

# **Corporate Presentation**

April 2024



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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," "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. Readers are cautioned not to place undue reliance on these forward-looking statements.

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



#### Establish obefazimod as a potential 1st 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)
- Initiation of a Phase 2b clinical trial in Crohn's disease is expected in Q3 2024, and exploration of potential combination therapy opportunities in UC is ongoing



#### Disrupt the IBD landscape in the near term with Phase 3 data beginning in 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 as observed in Phase 2 trials



#### 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 Q3 2024



# Experienced leadership team in the development and commercialization of therapeutics for chronic inflammatory diseases



Marc de Garidel, MBA Chief Executive Officer & Interim Board Chair









**Didier Blondel** Chief Financial Officer & **Corporate Secretary** 





Sheldon Sloan. M.D., M. Bioethics **Chief Medical Officer** 







**Ida Hatoum** Chief People Officer







Michael Ferguson, **MBA Chief Commercial Officer** 









**Pierre Courteille** Pharmacist, MBA Chief Business Officer







Didier Scherrer, Ph.D. Chief Scientific Officer









Jérôme Denis, Ph.D. EVP, Process Dev. & Manufacturing





Competencies from discovery to global commercialization



#### **Board of Directors**

International expertise and experience across North America and the EU



Marc de Garidel, MBA Chief Executive Officer & Interim Board Chair









Troy Ignelzi Chair of the Audit Committee rapport ( KARUNA CINCOR ESPERION<sup>®</sup>



June Lee, M.D. FACCP Chair of the Appointments and Compensation Committee





Corinna zur Bonsen-**Thomas** 



Shire



Baxalta







\*

**Professor Carol** Brosgart, M.D.











**Camilla Soenderby** 





Roche



scPharmaceuticals







Philippe Pouletty, M.D.











Kinam Hong, M.D., MBA, CFA

















### Financial Overview

#### Backed by top-tier US and European investors















~66%

of current shares held by 15 largest shareholders<sup>1</sup>

~66%

Of shares (ordinary shares and ADS's) held by US investors<sup>1</sup>

Abivax has been publicly traded on Euronext Paris since June 2015 and on Nasdaq since October 2023



### Abivax Pipeline

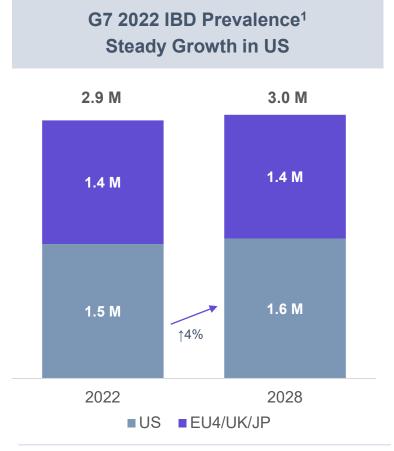
Actively exploring broad development options for obefazimod and follow-on compounds

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 Q1 2025</li> <li>Maintenance trial topline data readout in Q1 2026</li> </ul>
	Monotherapy	Crohn's Disease (CD)	Phase 2b Trial Planned	<ul> <li>IND filed Q4 2023</li> <li>Initiate Phase 2b trial in Q3 2024 (first patient in)</li> <li>Phase 2b induction topline results expected in 2H 2026</li> </ul>
	Combination Therapy	Moderately to Severely Active Ulcerative Colitis (UC)		<ul> <li>Preclinical data to support decision-making on combination agent expected in 2H 2024</li> <li>Decision on combination agent expected in 2025¹</li> </ul>
	Monotherapy	Other Inflammatory Indications		<ul> <li>Declare indication for PoC trial in 2024</li> </ul>

Follow-on drug candidate expected to be selected from optimized compound library in Q3 2024

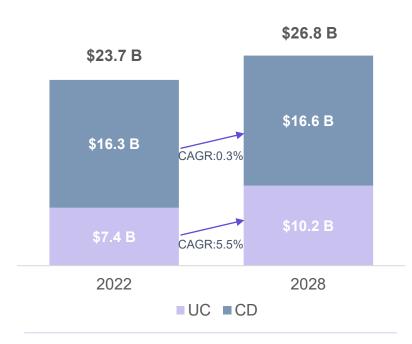


### Inflammatory bowel disease is an attractive and growing market



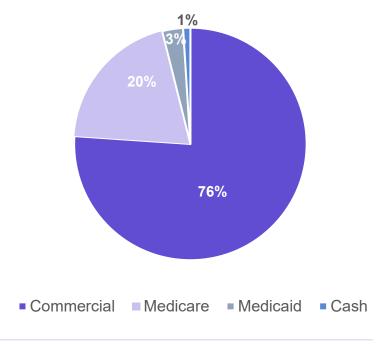
IBD prevalence expecting modest 4% growth over the next 6 years in the US





