## Modulating the Immune System to Fight Chronic Inflammatory Diseases

Abivax, a Phase 3 Clinical Biotech Company

March 2023



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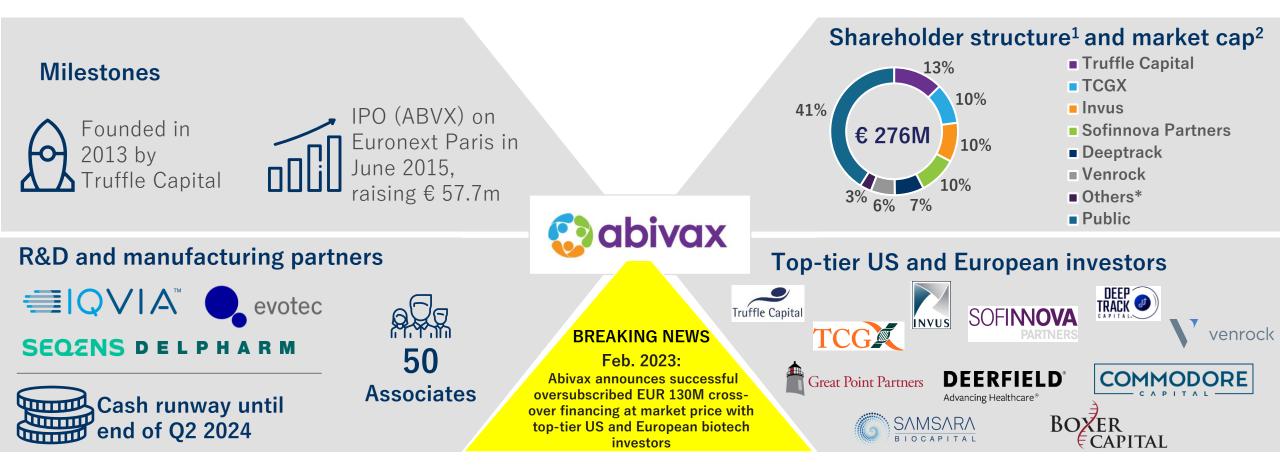
Ongoing and future clinical development, including the Phase 3 program, study design and initiation is subject to assessment of the overall nonclinical, CMC, toxicology, clinical efficacy and safety data of obefazimod by European Medicines Agency (EMA), US Food and Drug Administration (FDA) and other regulatory authorities. These authorities could request important modifications to the design of the ongoing and future clinical trials and/or request that additional studies be conducted prior to their initiation. Abivax cannot exclude that the FDA, the 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 trial for obefazimod in ulcerative colitis).

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#### Abivax in a Nutshell: A Phase 3 Biotech Company



Undiluted as of March 1<sup>st,</sup> 2023
 As of March 1<sup>st</sup>, 2023 EOB

DIVOX

\* Includes: Santé Holding, Management, Board, Employees, Consultants

Modulating the immune system to fight chronic inflammatory diseases

### Ulcerative colitis – A debilitating disease with significant societal burden

More than 2.5 million patients in the EU and over 1 million patients in the United States suffer from IBD The incidence rate is increasing in newly industrialized countries

(Kaplan GG. The global burden of IBD: from 2015 to 2025. Nature Reviews Gastroenterology & Hepatology, 2015, 12, 720–727)

#### The economic burden of UC was an estimated EUR 12.5-29.1B in Europe and USD 8.1-14.9B in the US as of 2008

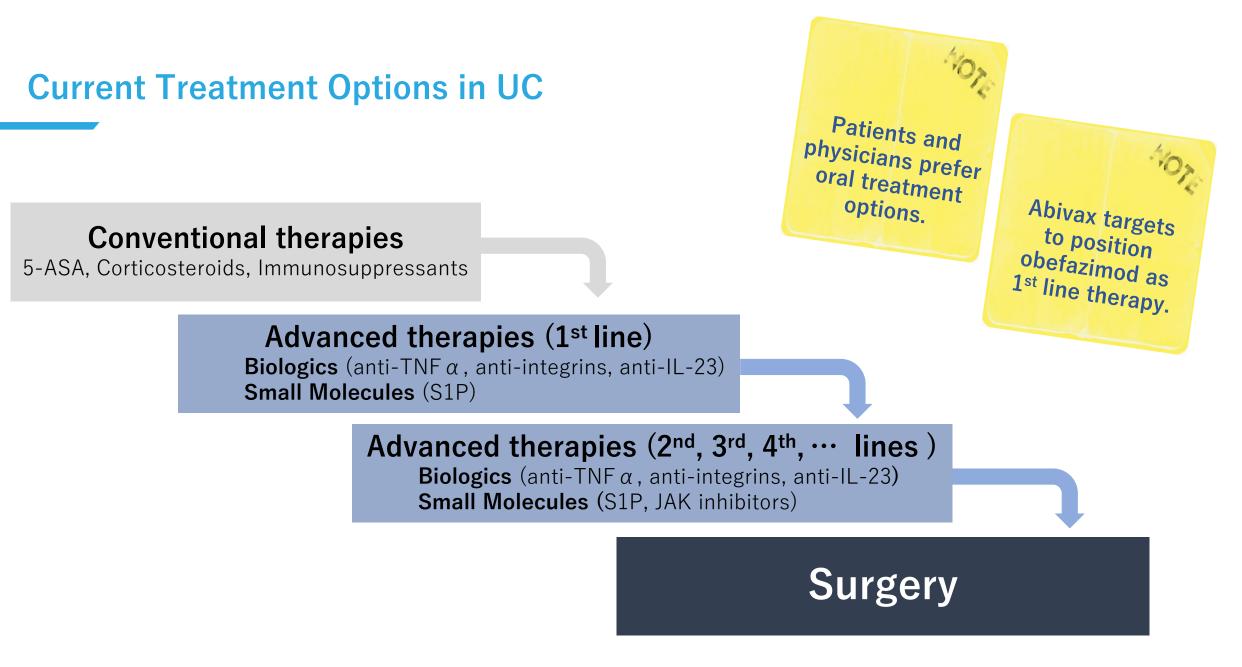
(Cohen RD, Yu AP, Wu EQ, et al. Systematic review: the costs of ulcerative colitis in Western countries. Aliment Pharmacol Ther. 2010;31:693–707)

Key symptoms of UC: 1) Frequent or increased number of bowel movements, 2) urgency, 3) rectal bleeding, 4) fatigue and 5) abdominal pain

Up to 57% of active IBD patients have symptoms of anxiety and up to 39% symptoms of depression

(Barberio, B., Zamani, M., Black, C. J., Savarino, E. V. & Ford, A. C. Prevalence of symptoms of anxiety and depression in patients with inflammatory bowel, disease: a systematic review and meta- analysis. Lancet Gastroenterol. Hepatol., 2021, 6, 359–370.)







