



# Modulating the Immune System to Fight Chronic Inflammatory Diseases

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Abivax, a Late-Stage Clinical Biotech Company

September 2022



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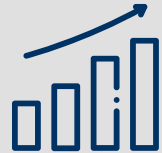
Future clinical development including phase 3 design and initiation is subject to assessment of the overall preclinical, CMC, toxicology, clinical efficacy and safety data of obefazimod by EMA, FDA and other regulatory authorities. These authorities could request important modifications to the design of the phase 3 clinical trial and/or request that additional studies be conducted prior to its 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).

# Abivax in a Nutshell: A Phase 3 Biotech

## Milestones

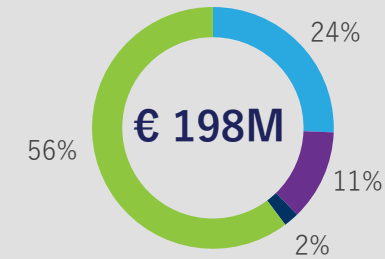


Founded in 2013 by Truffle Capital



IPO (ABVX) on Euronext Paris in June 2015, raising € 57.7m

## Shareholder structure<sup>1</sup> and market cap<sup>2</sup>



■ Truffle Capital  
■ Sofinnova Partners  
■ Board & management  
■ Public

## Operations



24 Employees



Cash runway until end of Q1 2023



## BREAKING NEWS

Sept. 2022:  
ABX464 (obefazimod)  
phase 2b induction trial and  
48-week, open-label extension  
published in *The Lancet Gastroenterol Hepatol* 2022

## Key R&D and manufacturing partners



SEQENS

DELPHARM

1) Undiluted – post capital raise Sept. 2022

2) As of 16/09/2022 EOB

# Obefazimod Clinical Differentiation Factors and Positioning

**First**-in-class small molecule with unique mechanism of action

**Easy**, oral once-daily administration

**Fast** onset of action

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

**Good** safety and tolerability profile

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

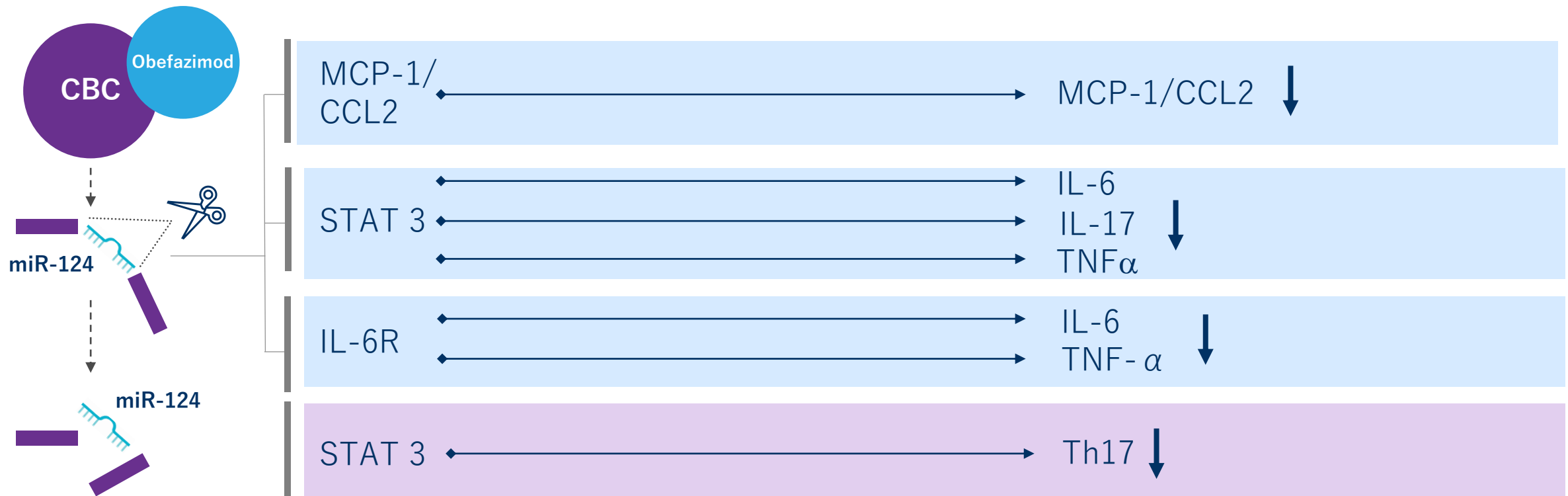
UC market size in G7:  
USD 10.2B in 2026

Global UC phase 3 program: FPI planned for end of Sept. 2022 with IRB approval granted in Aug. 2022

# Obefazimod: Mechanism of Action

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

- 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



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 (now in 4<sup>th</sup> year)

