

# **Corporate Presentation**

January 2025



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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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# Developing Oral Small Molecule Therapies That Harness the Body's Natural Regulatory Mechanisms



#### 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 in the near term with Phase 3 data in Q3 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 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 2025



# **Abivax Pipeline**

## Anticipated readout of ABTECT 8-Week Induction in Q3 2025

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> <li>Induction trial topline data readout in Q3 2025</li> <li>Maintenance trial topline data readout in Q2 2026</li> </ul>
	Monotherapy	Crohn's Disease (CD)	Phase 2b	<ul> <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> <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> <li>Selection of follow-on compound in 2025</li> </ul>



# ABTECT Study Recruitment: Striking the Balance of Quality and Speed

ABTECT recruitment rate among fastest of recently executed Phase 3 UC trials

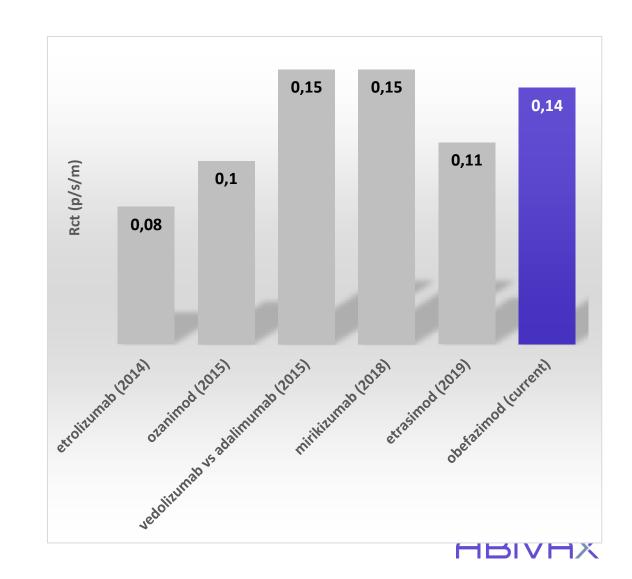
### **January 2025 ABTECT Update**

#### •Randomization Progress:

•1,003 of 1,224 patients randomized to date

#### Baseline Participant Characteristics:

- Aligned with pre-defined study criteria and consistent with Phase 2b population.
- Approximately equal distribution of bio-naive and bio-experienced participants (~50/50).
- Reduced use of corticosteroids among participants.
- Greater regional diversification of study sites.



# Provider and Payer Insights Highlight Significant Need for a Novel Oral Therapy Offering 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

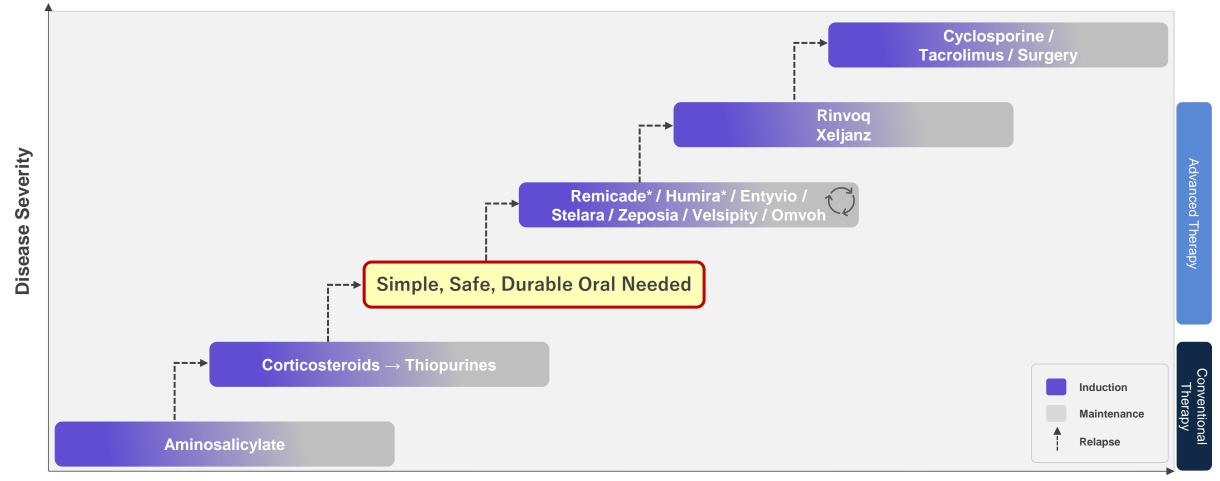
"Currently available agents are ineffective in longterm clinical remission."