### **Obefazimod Clinical Differentiation Factors and Positioning**

Potential **first-in-class** small molecule with unique mechanism of action

Easy, oral once-daily administration

Fast onset of action

**Durable** and further improved clinical efficacy, currently best clinical remission rates during 3-years maintenance

Favorable safety and tolerability profile

We believe obefazimod has all necessary clinical differentiation factors to be positioned as... ...1<sup>st</sup> line therapy in moderate to severe ulcerative colitis after failure of conventional therapies

> Expected UC market size in G7: USD 10.5B in 2027

Global UC phase 3 program: First patient enrolled in the US on Oct. 11, 2022



## **Abivax Pipeline in Chronic Inflammatory Diseases**

Drug Candidates	Indication	Research	Nonclinical	Phase 1	Phase 2	Phase 3	Anticipated Milestones
Obefazimod	Ulcerative colitis (UC)		program initiated in the US Oct. 11,			<ul> <li>Topline data readout end of 2024 (induction trials)</li> <li>Topline data readout end of 2025 (maintenance trial)</li> </ul>	
Obefazimod	Crohn's disease (CD)	Pivotal Phase 2	b/3 trial planned*				
Obefazimod	Rheumatoid arthritis (RA)	Phase 2a trial c Phase 2b optior	omplete 1s being evaluated	I			
ABX711	Inflammatory condition	Indication to be	selected				

#### Lead program

Completed and ongoing studies

\_\_\_\_ Obefazimod Pivotal Phase 2b/3 trial for CD planned based on the availability of necessary resources and funding

\* We believe the nonclinical and Phase 1 data generated in our UC trials is sufficient for completion of these equivalent trials in CD, which we believe will allow us to enter straight into Phase 2b/3 trials for this indication; however, we can provide no assurance that we will be able to do so



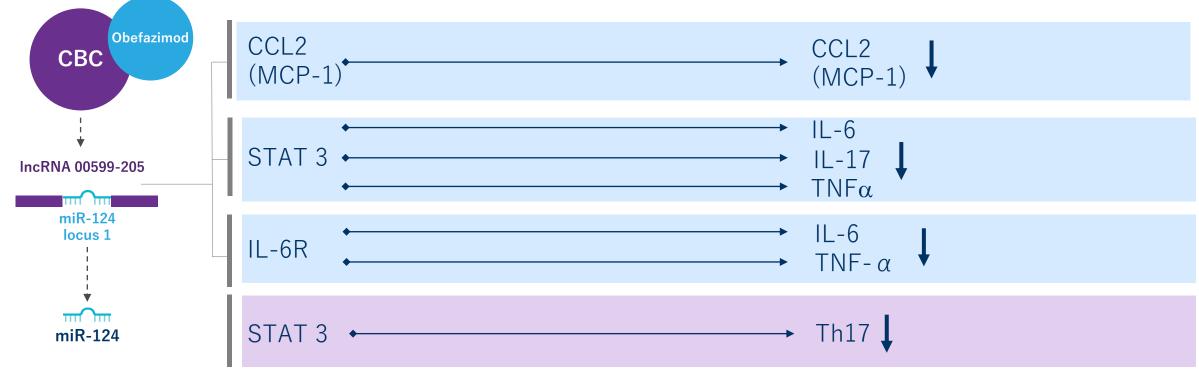
## **Obefazimod: Mechanism of Action**



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# **Obefazimod's Novel Mechanism of Action: Potent and Specific Upregulation of miR-124, Activating a "Physiological Brake" of Inflammation**

- Potential first-in-class mechanism of action related to intracellular upregulation of miR-124.
- microRNAs work by down-regulating the translation of their respective target genes.
  - → As a consequence, obefazimod leads to a "rebalancing" of the immune system



Apolit et al., *GTG*, published online Jan. 2023.; Tazi et al. *Drug Discov. Today* (2021); Poholek et al. *J Exp Med* (2020) 217 (10): e20191761; *Lin S, et al. Frontier in Onc (2020)* 



## **Obefazimod: Clinical Development in IBD**



#### **Obefazimod Phase 2a POC Study Results in Ulcerative Colitis** *Short-Term (Induction) and Long-Term (Maintenance) Efficacy Signal Observed*

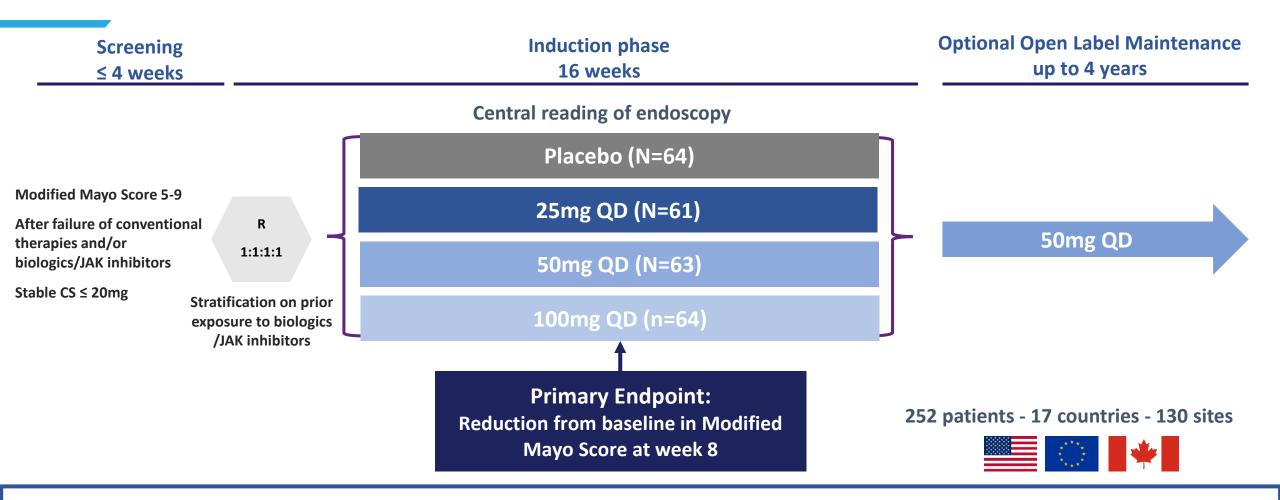
- PI: Prof. Severine Vermeire, Leuven, BE
- 32 patients with moderate to severe UC: randomized (2:1) 50mg obefazimod vs placebo, double blind, placebo controlled study
- Moderate to severe UC patients who failed/were intolerant to conventional treatments only (50%) and biologics (50%)
- Central blinded and independent reading of endoscopies (induction, 2<sup>nd</sup> and 3<sup>rd</sup> year maintenance)
- Followed by open-label maintenance study (4-year treatment completed)

