)	2030 (\$M)
1	Skyrizi	IL-23	AbbVie		2,073
2	Entyvio	α4β7	Takeda	2,274	1,883
3	Rinvoq	JAK	AbbVie	410	1,781
4	<b>Obefazimod</b>	<b>miR-124</b>	<b>Abivax</b>		<b>957</b>
5	Velsipity	S1P	Pfizer	5	881
6	OmvoH	IL-23	Eli Lilly	44	820
7	Zeposia	S1P	Bristol Myers Squibb	232	791
8	Stelara	IL-12/IL-13	Johnson & Johnson	2,413	747
9	Tremfya	IL-23	Johnson & Johnson		508
10	VTX002	S1P	Ventyx Biosciences		423
11	MK-7240	TL1A	Merck & Co		422
12	MORF-057	α4β7	Lilly / Morpnic Therapeutics		392
13	RG6631	TL1A	Roche		353
	Other*			2,372	1,022
	<b>Total</b>			~\$7.8B	~\$13.1B

# Mechanism of Action



# Obefazimod Development

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

## Discovery

2009 – 2015

### 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

## Transition to Inflammation

2015 – 2017

### 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

## Clinical Development

2017 – Present

### MOA Evidence in Humans

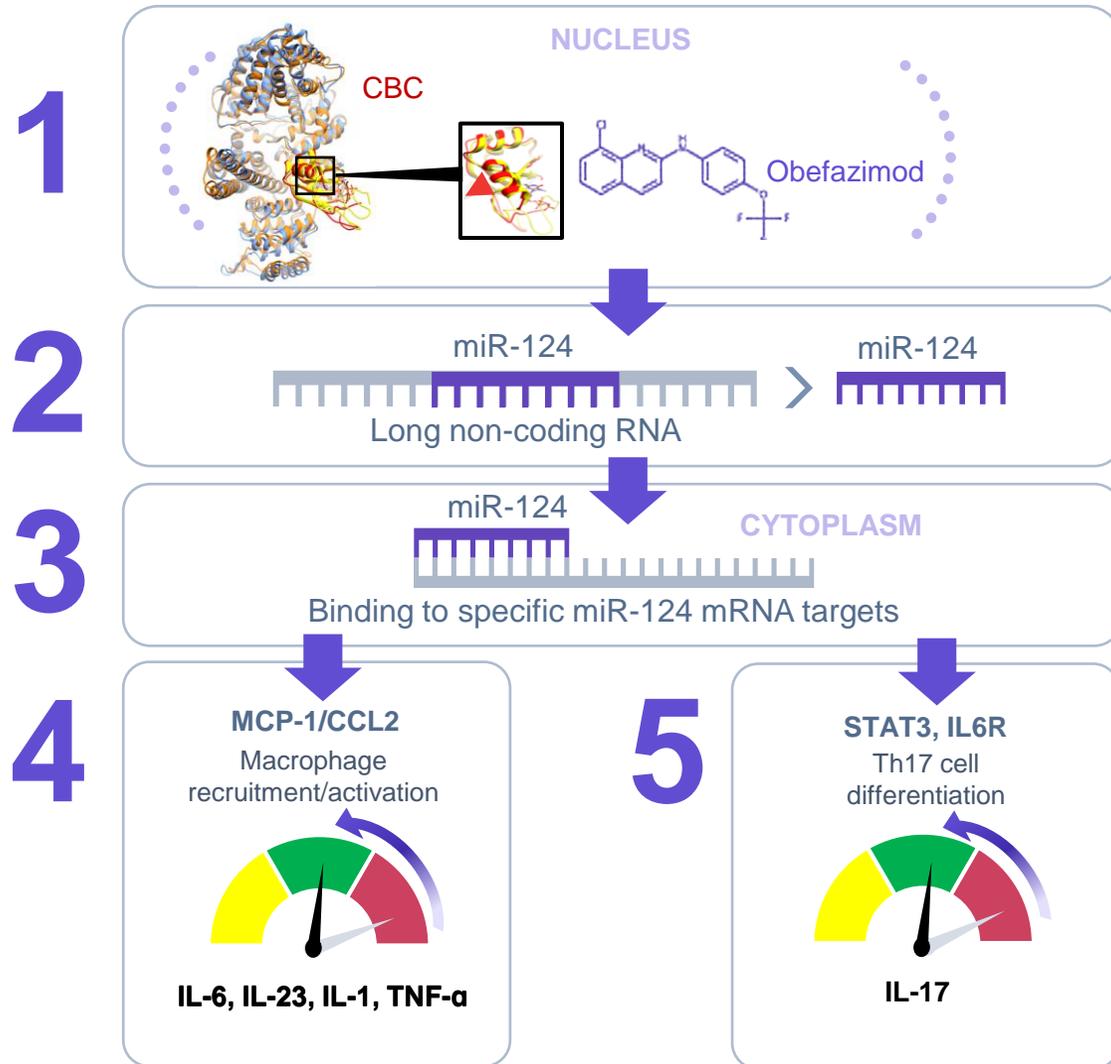
- Enhanced expression of miR-124 in blood and colonic tissue of UC patients
- Reduction of inflammatory cytokines, including IL-23 & IL-17 in UC patients, and IL-6 in RA patients

### UC Phase 3 Clinical Trial Program

- Initiation of ABTECT, global Phase 3 clinical trials for obefazimod in moderately to severely active UC, in Q4 2022

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

# Obefazimod enhances the expression of miR-124, resulting in stabilization of the dysregulated inflammatory response present in UC

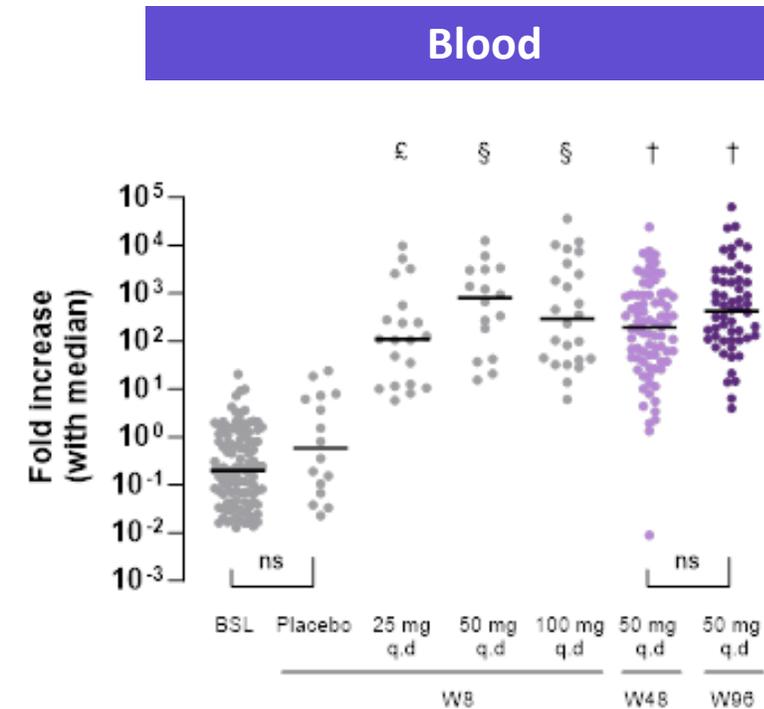
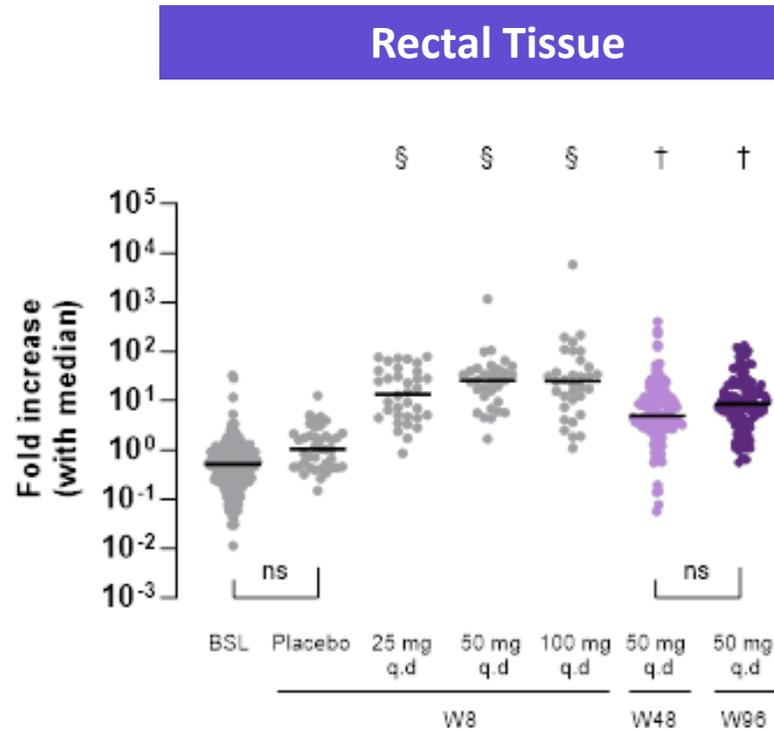


- 1** Obefazimod binds to cap binding complex (CBC) within the nucleus; demonstrated by cryo-electron microscopy\* (CryoEM)
- 2** Induces selective splicing of a single, long, non-coding RNA, leading to enhanced expression of miR-124
- 3** miR124 binds to its specific mRNA targets in the cytoplasm, reducing the translation into their respective proteins
- 4** Reduced translation of MCP-1/CCL2 stabilizes macrophage activation and recruitment to the gut
- 5** Reduced translation of STAT3 and IL-6R stabilizes Th17 differentiation and related cytokines

\*Cryo-electron microscopy is a technique to determine protein structure  
1. Vermeire S, et al. J Crohns Colitis. 2023;jjad067; Data on file. Abivax

# Phase 2b OLE: Enhanced Expression of miR-124 in Rectal Tissue and Blood Sustained Out to Week 96

## miR-124 Upregulation (fold increase, median)



£:  $p < 0.001$  vs. placebo week 8 (induction data)

§:  $p < 0.0001$  vs. placebo week 8 (induction data)

†:  $p < 0.001$  vs. baseline (induction data)

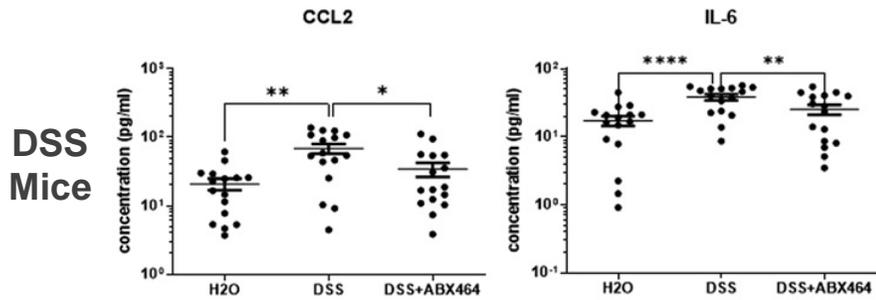
\* $p < 0.001$  for all timepoints vs baseline; each timepoint was compared using a Dunnett adjustment.