US National Health Plan<sup>2</sup>

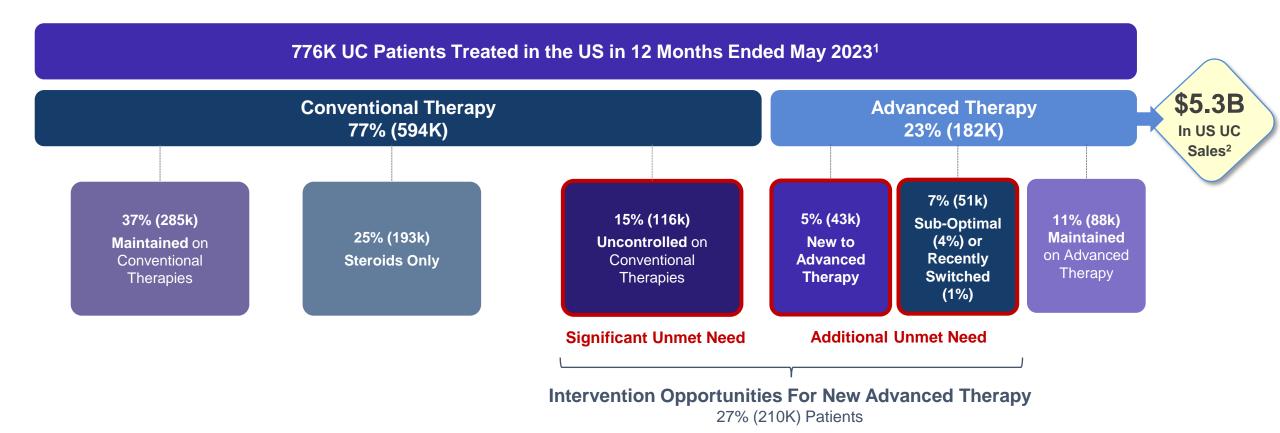


# A Simple, Safe, and Durable Oral Option Could Bridge the Gap Between Conventional and Advanced Therapies

#### **UC Treatment Paradigm with Disease Progression**



# Significant Opportunity for a Simple, Safe, and Durable Therapy to Address Patient Concerns About Stepping up to Advanced Therapy



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.



# Global IBD Sales Set to Climb 45% by 2030, with obefazimod Projected to Emerge as a Leading Advanced UC Therapy (Pending Approval)



#### 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	Obefazimod	miR-124	Abivax		957
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 / Morphic Therapeutics		392
13	RG6631	TL1A	Roche		353
	Other*			2,372	1,022
	Total			~\$7.8B	~\$13.1B





# **Obefazimod Development**

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

Disc	overy	Transition to	Inflammation	Clinical Development		
2009 – 2015		2015 – 2017		2017 – Present		
Obefazimod Discovery	Initial Development in HIV	miR-124 Selectivity	Pre-Clinical POC	MOA Evidence in Humans	UC Phase 3 Clinical Trial Program	
<ul> <li>Obefazimod was co- discovered with</li> </ul>	<ul> <li>Obefazimod was selected by functional</li> </ul>	<ul> <li>Among &gt;1000</li> <li>microRNAs</li> </ul>	<ul> <li>Effective in</li> <li>DSS-induced colitis</li> </ul>	■ Enhanced expression	<ul> <li>Initiation of ABTECT, global Phase 3</li> </ul>	

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

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

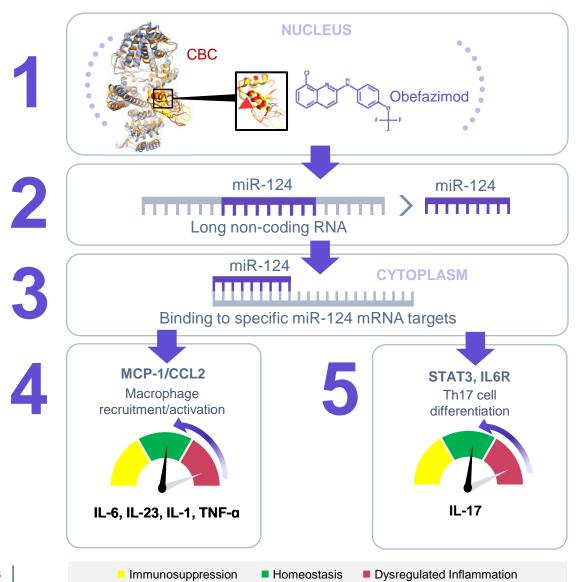
- Effective in DSS-induced colitis mouse model
- Consistent with known miR-124 profile, reduction of inflammatory cytokines and chemokines observed
- Enhanced expression of miR-124 in blood and colonic tissue of UC patients
- Reduction of inflammatory cytokines, including IL-23 & IL-17 in UC patients, and IL-6 in RA patients

 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



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

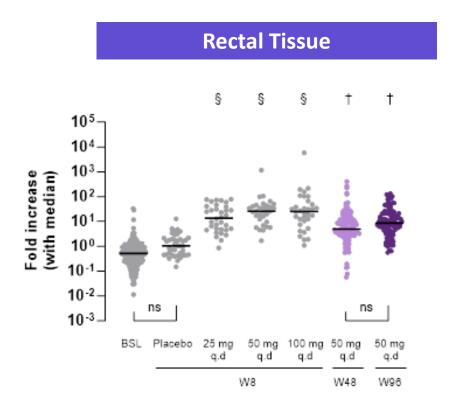
<sup>\*</sup>Cryo-electron microscopy is a technique to determine protein structure 1. Vermeire S, et al. J Crohns Colitis. 2023;jjad067; Data on file. Abivax