Vermeire et al., Induction and long-term follow-up with ABX464 for moderate-to-severe ulcerative colitis: Results of phase 2a trial. Gastroenterology, 2021;160:2595–2598	<b>Obefazimod</b> (n=23/20) ITT   PP	Placebo (n=9/9) ITT   PP	<b>p value*</b> (PP)
Clinical remission	30%   35%	11%   11%	0.16
Endoscopic improvement	43%   50%	11%   11%	0.03
Clinical response	<b>61%   70%</b>	33%   33%	0.06
miR-124 expression in rectal biopsies (fold increase)	7.69	1.46	0.004

\* POC Study was not powered for efficacy ITT: Intent-to-treat population PP: Per protocol treated population



## **Obefazimod Phase 2b in Moderate-to-Severe Ulcerative Colitis: Study Design**



Vermeire et al., ABX464 (obefazimod) for moderate-to-severe, active ulcerative colitis: a Phase 2b, double-blind, randomised, placebocontrolled induction trial and 48 week, open-label extension, Lancet Gastroenterol Hepatol, Volume 7, Issue 11, Sept. 2022, P.1024-1035



# Baseline Characteristics: Well-Balanced Among the Treatment Groups, Indicating a Moderate to Severe UC Population

		Placebo	25mg	50mg	100mg
		(n=64)	(n=61)	(n=63)	(n=64)
Age (years)	Mean (SD)	41.1 (14.43)	41.5 (14.16)	40.2 (13.94)	42.2 (12.34)
Male	n (%)	40 (62.5)	40 (65.6)	27 ( 42.9)	41 ( 64.1)
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%
Duration of disease (years)	Mean (SD)	8.82 (6.783)	7.35 (6.848)	8.22 (7.785)	7.77 (7.291)
Fecal Calprotectin (µg/g)	Median	1558	1743	1671	1623
Previous exposure to biologics/tofacitinib	n (%)	31 (48.4)	30 (49.2)	30 (47.6)	32 (50.0)
anti-TNFα	n (%)	27 (42.2)	25 (41.0)	25 (39.7)	31 (48.4)
anti-TNFα only	n (%)	1 (1.6)	3 (4.9)	0	1 (1.6)
Vedolizumab	n (%)	22 (34.4)	19 (31.1)	20 (31.7)	20 (31.3)
Tofacitinib	n (%)	12 (18.8)	10 (16.4)	12 (19.0)	13 (20.3)
Concomitant UC Medication					
Corticosteroids	n (%)	29 (45.3)	32 (52.5)	33 (52.4)	37 (57.8)
Immunosuppressants	n (%)	10 (15.6)	10 (16.4)	9 (14.3)	6 (9.4)



#### Week 8 Efficacy Results (ITT): Primary Endpoint met Clinical Activity observed in Patients and also for Subset of Bio-Refractory Patients

Week 8 Resul <sup>®</sup> (ITT <sup>1</sup> population / r	Placebo	25mg	50mg	100mg						
Modified Mayo Score	All patients	-1.9	-3.1 **	-3.2 **	-2.9 *					
Mean change from baseline	<b>Bio- refractory</b>	-1.0	-2.8 **	-2.9 **	-2.8 **					
*p-values of <0.01 versus placebo (ANCOVA)										
**p-values of <0.001 versus placeb										

1) ITT: Intent-to-treat patient population. Drop-out patients were considered as failure for all endpoints. Nearest neighbor imputation, as defined in the SAP. Patient characteristics well balanced between all groups (Modified Mayo Score, ConMeds, Gender, etc.).



### Week 8 Efficacy Results (ITT): Secondary Endpoints – Clinical Activity observed

Data presented as per final Clinical Study Repor					
Week 8 Results (ITT population / n=252)			25mg	50mg	100mg
Key Secondary End	points (not po	owered for st	atistical signi	ficance)	
Endoscopic Improvement <sup>a</sup> †	All patients	8 (13.6%)	20 (34.5%) *	21 (39.6%) *	24 (44.4%) *
Endoscopic improvement ~	<b>Bio-refractory</b>	1 (3.7%)	8 (28.6%) *	7 (30.4%) *	8 (26.6%) *
*p-values of <0.05 versus placebo using a lik	elihood ratio chi	-square test			
Clinical Remission <sup>b</sup> †	All patients	8 (12.5%)	17 (27.9%) *	11 (17.5%)	16 (25.0%)
	<b>Bio-refractory</b>	1 (3.2%)	6 (20.0%) *	2 (6.7%)	6 (18.8%) *
*p-values of <0.05 versus placebo using a lik Haenszel Chi Square test (p=0.06 to 0.08)	elihood ratio chi	-square test bu	t not according	to the predefine	d Mantel-
Clinical Response <sup>c</sup> †	All patients	23 (35.9%)	40 (65.6%) *	38 (60.3%) *	35 (54.7%) *
	<b>Bio-refractory</b>	5 (16.1%)	17 (56.6%) *	13 (43.3%) *	15 (46.8%) *
*p-values of <0.05 versus placebo using a lik	elihood ratio chi	-square test			

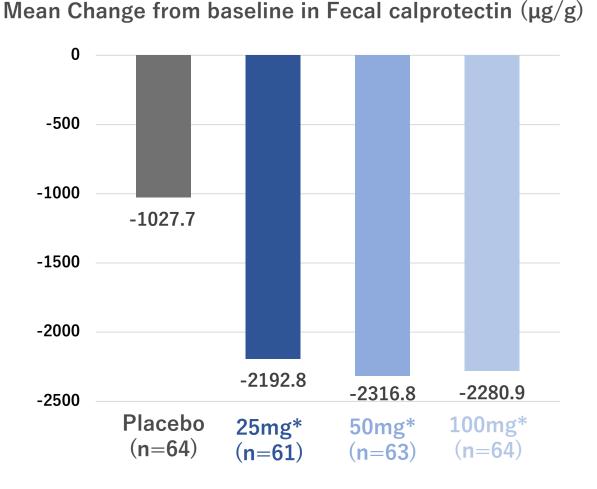
a Endoscopic improvement is defined as endoscopic subscore  $\leq 1$ .

b Clinical remission (per Modified Mayo Score) is defined as stool frequency subscore (SFS)  $\leq 1$ , rectal bleeding subscore (RBS) of 0 and endoscopic subscore  $\leq 1$ . c 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  $\leq 1$ .