Source: Santo J, et al. Long-term upregulation of mir-124 in blood and rectal biopsies of patients with moderate-to-severe ulcerative colitis receiving obefazimod 50 mg daily for 96-weeks.

Poster presented at United European Gastroenterology Week; 2023; Copenhagen, Denmark.

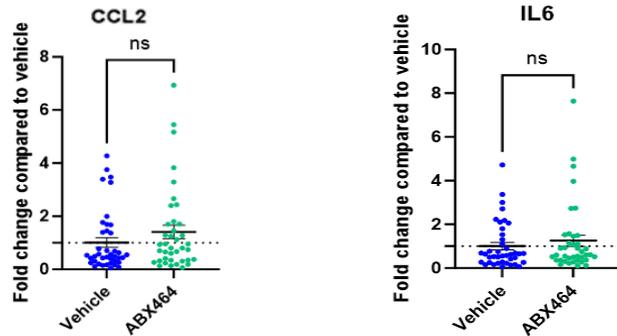
# Obefazimod stabilizes chemokines, cytokines, and Th17/Th1 cells only under dysregulated conditions

## Effects of Obefazimod on Cytokine Secretion in Colonic Tissue in DSS and Normal Mice



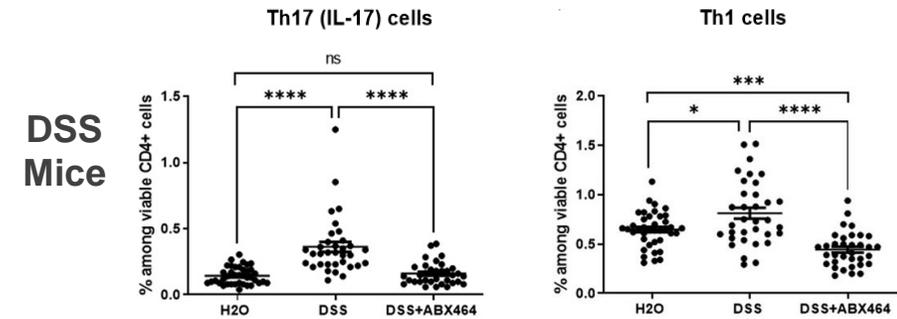
Stabilized CCL2/MCP-1 and IL-6 to Homeostatic Levels

Normal Mice



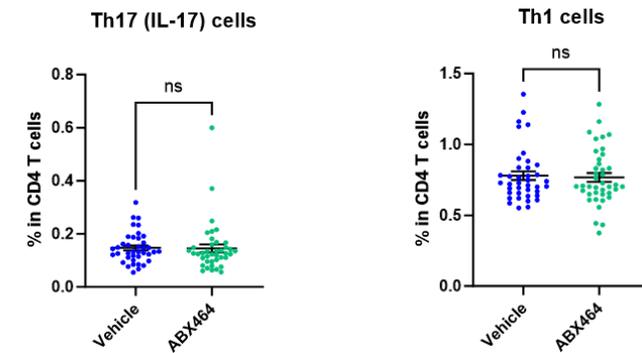
No Impact on CCL2/MCP-1 in Normal Mice

## Effects of Obefazimod on CD4+ Subsets in Mesenteric Lymph Nodes in DSS and Normal Mice



Stabilized Th17 and Th1 Cells to Homeostatic Levels

Normal Mice



No Impact on Th17 and Th1 Cells

# Obefazimod Pre-Clinical Combination Program Overview

Significant progress with important preclinical data generated since January 2024

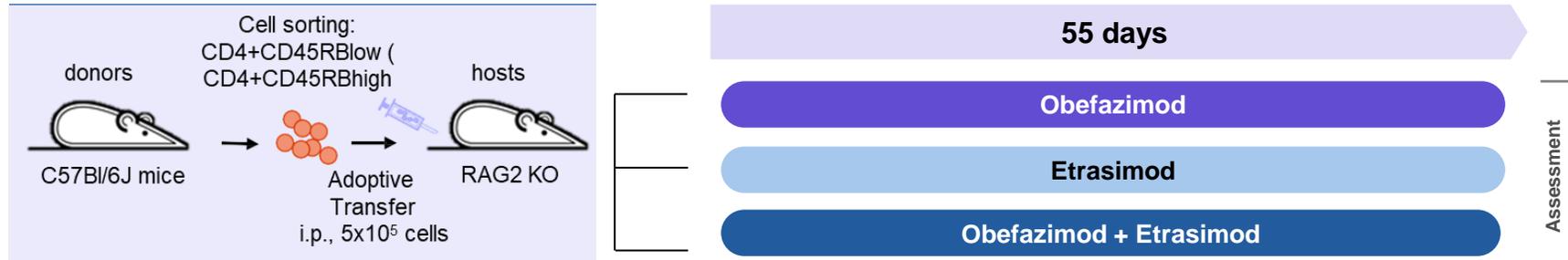
**Objective:** Evaluate combination treatment with obefazimod in mouse model to assess potential synergies to improve efficacy

## Process:

- 1- Identify appropriate preclinical model for each combination (T-cell transfer, acute DSS, chronic DSS)
- 2- Evaluate combination with Obefazimod and other IBD molecules (small molecules or antibodies)
- 3- Assess impact on key endpoints (weight loss protection, disease activity index, cytokines reduction)

Preliminary data in initial combination planned for presentation at upcoming scientific congress

# Early preclinical combination data of obefazimod and etrasimod in IBD mouse model showed synergistic effects



## Results for the treatment of obefazimod + etrasimod compared to each drug alone

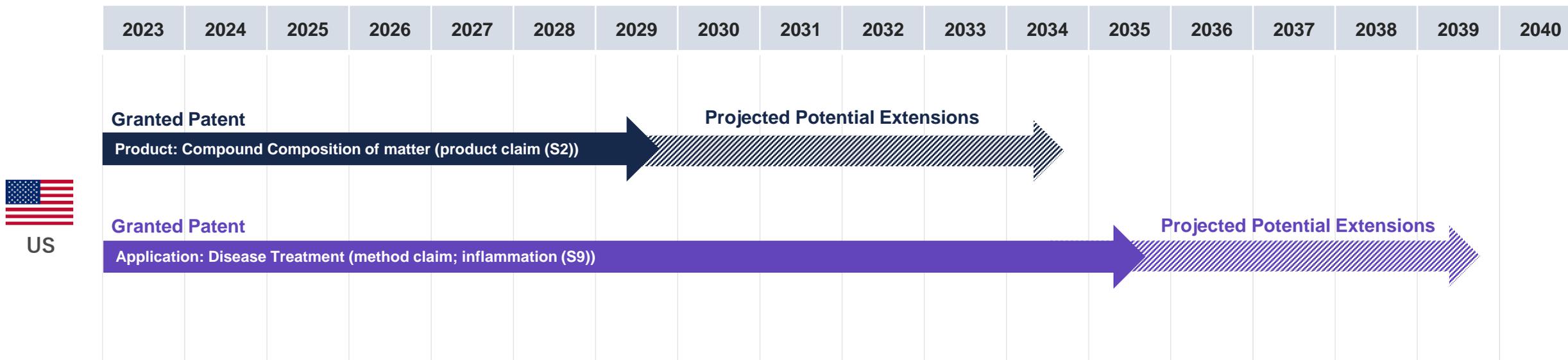
Improved the response on body weight protection

Improved the response on Disease Activity Index

**Synergistic** and statistically significant reduction of several cytokines (TNF $\alpha$ , IL-17, IL-6, IFN $\gamma$ ) in the blood

We are executing a strategy with the goal of extending obehazimod's patent protection in the US from 2035 up to 2039

### Patent Extension Timeline



We expect that one of these two patents will be selected for Patent Term Extension (PTE); eligibility of the method of use patents for PTE assessed and confirmed by two globally recognized IP law firms

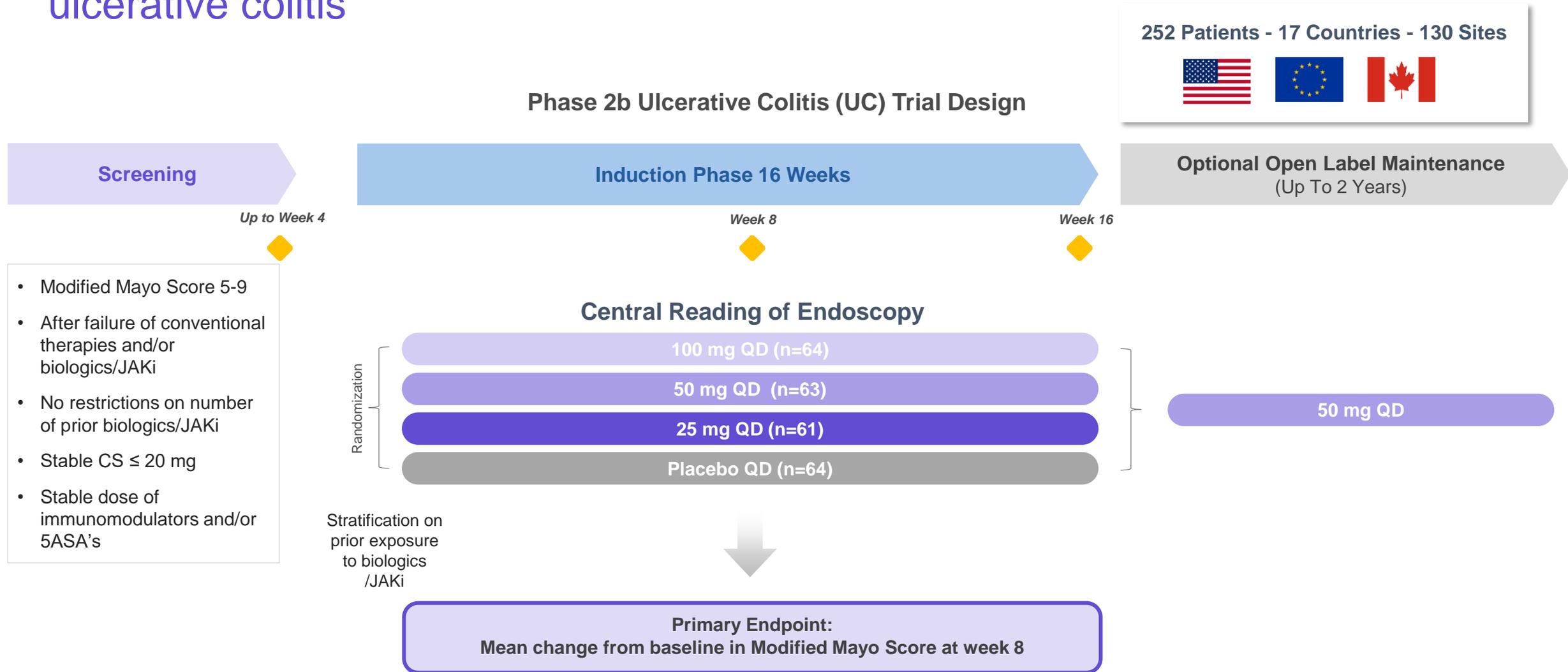


Composition of matter patent or method of use patent (both granted) would extend the product patent protection until 2035 or the use patent until 2040.