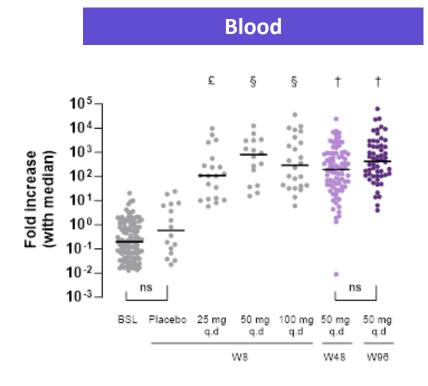


# Phase 2b OLE: Enhanced Expression of miR-124 in Rectal Tissue and Blood Sustained Out to Week 96

#### miR-124 Upregulation

(fold increase, median)





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

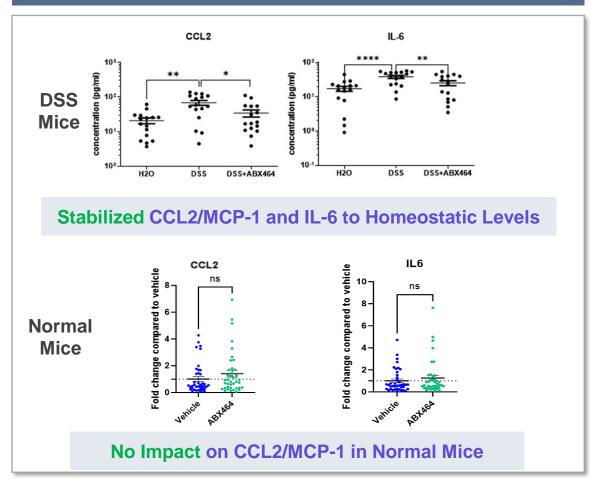
§: p<0.0001 vs. placebo week 8 (induction data)

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

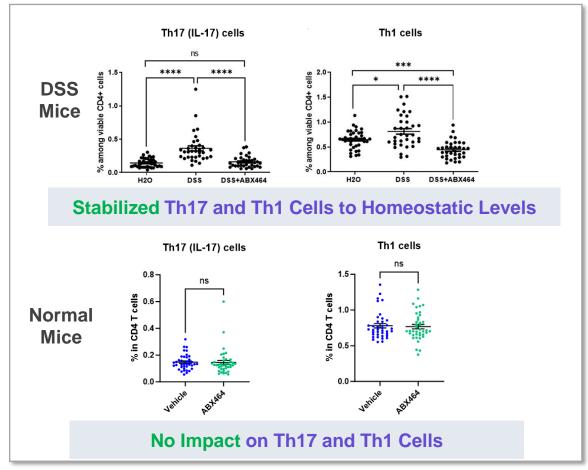


# Obefazimod Stabilizes Chemokines, Cytokines, and Th17/Th1 Cells Under Dysregulated Conditions

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



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





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

#### Patent Protection Expected to Extend from 2035 - 2039



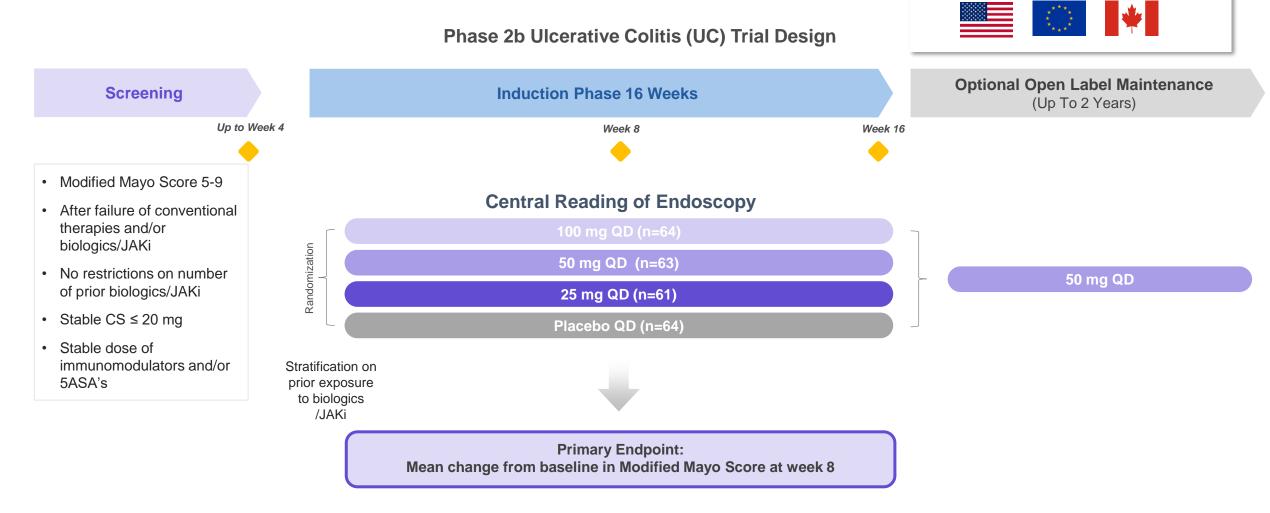


Composition of matter patent or method of use patent (both granted) would extend the product patent protection until 2035 or the use patent until 2040.





