

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

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Abivax, a late-stage clinical biotech company

April, 2021



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# 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

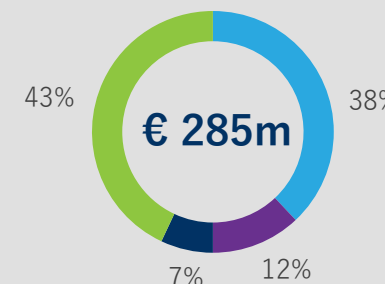
Cooperative  
Lab with CNRS  
Montpellier



## BREAKING NEWS

April 2021: Abivax completes  
induction treatment of last  
patient in ABX464 phase 2b  
clinical study in ulcerative colitis

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



- Truffle Capital
- Sofinnova
- Board & management
- Public

## Operations



27  
Employees



Cash<sup>3</sup>  
€ 29.3m

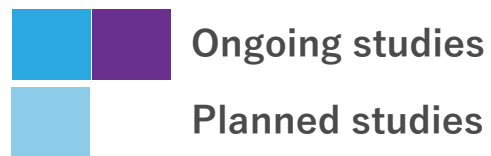
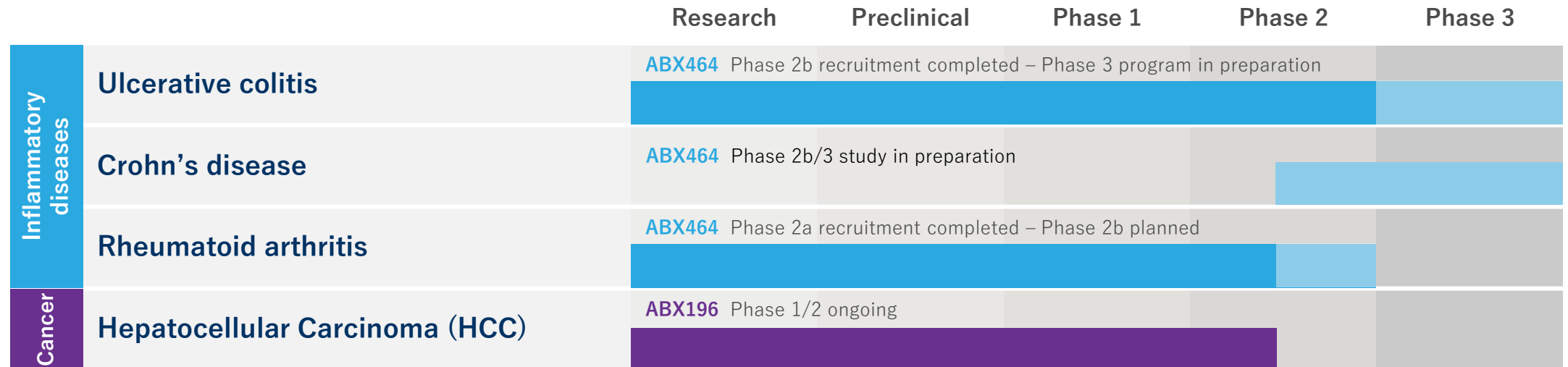
Cash runway until Q4 2021

## Key R&D and manufacturing partners

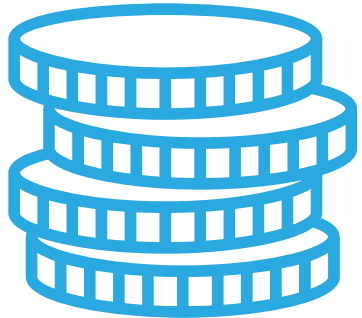


1) Undiluted – as of 31/01/2021  
2) As of 15/04/2021 EOB  
3) December 2020

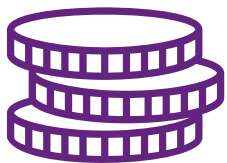
# Abivax: A late-stage biotech with a strong and diversified clinical pipeline addressing major medical needs and markets



# 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 8 B\*\***

\* 2020 data for Europe G5,  
U.S. and Japan  
\*\* 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> 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 **>800 patients and volunteers**

