Modulating the immune system to fight inflammatory and viral diseases, as well as cancer

Abivax, a late-stage clinical biotech company

May, 2021

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 ABX464 by EMA, FDA and other regulatory authorities. These top-line results have not yet been reviewed by regulatory authorities.

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

Sept. 2018: Focus ABX464 on chronic inflammation

Location

Head Office
Paris

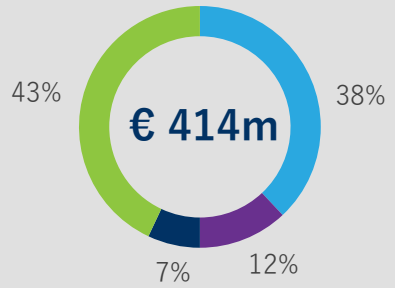
Cooperative Lab with CNRS
Montpellier

abivax

BREAKING NEWS

May 2021: Abivax reports excellent efficacy and safety of ABX464 in phase 2b trial in UC and plans to proceed to phase

Shareholder structure[1] and market cap[2]



Operations

28
Employees

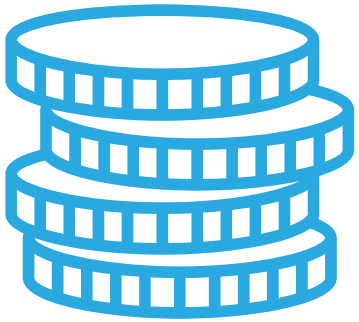
Cash[3]
€ 29.3m
Cash runway until Q4 2021

Key R&D and manufacturing partners

IQVIA™ evotec SEQENS DELPHARM

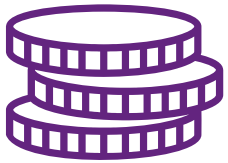
1) Undiluted – as of 31/01/2021
2) As of 26/05/2021 EOB
3) December 2020

ABX464: A promising candidate addressing large unmet medical needs



Total market size* in inflammatory diseases

greater than
USD 90 B



Market size* in ulcerative colitis

around
USD 6 B**

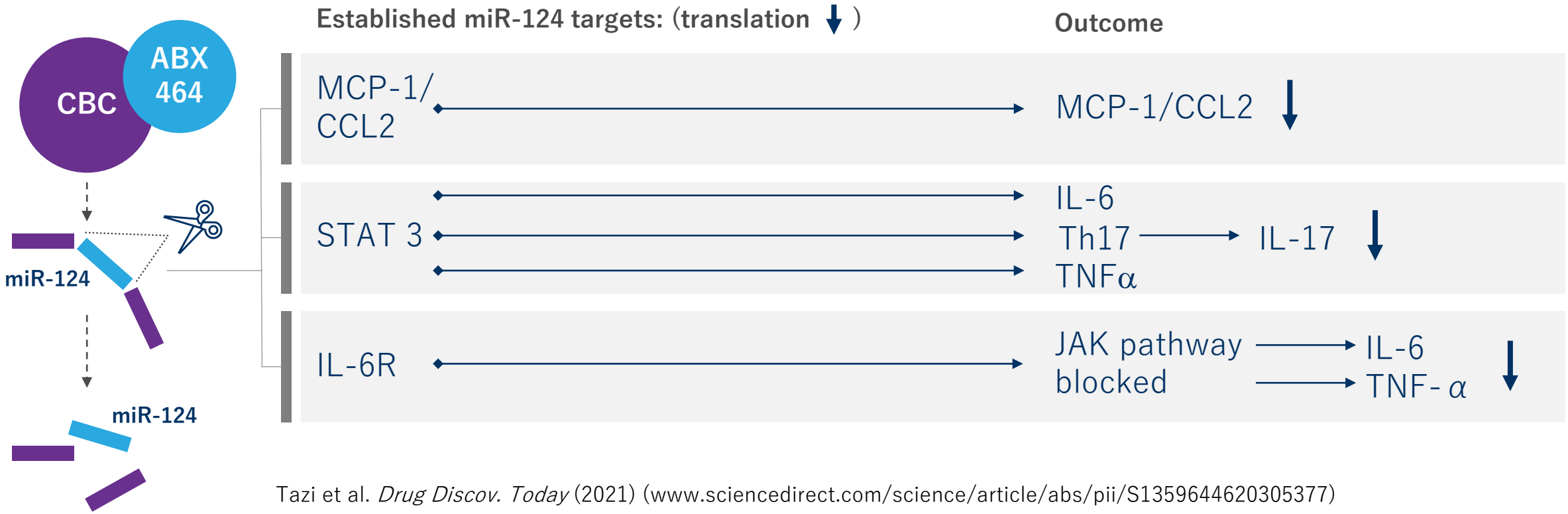
* 2020 data for Europe G5, U.S. and Japan
** 2nd and 3rd line

