Modulating the Immune System to Fight Chronic Inflammatory Diseases

Abivax, a Phase 3 Clinical Biotech Company

November 2022

abivax

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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

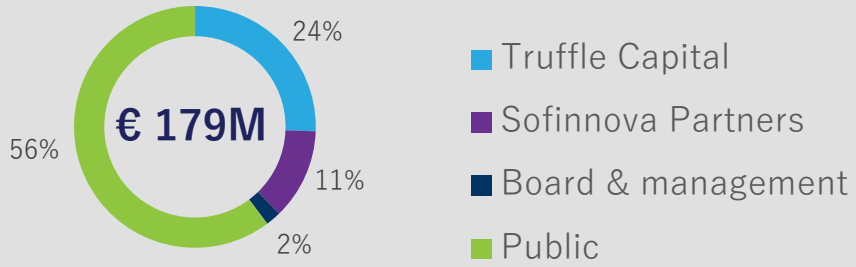
Operations

24
Employees

Cash runway until end of Q1 2023

BREAKING NEWS
Oct. 2022:
First US patient enrolled in global phase 3 program with obefazimod in ulcerative colitis

Shareholder structure[1] and market cap[2]



Key R&D and manufacturing partners

IQVIA™ evotec SEQENS DELPHARM

1) Undiluted – post capital raise Sept. 2022
2) As of 24/11/2022 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…

…1st line therapy in moderate to severe ulcerative colitis after failure of conventional therapies

UC market size in G7:
USD 10.2B in 2026

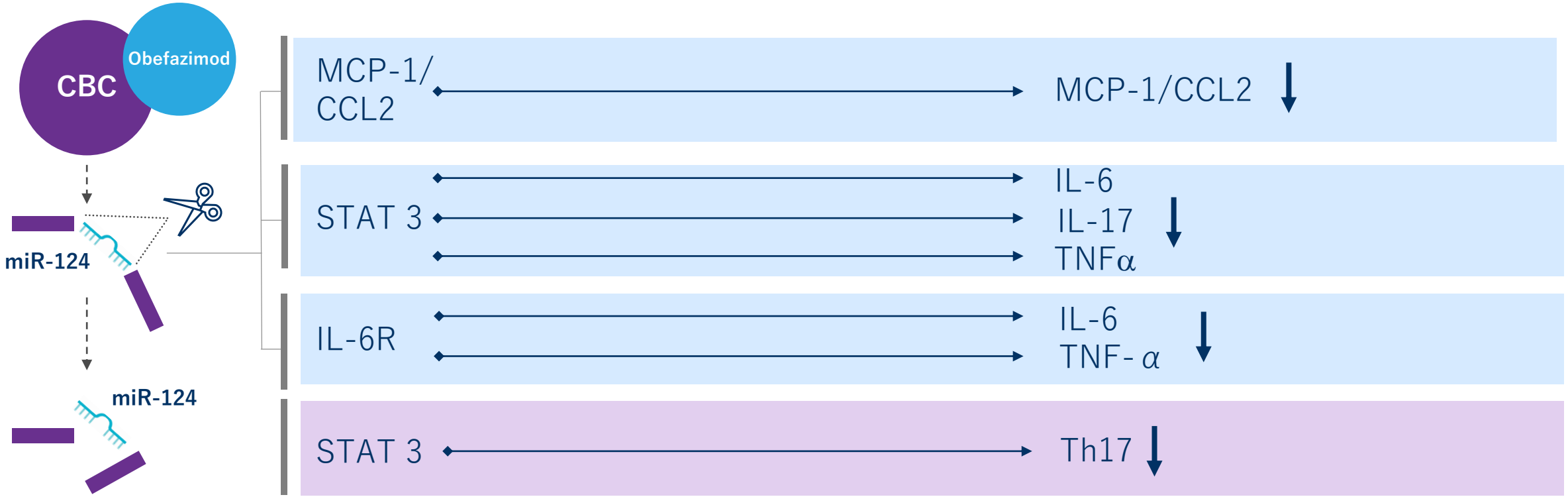
Global UC phase 3 program: First patient enrolled in the US on Oct. 11, 2022

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, 2nd and 3rd year maintenance)
- Followed by open-label maintenance study (now in 4th year)

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	Obefazimod (n=23/20) ITT | PP	Placebo (n=9/9) ITT | PP	p value* (PP)
	After 8 weeks of treatment		
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

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

- 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

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, Volume 7, Issue 11, P1024-1035

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-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[1] population / n=252)		Placebo	25mg	50mg	100mg
Modified Mayo Score Mean change from baseline	All patients	-1.9	-3.1 **	-3.2 **	-2.9 *
	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.).