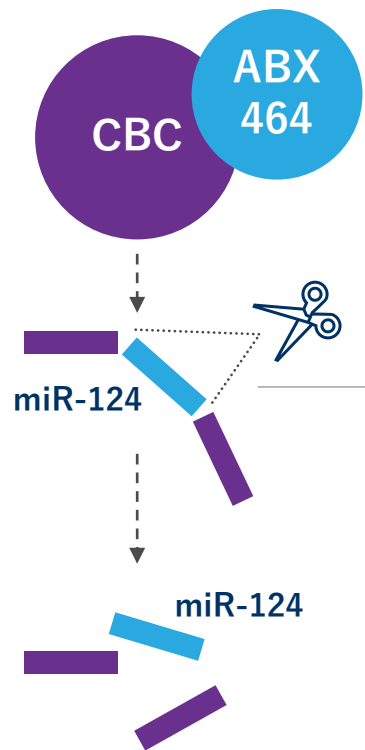
● **Strong anti-inflammatory effect** confirmed in phase 2a studies in ulcerative colitis

● **INN (International Nonproprietary Names) submitted** for ABX464 and final decision of WHO expected in Q2 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.



Established miR-124 targets: (translation ↓)

Outcome

MCP-1/  
CCL2

MCP-1/CCL2 ↓

STAT 3

IL-6  
Th17 → IL-17 ↓  
TNF $\alpha$

IL-6R

JAK pathway blocked → IL-6 ↓  
TNF- $\alpha$  ↓

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

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

# ABX464 phase 2a POC induction study in ulcerative colitis: Impressive efficacy achieved for all endpoints (day 56)

## Study Design:

PI: Prof. Severine Vermeire, Leuven, BE

32 patients with moderate to severe UC: randomized (2:1), double blind, placebo controlled study

Active and placebo groups well balanced re demographics

8-weeks treatment

Moderate to severe UC patients who failed/were intolerant to immunomodulation/steroids (50%) and/or biologics (50%)

Central blinded 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 et al. Induction and long-term follow-up with ABX464 for moderate-to-severe ulcerative colitis: Results of phase 2a trial. [Gastroenterology, 2021.02.054](#)

	ABX464 (n=20/23) PP/ITT**	Placebo (n=9/9) PP/ITT	p value*** (PP)
Clinical remission*	35%/30%	11%/11%	0.16
Endoscopic improvement	50%/43%	11%/11%	0.03
Clinical response	70%/61%	33%/33%	0.06
Total Mayo Score reduction	-53%	-27%	0.03
Partial Mayo Score reduction	-62%	-32%	0.02
miR-124 expression in rectal biopsies (fold increase)	7.69	1.46	0.004

\* Clinical remission according to previous FDA definition. With application of most recent FDA definition (excluding physician assessment), clinical remission rate was 40% in ABX464 group and remained at 11% with placebo

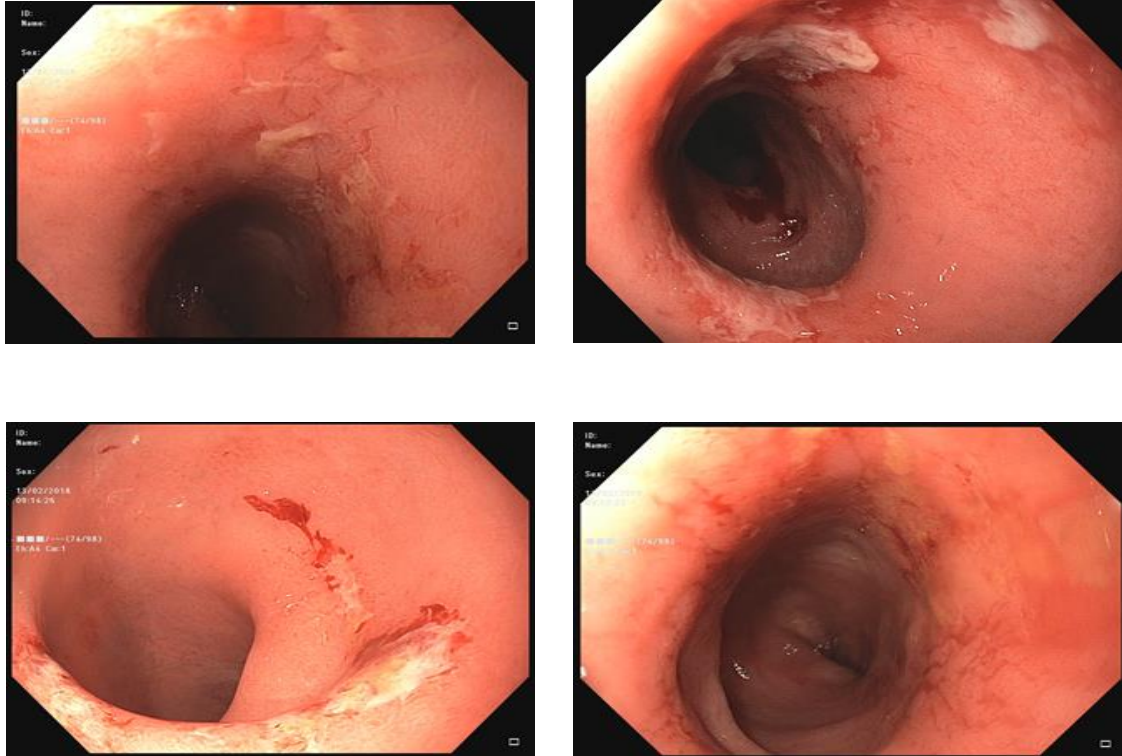
\*\* PP: Per protocol / ITT: Intent to treat