Vermeire at al. Induction and long-term follow-up with ABX464 for moderate-to-severe ulcerative colitis: Results of phase 2a trial. Gastroenterology, 2021.02.054	Obefazimod (n=23/20) ITT   PP	Placebo (n=9/9) ITT   PP	p value* (PP)
Clinical remission	30%   35%	11%   11%	0.16
Endoscopic improvement	43%   50%	11%   11%	0.03
Clinical response	61%   70%	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



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

Screening  
≤ 4 weeks

Induction phase  
16 weeks

Optional Open Label Extension  
up to 4 years

Central reading of endoscopy

Placebo (N=64)

25mg QD (N=61)

50mg QD (N=63)

100mg QD (n=64)

50mg QD

**Primary Endpoint:**  
Reduction from baseline in  
Modified Mayo Score at week 8

252 patients - 17 countries - 130 sites



Modified Mayo Score 5-9

After failure of  
conventional therapies  
and/or biologics/JAK  
inhibitors

Stable CS ≤ 20mg

R  
1:1:1:1  
Stratification on  
prior exposure to  
biologics /JAK  
inhibitors

Severine Vermeire et al., ABX464 (obefazimod) for moderate-to-severe, active ulcerative colitis: a phase 2b, double-blind, randomised, placebo-controlled induction trial and 48 week, open-label extension, Lancet Gastroenterol Hepatol, published online on Sept. 5, 2022.

# Baseline Characteristics Well-Balanced Among the Treatment Groups, Indicating a Moderate to Severe UC Population, very Similar to Data Published Recently

		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-TNF α	n (%)	27 (42.2)	25 (41.0)	25 (39.7)	31 (48.4)
anti-TNF α 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

## Efficacy Confirmed for all Patients and also for Subset of Bio-Refractory Patients

Week 8 Results (ITT <sup>1</sup> population / n=252)		Placebo	25mg	50mg	100mg
Modified Mayo Score	All patients	-1.9	-3.1 **	-3.2 **	-2.9 *
Mean change from baseline	Bio- refractory	-1.0	-2.8 **	-2.9 **	-2.8 **

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

\*\*p-values of <0.001 versus placebo (ANCOVA)

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 - Efficacy Confirmed

Week 8 Results (ITT population / n=252)		Placebo	25mg	50mg	100mg
Key Secondary Endpoints (not powered for statistical significance)					
Endoscopic Improvement <sup>a †</sup>	All patients	8 (13.6%)	20 (34.5%) *	21 (39.6%) *	24 (44.4%) *
	Bio-refractory	1 (3.7%)	8 (28.6%) *	7 (30.4%) *	8 (26.6%) *
*p-values of <0.05 versus placebo using a likelihood ratio chi-square test					
Clinical Remission <sup>b †</sup>	All patients	8 (12.5%)	17 (27.9%) *	11 (17.5%)	16 (25.0%)
	Bio-refractory	1 (3.2%)	6 (20.0%) *	2 (6.7%)	6 (18.8%) *
*p-values of <0.05 versus placebo using a likelihood ratio chi-square test but not according to the predefined Mantel-Haenszel Chi Square test (p=0.06 to 0.08)					
Clinical Response <sup>c †</sup>	All patients	23 (35.9%)	40 (65.6%) *	38 (60.3%) *	35 (54.7%) *
	Bio-refractory	5 (16.1%)	17 (56.6%) *	13 (43.3%) *	15 (46.8%) *
*p-values of <0.05 versus placebo using a likelihood ratio chi-square test					

a Endoscopic improvement is defined as endoscopic subscore ≤1.