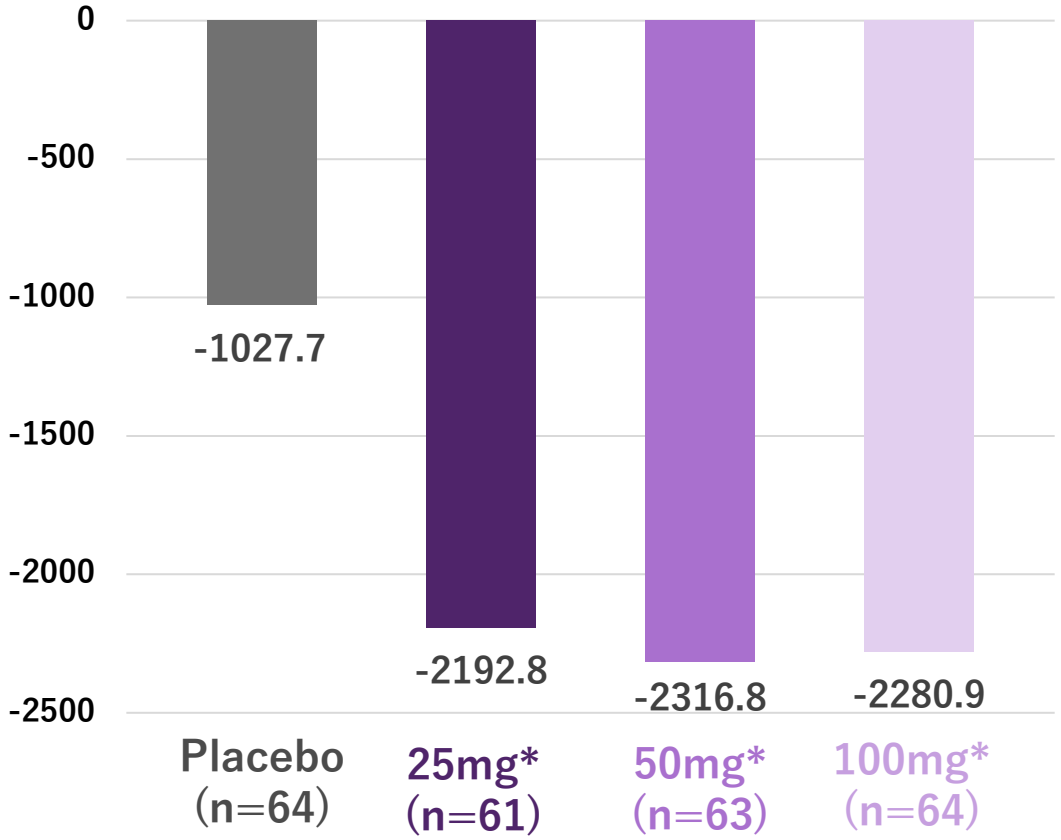
Week 8 Efficacy Results (ITT): Secondary Endpoints - Efficacy Confirmed

Week 8 Results (ITT population / n=252)		Placebo	25mg	50mg	100mg
Key Secondary Endpoints (not powered for statistical significance)					
Endoscopic Improvement [a] †	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 [b] †	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 [c] †	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