\*\*\* Study was not powered to show statistical significance

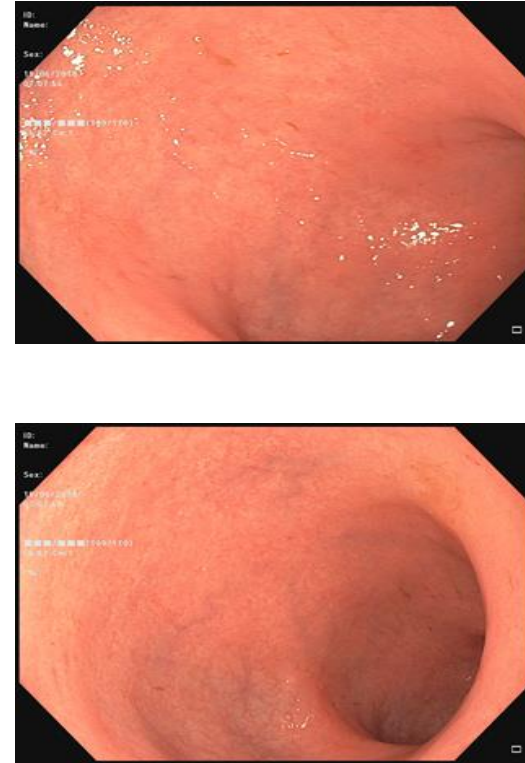


# Complete resolution of UC lesions in an ABX464 treated (vedolizumab, infliximab and adalimumab resistant) patient

## Endoscopy before ABX464



## Endoscopy after ABX464



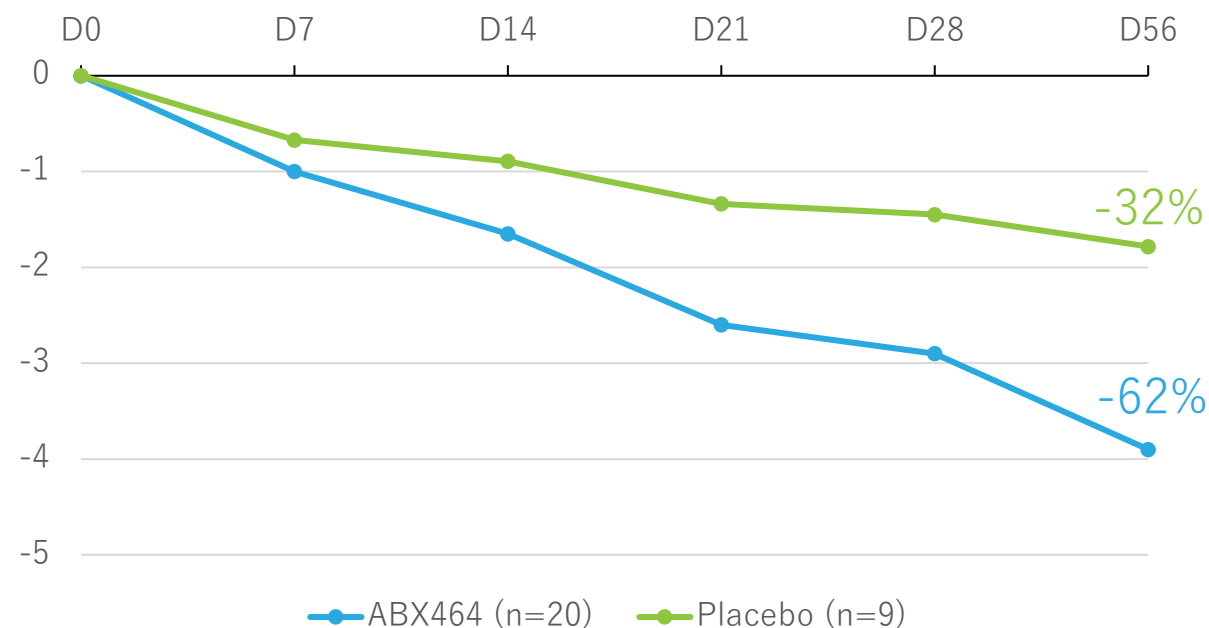
Courtesy of Prof. Severine Vermeire, Leuven, Belgium