Source: Global Data & Informa

- Coming from the **proprietary Abivax library of compounds**, designed to **modulate RNA biogenesis** (>2,200 molecules); Collaboration with EVOTEC
- **Small molecule**, administered as an **oral capsule** (once a day) ABX464 tablet form under development
- **First-in-Class, novel mechanism of action:** Selective upregulation of anti-inflammatory microRNA, miR-124
- **Good safety profile** after administration to **>850 patients and volunteers**
- **Strong short- and long-term anti-inflammatory effect** confirmed in phase 2a and 2b studies in ulcerative colitis
- **Start of phase 3 in UC and phase 2b/3 in Crohn's disease planned for end of 2021**
- **High unmet medical need and commercial opportunities** for novel safe and efficacious drugs for inflammatory diseases

ABX464 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.**



Tazi et al. *Drug Discov. Today* (2021) (www.sciencedirect.com/science/article/abs/pii/S1359644620305377)

Poholek et al. *J Exp Med* (2020) 217 (10): e20191761

ABX464 is moving to phase 3 by end of year

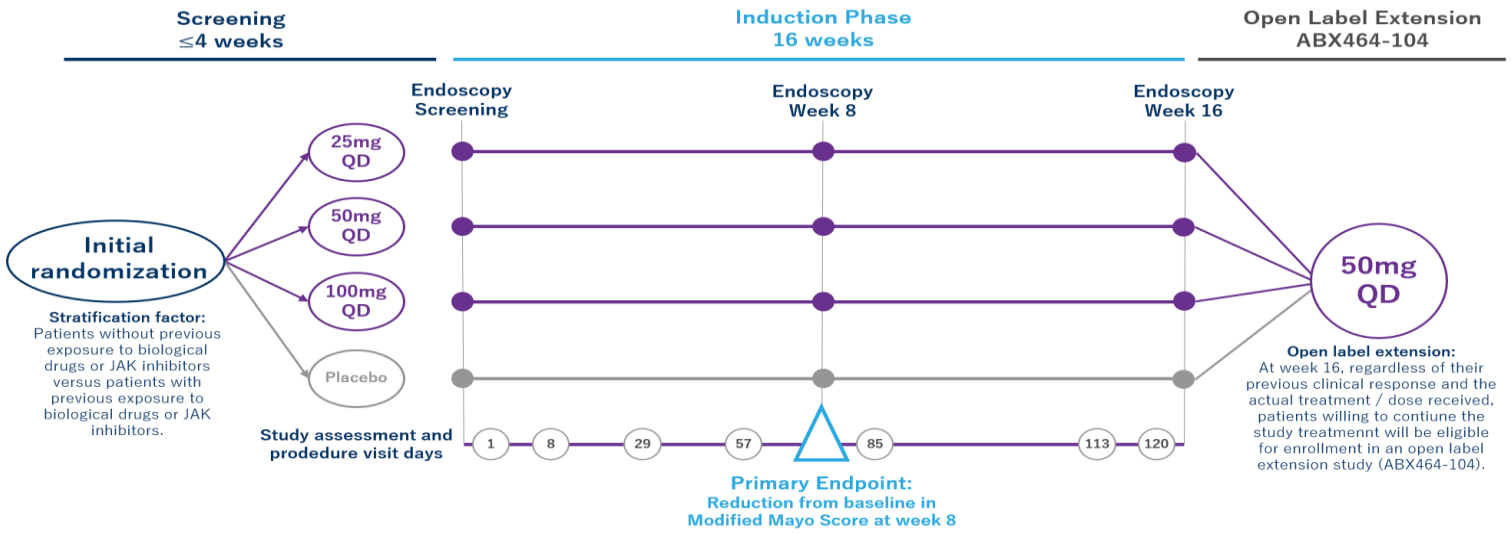
- Primary endpoint (statistically significant reduction of Modified Mayo Score) was met with once-daily ABX464 (25mg, 50mg, 100mg) at week 8 in these 254 patients randomized, double-blind and placebo-controlled clinical trial ($p<0.01$, intent-to-treat population [ITT])
- Key secondary endpoints, including endoscopic improvement, clinical remission, clinical response and the reduction of fecal calprotectin showed significant difference in patients dosed with ABX464 compared to placebo
- ABX464 also showed rapid efficacy in all patients, including those who were previously exposed to biologics and/or JAK inhibitors treatment
- ABX464 was safe and well tolerated
- Preliminary data from 51 patients treated with 50mg ABX464 in the open-label maintenance study showed further increased and durable clinical remission and endoscopic improvement after 48 weeks