# Clinical Trials

# Obefazimod Phase 2b trial design in moderately to severely active ulcerative colitis



# Baseline Characteristics

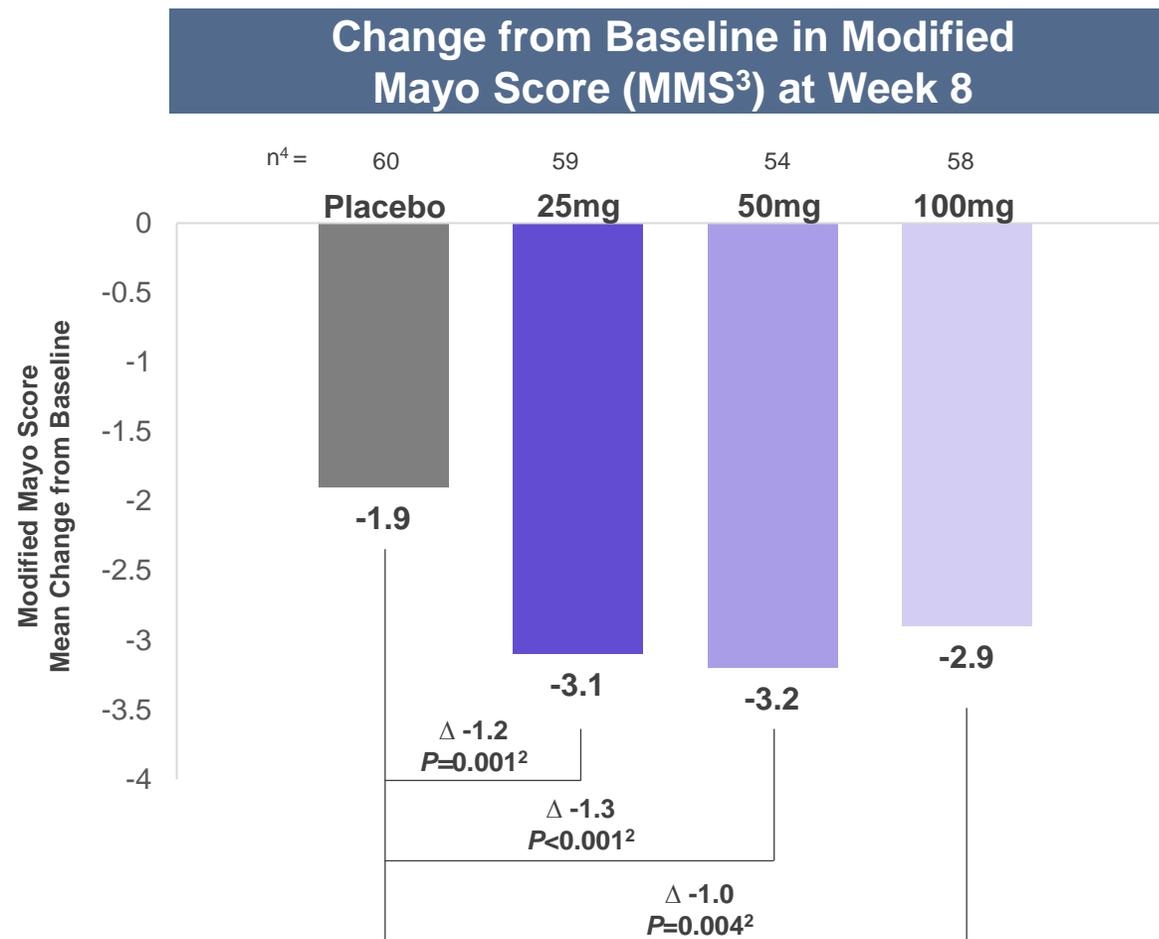
## Phase 2b UC Clinical Trial

		Placebo	25 mg	50 mg	100 mg
		(n=64)	(n=61)	(n=63)	(n=64)
<b>Modified Mayo Score (MMS)</b>	Mean (SD)	7.0 (1.20)	7.1 (1.09)	7.1 (0.96)	7.0 (1.07)
<b>7 to 9</b>	n (%)	42 (65.6)	44 (72.1)	47 (74.6)	47 (73.4)
<b>Endoscopic Sub-Score = 3</b>	%	75%	67%	75%	66%
<b>Duration of Disease (years)</b>	Mean (SD)	8.8 (6.8)	7.4 (6.8)	8.2 (7.8)	7.8 (7.3)
<b>Fecal Calprotectin (µg/g)</b>	Median	1558	1743	1671	1623
<b>Previous Exposure to Biologics/JAKi</b>	n (%)	31 (48.4)	30 (49.2)	30 (47.6)	32 (50.0)
<b>Previous Exposure to 2 or More Biologics/JAKi*</b>	n (%)	28 (90.3)	27 (90.0)	29 (96.7)	31 (96.9)
<b>Primary Non-Response to Biologic/JAKi*</b>	n (%)	15 (48.4)	14 (46.7)	18 (60.0)	19 (59.4)
<b>Concomitant UC Medication</b>					
<b>Corticosteroids</b>	n (%)	29 (45.3)	32 (52.5)	33 (52.4)	37 (57.8)

~70% of patients had severely active disease (MMS 7-9) and ~45% had prior experience with 2 or more biologics/JAKis

# Primary Endpoint Achieved

Statistically significant improvements observed across all doses



Source: Vermeire S, et al. *Lancet Gastroenterol Hepatol.* 2022;7(11):1024-1034.

1. ANCOVA model for change from baseline MMS at Week 8 which includes baseline MMS as a covariate and treatment, previous exposure to biological drugs or JAK inhibitors as fixed effects and a random error term. 2. p-values are based on nonparametric ANCOVA using ranked data. 3. MMS is the sum of assessment scores (0-3) of mucosal appearance on endoscopy, stool frequency, and rectal bleeding 4. n = Number of patients in the category with data available for baseline and week 8 visit.

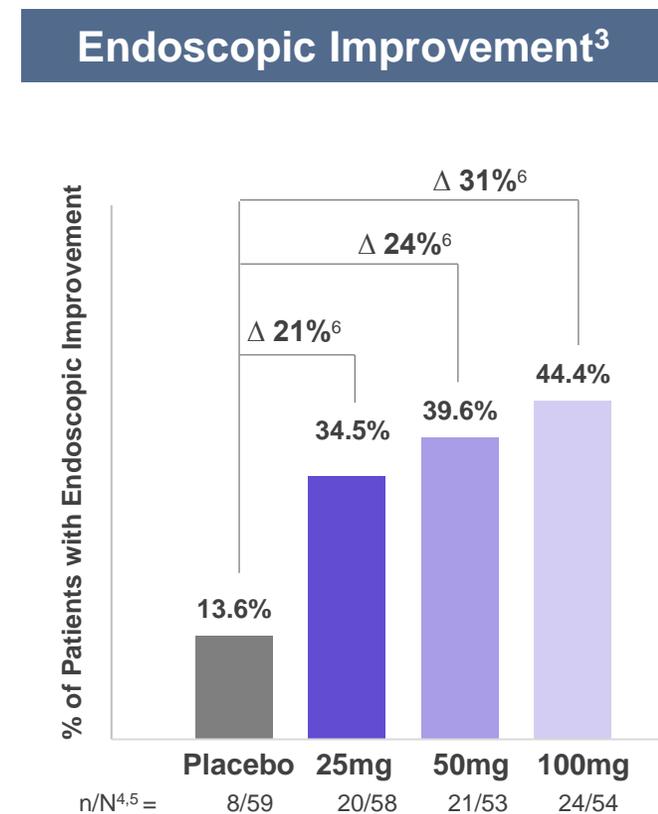
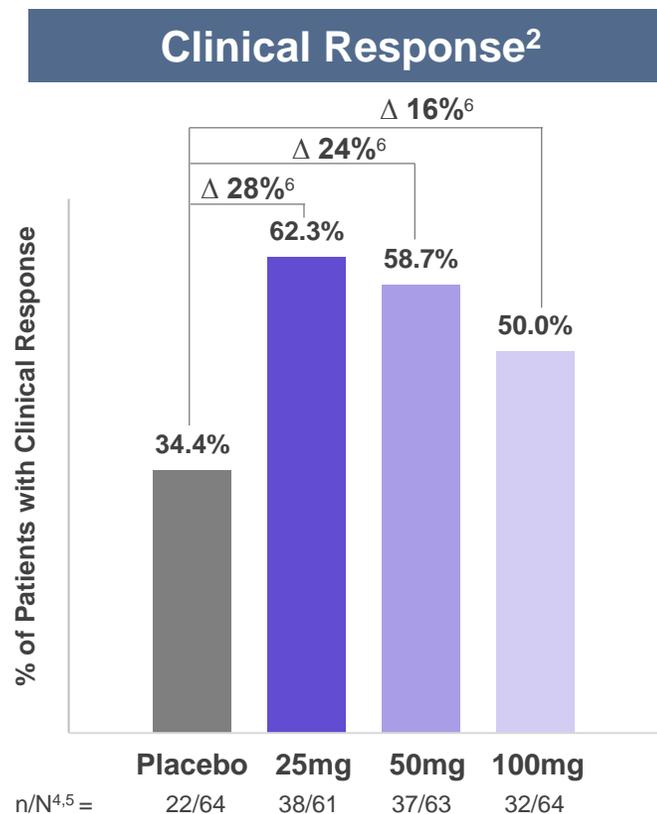
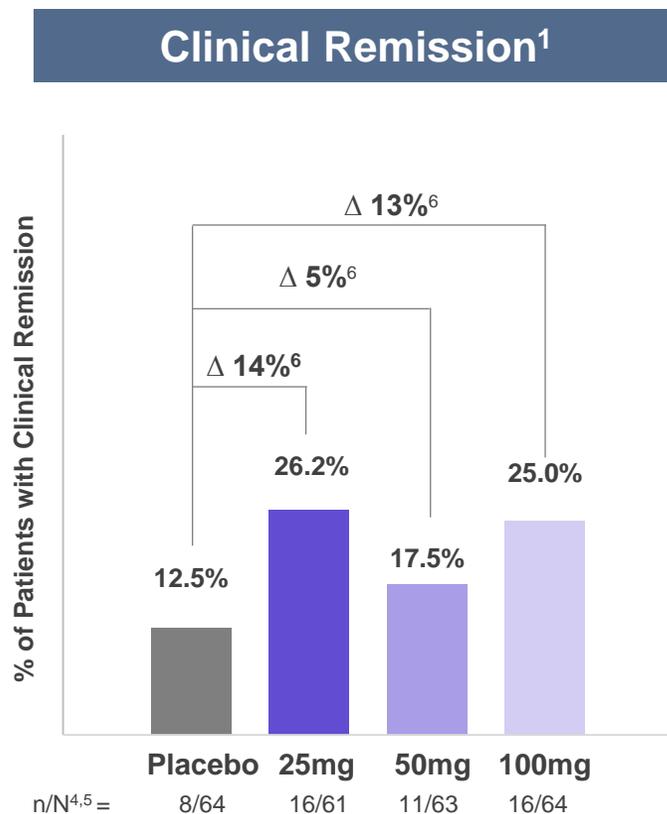
# Secondary Efficacy Endpoints