# ABX464 phase 2a UC induction study: Fast onset of action and comparable efficacy in both biologics naïve and refractory patients

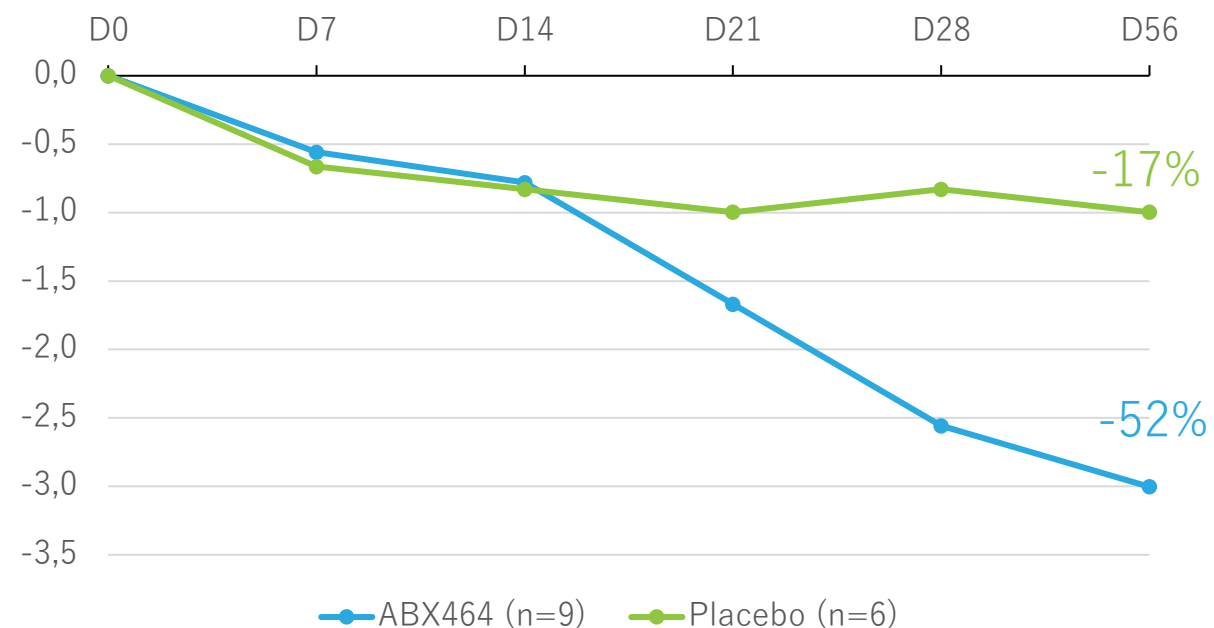
## Overall Patient Population

Change from Baseline Partial Mayo Score



## Patients previously treated with biologics

Change from Baseline Partial Mayo Score



# Confirmed durable and improved long-term efficacy in UC maintenance study: Several patients in 4<sup>th</sup> year of ABX464 continuous treatment

29/32

Patients completed the induction study

4/6

Countries granted regulatory approval for maintenance study

22/23

Eligible patients enrolled in the maintenance study, 19 out of 22 patients completed first year

16/19

16 out of 19 patients completed the second year of treatment

	Day 0 Maintenance	Month 12	Month 24
Clinical remission (TMS including endoscopy)	6/19 (31.6%)	12/16* (75.0%)	11/16 (68.8%)
Clinical response	14/19 (73.7%)	15/16* (93.8%)	15/16 (93.8%)

\* 16 out of 19 patients had endoscopy

Vermeire at al. Induction and long-term follow-up with ABX464 for moderate-to-severe ulcerative colitis: Results of phase 2a trial. J Gastro 2021.02.054

As of March 9, 2021, all ongoing phase 2a maintenance patients (N=15) have completed at least 31 months of continuous daily treatment with ABX464, with the longest treated patient being on ABX464 for over 39 months.