† Evidence of friability during endoscopy confers an endoscopic subscore of 2 or 3



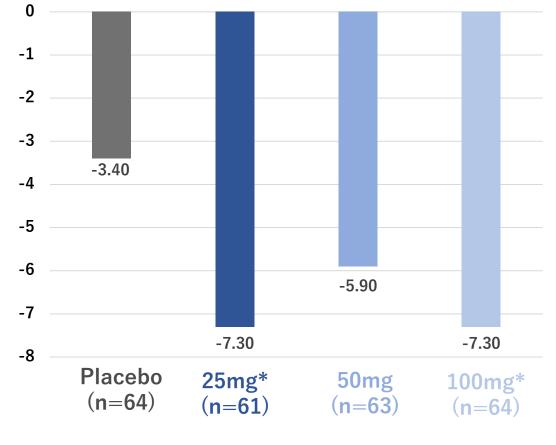
### Secondary Endpoints: Fecal Calprotectin and Robarts Histopathology Index



\*p-values of <0.01 versus placebo (MMRM)

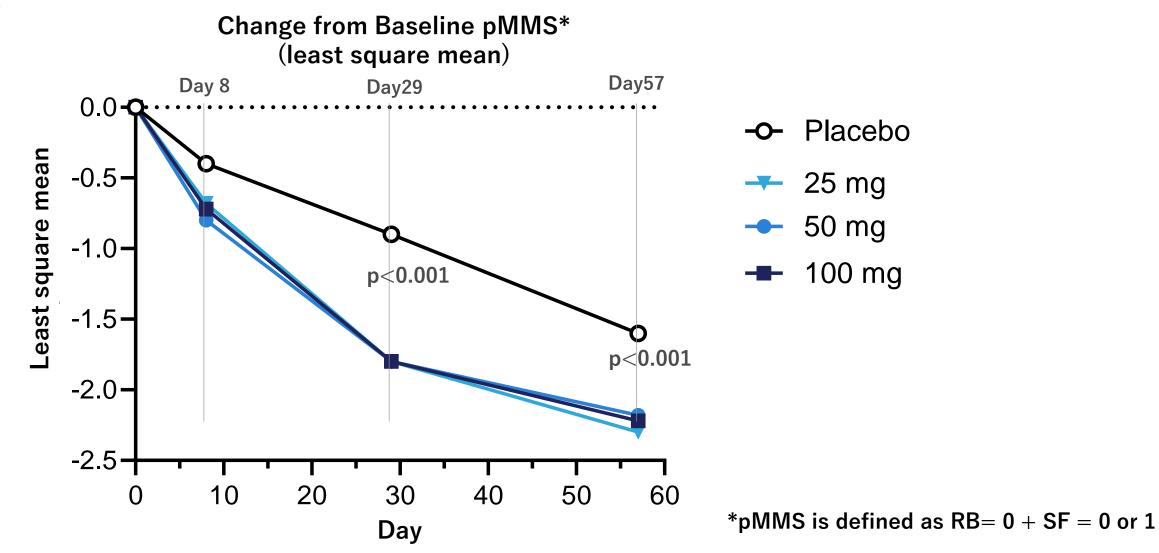
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Change from baseline in Robarts Histopathology Index



\*p-values of <0.05 versus placebo (MMRM)

#### Week 8 Efficacy Results (ITT): <u>Rapid</u> Onset of Action

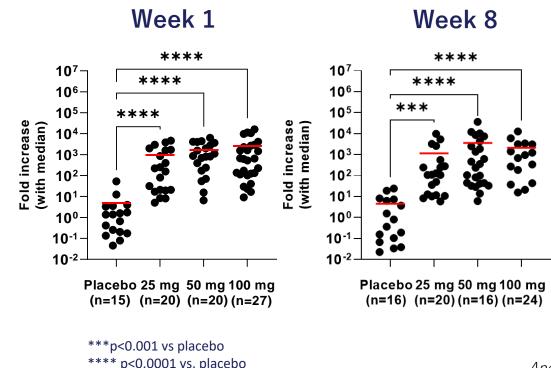




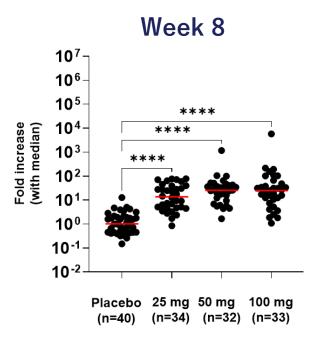
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#### **Obefazimod upregulates miR-124 Expression in UC Phase 2b Patients**

Blood: change from baseline in miR-124 expression is statistically higher with obefazimod compared with placebo after 1 week and 8 weeks



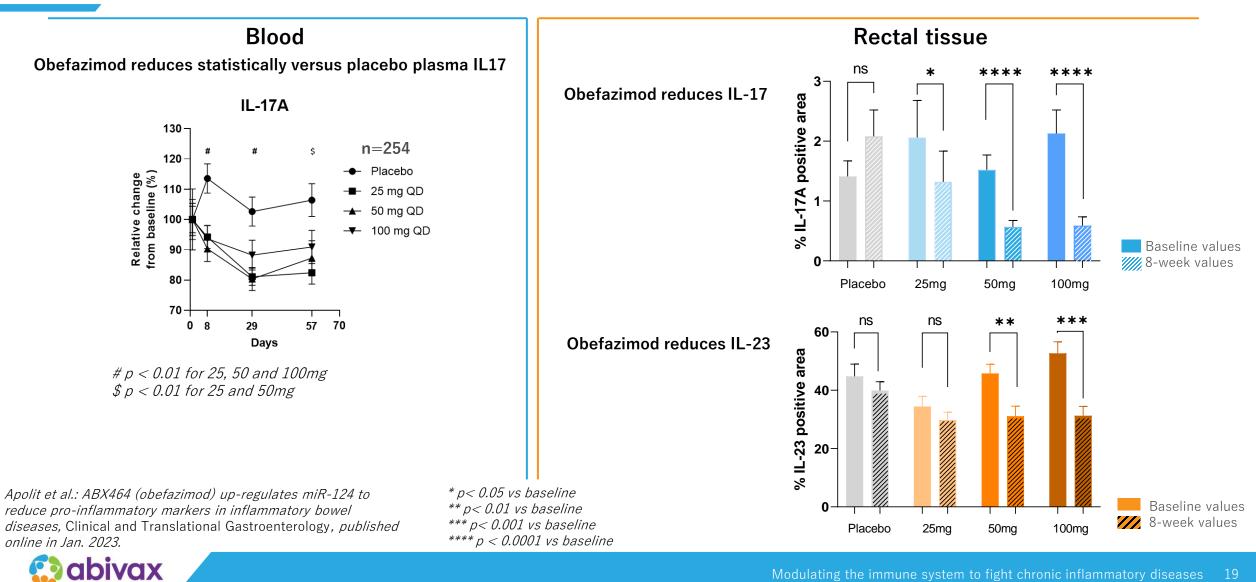
Rectal tissue: change from baseline in miR-124 expression is statistically higher with obefazimod compared with placebo after 8 weeks



*Apolit et al.: ABX464 (obefazimod) up-regulates miR-124 to reduce pro-inflammatory markers in inflammatory bowel diseases,* Clinical and Translational Gastroenterology, *published online in Jan. 2023.* 