Positive trends observed across all doses

## Secondary Efficacy Endpoints: Week 8\*

### Placebo response in naïve subgroup:

- 3 of 8 placebo clinical remitters from 1 site among 130 sites
- 8 total patients enrolled at this site



\*Study not powered for statistical significance for secondary endpoints.

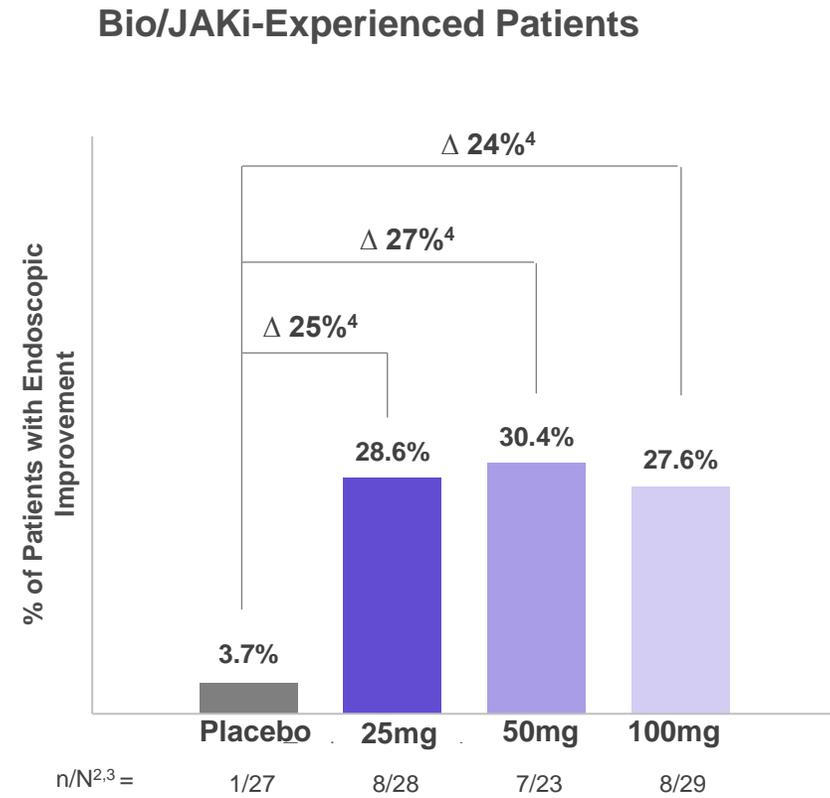
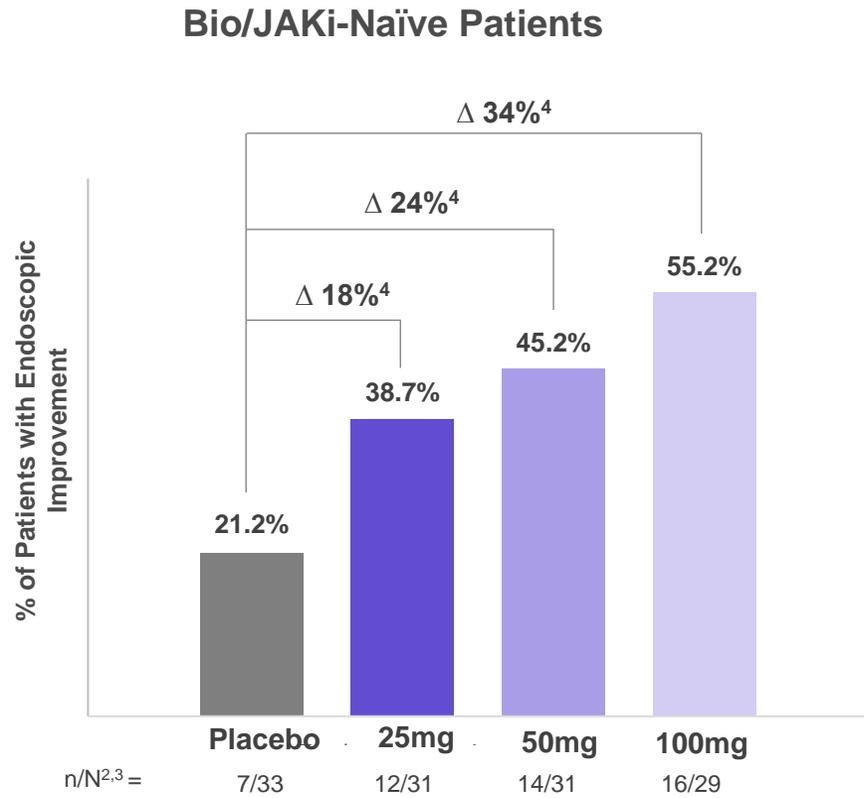
Source: Vermeire S, et al. *Lancet Gastroenterol Hepatol.* 2022;7(11):1024-1034.

1. Clinical remission (per Modified Mayo Score) is defined as stool frequency subscore (SFS) ≤1, rectal bleeding subscore (RBS) of 0 and endoscopic subscore ≤1. 2. Clinical response (per Adapted Mayo Score) is defined as a decrease from baseline in the Modified Mayo Score ≥2 points and ≥30 percent from baseline, plus a decrease in RBS ≥1 or an absolute RBS ≤1. 3. Endoscopic improvement is defined as endoscopic subscore ≤1 without friability. 4. n = Number of patients that met the respective endpoint. 5. N = Number of patients in the relevant analysis set. 6. Delta = arithmetic difference rounded to nearest full percentage.

# Sub-Group Analysis

Bio/JAKi-naïve and Bio/JAKi-experienced patients

## Endoscopic Improvement<sup>1</sup> at Week 8\*



**Note:**  
93% (115/123) had experience with 2 or more Bio/JAKis

Source: Data on File, Abivax.

\*Study not powered for statistical significance for sub-group analysis.

1. Endoscopic improvement is defined as endoscopic subscore  $\leq 1$  without friability. 2. n = Number of patients that met the respective endpoint. 3. N = Number of patients in the relevant analysis set. 4. Delta = arithmetic difference rounded to nearest full percentage.

# Most Commonly Reported Adverse Events

## Obefazimod Tolerability Overview

	Placebo (N=64)	Obefazimod 25 mg (N=62)	Obefazimod 50 mg (N=63)	Obefazimod 100 mg (N=64)	
<b><u>AEs Reported in ≥ 5% of patients in any treatment group</u></b>					
Headache	5 (7.8%)	13 (21.0%)	19 (30.2%)	27 (42.2%)	
<i>Discontinuation Due to Headache</i>	0 (0%)	1 (1.6%)	3 (4.8%)	4 (6.3%)	
Nausea	4 (6.3%)	5 (8.1%)	4 (6.3%)	9 (14.1%)	
Infections	6 (9.4%)	3 (4.8%)	8 (12.7%)	5 (7.8%)	
Colitis Ulcerative	4 (6.3%)	0	4 (6.3%)	1 (1.6%)	Only 100 mg AEs ≥5% below this line ↓
Arthralgia	3 (4.7%)	1 (1.6%)	1 (1.6%)	5 (7.8%)	
Vomiting	1 (1.6%)	1 (1.6%)	2 (3.2%)	5 (7.8%)	
Abdominal Pain Upper	0	3 (4.8%)	3 (4.8%)	4 (6.3%)	
Myalgia	0	0	0	5 (7.8%)	

### Characterization of Headache TEAEs:

Most Headache TEAEs

- At treatment initiation
- Transient; most resolved within 7 days
- Mild-to-moderate in severity
- Managed with or without standard medications