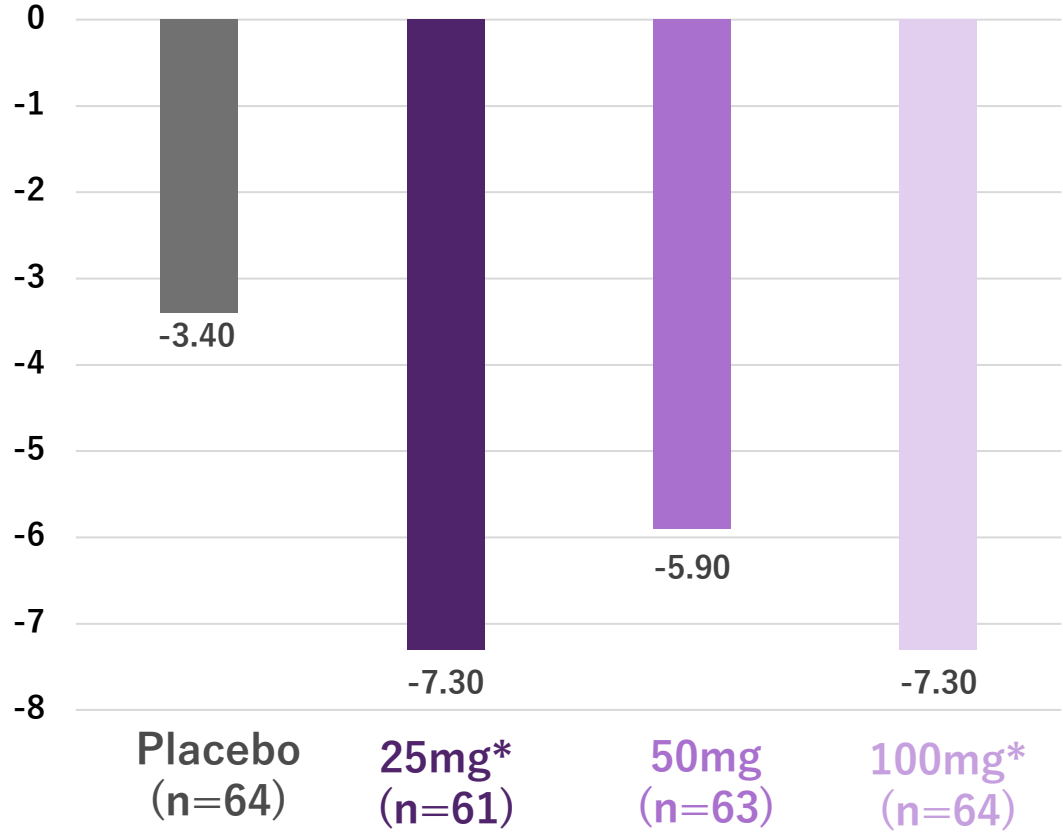
Secondary Endpoints: Fecal Calprotectin and Robarts Histopathology Index