# Obefazimod Phase 2b Trial Design in Moderately to Severely Active Ulcerative Colitis



252 Patients - 17 Countries - 130 Sites

## **Baseline Characteristics**

#### Phase 2b UC Clinical Trial

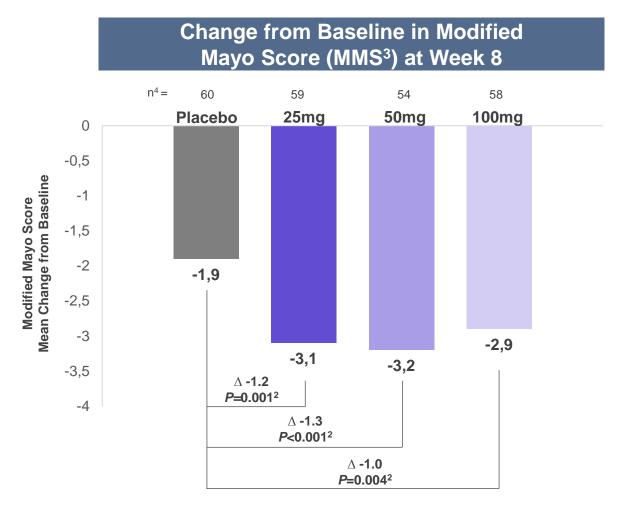
		Placebo	25 mg	50 mg	100 mg
		(n=64)	(n=61)	(n=63)	(n=64)
Modified Mayo Score (MMS)	Mean (SD)	7.0 (1.20)	7.1 (1.09)	7.1 (0.96)	7.0 (1.07)
7 to 9	n (%)	42 (65.6)	44 (72.1)	47 (74.6)	47 (73.4)
Endoscopic Sub-Score = 3	%	75%	67%	75%	66%
<b>Duration of Disease (years)</b>	Mean (SD)	8.8 (6.8)	7.4 (6.8)	8.2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







# **Secondary Efficacy Endpoints**

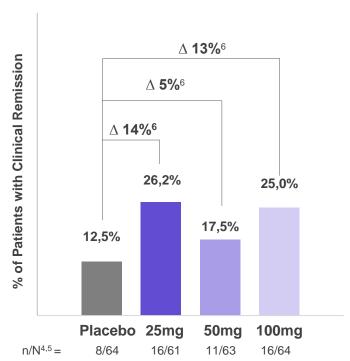
Positive trends observed across all doses

**Secondary Efficacy Endpoints: Week 8\*** 

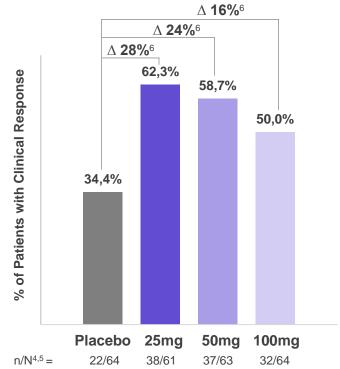
# Placebo response in naïve subgroup:

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

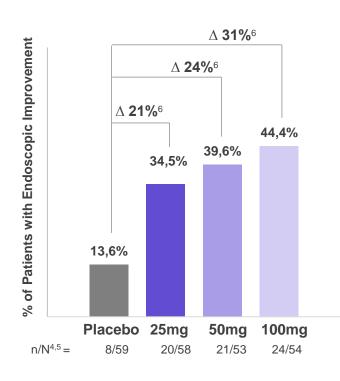
# Clinical Remission<sup>1</sup>



#### Clinical Response<sup>2</sup>



#### **Endoscopic Improvement<sup>3</sup>**



<sup>1.</sup> 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.

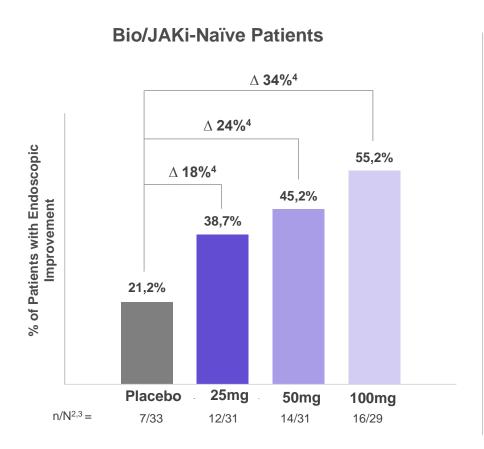


<sup>\*</sup>Study not powered for statistical significance for secondary endpoints. Source: Vermeire S, et al. *Lancet Gastroenterol Hepatol.* 2022;7(11):1024-1034.

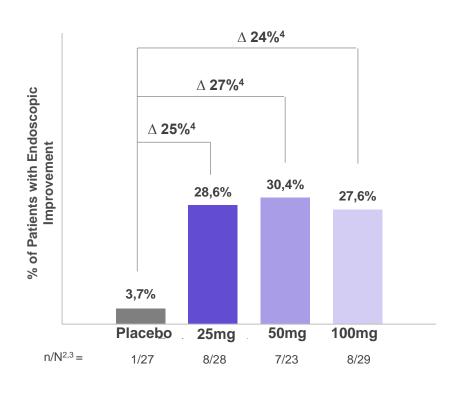
# **Sub-Group Analysis**

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

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



#### **Bio/JAKi-Experienced Patients**



#### Note:

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

Source: Data on File, Abivax.