# Safety Profile

Consistent with previously observed safety profile

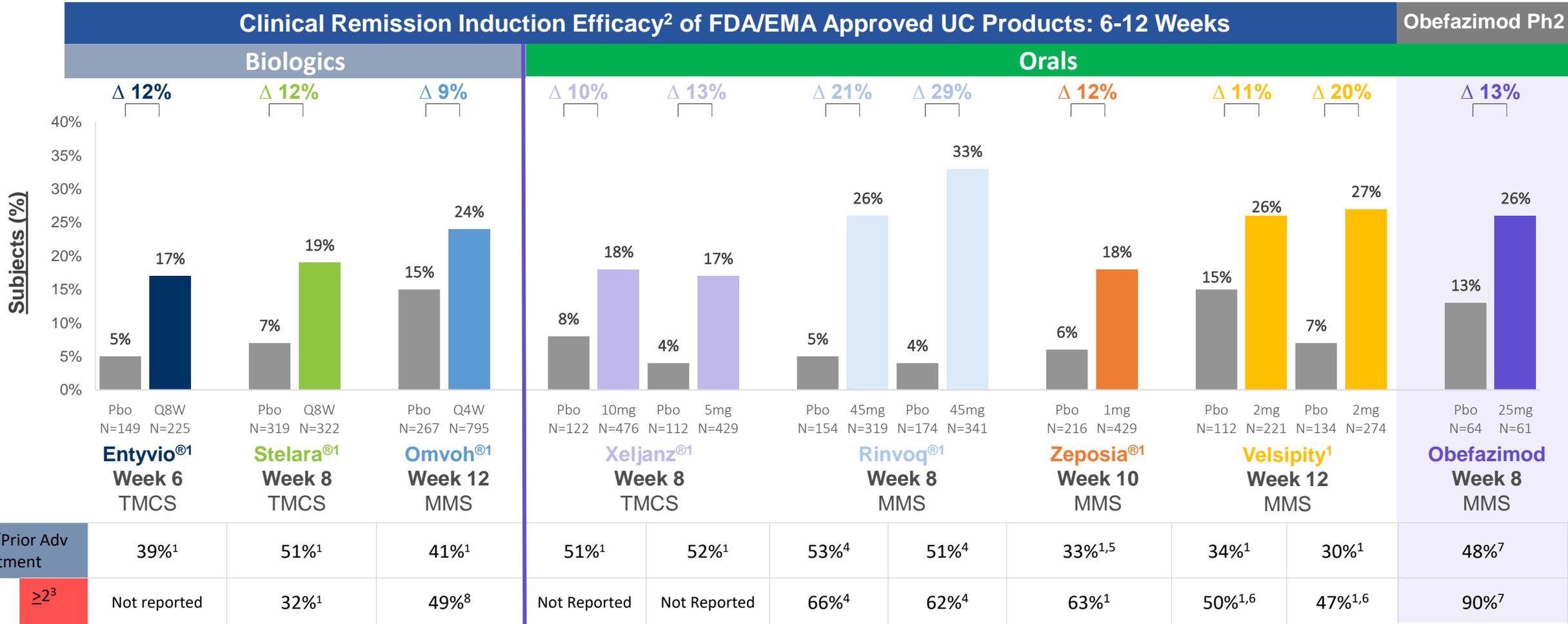
## Obefazimod Safety Overview

	Placebo (N=64)	Obefazimod 25 mg (N=62)	Obefazimod 50 mg (N=63)	Obefazimod 100 mg (N=64)
<b>TEAE Leading to Study Discontinuation</b>	5 (7.8%)	4 (6.5%)	9 (14.3%)	8 (12.5%)
<b>SAEs</b>	4 (6.3%)	1 (1.6%)	4 (6.3%)	4 (6.3%)
<b>Serious Infections</b>	0	0	1 (1.6%)	0
<b>Malignancies</b>	0	0	0	0

- No deaths or malignancies reported and no signal for serious infections; the single discontinuation for serious infections (for the 50-mg dose) was due to appendicitis
- **Labs:** No clinically significant changes in laboratory parameters (liver function tests, Hb, white blood cells) compared to placebo

# Clinical Remission Induction Data

Obefazimod's Phase 2 induction data is competitive vs. approved UC products despite more refractory population



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.

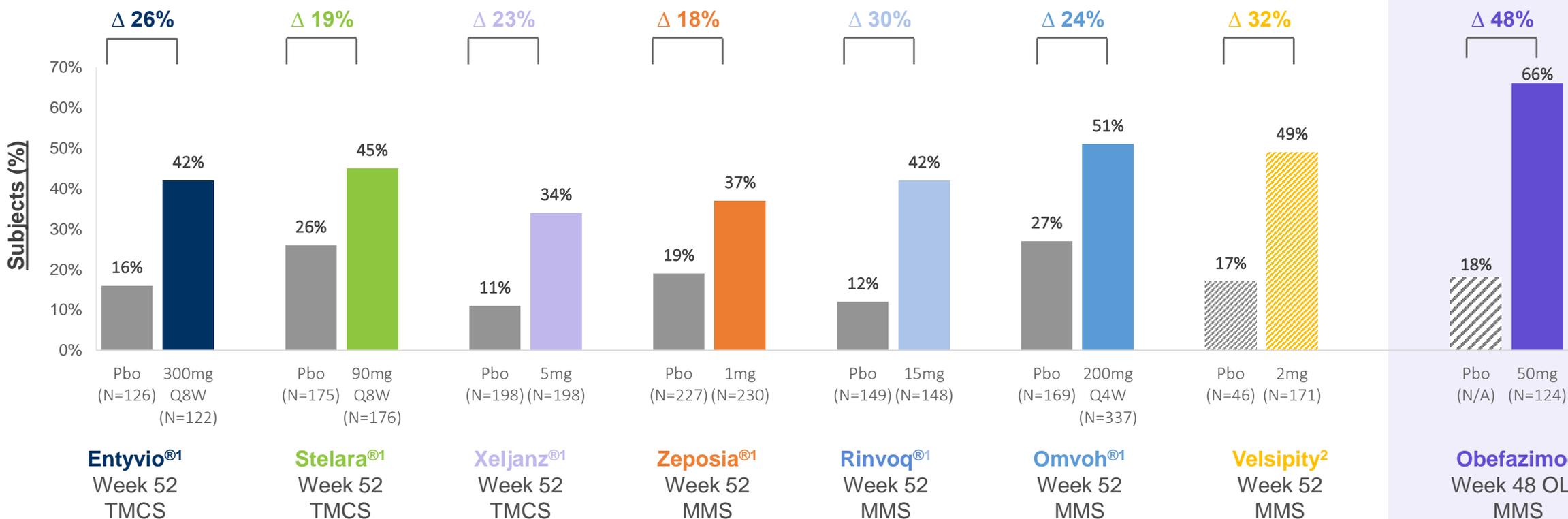
1. FDA package inserts. TCMS = Clinical Remission on 4-Component Mayo Score (TCMS ≤2 with no individual score >1). MMS = Clinical Remission on 3-Component Mayo Score\* (RB=0, SF≤1 with Improvement ≥1, Endo ≤1), MMS\*Current FDA Required Endpoint. 2. All clinical remission efficacy numbers are rounded 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>

# Clinical Remission Maintenance Data At 1 Year

Obefazimod OLE data provides potential read-through to Phase 3 ABTECT maintenance data

## Maintenance Efficacy of FDA Approved UC Products: Clinical Remission\* at 52 Weeks Induction Responders Only

Obefazimod Ph2 OLE  
+ Historic Control PBO Rate<sup>3</sup>



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.

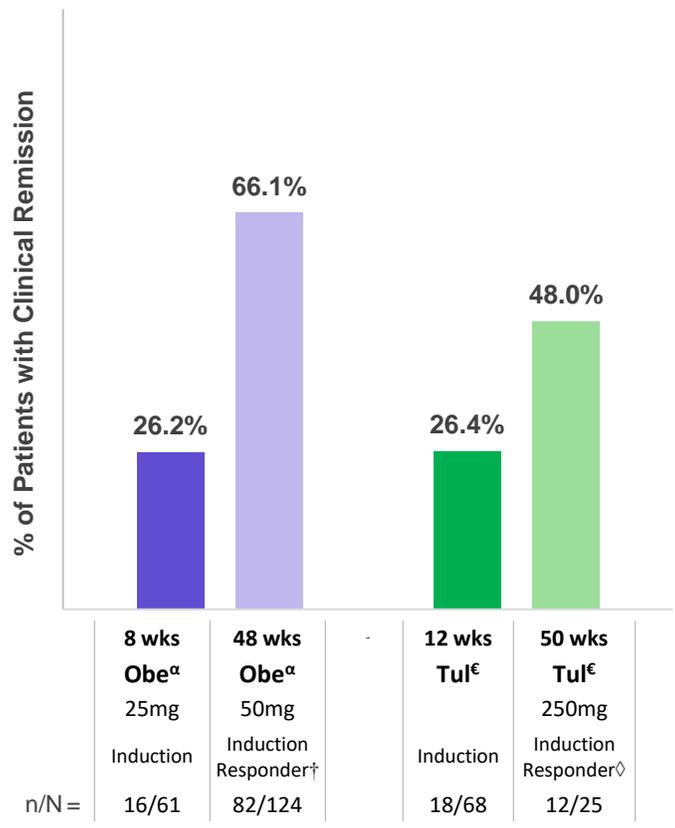
1. FDA package inserts. 2. Clinical remission among week 12 clinical responders; Vermeire et. al., ECCO 2023 Poster #582. 3. Historical placebo rate in maintenance ~18% as reported in a meta-analysis: Sedano R, et al. *J Crohns Colitis*. 2022;16(2):224-243; we did not run the open-label extension trial against a placebo arm, and such a comparison is provided for illustrative purposes only.\* All clinical remission efficacy numbers are rounded to the nearest whole number as reported in FDA prescribing information in package inserts.

# Induction and Open-Label Maintenance in Phase 2b

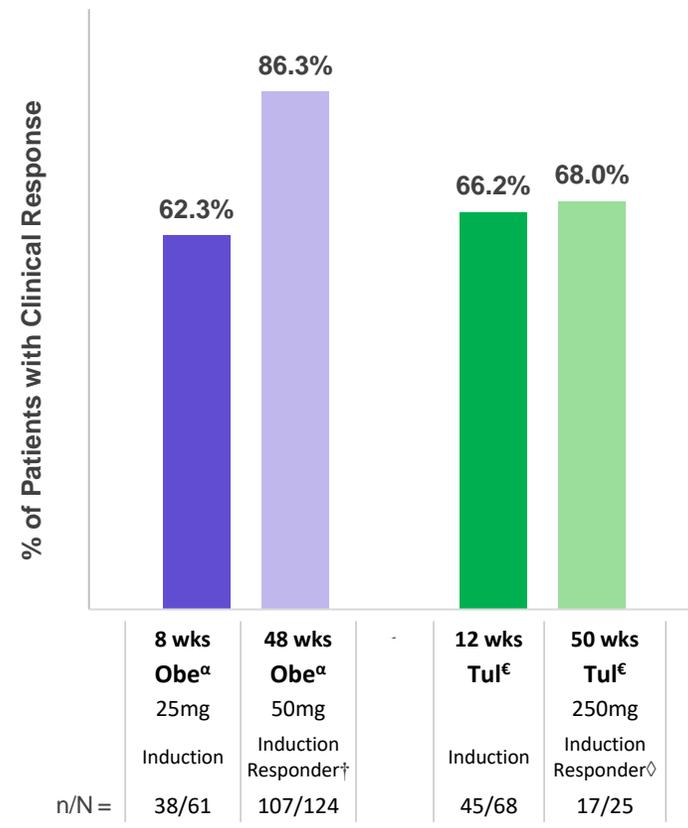
## Obefazimod vs. Merck's TL1A (tulisokibart)