# ABX464, Entyvio® and Xeljanz® efficacy in UC induction and maintenance clinical trials

	Vedolizumab* Phase 3			Tofacitinib** Phase 3			ABX464 Phase 2a***		
Post Induction	Active	Placebo	Delta	Active	Placebo	Delta	Active	Placebo	Delta
Clinical Remission (%)	16.9	5.4	11.5	16.8-18.5	3.6-8.2	13.2-10.3	35	11	24
Endoscopic improvement (%)	40.9	24.8	16.1	28.4-31.3	11.6-15.6	16.8-15.7	50	11	39
<b>Post 1<sup>st</sup> Year Maintenance</b>									
Clinical Remission (%)	41.8	15.9	25.9	34.3-40.6	11.1	23.2-29.5	75		
Endoscopic improvement (%)	51.6	19.8	31.8	37.4-45.7	13.1	24.3-32.6	100		

ABX464 phase 2a maintenance study allowed all patients irrespective of treatment assignment or response during induction to be included.

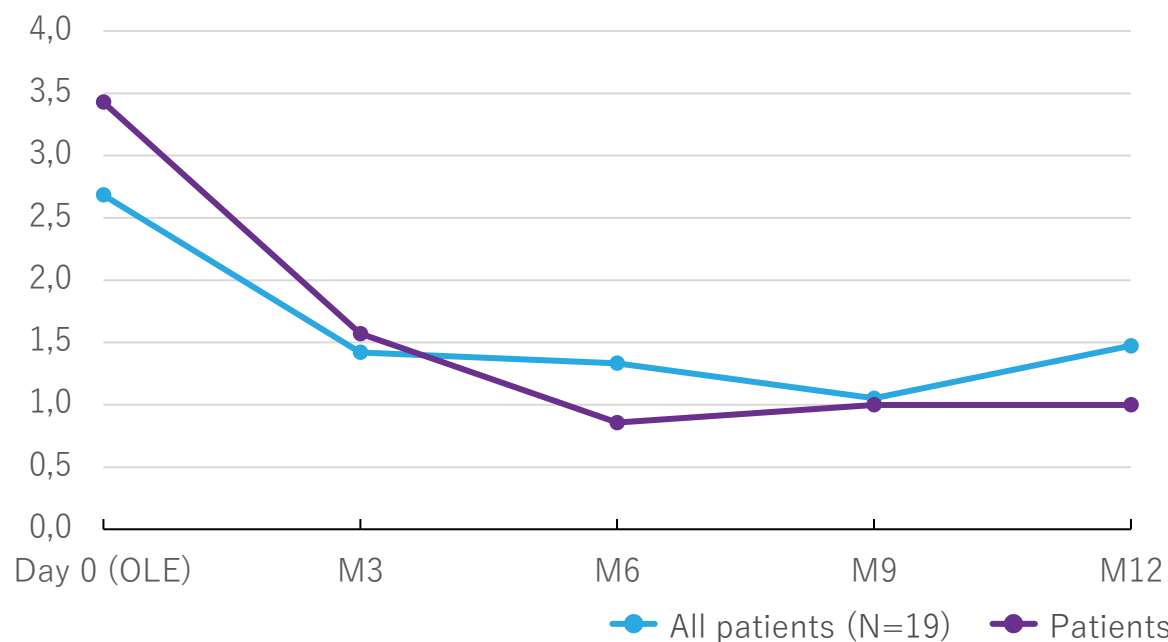
\* Feagan et al. Vedolizumab as induction and maintenance therapy for ulcerative colitis. N Engl J Med 2013;369:699-710

\*\* Sandborn et al. Tofacitinib as Induction and Maintenance Therapy for Ulcerative Colitis. N Engl J Med 2017;376:1723-36

\*\*\* Vermeire et al. Induction and long-term follow-up with ABX464 for moderate-to-severe ulcerative colitis: Results of phase 2a trial. J Gastro 2021.02.054