UC market growth driven by patients stepping up to advanced therapies earlier

US UC Payer Mix<sup>2</sup>
Large Commercial Opportunity in US



The majority of UC patients are covered by commercial insurance in the US



# 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

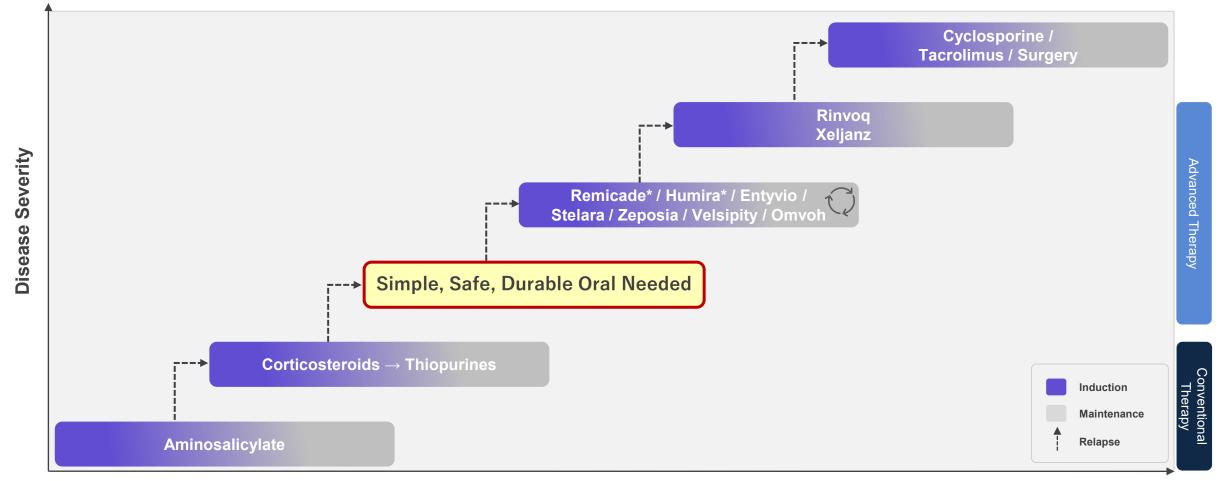
"Currently available agents are ineffective in longterm clinical remission."

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

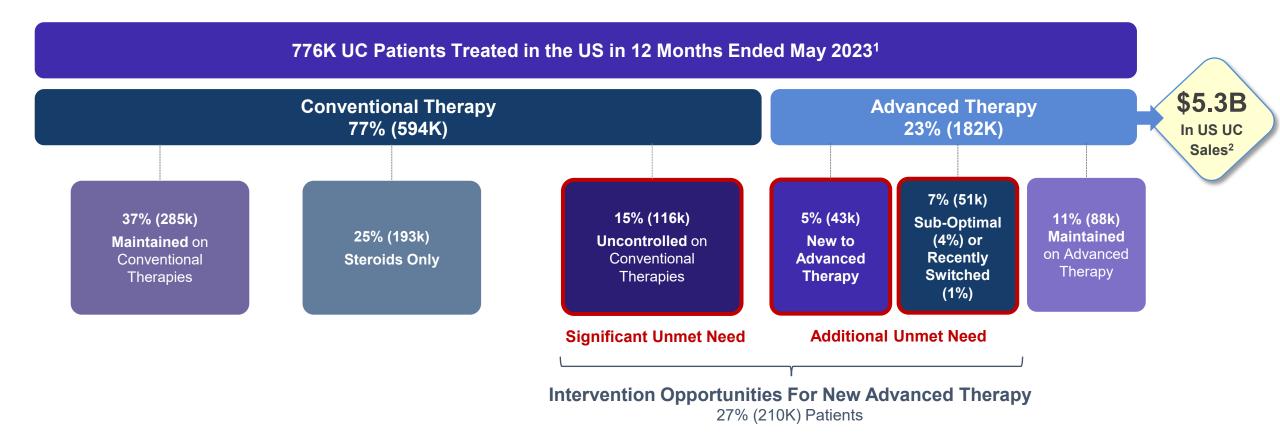


# A simple, safe, and durable oral option would help shorten the gap between conventional and advanced therapies

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



# Sizable opportunity exists for a simple, safe, and durable therapy that alleviates patients' 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.



# We are executing a strategy with the goal of extending obefazimod'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