#### **Obefazimod reduces IL17 & IL 23 in UC Phase 2b Patients**

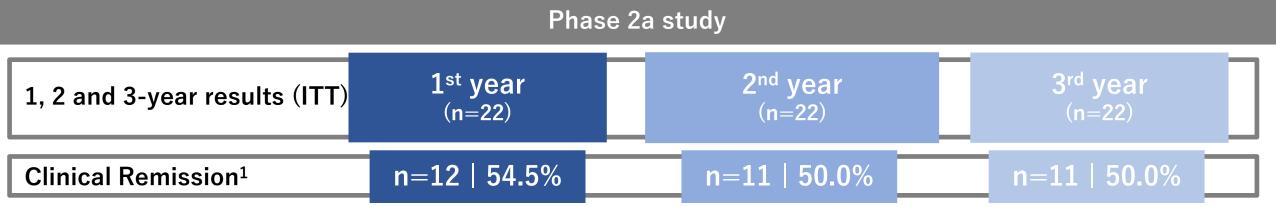


# **Obefazimod Phase 2a and 2b Open-Label Maintenance Study Results – ITT Favorable Long-Term Clinical Activity observed**

#### Phase 2b study: 217/222 eligible patients enrolled into maintenance

One-year results (ITT)	All patients <sup>1</sup> (n=217)	Patients with clinical sponse after induction (n=124)	Patients without clinical response after induction (n=93)	
Clinical Remission	n=119   54.8%	n=82   66.1%	n=37   39.8%	

<sup>1</sup> Irrespective of patient outcome at the end of the induction phase



<sup>1</sup> Irrespective of patient outcome at the end of the induction phase



## **Obefazimod well-positioned in the Competitive Landscape for both Induction and 1-Year Maintenance** - *Clinical Remission Rates*

Study	Active	Placebo	Delta	Acti	ve	Placebo	Delta
	Results of Inc	Juction stu	dies (ITT)*	Resul	Its of Mainten	ance studies	(ITT)*
			res		All comers		
ULTRA I (Ph 3, 260 Pt.)	18.5%	9.2%	9.3%	-	-	-	-
ULTRA II (Ph 3, 494 Pt.)	16.5%	9.3%	7.2%	17.3%	-	8.5%	8.8%
GEMINI I (Ph 3, 374 + 521 Pt.)	16.9%	5.4%	11.5%	44.8%	-	15.9%	28.9%
U-Achieve (473 Pt.)	26.0%	5.0%	21.0%	42.0% (15mg)		12.0% (15mg)	30.0% (15mg)
U-Accomplish (515 Pt.)	33.0%	4.0%	29.0%	52.0% (30mg)	-	12.0% (30mg)	40.0% (30mg)
Phase 2 (250 Pt.)	19.6%	0.0%	19.6%	-	-	-	-
Lucent (1,162 Pt.)	24.2%	13.3%	11.1%	49.9%	-	25.1%	24.8%
Elevate 52 (433 Pt.)	27.0%	7.4%	19.8%	32.1%	-	6.7%	25.4%
Elevate 12 (330 Pt.)	24.8%	Induction responders onlyAll comers $9.2\%$ $9.3\%$ $9.3\%$ $7.2\%$ $17.3\%$ - $9.3\%$ $7.2\%$ $17.3\%$ - $5.4\%$ $11.5\%$ $44.8\%$ - $5.0\%$ $21.0\%$ $42.0\%$ (15mg) recommended dose $52.0\%$ (30mg)- $4.0\%$ $29.0\%$ $52.0\%$ (30mg) $0.0\%$ $19.6\%$ - $13.3\%$ $11.1\%$ $49.9\%$ $7.4\%$ $19.8\%$ $32.1\%$ $7.4\%$ $19.8\%$ $32.1\%$ $15.2\%$ $9.7\%$ - $1.5\%$ $25\%$ - $1.5\%$ $25\%$ - $11.1\%$ $19.3\%$ $66.7\%$ (50mg) $54.5\%$ - $12.5\%$ $15.4\%$ $66.1\%$ (50mg)	-	-			
ARTEMIS Ph 2 (135 Pt.)	26.5%	1.5%	25%	-	-	-	-
Phase 2a (32 Pt.) 50mg	30.4%	11.1%	19.3%	66.7% (50mg)	54.5%	-	-
Phase 2b (254 Pt.) 25mg	27.9%	12.5%	15.4%	66.1% (50mg)	54.8%	-	-
	JLTRA II (Ph 3, 494 Pt.)         GEMINI I         (Ph 3, 374 + 521 Pt.)         U-Achieve (473 Pt.)         U-Accomplish (515 Pt.)         Phase 2 (250 Pt.)         Lucent (1,162 Pt.)         Elevate 52 (433 Pt.)         Elevate 12 (330 Pt.)         ARTEMIS Ph 2 (135 Pt.)         Phase 2a (32 Pt.) 50mg         Phase 2b (254 Pt.) 25mg	ULTRA I (Ph 3, 260 Pt.)       18.5%         JLTRA II (Ph 3, 494 Pt.)       16.5%         GEMINI I       16.9%         (Ph 3, 374 + 521 Pt.)       16.9%         U-Achieve (473 Pt.)       26.0%         U-Accomplish (515 Pt.)       33.0%         Phase 2 (250 Pt.)       19.6%         Lucent (1,162 Pt.)       24.2%         Elevate 52 (433 Pt.)       27.0%         Elevate 12 (330 Pt.)       24.8%         ARTEMIS Ph 2 (135 Pt.)       26.5%         Phase 2a (32 Pt.) 50mg       30.4%         Phase 2b (254 Pt.) 25mg       27.9%	ULTRA I (Ph 3, 260 Pt.)       18.5%       9.2%         JLTRA II (Ph 3, 494 Pt.)       16.5%       9.3%         GEMINI I (Ph 3, 374 + 521 Pt.)       16.9%       5.4%         U-Achieve (473 Pt.)       26.0%       5.0%         U-Accomplish (515 Pt.)       33.0%       4.0%         Phase 2 (250 Pt.)       19.6%       0.0%         Lucent (1,162 Pt.)       24.2%       13.3%         Elevate 52 (433 Pt.)       27.0%       7.4%         Elevate 12 (330 Pt.)       24.8%       15.2%         ARTEMIS Ph 2 (135 Pt.)       26.5%       1.5%         Phase 2a (32 Pt.) 50mg       30.4%       11.1%         Phase 2b (254 Pt.) 25mg       27.9%       12.5%	JLTRA II (Ph 3, 494 Pt.)16.5%9.3%7.2%GEMINI I (Ph 3, 374 + 521 Pt.)16.9%5.4%11.5%U-Achieve (473 Pt.)26.0%5.0%21.0%U-Accomplish (515 Pt.)33.0%4.0%29.0%Phase 2 (250 Pt.)19.6%0.0%19.6%Lucent (1,162 Pt.)24.2%13.3%11.1%Elevate 52 (433 Pt.)27.0%7.4%19.8%Elevate 12 (330 Pt.)24.8%15.2%9.7%ARTEMIS Ph 2 (135 Pt.)26.5%1.5%25%Phase 2a (32 Pt.) 50mg30.4%11.1%19.3%Phase 2b (254 Pt.) 25mg27.9%12.5%15.4%	ULTRA I (Ph 3, 260 Pt.)18.5%9.2%9.3%-JLTRA II (Ph 3, 494 Pt.)16.5%9.3%7.2%17.3%GEMINI I (Ph 3, 374 + 521 Pt.)16.9%5.4%11.5%44.8%U-Achieve (473 Pt.)26.0%5.0%21.0%42.0% (15mg) recommended dose recommended	Induction responders only         All comers           ULTRA I (Ph 3, 260 Pt.)         18.5%         9.2%         9.3%         -         -           JLTRA II (Ph 3, 494 Pt.)         16.5%         9.3%         7.2%         17.3%         -           GEMINI I (Ph 3, 374 + 521 Pt.)         16.9%         5.4%         11.5%         44.8%         -           U-Achieve (473 Pt.)         26.0%         5.0%         21.0%         42.0% (15mg) recommended dose         -           U-Accomplish (515 Pt.)         33.0%         4.0%         29.0%         52.0% (30mg)         -           Lucent (1,162 Pt.)         24.2%         13.3%         11.1%         49.9%         -           Elevate 52 (433 Pt.)         27.0%         7.4%         19.8%         32.1%         -           KTEMIS Ph 2 (135 Pt.)         26.5%         1.5%         9.7%         -         -           NRTEMIS Ph 2 (135 Pt.)         26.5%         1.5%         25%         -         -           Phase 2a (32 Pt.) 50mg         30.4%         11.1%         19.3%         66.7% (50mg)         54.5%           Phase 2b (254 Pt.) 25mg         27.9%         12.5%         15.4%         66.1% (50mg)         54.8% <td>Induction responders only         All comers           ULTRA I (Ph 3, 260 Pt.)         18.5%         9.2%         9.3%         -         -         -           JLTRA II (Ph 3, 494 Pt.)         16.5%         9.3%         7.2%         17.3%         -         8.5%           GEMINI I (Ph 3, 374 + 521 Pt.)         16.9%         5.4%         11.5%         44.8%         -         15.9%           U-Achieve (473 Pt.)         26.0%         5.0%         21.0%         42.0% (15mg) recommended dose 52.0% (30mg)         12.0% (15mg) 12.0% (30mg)           Phase 2 (250 Pt.)         19.6%         0.0%         19.6%         -         -           Lucent (1,162 Pt.)         24.2%         13.3%         11.1%         49.9%         -         25.1%           Elevate 52 (433 Pt.)         27.0%         7.4%         19.8%         32.1%         -         6.7%           Elevate 12 (330 Pt.)         24.8%         15.2%         9.7%         -         -         -           VRTEMIS Ph 2 (135 Pt.)         26.5%         1.5%         25%         -         -         -           Phase 2a (32 Pt.) 50mg         30.4%         11.1%         19.3%         66.7% (50mg)         54.5%         -</td>	Induction responders only         All comers           ULTRA I (Ph 3, 260 Pt.)         18.5%         9.2%         9.3%         -         -         -           JLTRA II (Ph 3, 494 Pt.)         16.5%         9.3%         7.2%         17.3%         -         8.5%           GEMINI I (Ph 3, 374 + 521 Pt.)         16.9%         5.4%         11.5%         44.8%         -         15.9%           U-Achieve (473 Pt.)         26.0%         5.0%         21.0%         42.0% (15mg) recommended dose 52.0% (30mg)         12.0% (15mg) 12.0% (30mg)           Phase 2 (250 Pt.)         19.6%         0.0%         19.6%         -         -           Lucent (1,162 Pt.)         24.2%         13.3%         11.1%         49.9%         -         25.1%           Elevate 52 (433 Pt.)         27.0%         7.4%         19.8%         32.1%         -         6.7%           Elevate 12 (330 Pt.)         24.8%         15.2%         9.7%         -         -         -           VRTEMIS Ph 2 (135 Pt.)         26.5%         1.5%         25%         -         -         -           Phase 2a (32 Pt.) 50mg         30.4%         11.1%         19.3%         66.7% (50mg)         54.5%         -