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



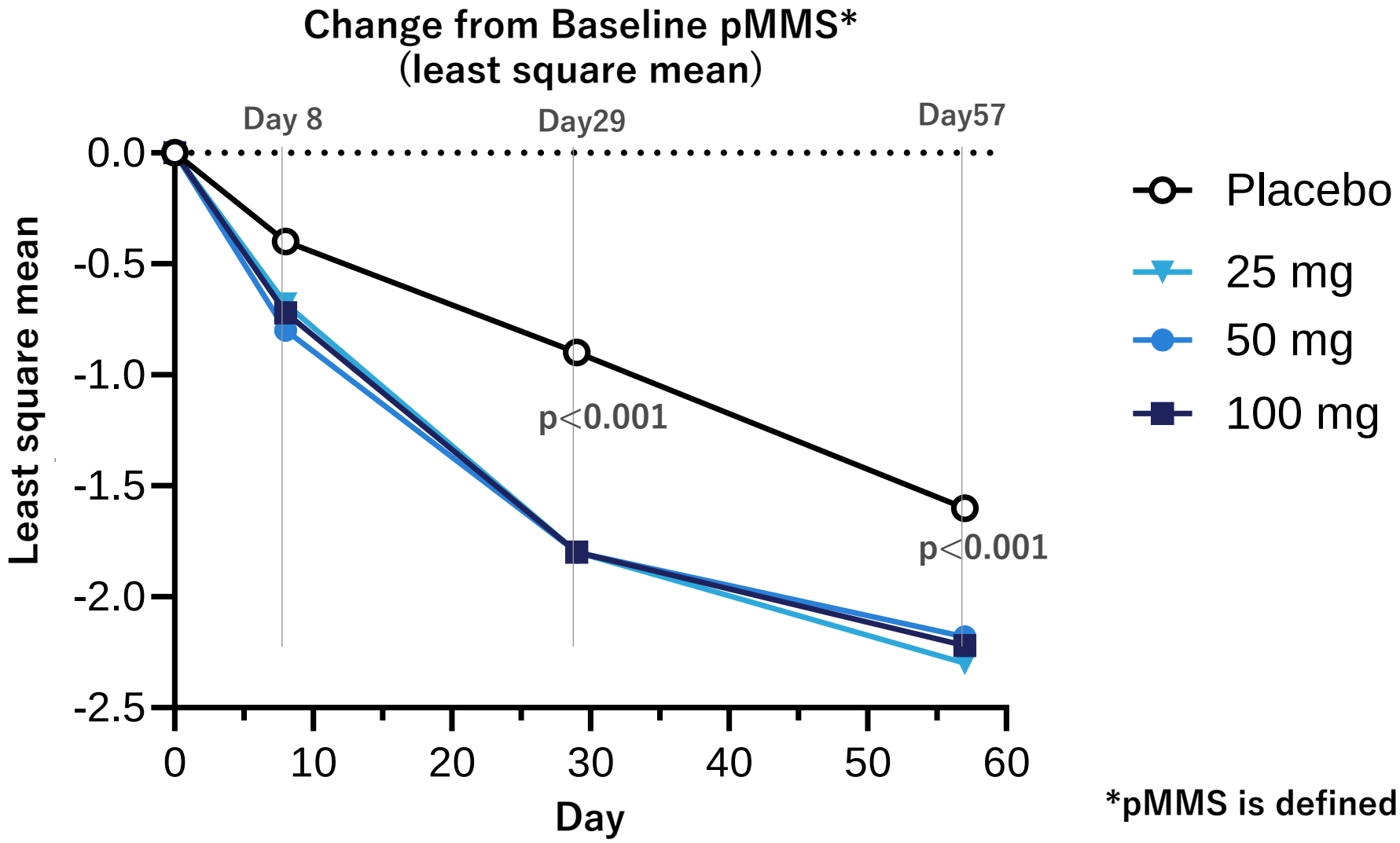
*p-values of <0.01 versus placebo (MMRM)

Change from baseline in Robarts 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

One-year results (ITT)	All patients [1] (n=217)	Patients with clinical response after induction (n=121)	Patients without clinical response after induction (n=96)
Clinical Remission	n=120 | 55.3%	n=79 | 65.3%	n=41 | 42.7%

[1] Irrespective of patient outcome at the end of the induction phase

Phase 2a study

1, 2 and 3-year results (ITT)	1st year (n=22)	2nd year (n=22)	3rd year (n=22)
Clinical Remission[1]	n=12 | 54.5%	n=11 | 50.0%	n=11 | 50.0%

[1] 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) 12.0% (30mg)	30.0% (15mg) 40.0% (30mg)
	U-Accomplish (515 Pt.)	33.0%	4.0%	29.0%				
	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%	-	-

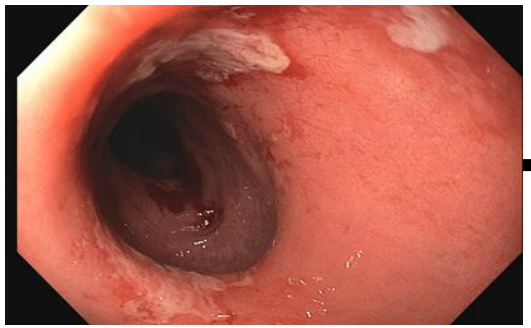
Marketed drugs in IBD Drug candidates in late-stage development in IBD