<sup>\*</sup>Study not powered for statistical significance for sub-group analysis.

**ABIVAX** 

## **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)	
AEs Reported in ≥ 5%	of patients in any treatment group					
Headache	Discontinuation Due to Headache	5 (7.8%) 0 (0%)	13 (21.0%) 1 (1.6%)	19 (30.2%) 3 (4.8%)	27 (42.2%) 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%)	Only 100 mg
Colitis Ulcerative		4 (6.3%)	0	4 (6.3%)	1 (1.6%)	AEs <u>&gt;</u> 5% below this
Arthralgia		3 (4.7%)	1 (1.6%)	1 (1.6%)	5 (7.8%)	line
Vomiting		1 (1.6%)	1 (1.6%)	2 (3.2%)	5 (7.8%)	
<b>Abdominal Pain Upper</b>		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**

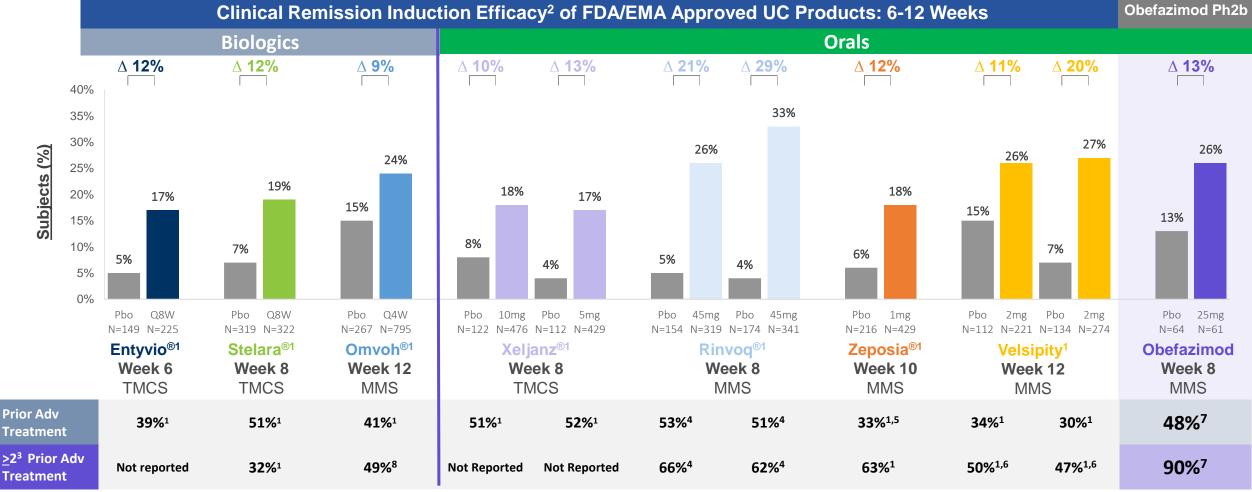
	Placebo (N=64)	Obefazimod 25 mg (N=62)	Obefazimod 50 mg (N=63)	Obefazimod 100 mg (N=64)
TEAE Leading to Study Discontinuation	5 (7.8%)	4 (6.5%)	9 (14.3%)	8 (12.5%)
SAEs	4 (6.3%)	1 (1.6%)	4 (6.3%)	4 (6.3%)
Serious Infections	0	0	1 (1.6%)	0
Malignancies	0	0	0	0

- 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

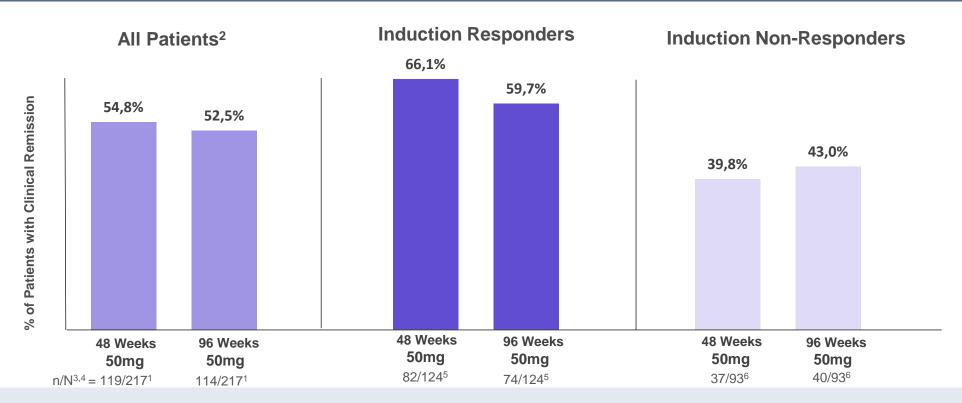


For illustrative purposes only. Not a head-to-head comparison. Differences exist between trial designs and subject characteristics, and caution should be exercised when comparing data across trials.