ABX464 phase 2b clinical study in ulcerative colitis

Ulcerative colitis phase 2b:

- 254 patients in 15 European countries, US and Canada in 130 study sites
- 4 study arms (placebo, 25, 50, 100mg QD) / Central blinded reading of endoscopies
- 85-90% of the patients received CS, IM or/and ASA as background therapy during the study
- 50% of patients were refractory to biologics and/or Jak inhibitors as per stratification

Study design: ABX464 phase 2b clinical study in ulcerative colitis



Top-Line Efficacy Results (ITT): Primary Endpoint met - Efficacy confirmed

Week 8 top-line Results (ITT[1] population / n=252)		Placebo	25mg	50mg	100mg
Primary Endpoint					
Modified Mayo Score Mean change from baseline	All patients	-1.9	-3.1 **	-3.2 **	-2.9 *
	Bio exposed	-1.0	-2.8 **	-2.9 **	-2.8 **

***p-values of <0.01 versus placebo (ANCOVA)**
****p-values of <0.001 versus placebo (ANCOVA)**

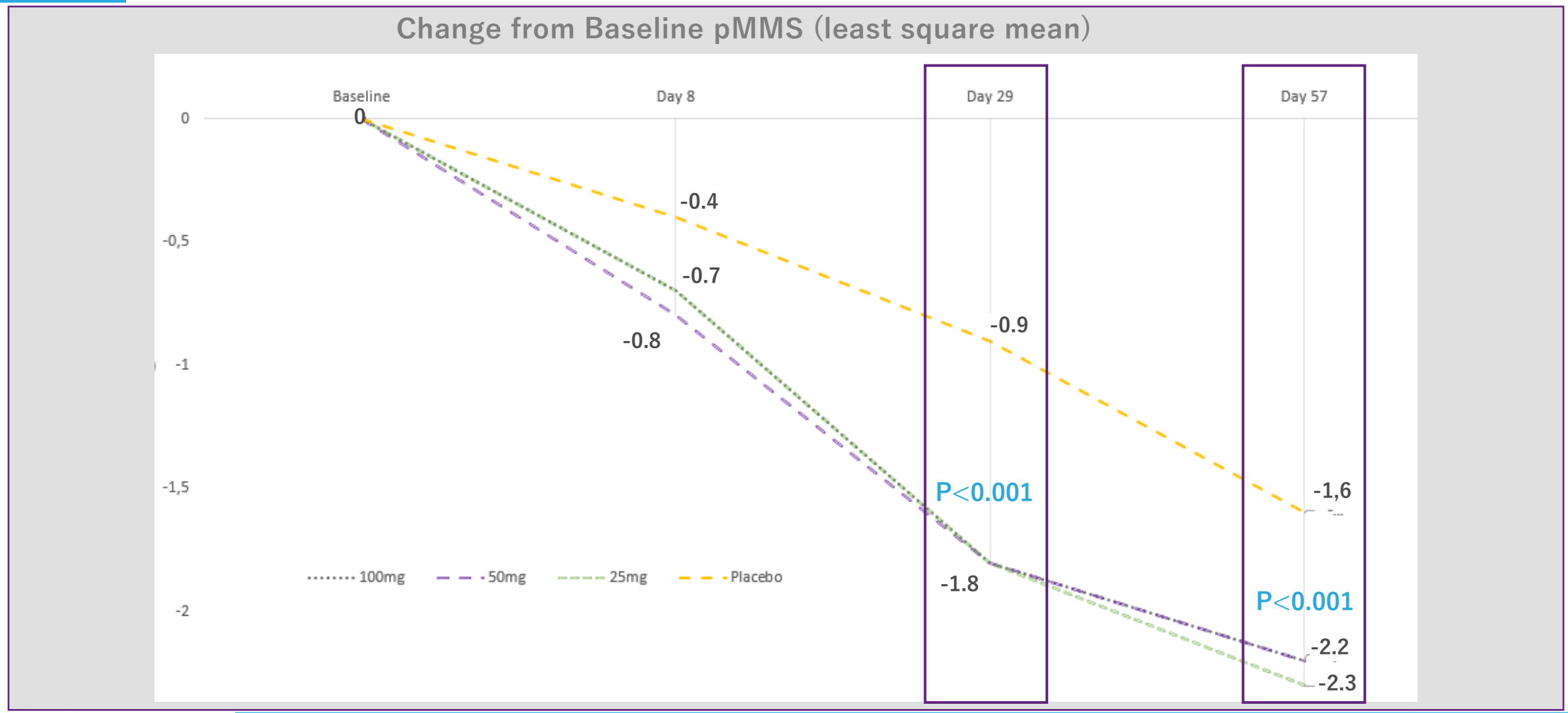
1) Intent-to-treat patient population. Drop-out patients were considered as failure for all endpoints. Nearest neighbor imputation, as defined in the SAP. Patient characteristics well balanced between all groups (Modified Mayo Score, ConMeds, Gender, etc.).