*non-comparative studies conducted versus placebo

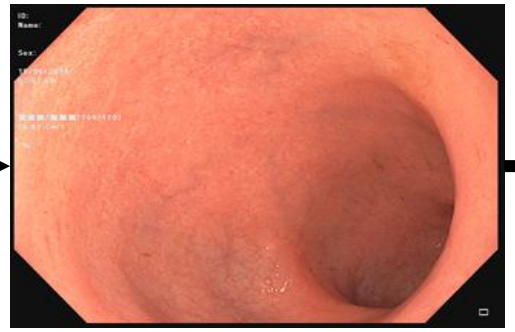
Complete Resolution of UC Lesions in an Obefazimod Treated Patient (Humira, Remicade and Entyvio Resistant) during 4 years of Open-Label Maintenance Treatment

- 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

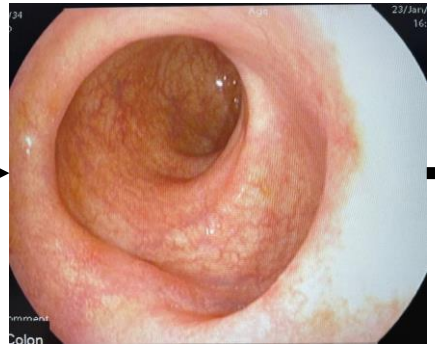
Endoscopy before obefazimod



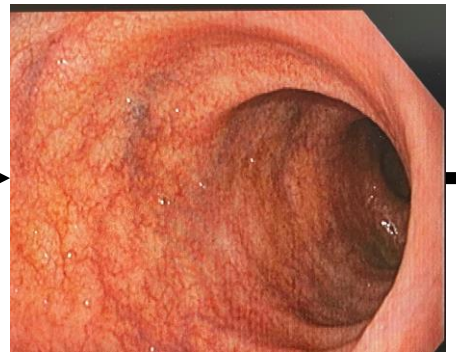
Endoscopy after 1st year of obefazimod



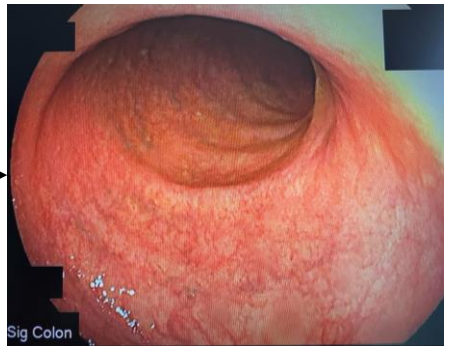
Endoscopy after 2nd year of obefazimod



Endoscopy after 3rd year of obefazimod



Endoscopy after 4th 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 ≥ 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[1]	6.3%	1.6%	6.3%	6.3%
Severe Grade 3-4 TEAEs[1]	4.7%	4.8%	7.9%	10.9%
Infections	9.4%	4.8%	12.7%	7.8%