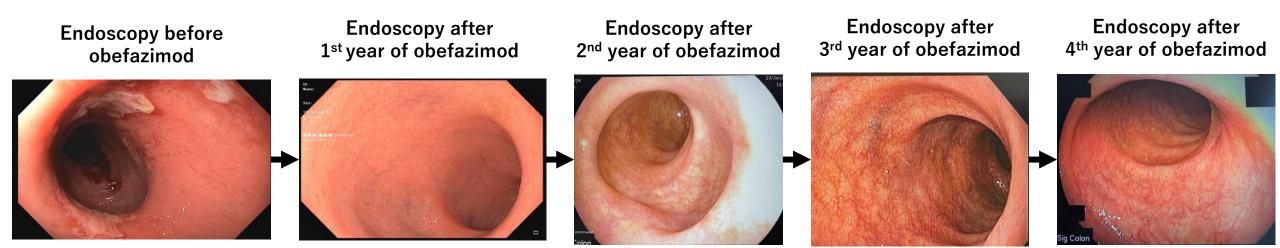
Marketed drugs in IBD

Drug candidates in development or licencing prodedure in IBD <sup>\*No</sup> head-to-head studies conducted with obefazimod against other products or candidates. Results of head-to-head comparisons may differ from those set forth herein.



### **Complete Resolution of UC Lesions in an Obefazimod Treated Patient** (Humira, Remicade and Entyvio Resistant) during 4 years of Open-Label Maintenance Treatment

- > 52-year-old patient with severe UC, who had failed on Humira, Remicade and Entyvio
- Fall 2017: Patient was counseled for colectomy
- > Nov. 2017: Patient was enrolled in Phase 2a induction study with obefazimod
- Jan. 2018: Patient was enrolled in open-label maintenance study with obefazimod



Courtesy of Prof. Severine Vermeire, Leuven, Belgium



## Favorable Obefazimod Safety and Tolerability Profile

Phase 2b Study in UC Patients supported Profile observed in the Phase 2a Study

#### No new safety signal, no death, no malignancy

- Most frequently reported AEs were headaches (20% for 25mg and 8% for placebo), which occurred early (first 10 days of treatment) and were transient (few days), mild or moderate (grade 1 or 2) and manageable with or without OTC medications
- Other AEs ≥ 5% (related and non-related) are gastrointestinal disorders (nausea, vomiting, upper abdominal pain) and musculoskeletal (arthralgia, myalgia)
- > Labs: No clinically significant changes in laboratory parameters (liver function tests, Hb, white blood cells)