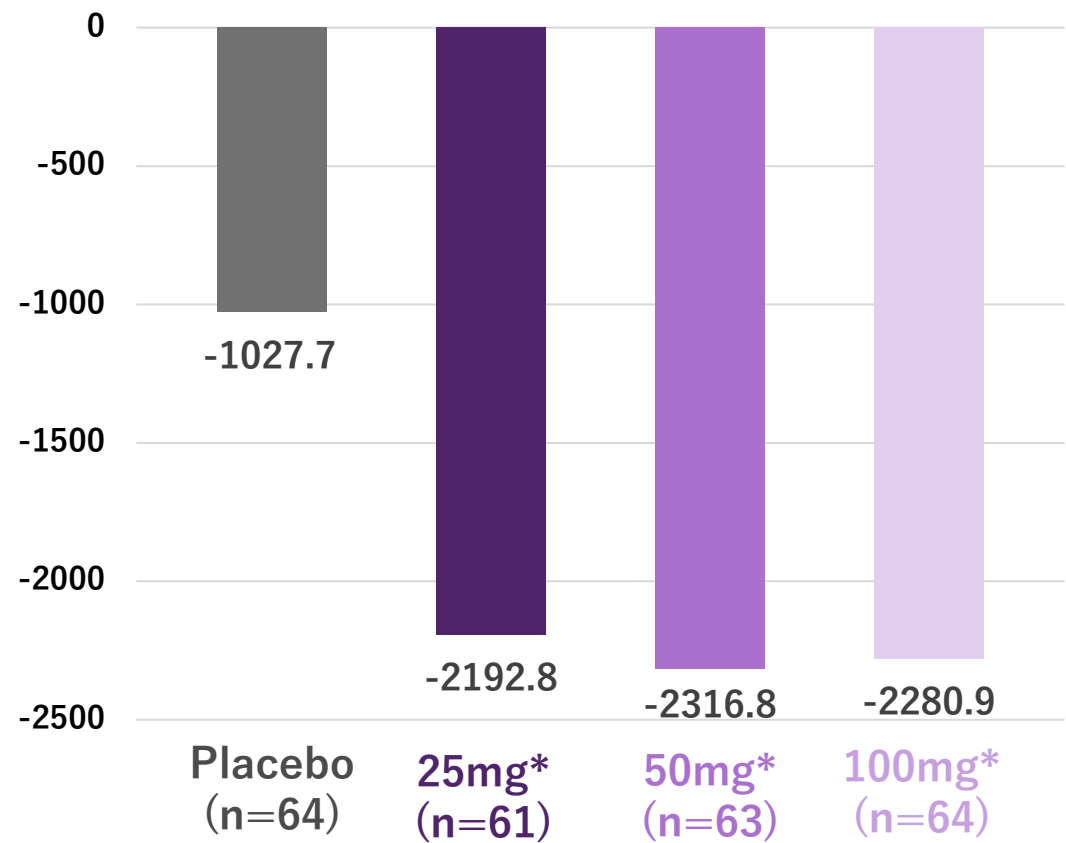
b Clinical remission (per Modified Mayo Score) is defined as stool frequency subscore (SFS) ≤1, rectal bleeding subscore (RBS) of 0 and endoscopic subscore ≤1.

c 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.

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

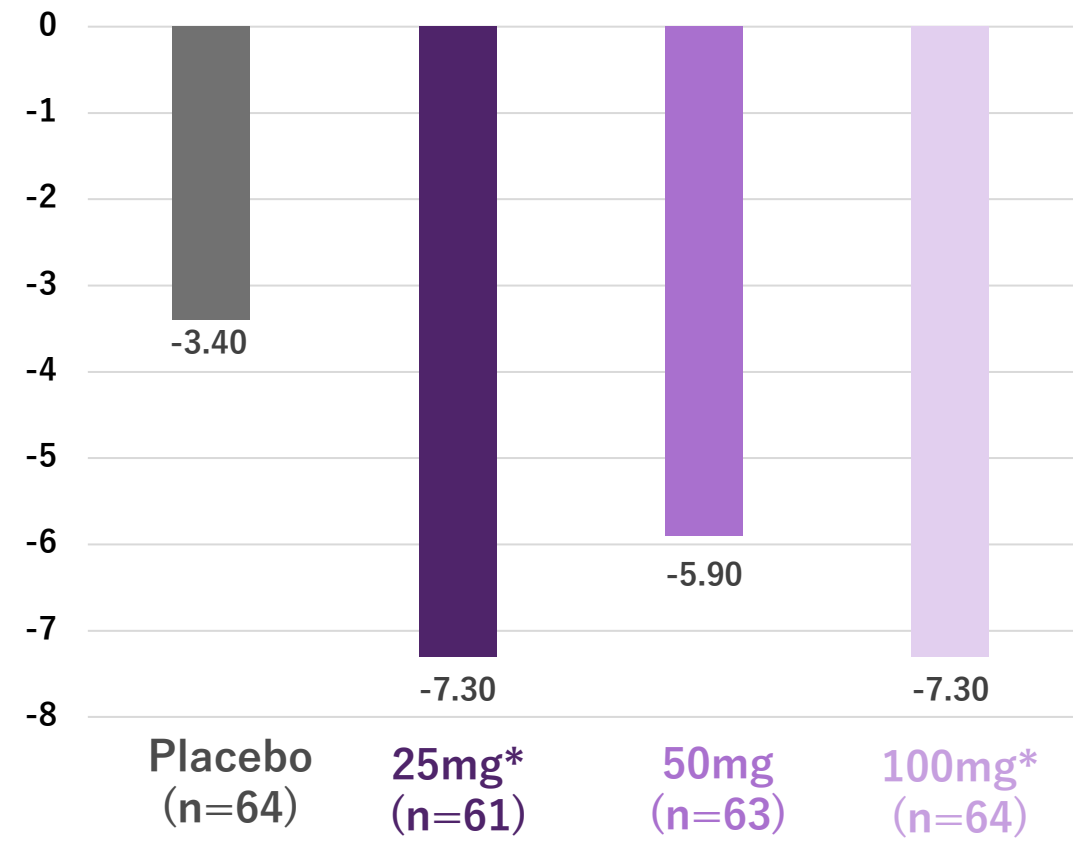
# Secondary Endpoints: Fecal Calprotectin and Roberts Histopathology Index