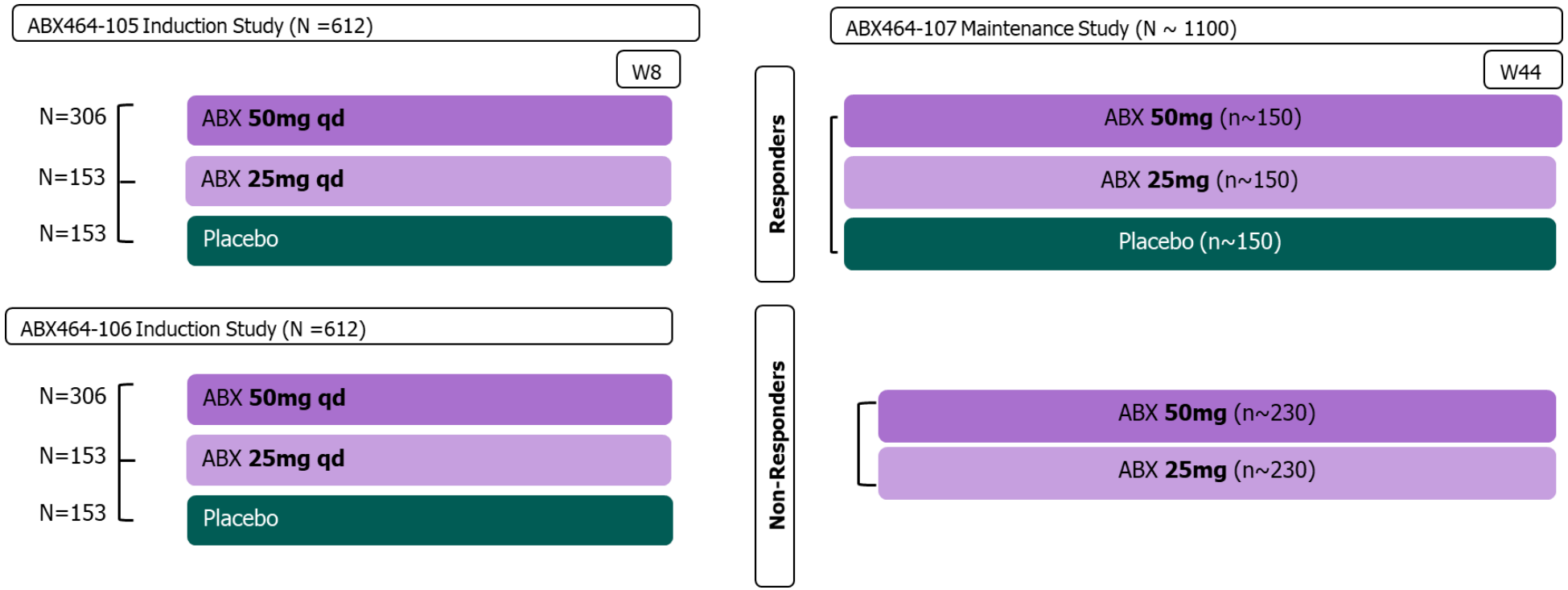
[1]related and not related to study drug

- 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 enrolled in the US on Oct. 11, 2022**
- **No major differences for selection of patient population between phase 3 and 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
- **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
- > **460 out of 600 planned study sites in 36 countries** have already been qualified
- Out of the 600 sites, 25% are located in **North America**, 42% in **Europe**, 26% in **Asia** and 7% sites 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

UC Program Upcoming Milestones

	2022	2023	2024	2025	2026
Obefazimod in UC	Oct. 11, 2022 FPI Phase 3 ✓ Sept. 2022 Phase 2b publication in Lancet GH ✓	Q2: 2-year phase 2b maintenance study data	Q2: LPI phase 3* Q4: Top-line data of phase 3 induction study	Q3: Top-line data of phase 3 maintenance study	NDA approval

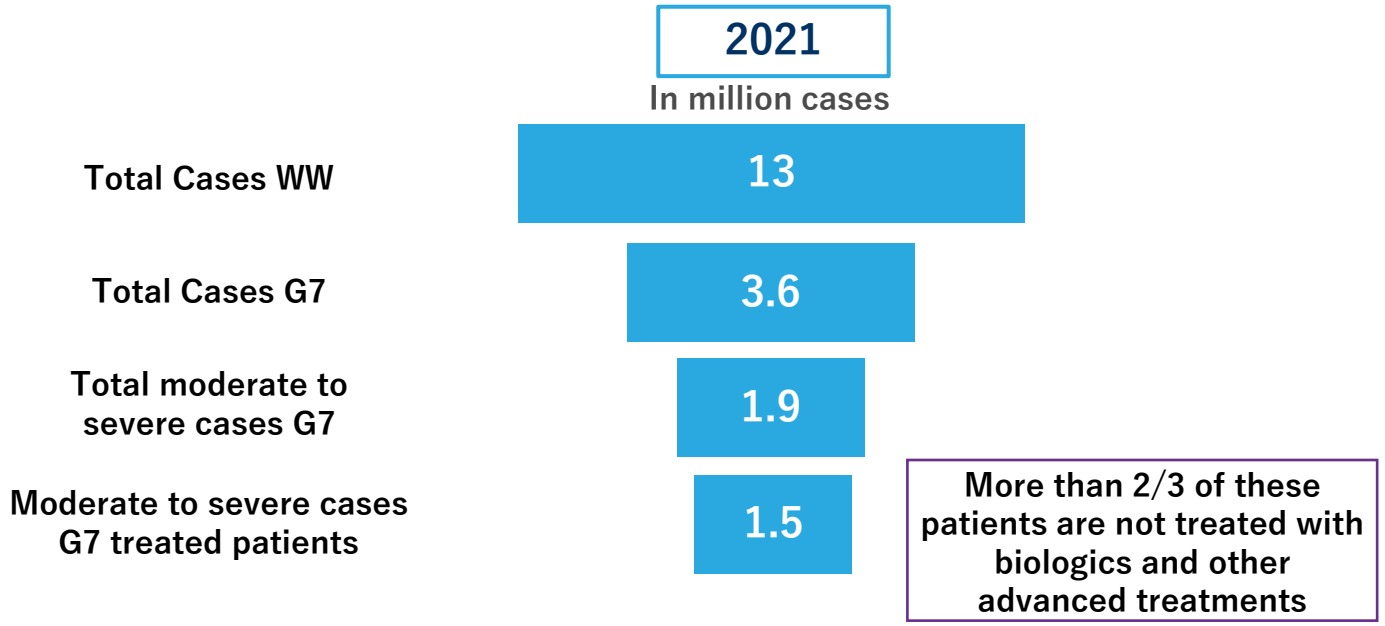
*Based on the recent revisions of the protocol, timelines and costs of the phase 3 program are currently under revision, with the risk of a potential delay of up to 3 months for the end of enrollment and additional costs up to 10-15% of the total study costs.