Top-Line Efficacy Results (ITT): Secondary endpoints - Efficacy confirmed

Week 8 top-line 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 exposed	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 exposed	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 exposed	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					
Fecal Calprotectin (µg/g) Mean change from baseline	All patients	-1027.7	-2192.8 **	-2316.8 **	-2280.9 **
**p-values of <0.01 versus placebo (MMRM)					

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

Top-Line Efficacy Results (ITT): Fast onset of action



Excellent safety results

- ✓ **No new safety signal**
- ✓ **Low overall drop-out rate (8.7%) at week 8 despite COVID-19**
- ✓ **Serious adverse events (SAEs)** (related and non-related)
  - **6.2% (placebo), 1.6% (25mg), 6.3% (50mg), 6.2% (100mg)**
- ✓ **Severe** (grade 3 or 4) **treatment emergent adverse events (TEAEs)** (related and non-related) :
  - **4.7% (placebo), 4.8% (25mg), 7.9% (50mg), 10.9% (100mg)**
- ✓ **No death and no malignancy**
- ✓ **Similar low infection rates between ABX464 (8.4% all doses) and placebo (9.4%)**
- ✓ **Labs:**
  - **No clinically significant changes in laboratory parameters (Liver function tests, Hb, lymphocytes, neutrophils, etc.)**
  - **No imbalances across groups**