Mean Change from baseline in Fecal calprotectin (µg/g)



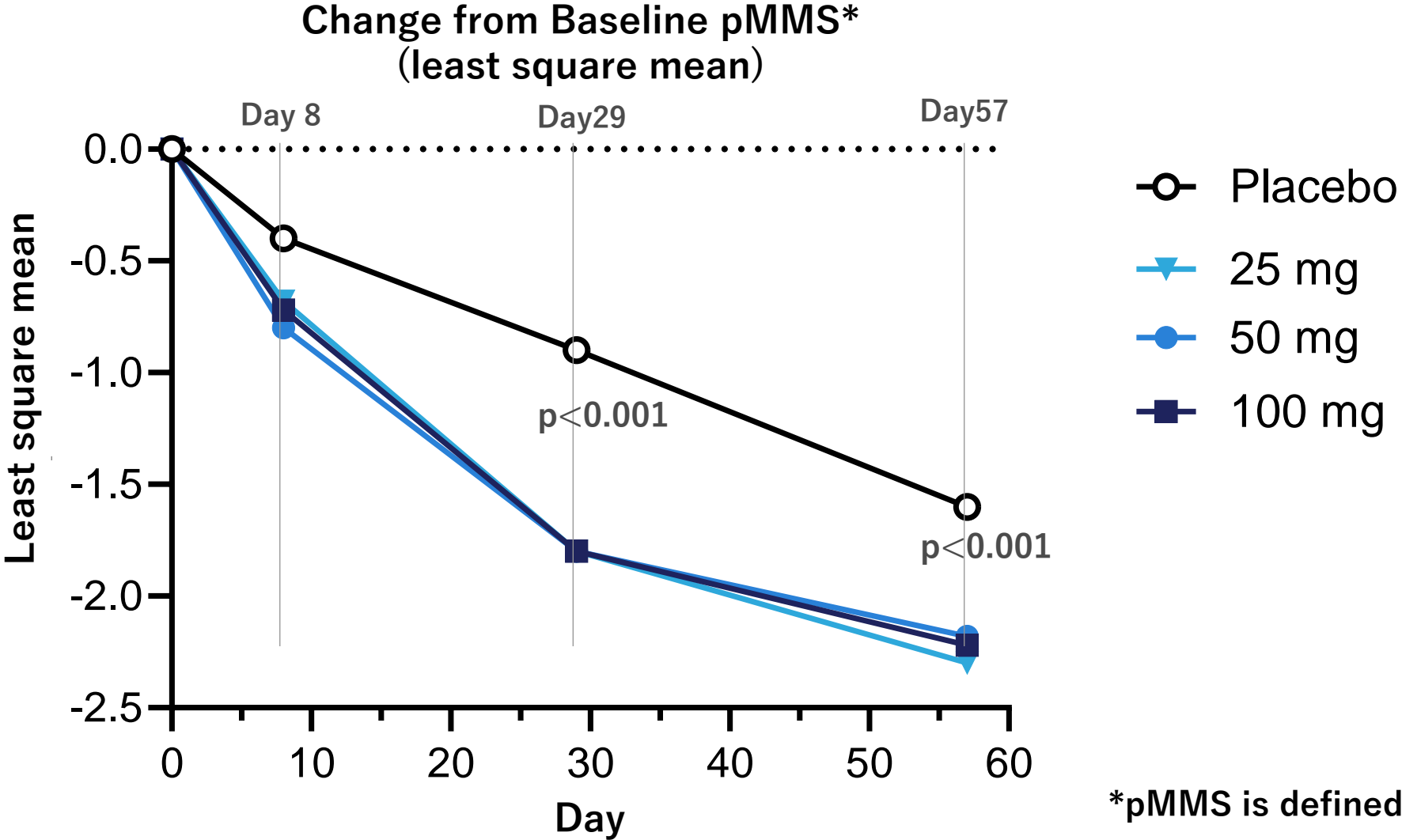
\*p-values of <0.01 versus placebo (MMRM)