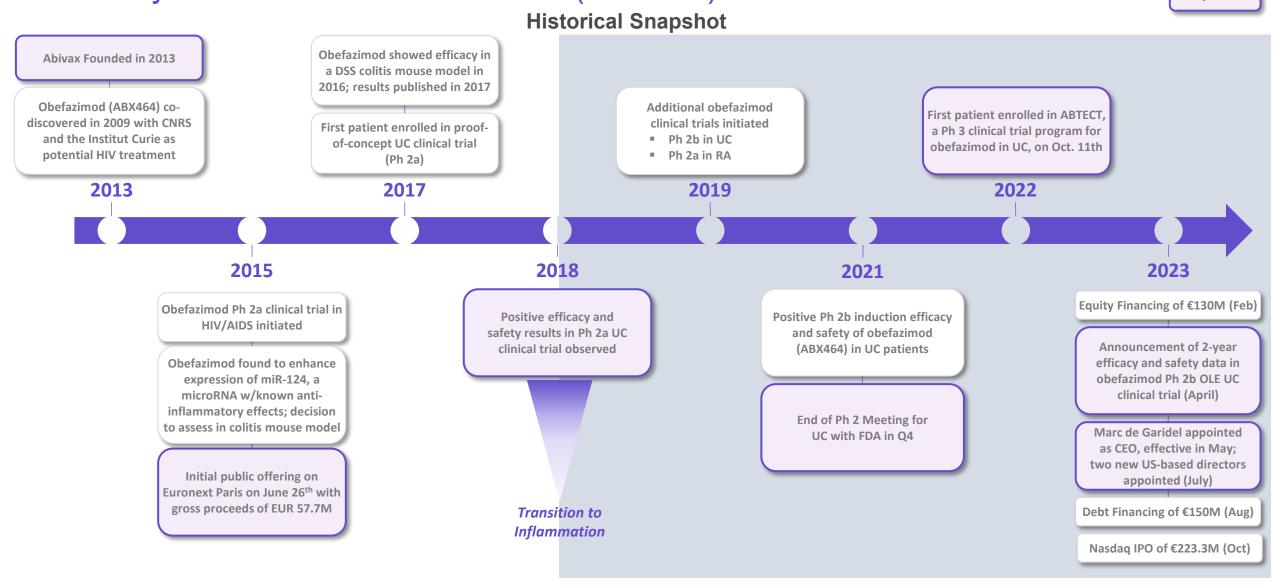
Composition of matter patent or method of use patent (both granted) would extend the product patent protection until 2035 or the use patent until 2040.





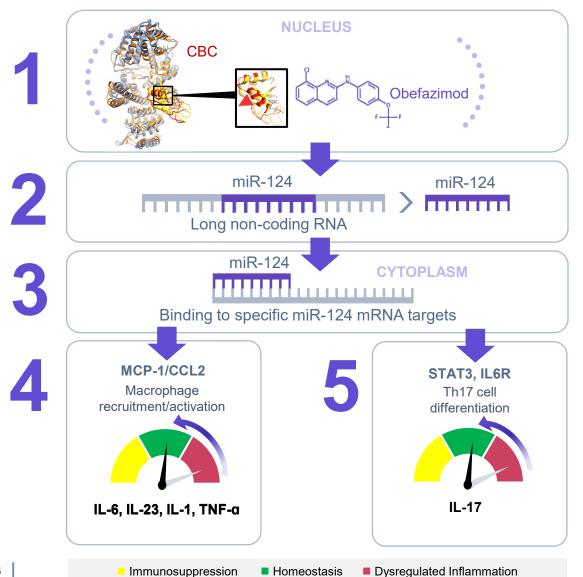
# The transition of Abivax to IBD was prompted by significant anti-inflammatory activity observed with obefazimod (ABX464)

**Key Event** 





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



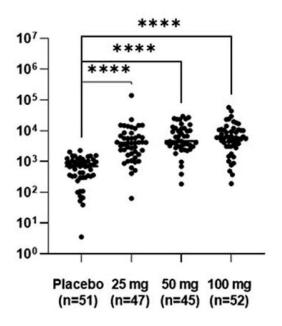
- Obefazimod binds to cap binding complex (CBC) within the nucleus; demonstrated by cryo-electron microscopy\* (CryoEM)
- Induces selective splicing of a single, long, non-coding RNA, leading to enhanced expression of miR-124
- miR124 binds to its specific mRNA targets in the cytoplasm, reducing the 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



# Obefazimod demonstrated enhanced expression of miR-124 in the blood and rectal tissue in UC Phase 2b patients

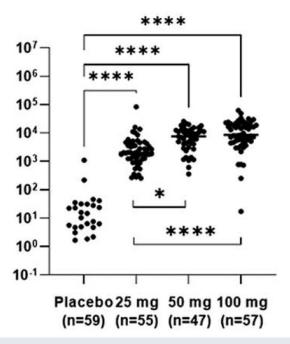
#### miR-124 Levels in Blood at Weeks 8



miR-124 expression in the blood is statistically higher with obefazimod compared with placebo after 8 weeks

\*p<0.05 \*\*\*p<0.001 \*\*\*\*p<0.0001

#### miR-124 Levels in Rectal Tissue at Week 8

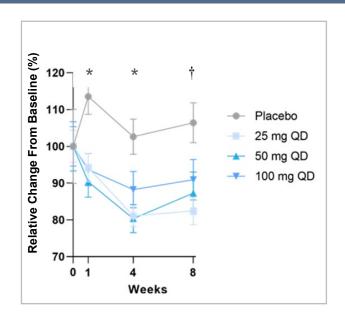


miR-124 expression in the rectal tissue is statistically higher with obefazimod compared with placebo after 8 weeks