Favorable ABX464 safety profile

Most common (> 5%) Adverse Events (AE): Drug-related or non-drug-related

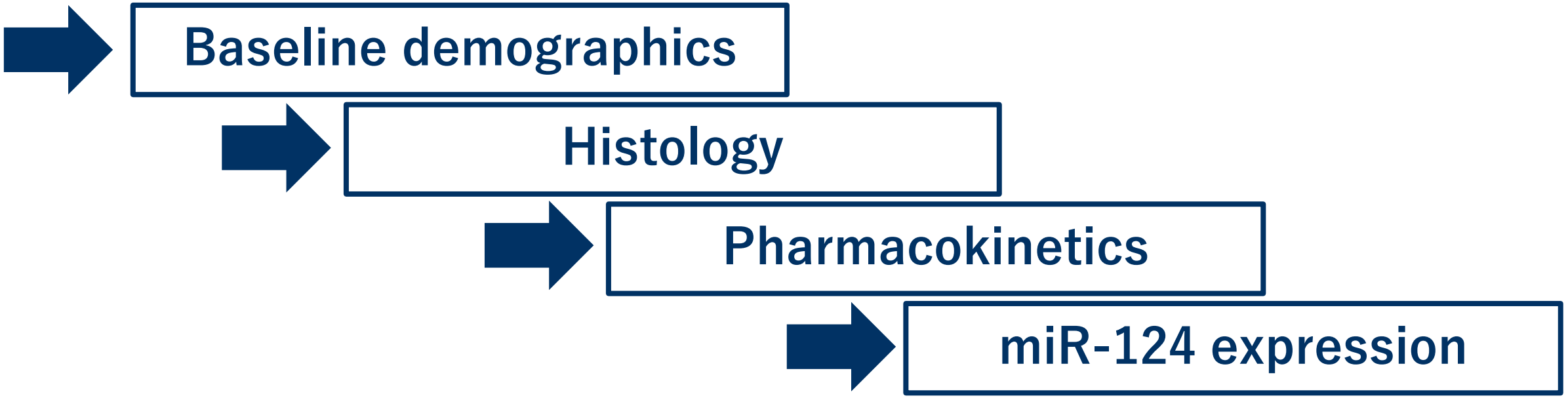
System Organ Class	Adverse effect	Placebo (N=64)		ABX464 25mg (N=63)		ABX464 50mg (N=63)		ABX464 100mg (N=64)	
		Number of reports	n (%) of pts with AE (Incidence)	Number of reports	n (%) of pts with AE (Incidence)	Number of reports	n (%) of pts with AE (Incidence)	Number of reports	n (%) of pts with AE (Incidence)
Nervous System Disorders	Headache	5	5 (7.8)	14	13 (20.6)	21	19 (30.2)	29	27 (42.2)
Gastrointestinal Disorders	Nausea	4	4 (6.3)	5	5 (7.9)	5	4 (6.3)	9	9 (14.1)
	Vomiting	1	1 (1.6)	1	1 (1.6)	2	2 (3.2)	5	5 (7.8)
	Upper abdominal pain	0	0 (0)	4	3 (4.8)	4	3 (4.8)	4	4 (6.3)
Musculo-skeletal Disorders	Arthralgia	3	3 (4.7)	1	1 (1.6)	1	1 (1.6)	6	5 (7.8)
	Myalgia	0	0 (0)	0	0 (0)	0	0 (0)	6	5 (7.8)

Most frequently reported adverse events are transient (few days) and mild (headache, nausea, gastrointestinal pain) and manageable with or without OTC medications

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

From top-line to final induction phase results

Final results expected second half of June, that will be important for phase 3 dose selection



Preliminary data from the maintenance study (ABX464-104): Further increased and durable efficacy at one year (Cut-off date: May 11, 2021)

Preliminary data from the first 51 patients* enrolled and treated with once-daily 50mg ABX464 in the open-label maintenance study showed increased and durable clinical remission and endoscopic improvement after 48 weeks