Change from baseline in Roberts Histopathology Index



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

# Week 8 Efficacy Results (ITT): Rapid Onset of Action

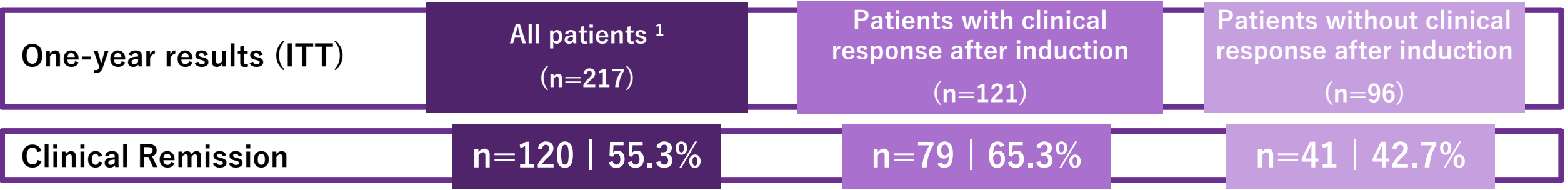


\*pMMS is defined as  $RB = 0 + SF = 0$  or 1

# Obefazimod Phase 2a and 2b Open-Label Maintenance Study Results – ITT

## Impressive Long-Term Efficacy Confirmed

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



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

Phase 2a study



<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*

Drug	Study	Active	Placebo	Delta	Active		Placebo	Delta
		Results of Induction studies (ITT)*			Results of Maintenance studies (ITT)*			
					Induction responders only	All comers		
Humira (AbbVie)	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%
Entyvio (Takeda)	GEMINI I (Ph 3, 374 + 521 Pt.)	16.9%	5.4%	11.5%	44.8%	-	15.9%	28.9%
Rinvoq (AbbVie)	U-Achieve (473 Pt.)	26.0%	5.0%	21.0%	42.0% (15mg) recommended dose 52.0% (30mg)	-	12.0% (15mg)	30.0% (15mg)
	U-Accomplish (515 Pt.)	33.0%	4.0%	29.0%			12.0% (30mg)	40.0% (30mg)
	Phase 2 (250 Pt.)	19.6%	0.0%	19.6%	-	-	-	-
Mirikizumab (Eli Lilly)	Lucent (1,162 Pt.)	24.2%	13.3%	11.1%	49.9%		25.1%	24.8%
Etrasimod (Pfizer)	Elevate 52 (433 Pt.)	27.0%	7.4%	19.8%	32.1%	-	6.7%	25.4%
	Elevate 12 (330 Pt.)	24.8%	15.2%	9.7%	-	-	-	-
Obefazimod (Abivax)	Phase 2a (32 Pt.) 50mg	30.4%	11.1%	19.3%	66.7% (50mg)	54.4%	-	-
	Phase 2b (254 Pt.) 25mg	27.9%	12.5%	15.4%	65.3% (50mg)	55.3%	-	-

Marketed drugs in IBD
  Drug candidates in late-stage development in IBD

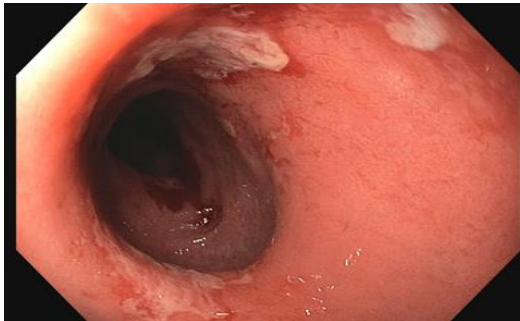
\*non-comparative studies conducted versus placebo

\*\*Sandborn et al, 2020: 12W Induction results

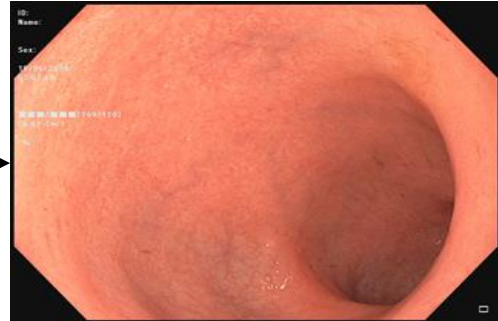
# Complete Resolution of UC Lesions in an Obefazimod Treated Patient (Humira, Remicade and Entyvio Resistant) during 4 years of Open-Label Maintenance Treatment

- 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

Endoscopy before  
obefazimod



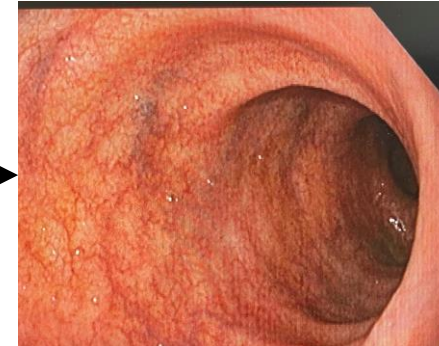
Endoscopy after  
1<sup>st</sup> year of obefazimod