% Patients with at least one AE	Placebo (N=64)	Obefazimod 25mg (N=62)	Obefazimod 50mg (N=63)	Obefazimod 100mg (N=64)
<b>TEAE</b> leading to Study Discontinuation	6.3%	1.6%	9.5%	9.4%
SAEs1	6.3%	1.6%	6.3%	6.3%
Severe Grade 3-4 TEAEs <sup>1</sup>	4.7%	4.8%	7.9%	10.9%
Infections	9.4%	4.8%	12.7%	7.8%
<sup>1</sup> related and not related to study drug				

> 25mg clearly stands out with a similar safety profile observed in the placebo group (except transient headaches)

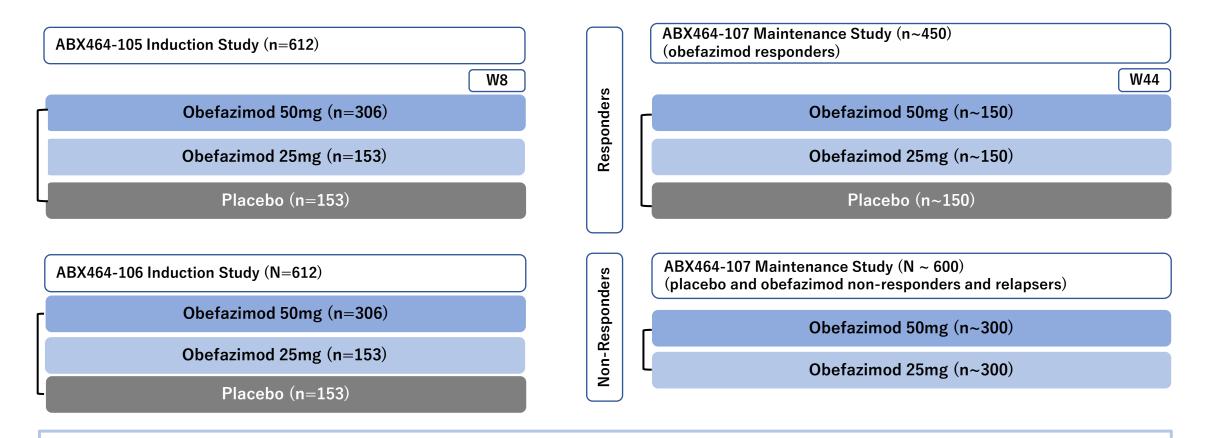


# Favorable Obefazimod Safety and Tolerability Profile across all Clinical Studies (UC, RA, HIV, Covid-19, Healthy Volunteers)

• More than 1,000 subjects exposed to obefazimod (as of safety data cut-off Nov. 2022)

- → Subjects exposed at 25mg: 80
- Subjects exposed at 50mg: 842 (including more than 200 patients treated for more than one year, of whom > 150 patients were treated for two years or more)
- → Subjects exposed at 100mg: 95

### **Obefazimod in Ulcerative Colitis – Phase 3 Study Design**



First subject enrolled in the US on Oct. 11, 2022



## Our Strategy how to bring Obefazimod to the Market in Ulcerative Colitis

#### **Ulcerative colitis Phase 3 preparation on track**

- Clinical protocols submitted to FDA on June 22 and approved by central US IRB in Aug. 2022
- First patient enrolled in the US on Oct. 11, 2022
- **25mg and 50mg** will be studied in the induction and maintenance trials
- IQVIA and US and EU KOLs involved in setup of study design
- **2 x 600 patients** planned for two induction studies which will feed the single placebo-controlled maintenance study
- > 530 out of 600 planned study sites in 36 countries have already been qualified
- Out of the 600 sites, app. 25% are expected to be located in North America, 42% in Europe, 26% in Asia and 7% in other geographies

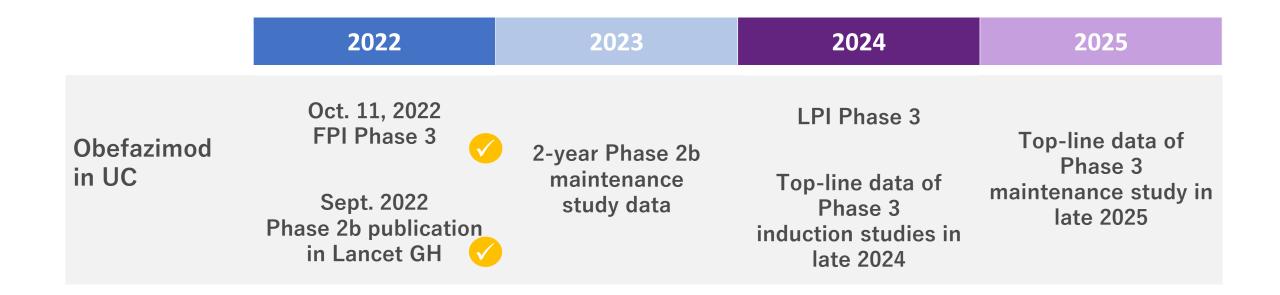
#### Inclusion of Japan in the global obefazimod Phase 3 study program

#### Phase 1 study in Japanese healthy volunteers

- Study completed showing similar PK characteristics in Japanese vs. non-Japanese subjects
- PMDA meeting (Oct. 2022) confirmed Japan participation in Phase 3 program



## **Expected UC Program upcoming Milestones**



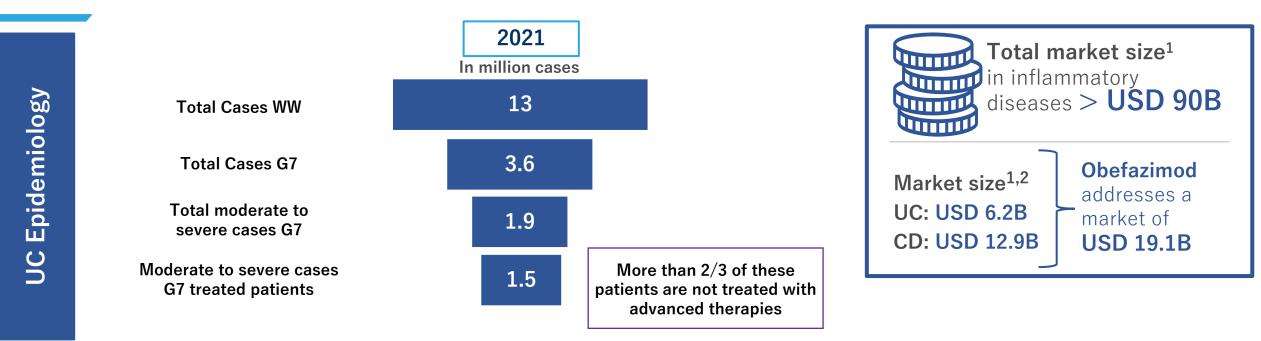
\*Based on the recent revisions of the protocols, timelines and costs of the phase 3 program are currently under revision, with the risk of a potential delay of up to 3 months for the end of enrollment and additional costs around 10% of the total study costs.