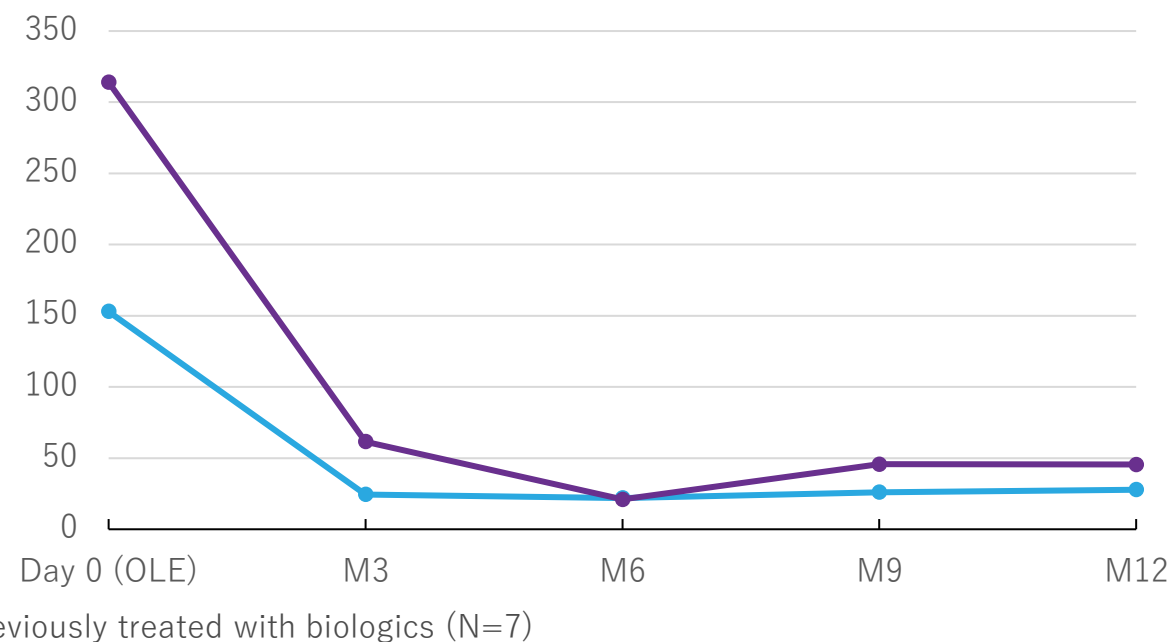
# Changes of Partial Mayo Score and fecal calprotectin during the maintenance phase for all patients and patients previously on biologics

## Partial Mayo Score – Mean



➔ Partial Mayo Score continued to decrease

## Fecal calprotectin $\mu\text{g/g}$ – Median



➔ Fecal calprotectin levels went down to normal values (< 50  $\mu\text{g/g}$ )

Median fecal calprotectin remained in normal range after two years (31.6  $\mu\text{g/g}$ ).

# Completed studies: Favorable ABX464 safety profile

*Common (> 5%) adverse events (cut-off date Nov. 30, 2020)*

System Organ Class	Adverse effect	ABX464 (50mg QD) (N=115 subjects)		ABX464 (All doses) (N=203 subjects)		Placebo (N=33 subjects)	
		Number of reports	n (%) of pts with TEAE (Incidence)	Number of reports	n (%) of pts with TEAE (Incidence)	Number of reports	n (%) of pts with TEAE (Incidence)
<b>Nervous System Disorders</b>	Headache	49	35 (30.4)	115	83 (40.9)	6	4 (12.1)
<b>Gastrointestinal Disorders</b>	Abdominal pain	6	6 (5.2)	15	13 (6.4)	1	1 (3.0)
	Abdominal pain (upper)	9	7 (6.1)	34	16 (7.9)	0	0
	Diarrhea	5	4 (3.5)	15	10 (4.9)	4	3 (9.1)
	Nausea	13	9 (7.8)	47	35 (17.2)	3	2 (6.1)
	Vomiting	11	7 (6.1)	37	26 (12.8)	0	0
<b>Musculoskeletal and Connective Tissue Disorders</b>	Arthralgia	4	4 (3.5)	12	10 (4.9)	1	1 (3.0)
	Back Pain	4	4 (3.5)	24	19 (9.4)	1	1 (3.0)

Most frequently reported adverse events are transient and mild (headache, nausea, gastrointestinal pain)

Similar AE profile in non completed studies (> 500 patients) across various indications

No new type of AE in long term maintenance studies with chronic ABX464 treatment up to 39 months

No clinically meaningful changes in laboratory parameters (LFTs, Hb, lymphocytes, neutrophils, etc.)