Endoscopy after  
2<sup>nd</sup> year of obefazimod



Endoscopy after  
3<sup>rd</sup> year of obefazimod



Endoscopy after  
4<sup>th</sup> year of obefazimod



Courtesy of Prof. Severine Vermeire, Leuven, Belgium

# Favorable Obefazimod Safety Profile

Safety in Phase 2b Study in UC Patients Confirms Profile Observed in the Phase 2a Study

- No new safety signal, no death, no malignancy
- Most frequently reported AEs are **headaches** (20% for 25mg and 8% for placebo), **which occur early** (first 10 days of treatment) and are **transient** (few days), **mild or moderate** (grade 1 or 2) and **manageable with or without OTC medications**
- Other AEs  $\geq 5\%$  (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)
TEAE leading to Study Discontinuation	6.3%	1.6%	9.5%	9.4%
SAEs <sup>1</sup>	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%

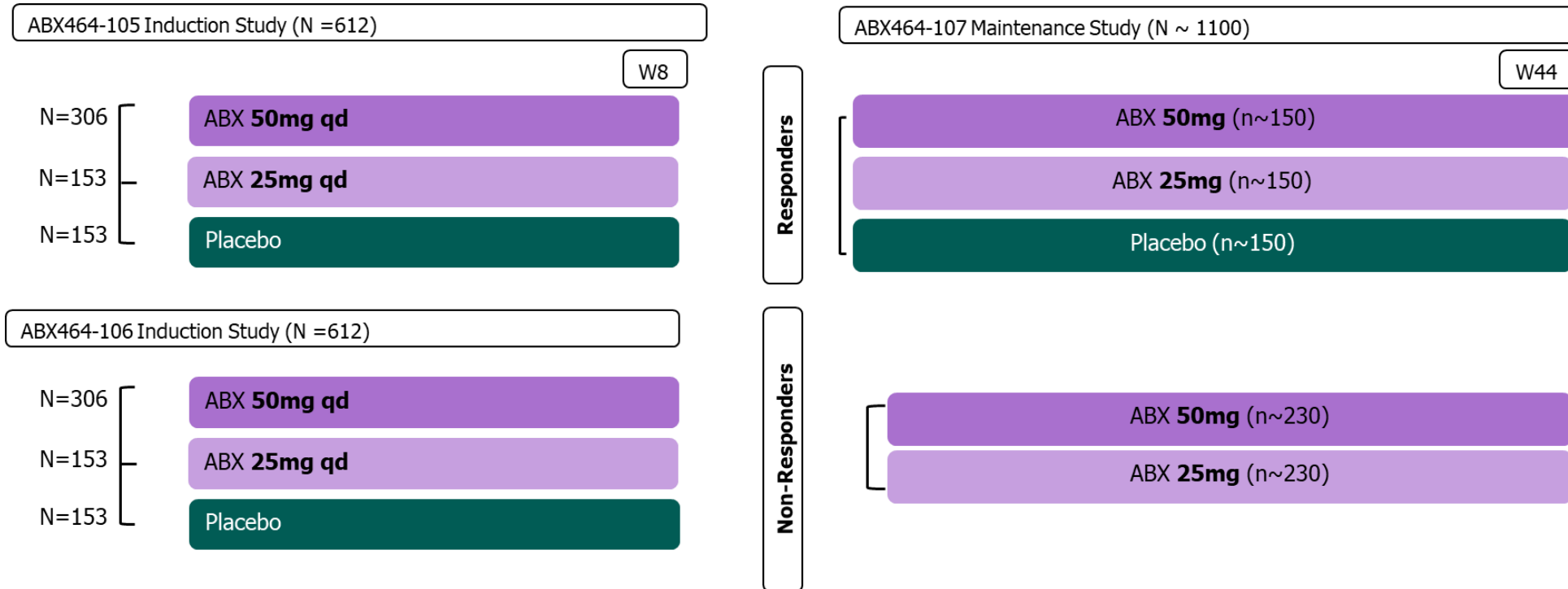
<sup>1</sup>related and not related to study drug

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

# Favorable Obefazimod Safety 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. 2021)**
  - **Subjects exposed at 25mg: 80**
  - **Subjects exposed at 50mg: 830**  
(including 240 for longer than 6 months with 197 patients more than a year)
  - **Subjects exposed at 100mg: 95**

# Obefazimod in Ulcerative Colitis – Phase 3 Study Design



- Final protocols submitted to FDA: June 22, 2022
- Studies submitted to central IRBs (US): July 15, 2022
- **First Subject In (US) expected end of Sept. 2022**
- **Key differences of phase 3 design from phase 2b**

# 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 and Abivax is **on track for FPI end of Sept. 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
- **> 430 out of 600 planned study sites in 36 countries** have already been qualified
- 137 sites (25%) in **North America**, 234 sites (42%) in **Europe**, 146 sites (26%) in **Asia** and 39 sites (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 planned for Oct. 2022