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

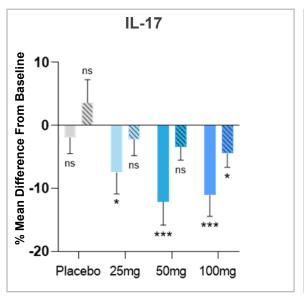
# IL-17 Levels in Blood at Weeks 1, 4 & 8 (relative change from baseline, %)

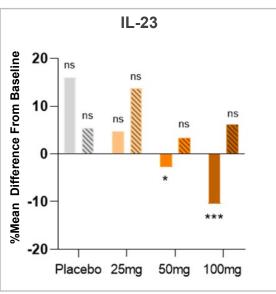


IL-17 is statistically lower in obefazimod treated subjects at week 1, 4, and 8

\*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, %)





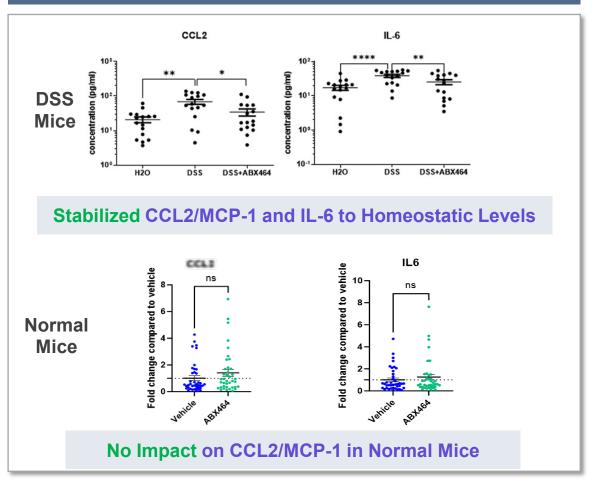
Change from baseline in IL-17 is statistically significant with obefazimod 25 and 50 mg and in IL-23 with obefazimod 50 mg

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

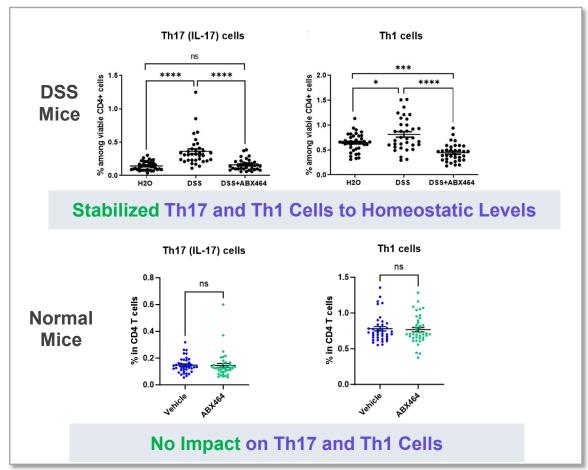


# Obefazimod stabilizes chemokines, cytokines, and Th17/Th1 cells only under dysregulated conditions

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



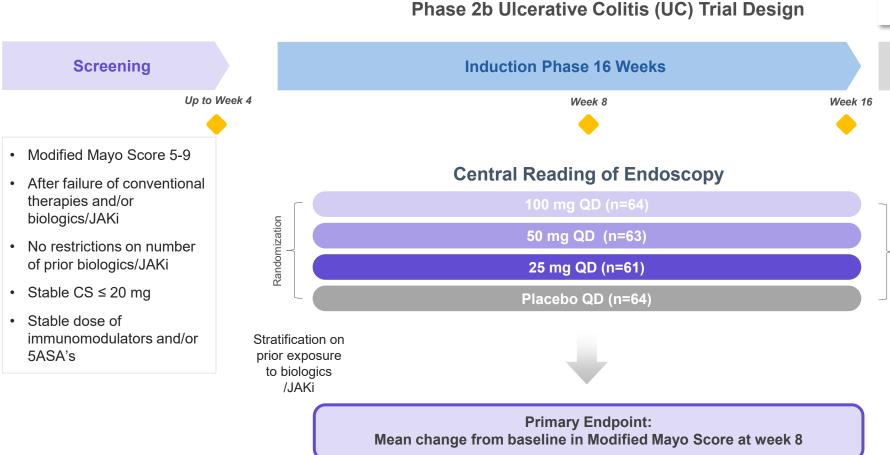
# Effects of Obefazimod on CD4+ Subsets in Mesenteric Lymph Nodes in DSS and Normal Mice







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





Optional Open Label Maintenance (Up To 2 Years)