No increased incidence of infections

# ABX464 phase 2b clinical study in ulcerative colitis

## Ulcerative colitis phase 2b ongoing:

- Enrollment completed with 254 patients in 15 European countries, US and Canada in 130+ study sites
- 4 study arms (placebo, 25, 50, 100 mg QD)
- Central blinded reading of endoscopies
- Conducted with IQVIA as CRO
- Top-line data for induction phase and initial maintenance data available in the **second half of May 2021**
- 1<sup>st</sup> year maintenance data expected in **Q1 2022**

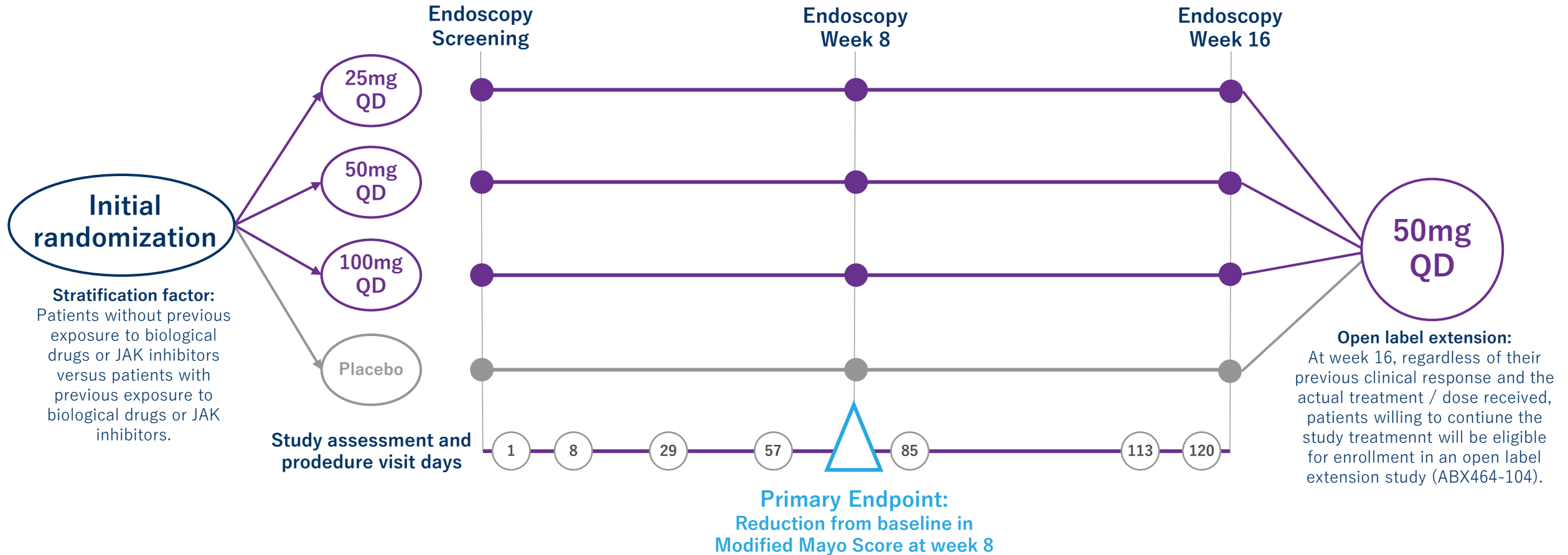


# Study design: ABX464 phase 2b clinical study in ulcerative colitis

Screening  
≤4 weeks

Induction Phase  
16 weeks

Open Label Extension  
ABX464-196



# How to bring ABX464 to the finish line

## Phase 1 TQT study:

- 78/120 subjects enrolled
- Results expected in Q3 2021

## Phase 1 DDI study:

- 51/60 subjects enrolled
- 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 ongoing
- 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**