## **Obefazimod: Commercial Perspectives** in IBD



# Obefazimod: Size of Target Market expected to Increase by 70% in UC and by nearly 20% in CD (2021 - 2027)



	Ulcerative Colitis	Crohn's Disease	
Our obefazimod TPP	Patients with moderate to severe U0 therapies, therefore positioned as 1		
G7 Market Size (2 <sup>nd</sup> & 3 <sup>rd</sup> line)	2021: USD 6.2B for UC 2027: Expected USD 10.5B for UC	2021: USD 12.9B for CD 2027: Expected USD 15.4B for CD	1) 2021 data for Europe G5, U.S. and Japan
Our obefazimod Market Share Assumptions	10-20% market share at peak sales	for both indications	2) 2 <sup>nd</sup> and 3 <sup>rd</sup> line Source: Global Data & Informa

UC & CD Market Potential

abivax

#### Modulating the immune system to fight chronic inflammatory diseases 29

## **Obefazimod Patents**

		Actual or Projected Patent Expiration Date	Projected Patent Term Extensions	US	EP	JP	CN	нк	CA	AU	RU	BR	KR	ZA	MX	IN
Products	<b>Compound</b> <b>Composition of matter</b> (product claim)	6/2030	US 2034 EU 2035		*											
Applications	<i>Disease treatment</i> (use or method claims) <i>Inflammation</i> (S9)	7/2035	US 2039 EU 2040		*											*

Granted patent

Pending application

\* Claims allowed

\* Methods of treatment not patentable under Indian patent law



## **Our Financing Strategy – Multi-Pronged Approach**



- With EUR 130M gross financing (EUR 123M net proceeds) raised in Feb. 2023, we have an existing cash runway until end of Q2 2024
- We estimate the total costs of the UC Phase 3 program until the end of 2025 (the expected results date of the UC Phase 3 maintenance trial) to be EUR 224M, of which:
  - EUR 123M have been raised recently
  - approximately EUR 31M additional funding required until the end of 2024 (the expected results date of the two UC Phase 3 induction trials); and
  - approximately another EUR 70M additional funding required until the end of 2025 to complete the maintenance study
- In total, additional funding of EUR 101M required to complete the UC Phase 3 program. We evaluate further short-term financing options:
  - 1. Carrying out one or more new capital increases
  - 2. Entering into loan or issuing bonds
  - 3. Conclusion of regional licensing agreements for obefazimod, specifically targeting Asia



### **Oversubscribed EUR 130M Cross-Over Financing at Market Price**

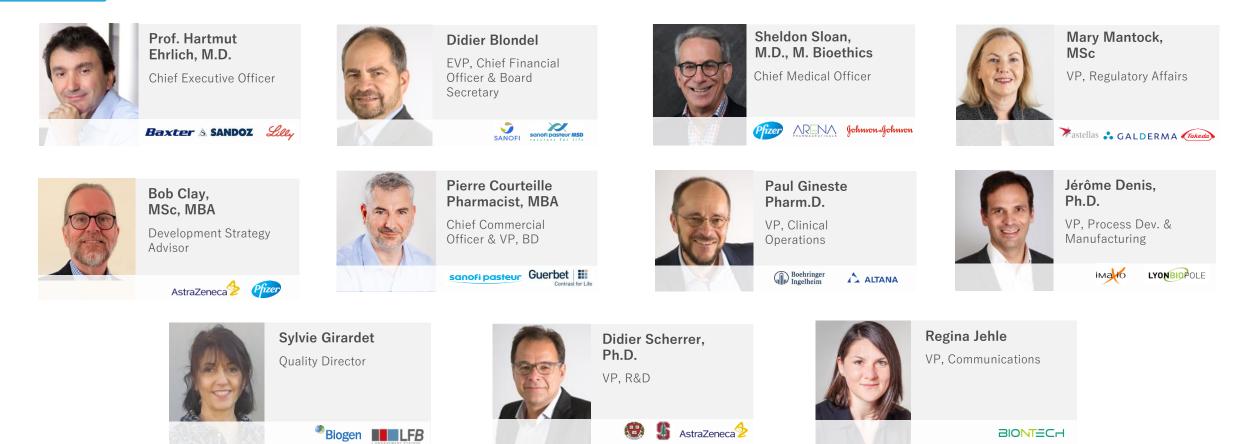
#### **EUR 130M Capital Increase**

- Oversubscribed capital increase totaling EUR 130M gross (EUR 123M net)
- Subscription price at market closing price at EUR 6.5 (Feb. 22, 2023)
- 20M newly-issued ordinary shares, representing 89.6% of the current share capital, amounting to a new capital of 42.3M shares
- Six existing shareholders, led by TCGX with the participation of Invus, Sofinnova Partners, Deeptrack Capital, Venrock and Santé Holding
- Nine new US and European tier-one investors

apivax



## **Highly Experienced Executive Committee**



#### Competencies from discovery to global commercialization



#### **Obefazimod – Major Peer-Reviewed Publications**

ABX464 (obefazimod) up-regulates miR-124 to reduce pro-inflammatory markers in inflammatory bowel diseases

Cécile Apolit et al., Clinical and Translational Gastroenterology, published online Jan. 2023

<u>ABX464 (obefazimod) for moderate-to-severe, active ulcerative colitis: a phase 2b, double-blind, randomised, placebo-controlled induction trial</u> and 48 week, open-label extension

Severine Vermeire et al., Lancet Gastroenterol Hepatol, Volume 7, Issue 11, Sept. 2022, P. 1024-1035

Safety and efficacy of the miR-124 upregulator ABX464 (obefazimod, 50 and 100 mg per day) in patients with active rheumatoid arthritis and inadequate response to methotrexate and/or anti-TNF α therapy: a placebo-controlled phase II study

Claire Daien et al., Annals of the Rheumatic Disease, 2022;81:1076–1084

Induction and long-term follow-up with ABX464 for moderate-to-severe ulcerative colitis: Results of phase 2a trial

Severine Vermeire et al., Gastroenterology, Volume 160, Issue 7, June 2021, P. 2595-2598.E3

Specific and selective induction of miR-124 in immune cells by the quinoline ABX464: a transformative therapy for inflammatory diseases

Jamal Tazi et al., Drug Discovery Today, Volume 26, Issue 4, April 2021, P. 1030-1039

Both anti-inflammatory and antiviral properties of novel drug candidate ABX464 are mediated by modulation of RNA splicing

Audrey Vautrin et al., Nature Scientific Reports, Volume 9, Article number: 792, January 2019

Randomized Trial of Food Effect on Pharmacokinetic Parameters of ABX464 Administered Orally to Healthy Male Subjects

Didier Scherrer et al., Antimicrobial Agents and Chemotherapy Jan. 2017

Pharmacokinetics and tolerability of ABX464, a novel first-in-class compound to treat HIV infection, in healthy HIV-uninfected subjects

Didier Scherrer et al., Journal of Antimicrobial Chemotherapy Advance Access published Dec. 20, 2016