# **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)

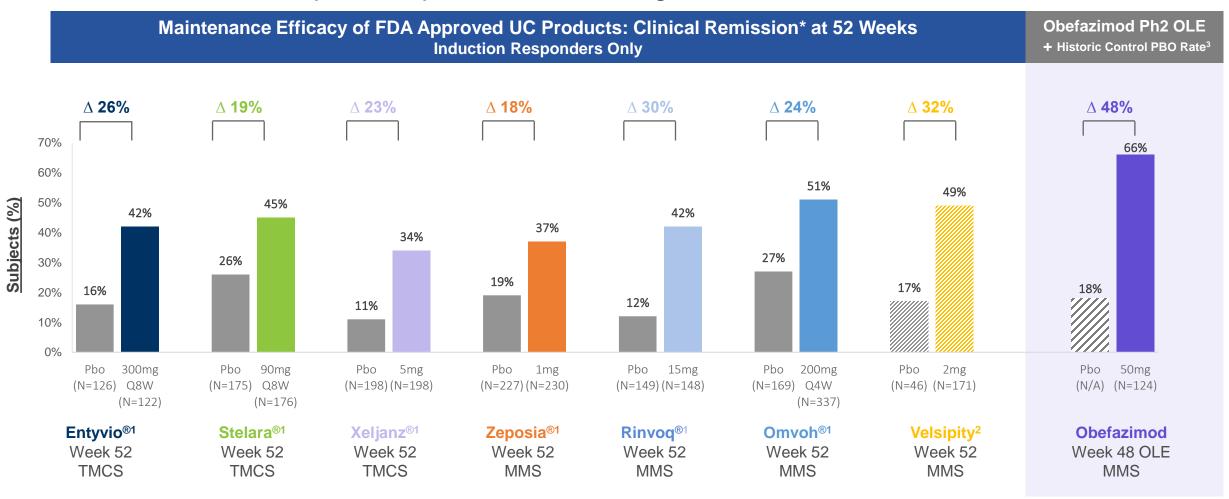


119 patients in clinical remission at week 48 and 114 in clinical remission at week 967



### **Clinical Remission Maintenance Data At 1 Year**

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

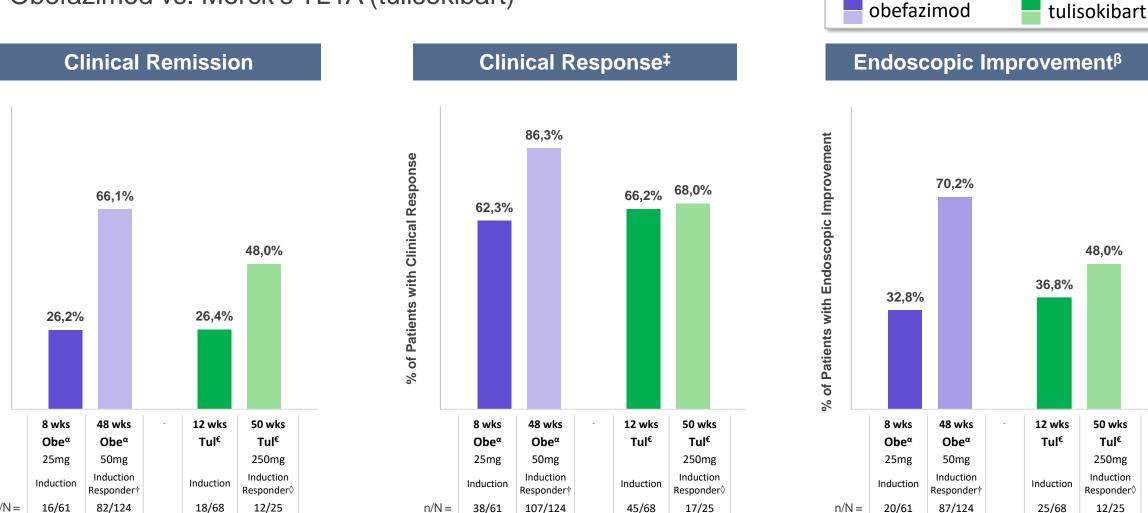


For illustrative purposes only. Not a head-to-head comparison. Differences exist between trial designs and subject characteristics, and caution should be exercised when comparing data across trials.



## **Induction and Open-Label Maintenance in Phase 2b**

Obefazimod vs. Merck's TL1A (tulisokibart)



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.



of Patients with Clinical Remission

<sup>\*250</sup> 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 Olnduction 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  $\alpha$  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 ≥1 pt improvement from baseline

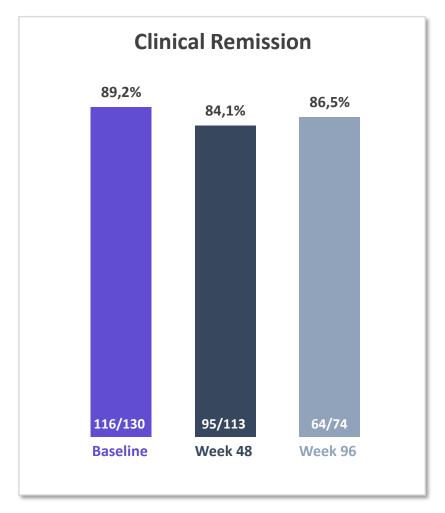
β Endoscopic improvement was defined as ES of 0 or 1 in both studies