n=51 Patients at W48: ITT

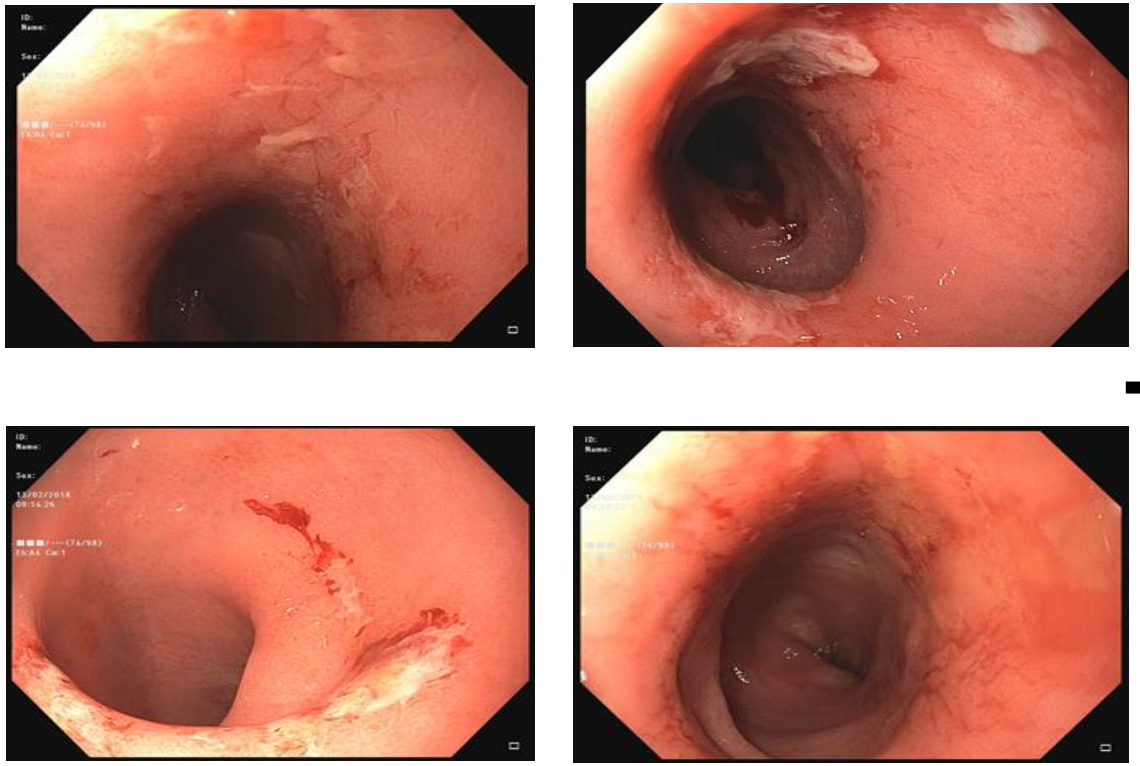
53% Clinical Remission

59% Endoscopic Improvement

*Irrespective of patient outcome at the end of the induction phase

Complete resolution of UC lesions in an ABX464 treated (vedolizumab, infliximab and adalimumab resistant) patient

Endoscopy before ABX464



Endoscopy after ABX464

Courtesy of Prof. Severine Vermeire, Leuven, Belgium

How to bring ABX464 to the finish line

Phase 1 TQT study:
- 105/120 subjects enrolled
- Results expected in Q3 2021

Phase 1 DDI study: COMPLETED
- 59 subjects treated
- Results expected in Q3 2021

Phase 1 ADME study:
- 12 subjects to be enrolled, starting Q2 2021
- Results expected in late Q4 2021

Phase 1 study in Japanese subjects
- PMDA interactions in March 2021
- Subjects to be enrolled in Japan, starting Q3 2021

Ulcerative colitis phase 3 in preparation:
- End of phase 2b meeting planned for **Q3 2021**
- **IQVIA** involved in study preparation
- **~ 2 x 600 patients** planned
- FPI planned for **Q4 2021**