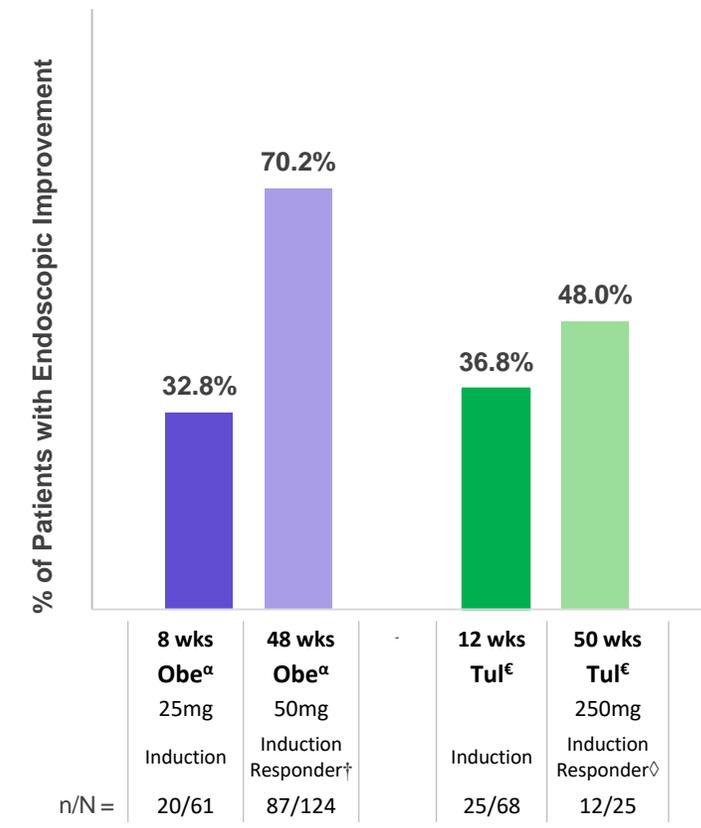
### Clinical Remission



### Clinical Response<sup>‡</sup>



### Endoscopic Improvement<sup>β</sup>



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.

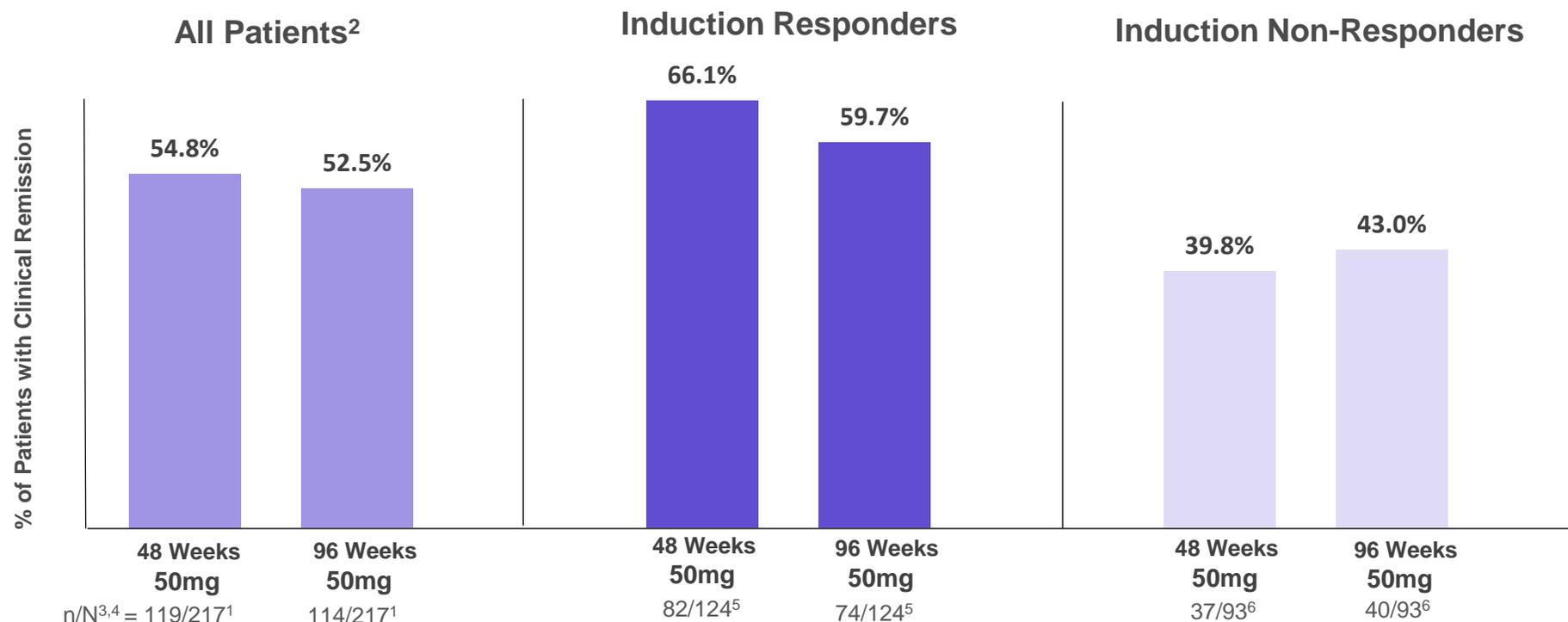
\*250 mg is the high Tul Dose; 100 mg data not shown—lower efficacy rates were achieved  
<sup>†</sup>Induction responders were defined as patients who were treated with any obefazimod dose or placebo and achieved clinical response at week 8 of the obefazimod induction trial and entered the open-label maintenance study  
<sup>∅</sup>Induction responders were defined as patients who were treated with the tulisokibart induction dosing regimen and achieved clinical response at week 8 of the tulisokibart induction trial and entered the open-label maintenance study  
<sup>α</sup> Clinical remission was defined with the modified Mayo Clinic Score; RB=0, ES=0 or 1, SF=0 or 1  
<sup>€</sup> Clinical remission was defined with the modified Mayo Clinic Score; RB=0, ES=0 or 1, SF=0 or 1 with  $\geq 1$  pt improvement from baseline  
<sup>β</sup> Endoscopic improvement was defined as ES of 0 or 1 in both studies  
<sup>‡</sup> Clinical response (per Adapted Mayo Score) is defined as a decrease from baseline in the Modified Mayo Score  $\geq 2$  points and  $\geq 30$  percent from baseline, plus a decrease in RBS  $\geq 1$  or an absolute RBS  $\leq 1$  in both programs  
 Link to IJEGW 2024 Merck abstract: <https://programme.ueg.eu/week2024/#/details/presentations/1076>



# Open-Label Maintenance Study

Clinical Remission at weeks 64 and 112 (16-week induction period + 48wk or 96wk maintenance)

## Clinical Remission Among All Patients and Week 8 Induction Responders (ITT Analysis)



**119 patients in clinical remission at week 48 and 114 in clinical remission at week 96<sup>7</sup>**

Source: Data on File, Abivax.

1. 217/222 eligible patients enrolled into open-label maintenance study. 2. Irrespective of the outcome at the end of the 8-week induction phase. 3. n = Number of patients that met the respective endpoint. 4. N = Number of patients in the relevant analysis set. 5. 124 patients achieved clinical response at end of the 8-week induction phase. 6. 93 patients did not achieve clinical response at end of the 8-week induction phase. 7. From week 48 to week 96, 19 patients began experiencing symptoms of UC again (i.e., were not in clinical remission anymore), and 14 patients achieved clinical remission.

# Obefazimod Phase 2b long-term safety trial in moderately to severely active ulcerative colitis

131 Patients Enrolled



## Phase 2b Long-Term Safety Trial (ABX464-108)

Run-in  
(LTE with obefazimod 50 mg QD)