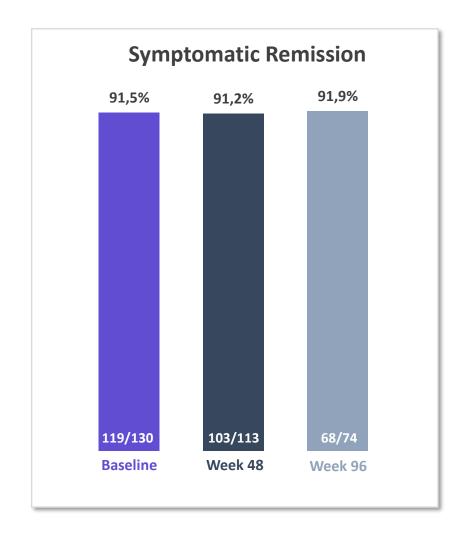
Obefazimod Phase 2b Long-Term Safety Trial in Moderately to Severely Active Ulcerative Colitis

131 Patients Enrolled Phase 2b Long-Term Safety Trial (ABX464-108) Run-in Maintenance up to 4 years (LTE with obefazimod 50 mg QD) Yearly Endoscopy 2-Year LTE (ABX464-104) 50 mg QD 25 mg QD 4-Year LTE (ABX464-102) 50 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)





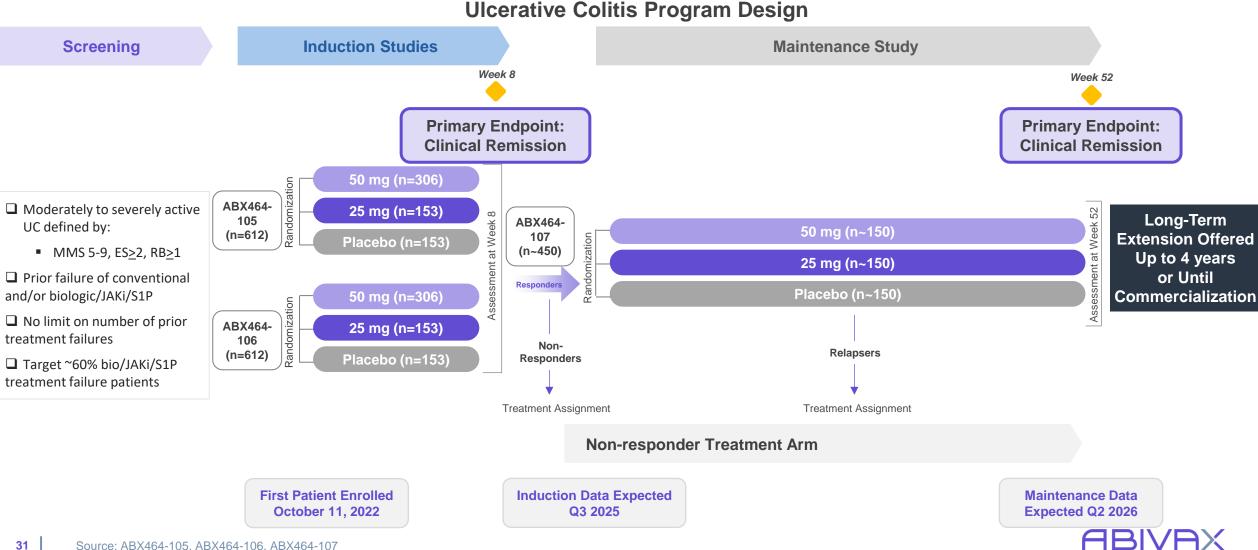
Data are reported in an as observed analysis

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



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

ABTECT on pace to complete enrollment in Q2 2025 with top-line induction readout in Q3 2025

# Increase Clinical Trial **e-e** 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



- 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

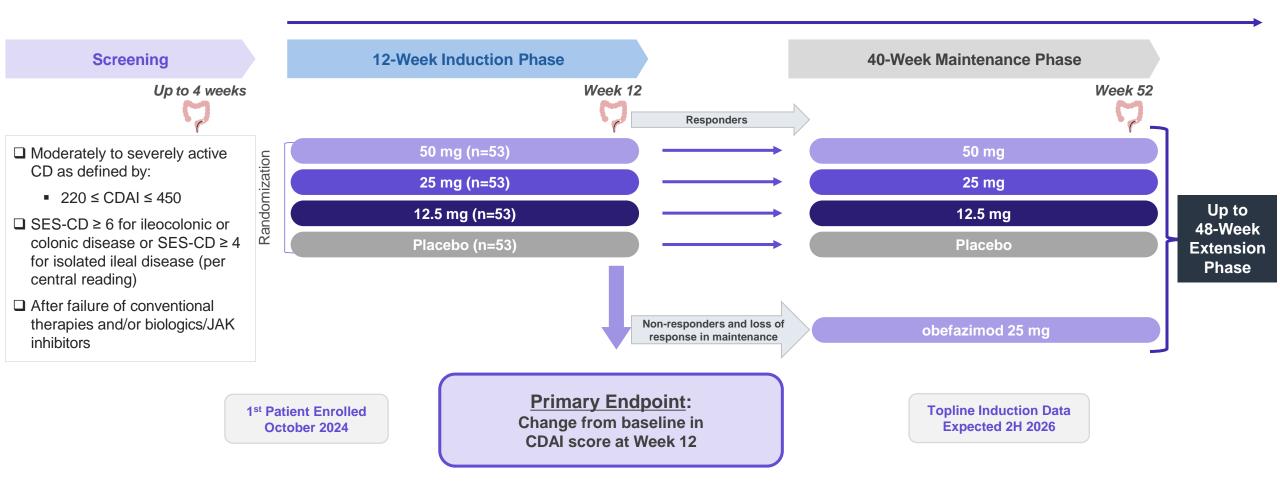
600 Study Sites Activated and Creating Strong Momentum in Enrollment Rate