50 mg QD



### **Baseline Characteristics**

#### Phase 2b UC Clinical Trial

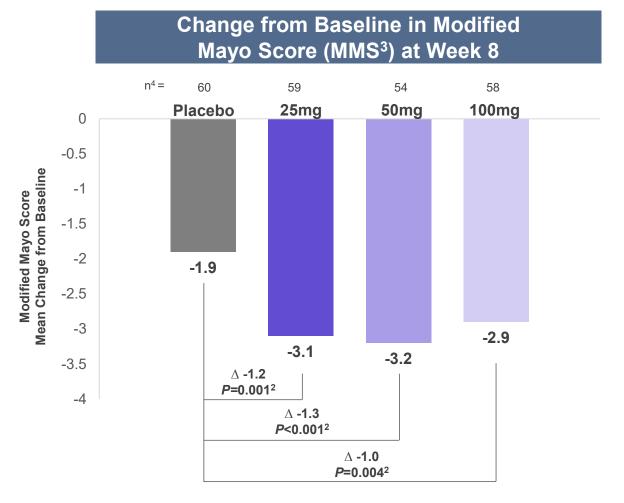
		Placebo	25 mg	50 mg	100 mg
		(n=64)	(n=61)	(n=63)	(n=64)
Modified Mayo Score (MMS)	Mean (SD)	7.0 (1.20)	7.1 (1.09)	7.1 (0.96)	7.0 (1.07)
7 to 9	n (%)	42 (65.6)	44 (72.1)	47 (74.6)	47 (73.4)
Endoscopic Sub-Score = 3	%	75%	67%	75%	66%
<b>Duration of Disease (years)</b>	Mean (SD)	8.8 (6.8)	7.4 (6.8)	8.2 (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







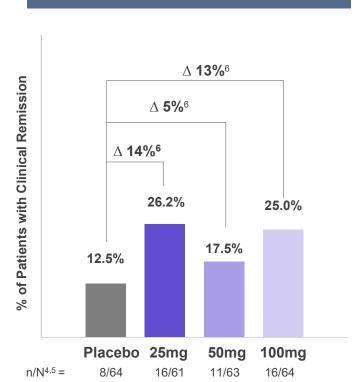
## **Secondary Efficacy Endpoints**

#### 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>

# 

25mg

38/61

Placebo

22/64

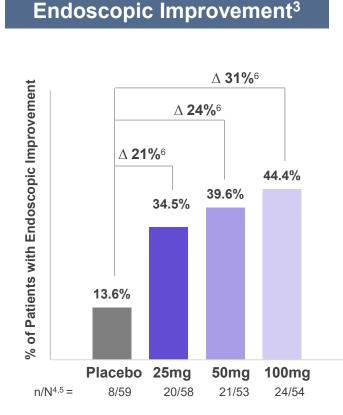
 $n/N^{4,5} =$ 

50mg

37/63

100mg

32/64



<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.

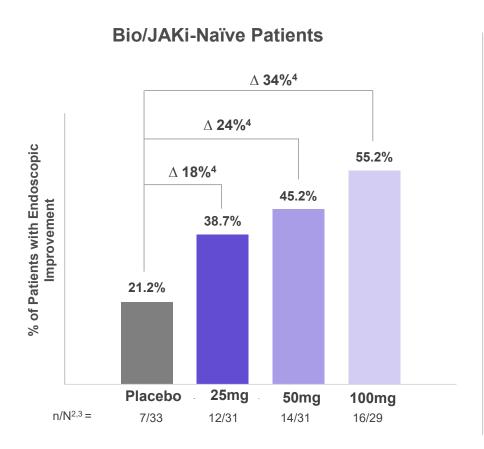


<sup>\*</sup>Study not powered for statistical significance for secondary endpoints. Source: Vermeire S, et al. *Lancet Gastroenterol Hepatol.* 2022;7(11):1024-1034.