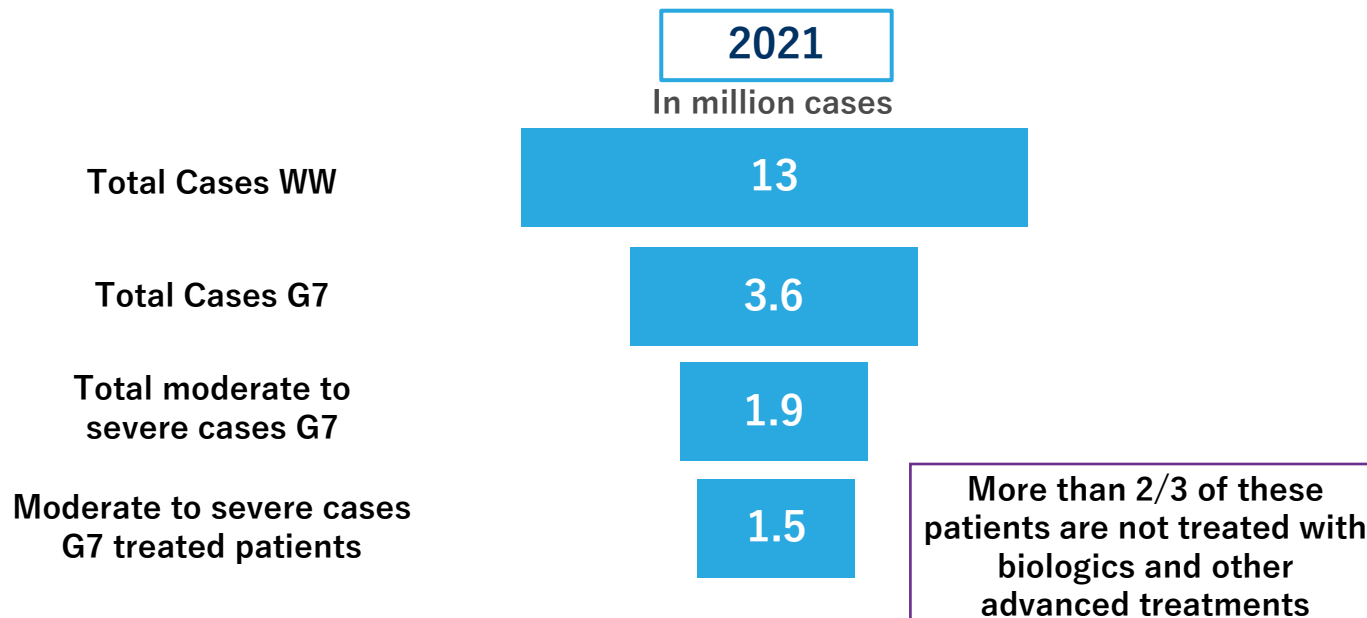
# Obefazimod: Commercial Opportunity in IBD



# Obefazimod: A Potential Mega-Blockbuster in IBD

Size of Target Market Increasing by 70% in UC and by Nearly 20% in CD (2021 - 2027)

## UC Epidemiology



**Total market size<sup>1</sup>**  
in inflammatory diseases > **USD 90B**

**Market size<sup>1,2</sup>**  
**UC: USD 6.2B**  
**CD: USD 12.9B**  
**RA: USD 22.3B**

**Obefazimod**  
addresses a  
market of  
**USD 41.4B**

## UC & CD Market Potential

	Ulcerative Colitis	Crohn's Disease
Obefazimod TPP	Patients with moderate to severe UC and CD who failed conventional therapies, therefore positioned as 1 <sup>st</sup> and 2 <sup>nd</sup> line treatment	
Obefazimod NDA approval	2026 for UC	2028 for CD
G7 Market Size (2 <sup>nd</sup> & 3 <sup>rd</sup> line)	2021: USD 6.2B for UC 2026: USD 10.2B for UC	2021: USD 12.9B for CD 2027: USD 15.4B for CD
Obefazimod Market Share Assumptions	10-20% market share at peak sales for both indications	