Maintenance up to 4 years

Yearly Endoscopy

2-Year LTE (ABX464-104) 50 mg QD

4-Year LTE (ABX464-102) 50 mg QD

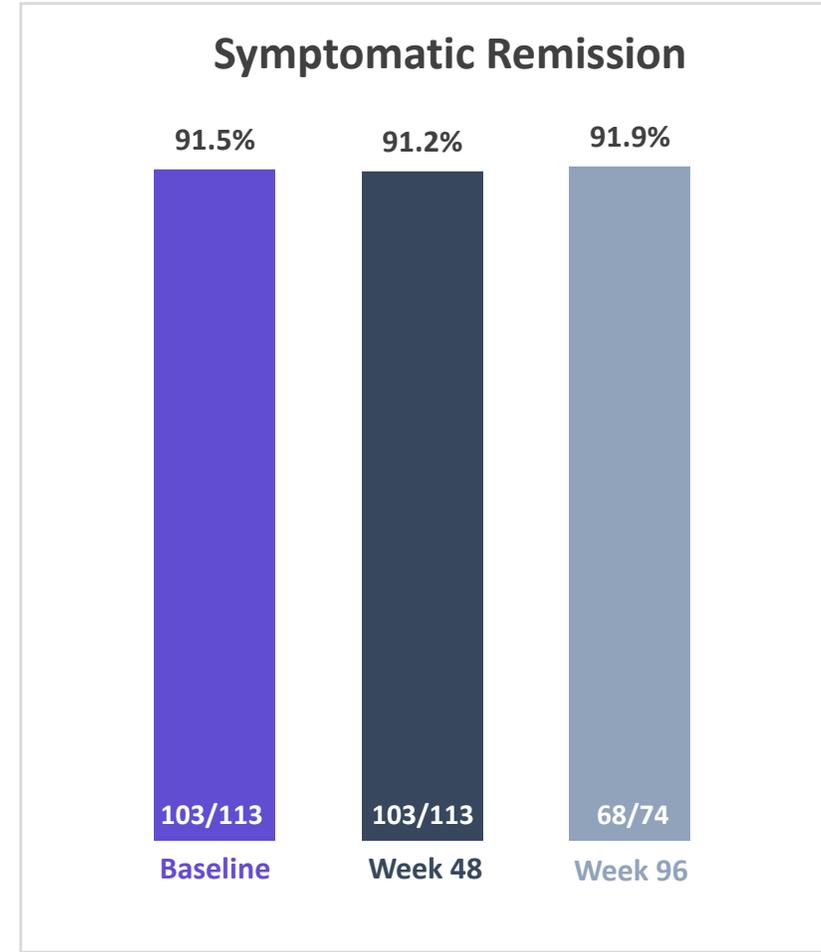
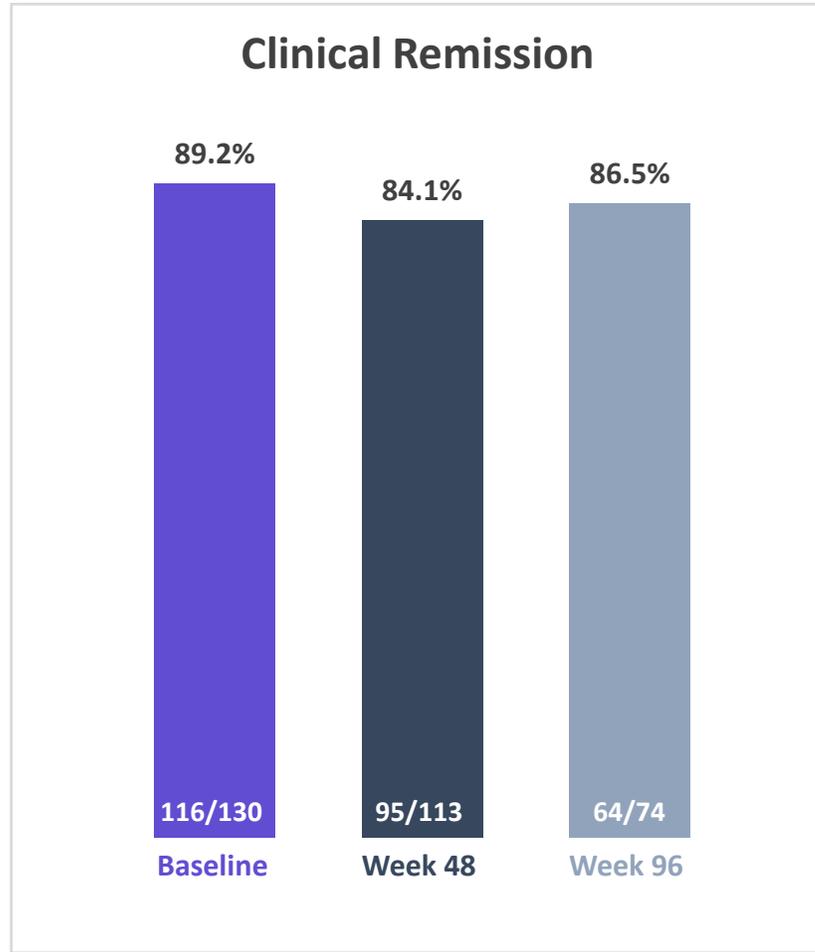
25 mg QD

Only patients with  
MES 0 or 1 were  
eligible

### Interim Analysis (cut-off date September 11, 2024)

- 74 patients dosed with obefazimod 25mg QD evaluated at Week 96
- 113 patients dosed with obefazimod 25mg QD evaluated at Week 48

# Interim Efficacy Results at 3<sup>rd</sup>/4<sup>th</sup> Year (W48) or 5<sup>th</sup>/6<sup>th</sup> Year (W96)



Data are reported in an as observed analysis

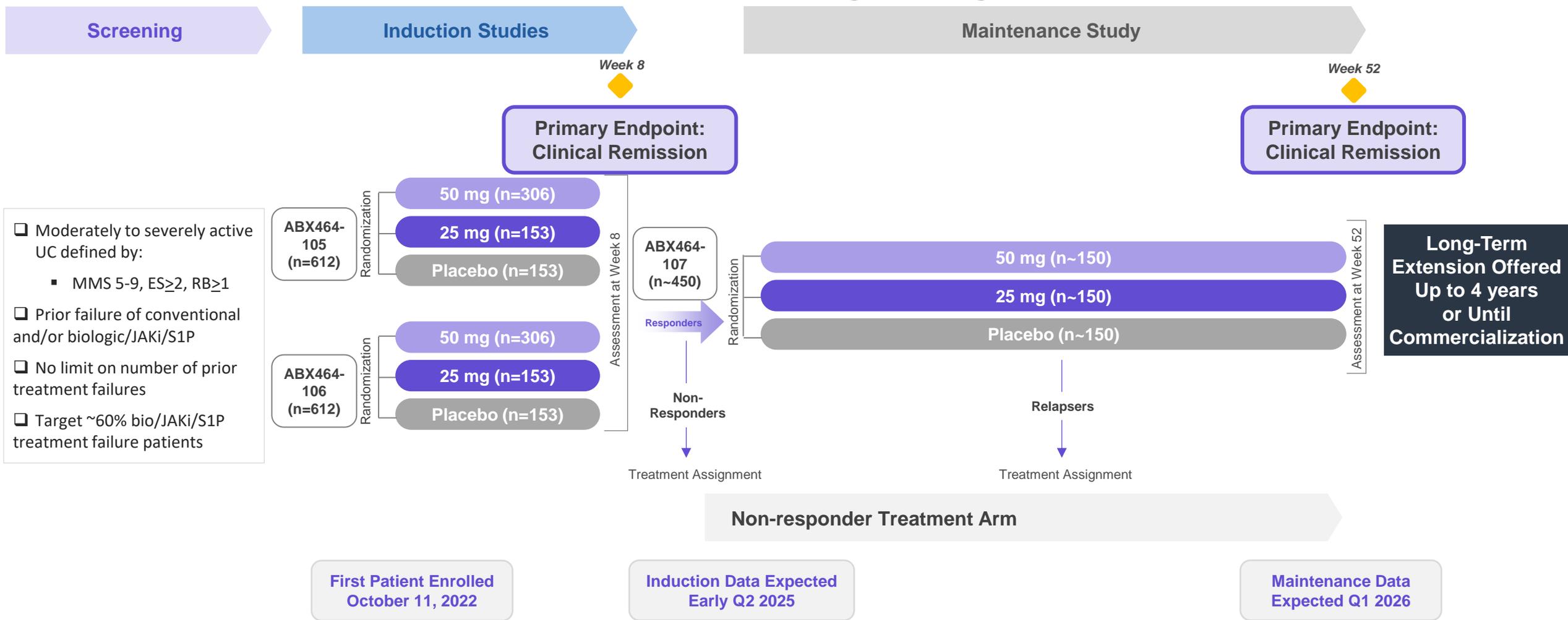
Clinical remission was defined based on the modified Mayo Clinic Score: rectal bleeding subscore of 0, an endoscopic subscore of 0 or 1, and a stool frequency subscore of 0 or 1.

Symptomatic remission was defined based on the modified partial Mayo Clinic Score: rectal bleeding subscore of 0 and a stool frequency subscore of 0 or 1

# ABTECT Phase 3 Program Design: 2 Induction Trials and 1 Maintenance Trial

## Contemporary re-randomization of induction responders

### Ulcerative Colitis Program Design



- Moderately to severely active UC defined by:
  - MMS 5-9, ES $\geq$ 2, RB $\geq$ 1
- Prior failure of conventional and/or biologic/JAKi/S1P
- No limit on number of prior treatment failures
- Target ~60% bio/JAKi/S1P treatment failure patients

# Multiple Initiatives Aimed At De-Risking Phase 3 Execution and Outcomes

ABTECT on pace to complete enrollment in early Q1 2025 with top-line induction readout in early Q2 2025



## Increase Clinical Trial Awareness and Education

- Deployed global team of medical science liaisons (MSLs) to engage and educate study sites
- Site engagement plan includes R&D Leadership visits with investigators and clinical research teams
- Accelerate ABTECT Phase 3 enrollment through expanded global GI congress presence



## Minimize Placebo Response

- Wide diversification of trial sites with no single region accounting for more than ~25%
- Unlike Phase 2b trial, Phase 3 protocol does not allow concurrent treatment with immunomodulators
- Concomitant corticosteroid dose limit reduced from 20 mg in Phase 2b trial to 15 mg in Phase 3 trial



## Drive Consistency of Results from Ph2 to Ph3

- Dropoff in efficacy from Phase 2 to Phase 3 linked to studying more refractory patients in Phase 3 than Phase 2
- Rinvoq's\* efficacy between Phase 2 and Phase 3 remained consistent by studying the same percentage of refractory patients in Phase 2
- Abivax is targeting approximately the same percentage of refractory patients in Phase 3 as studied in Phase 2

600 Study Sites Activated and Creating Strong Momentum in Enrollment Rate

# ABTECT Trial Update

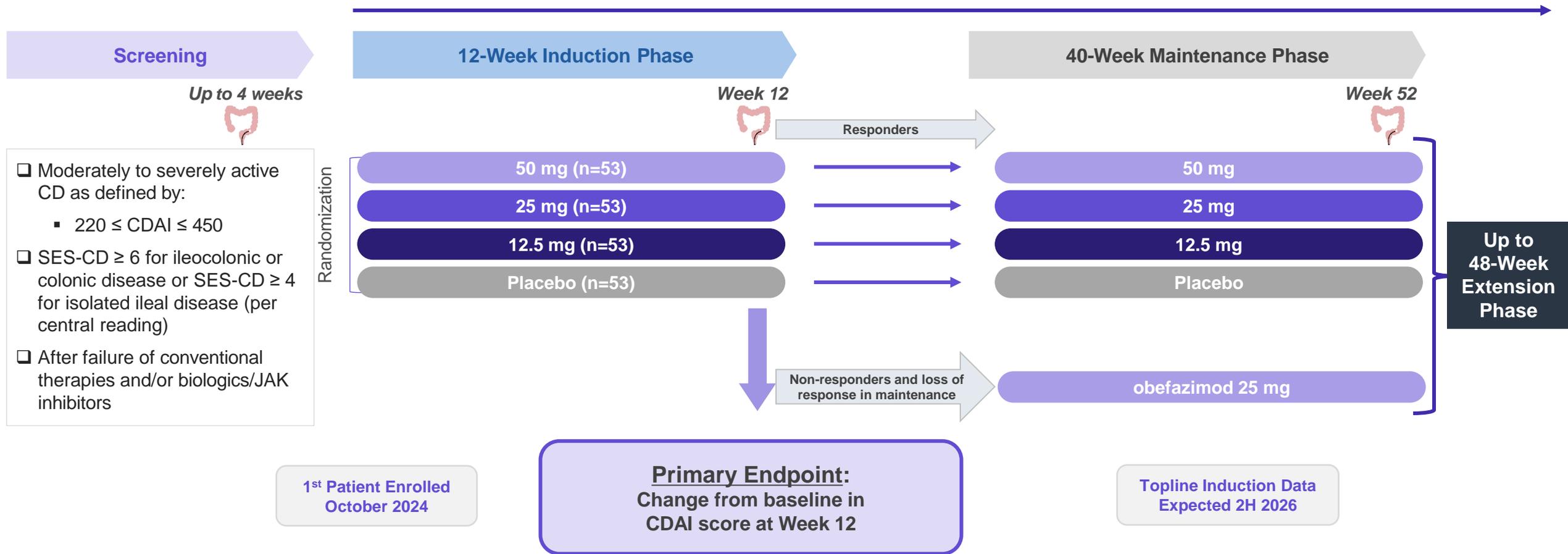
Critical enrollment milestone reached in late July 2024