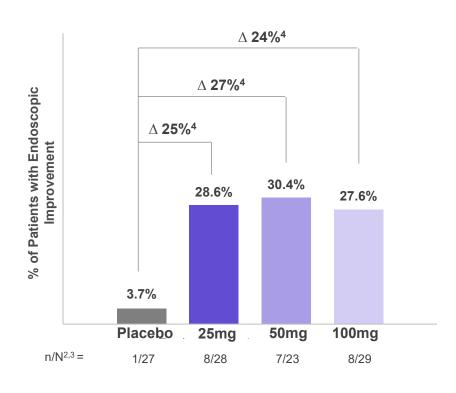
## **Sub-Group Analysis**

### 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

## 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 n
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**

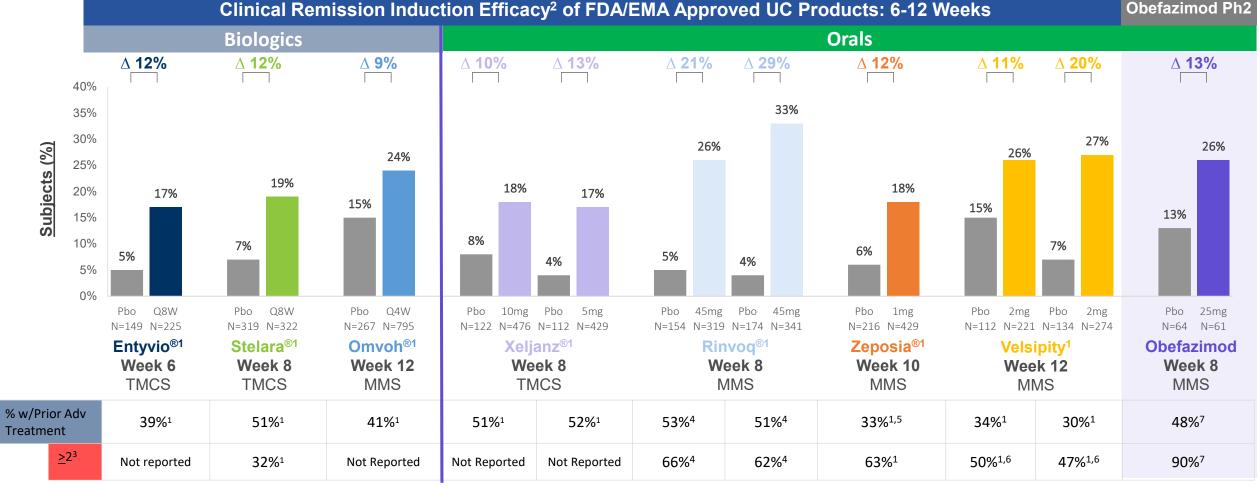
	Placebo (N=64)	Obefazimod 25 mg (N=62)	Obefazimod 50 mg (N=63)	Obefazimod 100 mg (N=64)
TEAE Leading to Study Discontinuation	5 (7.8%)	4 (6.5%)	9 (14.3%)	8 (12.5%)
SAEs	4 (6.3%)	1 (1.6%)	4 (6.3%)	4 (6.3%)
Serious Infections	0	0	1 (1.6%)	0
Malignancies	0	0	0	0

- 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



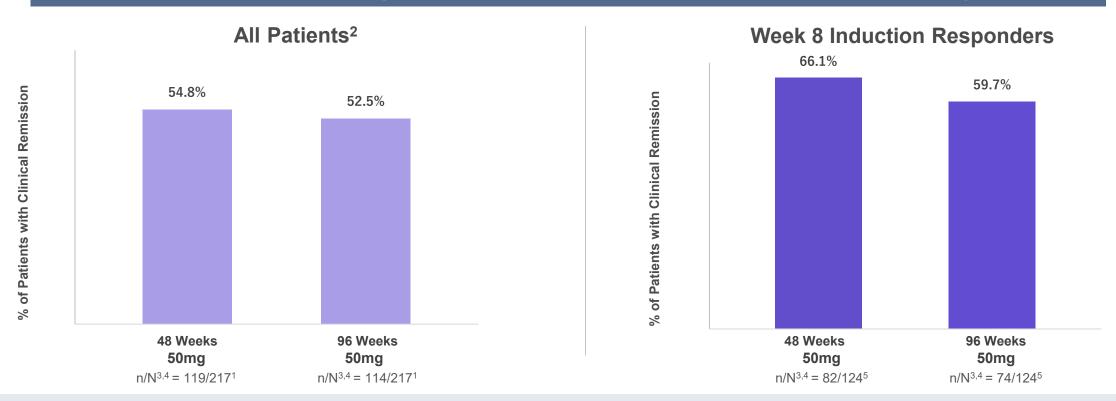
For illustrative purposes only. Not a head-to-head comparison. Differences exist between trial designs and subject characteristics, and caution should be exercised when comparing data across trials.



## **Open-Label Maintenance Study**

Clinical Remission at 48 and 96 Weeks after 16-week induction period (Weeks 64 and 112)

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

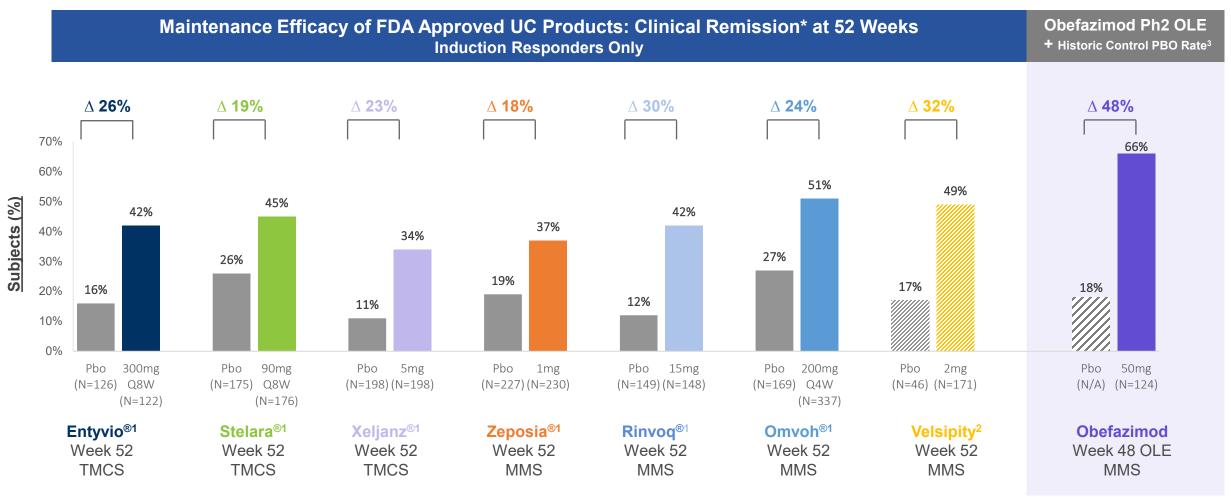


119 patients in clinical remission at week 48 and 114 in clinical remission at week 966