Obefazimod: Commercial Perspectives 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[1] in inflammatory diseases > **USD 90B**

Market size[1,2]
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 1st and 2nd line treatment	
Obefazimod NDA approval	2026 for UC	2028 for CD
G7 Market Size (2nd & 3rd 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) 2nd and 3rd line

Source: Global Data & Informa

Obefazimod Patents

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

Granted patent

Pending application

* Claims allowable

* No allowed protection according to patent law in India (IN)

Financing Strategy – Multi-Pronged Approach

September 2nd, 2022

abivax

Cross-over Financing

Equity & Royalty certificates

EURONEXT Paris

EUR 49,200,000

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

New US Shareholders

TCGX

venrock

DEEP TRACK CAPITAL

Existing shareholders

SOFINNOVA PARTNERS

INVUS

Truffle Capital

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.

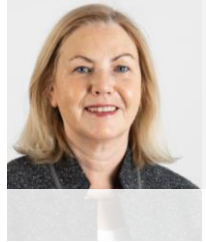
Chief Executive Officer

Baxter · SANDOZ · Lilly

Didier Blondel

EVP, Chief Financial Officer & Board Secretary

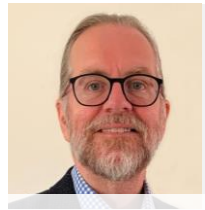
SANOFI · sanofi pasteur MSD



Mary Mantock, MSc

VP, Regulatory Affairs

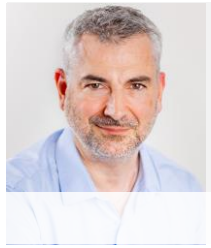
astellas · GALDERMA · Takeda



Bob Clay, MSc, MBA

Development Strategy Advisor

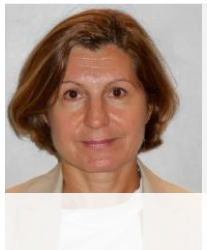
AstraZeneca · Pfizer



Pierre Courteille Pharmacist, MBA

Chief Commercial Officer & VP, BD

sanofi pasteur · Guerbet Contrast for Life



Laurence d'Agay, M.D.

Senior Clinical & Medical Advisor

Celgene · Bristol-Myers Squibb · SANOFI · NOVARTIS

Paul Gineste Pharm.D.

VP, Clinical Operations

Boehringer Ingelheim · ALTANA

Jérôme Denis, Ph.D.

VP, Process Dev. & Manufacturing

imaXio · LYONBIOPOLE

Didier Scherrer, Ph.D.

VP, R&D

AstraZeneca

Prof. Jamal Tazi, Ph.D.

VP, Research

Regina Jehle

VP, Communications

BIONTECH

Competencies from discovery to global commercialization