- Enrolled 600<sup>th</sup> participant putting the trial on pace for full enrollment in early Q1 2025
- Baseline patient characteristics to date in line with targets and consistent with Phase 2b patient population
- Blinded dropout rate and clinical response rates consistent with observations from Phase 2b trial

# ENHANCE CD: Phase 2b Trial Design

## Obefazimod in Crohn's Disease

Total Study Duration: Up to 2 years





# Financial Planning

# Anticipated Key Catalysts Over Next 12 Months

- 2H '24 Combination Data with Additional Therapies
- 2H '24 miR-124 Follow on Compound Announcement
- Q1 '25 Anticipated completion of ABTECT enrollment (Early Q1 2025)
- Q2 '25 Phase 3 UC Induction Topline Data Expected (Early Q2 2025)

2024	2025	
Q4	Q1	Q2
<p style="text-align: center;">★ Combination Data with additional therapies</p> <p style="text-align: center;">★ miR-124 Follow on Compound</p>	<p style="text-align: center;">★ Last patient randomized in ABTECT Ph 3</p>	<p style="text-align: center;">★ Expected Ph 3 Topline Induction Readout Early Q2 2025</p>

# Strong Cash Position Providing Runway Into Q4 2025



## Strategic Initiatives

Existing and New Strategic Initiatives Require Significant R&D Spend

- Beyond **current ABTECT program**, UC Phase 3 **long-term extension**
- Execution of **CD Phase 2b clinical trial**
- Exploration of additional potential clinical development opportunities for obefazimod (**combination therapies**, etc.)
- Selecting an **additional compound from our miR-124 library** by **Q4 2024**



## Organization / US Footprint

Expansion of Clinical and Medical Capabilities, as well as US Footprint

- **Strengthening our organizational structure**, notably in Clinical and Medical capabilities
- **Expanding our US footprint**, and opened a US office in Boston in Q4 2023



## Cash Runway

Cash Runway into Q4'25

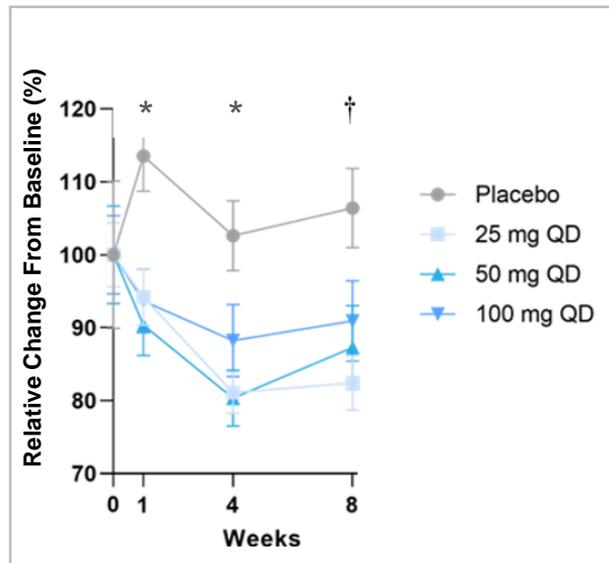
- **Cash (including financial assets)** amounting to €222m as of June 30, 2024
- **Outstanding shares** ~62.9M outstanding shares (Ordinary shares and ADS) as of June 30, 2024.
- **Cash runway into Q4'25** including cash resources and draw-down of €25M Kreos/Claret Tranche B in Q1'2024 and €25M Tranche C in Q2'2024

# Thank You

Nasdaq: ABVX / Euronext Paris: ABVX

# Obefazimod returned pro-inflammatory cytokines IL-17 and IL-23 to homeostatic levels in UC patients

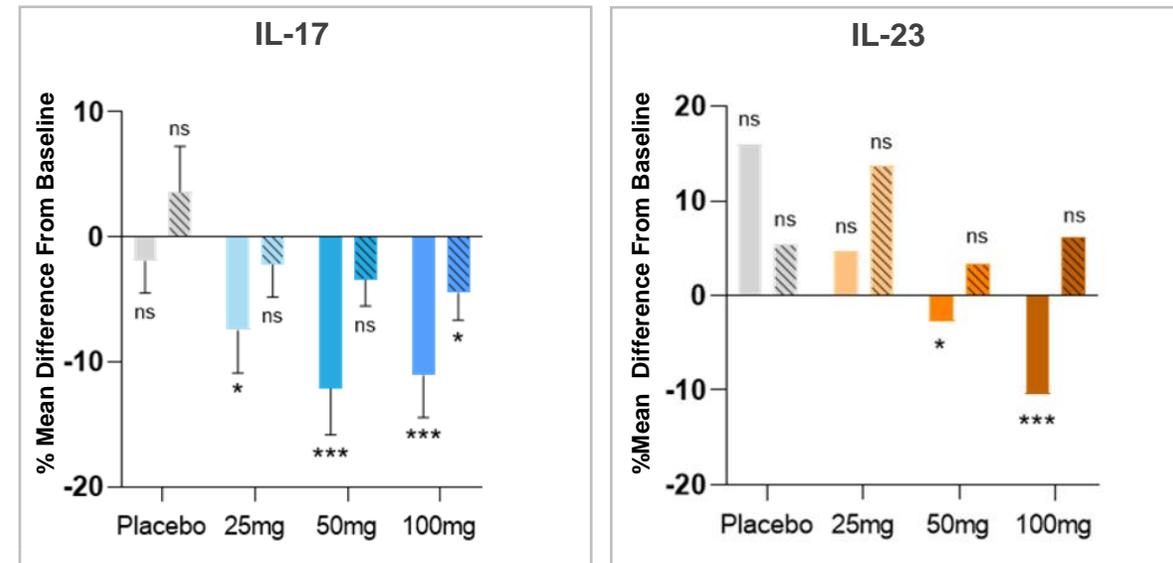
**IL-17 Levels in Blood at Weeks 1, 4 & 8**  
(relative change from baseline, %)



**IL-17 is statistically lower in obefazimod treated subjects at week 1, 4, and 8**

\*p-value <0.01 for all 3 doses  
†p-value <0.01 for 25mg and 50mg only

**IL-17 & IL-23 Levels in Rectal Tissues at Week 8**  
(mean difference from baseline, %)



**Change from baseline in IL-17 is statistically significant with obefazimod 25 and 50 mg and in IL-23 with obefazimod 50 mg**

**Solid Bars:** Patients with a clinical response at week 8  
**Shaded Bars:** Patients without a clinical response at week 8  
\*p<0.05; \*\*p<0.01; \*\*\*p<0.001

# Phase 3 Trial Design Considerations

## Dose Selection and Length of Induction Period

### Rationale for Inclusion of Two Doses in Phase 3 Program:

- 25 mg and 50 mg had similar AE profiles in Phase 2b
- Induction data indicate dose response between 25 and 50 mg for selected endpoints in Phase 2b
- Long term efficacy and safety data for 50 mg, but not 25 mg, available from 2-year open-label maintenance
- Regulatory guidelines encourage studying lowest effective dose in maintenance

### Rationale for 8 Week Induction Period:

- Primary efficacy induction endpoint met at week 8 in Phase 2b trial for both 25 and 50 mg doses
- Positive efficacy trends observed in Phase 2a trial at week 8
- pMMS\* improvements leveled off by week 8 in Phase 2b
- Week 16 data from Phase 2b trial indicate potential for elevated placebo rate by week 16

### Phase 2b Trial Indicates Vast Majority of Symptom Improvement Occurred by Week 8<sup>1</sup>

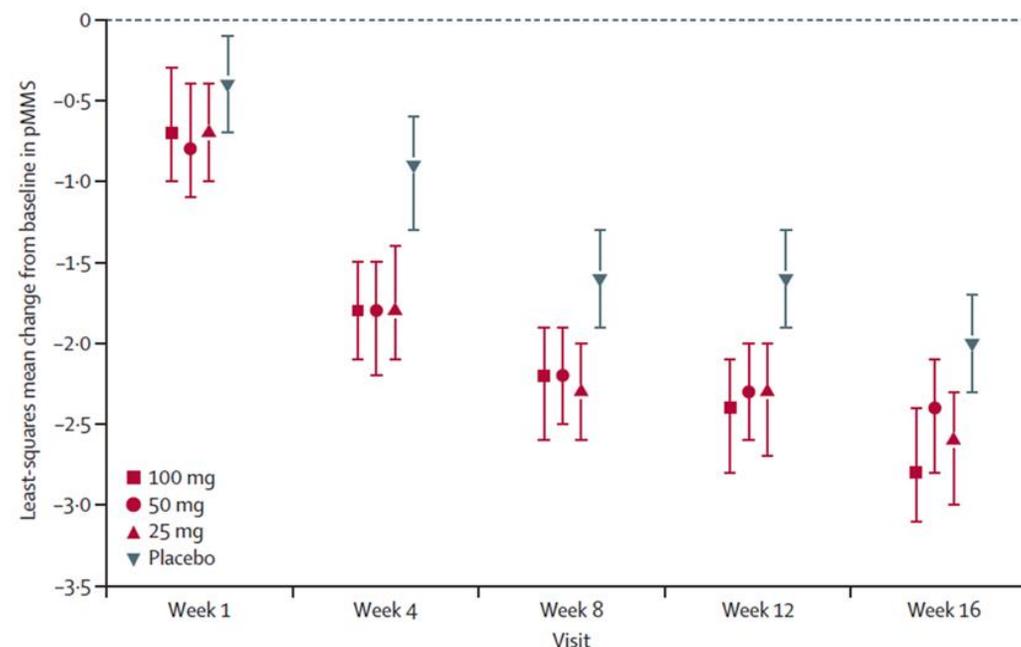


Figure 2: Mean change from baseline in pMMS in full analysis set  
Vertical bars show 95% CIs. pMMS is the sum of assessment scores (0-3) of stool frequency and rectal bleeding. pMMS=partial modified Mayo Score.