### 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.



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

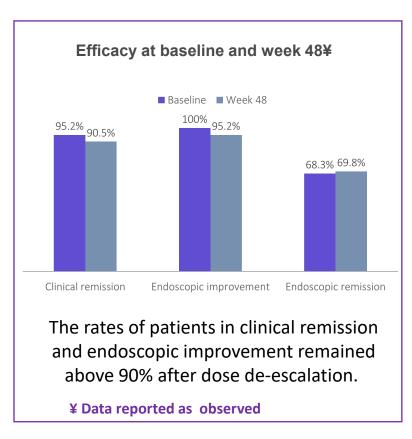
Week 48

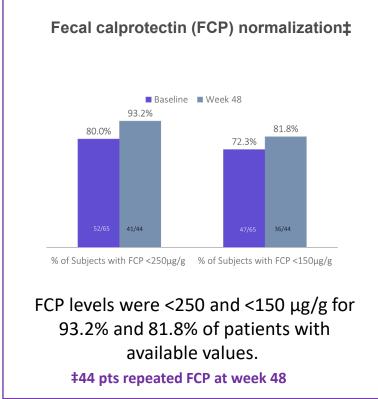
131 Patients Enrolled Phase 2b Long-Term Safety Trial (ABX464-108) Run-in Maintenance up to 4 years (LTE with obefazimod 50 mg QD) Yearly Endoscopy 2-Year LTE (ABX464-104) 50 mg QD 25 mg QD 4-Year LTE (ABX464-102) 50 mg QD Only patients with MES 0 or 1 were eligible Interim Analysis (cut-off date July 31, 2023) 74 patients dosed with obefazimod 25mg QD evaluated at



# Obefazimod efficacy and safety results at week 48 after dose de-escalation from 50 mg to 25 mg for the third and fifth year of open-label maintenance treatment

#### **Efficacy Results**





#### Change from baseline in MMS at week 48

MMS change at week 48	n (%)
Stable	40 (63.5)
Improved	13 (20.6)
Worsened <sup>†</sup>	10 (15.9)

MMS: Modified Mayo Score; †:One of 10 patients discontinued due to an AE; 6 patients worsened but still met the definition for clinical remission; one patient worsened 1 point and fell out of remission; the remaining 2 patients worsened 3 and 6 points.

The disease control rate (stable or improved MMS) was 84%.

No new safety findings were identified over these 48 weeks



## 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>

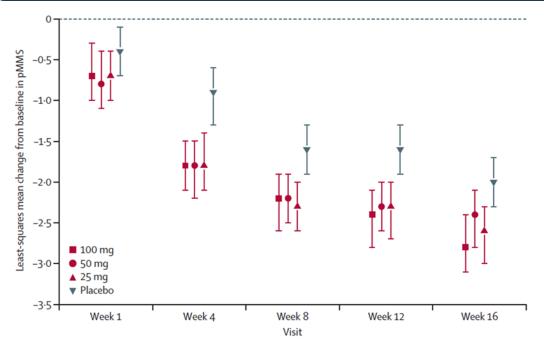


Figure 2: Mean change from baseline in pMMS in full analysis set

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

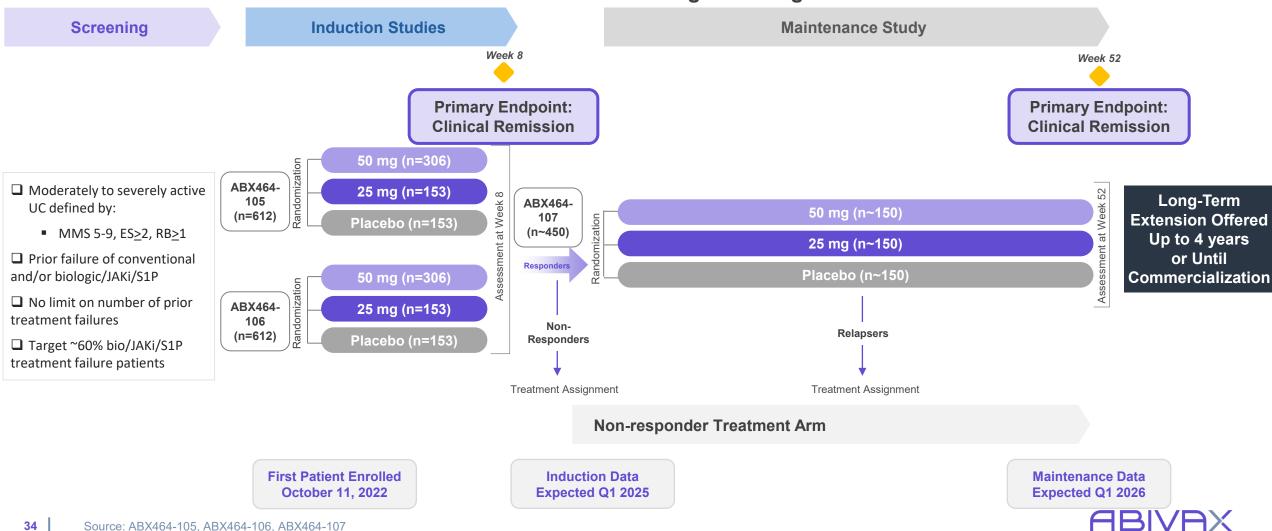
pMMS=partial modified Mayo Score.