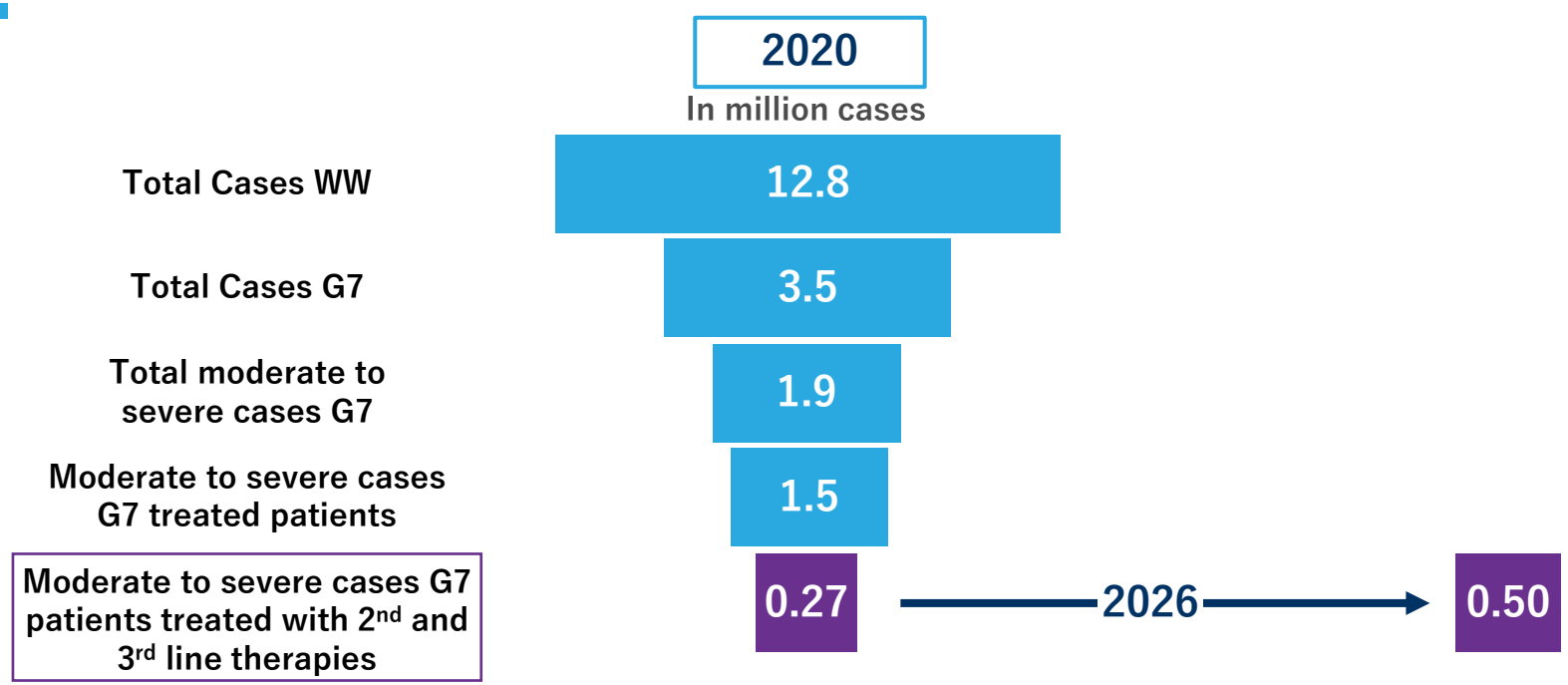
Crohn's disease phase 2b/3 study in preparation:
- **~ 900 patients** in Europe and the US
- FPI expected for **Q4 2021**

Rheumatoid arthritis phase 2a study ongoing:
- Enrollment completed (60 patients in 5 European countries)
- Top-line data for induction phase in **Q3 2021**
- Phase 2b study planned for **Q1 2022**

ABX464: A future blockbuster in IBD

Size of target market doubling in UC and increasing by nearly 25% in CD (2020 - 2026)