# **ENHANCE CD: Phase 2b Trial Design**

Obefazimod in Crohn's Disease

**Total Study Duration: Up to 2 years** 







# **Anticipated Catalysts Over Next 12 Months**

- ☐ Q1 '25 Combination Data with Additional Therapies
- ☐ Q1 '25 New obefazimod MOA and cytokine data
- □ Q2 '25 Anticipated Completion of ABTECT enrollment
- □ Q3 '25 Expected Phase 3 UC Induction Topline Data

2025						
Q1	Q2	Q3				
Combination Data with additional therapies  New obefazimod MOA and cytokine data	Last patient randomized in ABTECT Ph 3	Expected Ph 3 topline induction Data readout				



# Cash Position Providing Runway Through Anticipated Induction Data and 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.)



**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 €180.5M as of September 30, 2024
- Outstanding shares ~63.3M outstanding shares (Ordinary shares and ADS) as of Sept 30, 2024.
- Cash runway into Q4'25

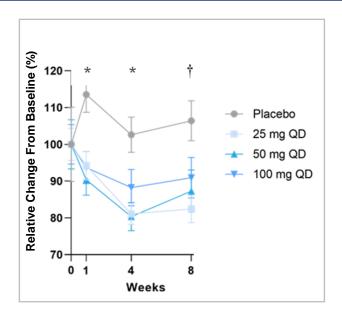


# Thank You

Nasdaq: ABVX / Euronext Paris: ABVX

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

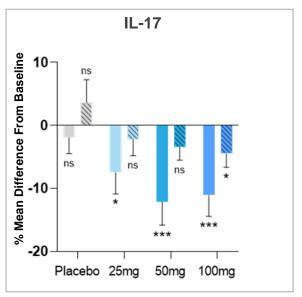
# IL-17 Levels in Blood at Weeks 1, 4 & 8 (relative change from baseline, %)

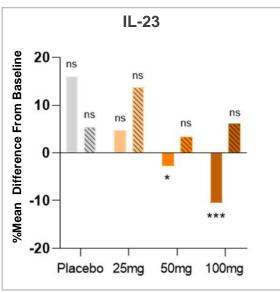


IL-17 is statistically lower in obefazimod treated subjects at week 1, 4, and 8

\*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>

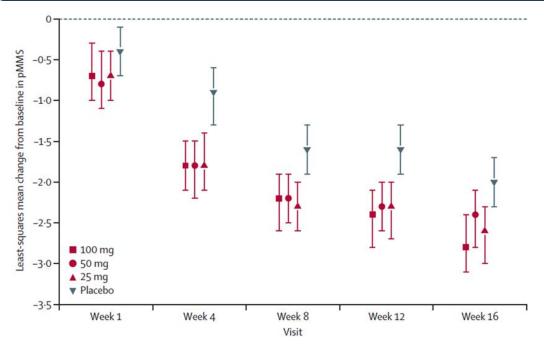


Figure 2: Mean change from baseline in pMMS in full analysis set

Vertical bars show 95% Cls. pMMS is the sum of assessment scores (0–3) of stool frequency and rectal bleeding.

pMMS=partial modified Mayo Score.

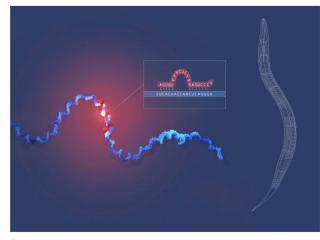


# Obefazimod: A Breakthrough Inspired by Nobel Prize Awarded Research

The Nobel Prize in Physiology or Medicine 2024

# Tiny RNAs with profound physiological importance

Victor Ambros and Gary Ruvkun discovered microRNA, a new class of tiny RNA molecules that play a crucial role in gene regulation. Their groundbreaking discovery in the small worm *C. elegans* revealed a completely new principle of gene regulation. This turned out to be essential for multicellular organisms, including humans. MicroRNAs are proving to be fundamentally important for how organisms develop and function.



© The Nobel Committee for Physiology or Medicine, Ill. Mattias Karlén



The 2024 Nobel Prize in Physiology or Medicine was awarded to Victor Ambros and Gary Ruvkun for their discovery of microRNA & its role in post-transcriptional gene regulation

- microRNA-124 (miR-124) is a natural regulator that influences how our genes behave, affecting various processes, including those related to the immune system
- Obefazimod works by enhancing miR-124 expression
- In immune inflammatory conditions such as ulcerative colitis (UC) obefazimod-induced enhanced expression of miR-124 leads to the stabilization of the dysregulated inflammatory response present in UC.



# **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 Demonstrated Synergistic Effects