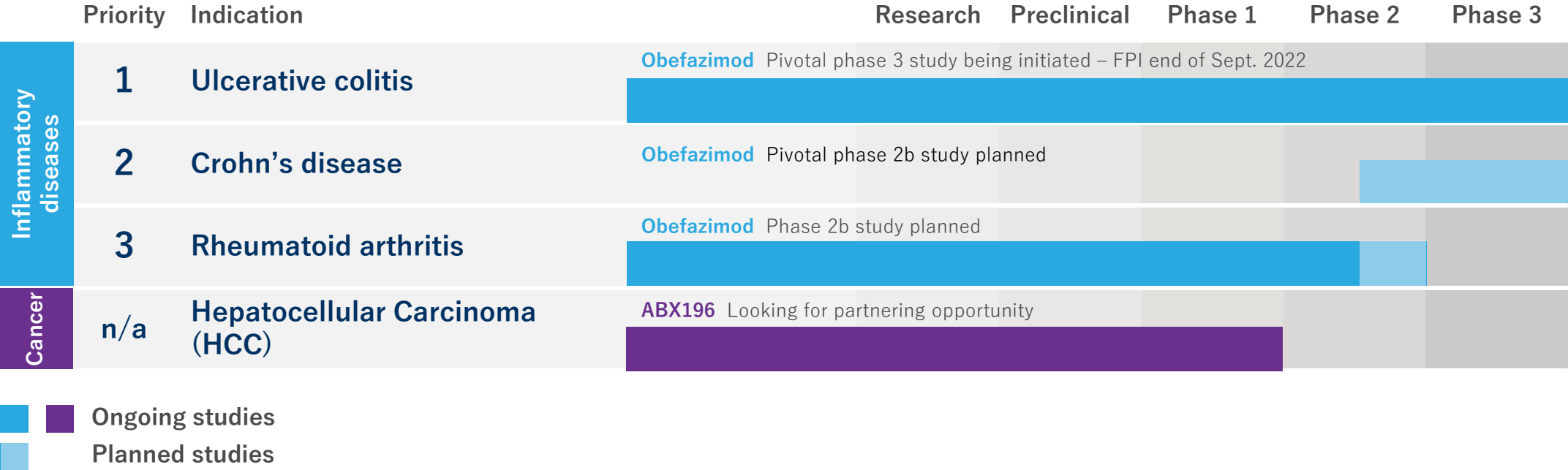
- 1) 2021 data for Europe G5, U.S. and Japan  
 2) 2<sup>nd</sup> and 3<sup>rd</sup> line

Source: Global Data & Informa

## Value Creation Continues

	Q4 2021	Q1 2022	Q2 2022	Q3 2022
<b>UC</b> - Phase 2b (Obefazimod)		<b>Top-line results</b> (One-year maintenance data) ✓		<b>Publication of full-length phase 2b manuscript</b> ✓
<b>UC</b> - Phase 3 (Obefazimod)	<b>FDA feedback</b> ✓	<b>EMA feedback</b> ✓		<b>FPI phase 3 study</b>
<b>RA</b> - Phase 2a (Obefazimod)		<b>Top-line results</b> (One-year maintenance data) ✓	<b>Publication of full-length phase 2a manuscript</b> ✓	

# Abivax Pipeline



# Financing Strategy – Multi-Pronged Approach

September 2<sup>nd</sup>, 2022



*Cross-over Financing*  
*Equity & Royalty certificates*



**EUR 49,200,000**

Attracting Top Tier US Biotech investors  
with continued commitment from historical shareholders

*New US Shareholders*



*Existing shareholders*



*Santé Holding*

- The total costs of the priority phase 3 UC program until the end of 2024, which is the expected date of the results of the two phase 3 induction studies, is estimated by the Company to amount to EUR 200M
- With EUR 49.2M cross-over financing raised in Sept. 2022, Abivax has an existing cash runway until end of Q1 2023
- An additional financing of EUR 154M is required to complement the EUR 46M proceeds of the transaction
- To cover these additional cash needs, Abivax is evaluating various different financing tools, both dilutive and non-dilutive

# Highly Experienced Executive Committee



**Prof. Hartmut Ehrlich, M.D.**  
Chief Executive Officer



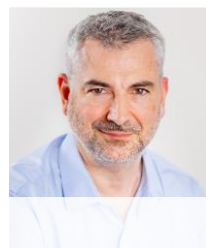
**Didier Blondel**  
EVP, Chief Financial Officer & Board Secretary



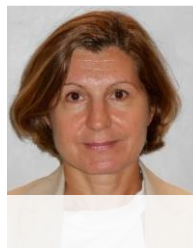
**Bob Clay, MSc, MBA**  
Senior Regulatory Strategy Advisor



**Mary Mantock, MSc**  
VP, Regulatory Affairs



**Pierre Courteille**  
Pharmacist, MBA  
Chief Commercial Officer & VP, BD



**Laurence d'Agay, M.D.**  
Senior Clinical & Medical Advisor



**Paul Gineste, Pharm.D.**  
VP, Clinical Operations



**Jérôme Denis, Ph.D.**  
VP, Process Dev. & Manufacturing



**Didier Scherrer, Ph.D.**  
VP, R&D



**Prof. Jamal Tazi, Ph.D.**  
VP, Research



**Regina Jehle**  
VP, Communications



Competencies from discovery to global commercialization