UC Epidemiology

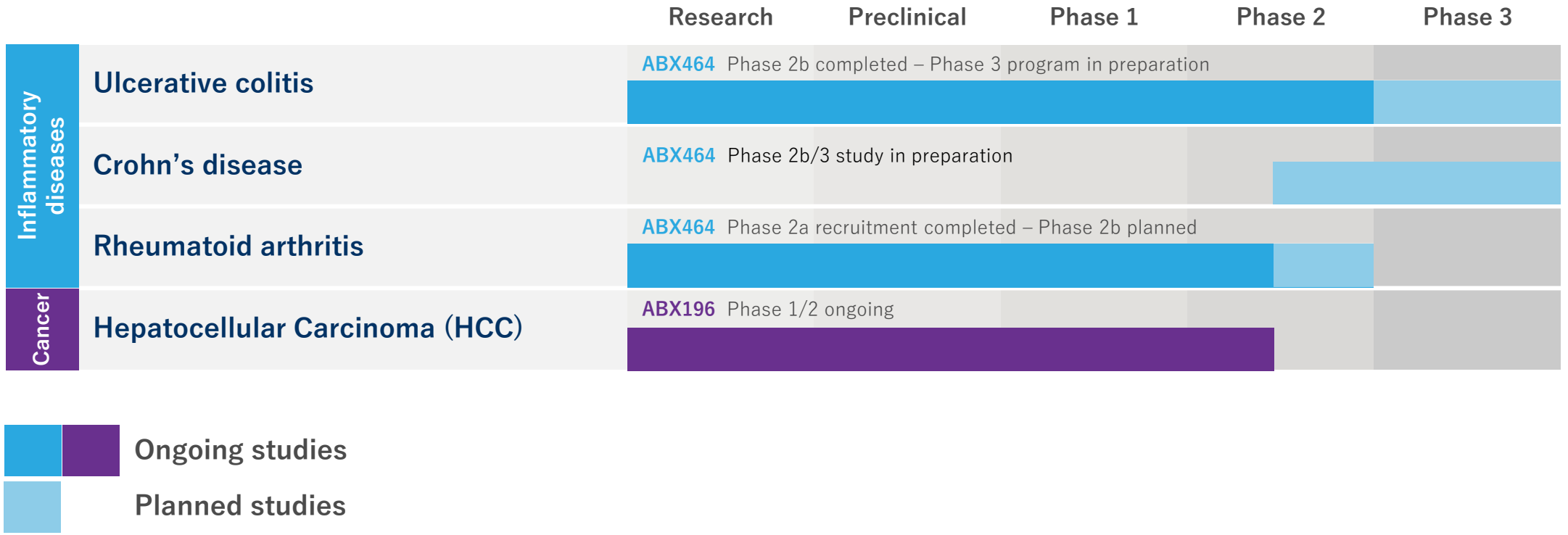


UC & CD Market Potential

	Ulcerative Colitis	Crohn's Disease
ABX464 TPP	Patients with moderate to severe UC and CD who failed on first line therapy Therefore, positioned as 2nd and 3rd line treatment	
ABX464 First Launch	2025 for UC	2026 for CD
G7 Market Size (2nd & 3rd line)	2020: USD 6.0 B for UC 2026: USD 11.7 B for UC	2020: USD 11.9 B for CD 2026: USD 14.7 B for CD
ABX464 Market Share Assumptions	10-20% market share at peak sales for both indications	

Source: Informa

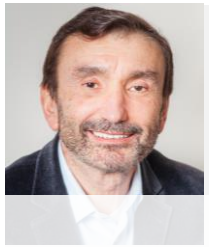
Abivax: A late-stage biotech with a strong and diversified clinical pipeline addressing major medical needs and markets



Newsflow through end of 2021

	Q1 2021	Q2 2021	Q3 2021	Q4 2021	Q1 2022
UC - Phase 2b (ABX464)		Top-line results (Induction and initial maintenance data) ✓		FPI Phase 3	Top-line results (One-year maintenance data)
CD - Phase 2b/3 (ABX464)				FPI Phase 2b/3	
RA - Phase 2a (ABX464)	Enrollment completed ✓		Top-line results (Induction and initial maintenance data)		FPI Phase 2b
HCC - Phase 1/2 (ABX196)			Enrollment completed and top-line results (Dose escalation) Start of expansion phase		

Highly experienced Executive Committee

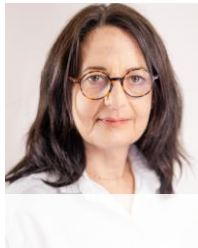


Prof. Hartmut Ehrlich, M.D.

Chief Executive Officer

Didier Blondel

Chief Financial Officer & Board Secretary

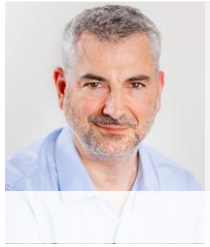


Sophie Biguenet, M.D.

Chief Medical Officer

Jean-Marc Steens, M.D.

Chief Medical Advisor



Pierre Courteille Pharmacist, MBA

Chief Commercial Officer & VP, BD

Paul Gineste Pharm.D.

VP, Clinical Operations

Jérôme Denis, Ph.D.

VP, Process Dev. & Manufacturing

Alexandra Pearce, Ph.D.

VP, Regulatory Affairs, Quality, PV

Didier Scherrer, Ph.D.

VP, R&D

Prof. Jamal Tazi, Ph.D.

VP, Research

Regina Jehle

Director Communications

Competencies from discovery to global commercialization