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

Contemporary re-randomization of induction responders

**Ulcerative Colitis Program Design** 



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

#### Approaches Implemented Designed to De-Risk UC Phase 3 Clinical Trial Program

# Increase Clinical Trial 6-8 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



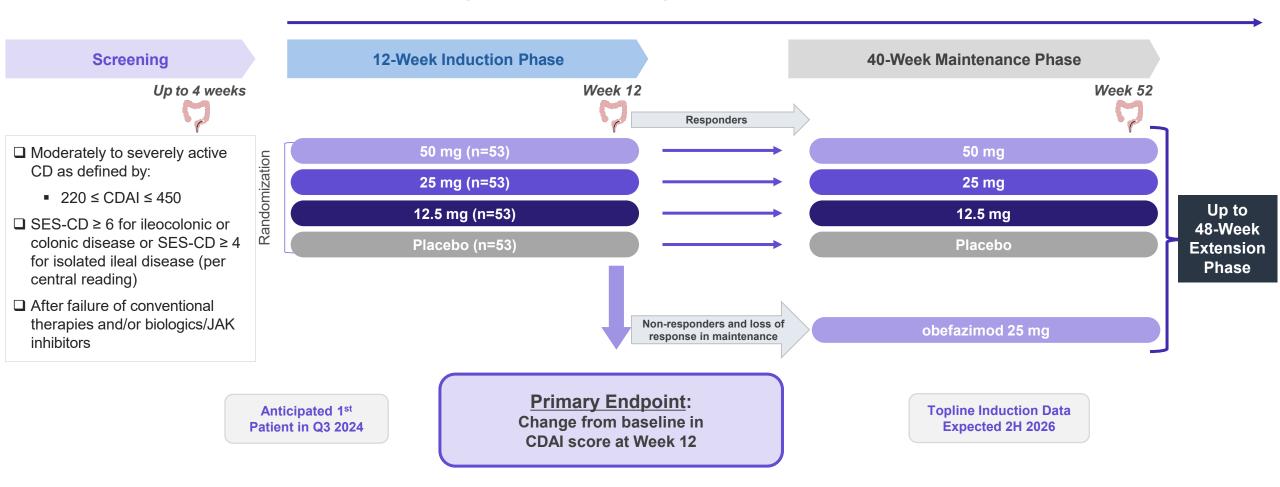
- Dropoff in efficacy from Phase 2 to Phase 3 linked to studying more refractory patients in Phase 3 than Phase 2
- Rinvoq's\* efficacy between Phase 2 and Phase 3 remained consistent by studying the same percentage of refractory patients in Phase 2
- Abivax is targeting approximately the same percentage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



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

#### Obefazimod in Crohn's Disease

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







## Expected Key Catalysts From 2023-2026

#### Drivers of Abivax value

✓ Q2 '23 Phase 2b Positive 2 Year Clinical Remission Data Released
 ✓ Q3 '23 Externally Validated IP Runway
 ✓ Q4 '23 File IND for CD Phase 2 Induction Trial
 ✓ Q3 '24 Initiate Phase 2b CD Induction Trial
 ✓ Q3 '24 Initiate Phase 2b CD Induction Trial





## Strong Cash Position Providing Runway Into Q4 2025



Existing and New Strategic
Initiatives Require Significant R&D
Spend

- Beyond current ABTECT program,
   UC Phase 3 long-term extension
- Initiation of CD Phase 2b clinical trial
- Exploration of additional potential clinical development opportunities for obefazimod (combination therapies, new clinical indications, etc.)
- Selecting an additional compound from our miR-124 library by Q3 2024



**Organization / US Footprint** 

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

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



#### **Cash Runway**

Cash Runway into Q4'25 with potential to extend through Q1'26

- Cash (including financial assets) amounting to €261m as of December 31, 2023
- Outstanding shares ~62.9M outstanding shares (Ordinary shares and ADS) as of March 7, 2024.
- Cash runway into Q4'25 including cash resources and draw-down of €25M Kreos/Claret Tranche B in Q1'24
- Potential to further extend our runway through Q1 2026 (through planned UC Phase 3 maintenance readout) by potential draw-down up to €65M (€25M Kreos/Claret Tranche C and €40M Heights Tranche B in Q3'24)



# Thank You

Nasdaq: ABVX / Euronext Paris: ABVX