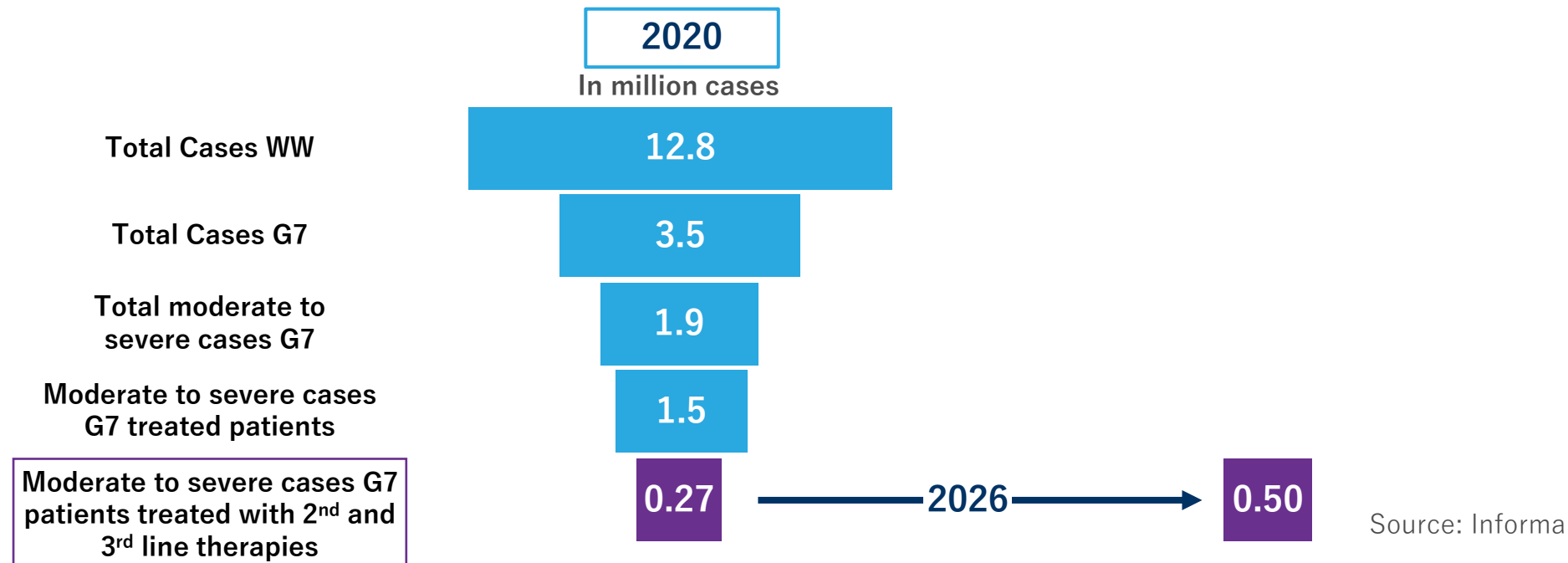
## Rheumatoid arthritis phase 2a study ongoing:

- Enrollment completed (60 patients in 5 European countries)
- Top-line data for induction phase in **Q2 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 2 <sup>nd</sup> and 3 <sup>rd</sup> line treatment	
ABX464 First Launch	2025 for UC	2026 for CD
G7 Market Size (2 <sup>nd</sup> & 3 <sup>rd</sup> 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	

# ABX196: An iNKT agonist for the treatment of checkpoint inhibitor refractory liver cancer patients

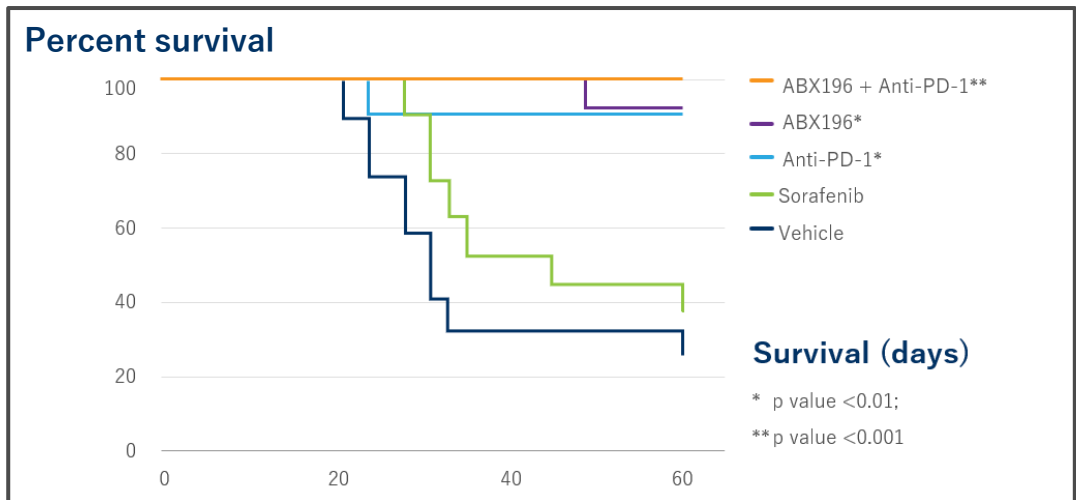
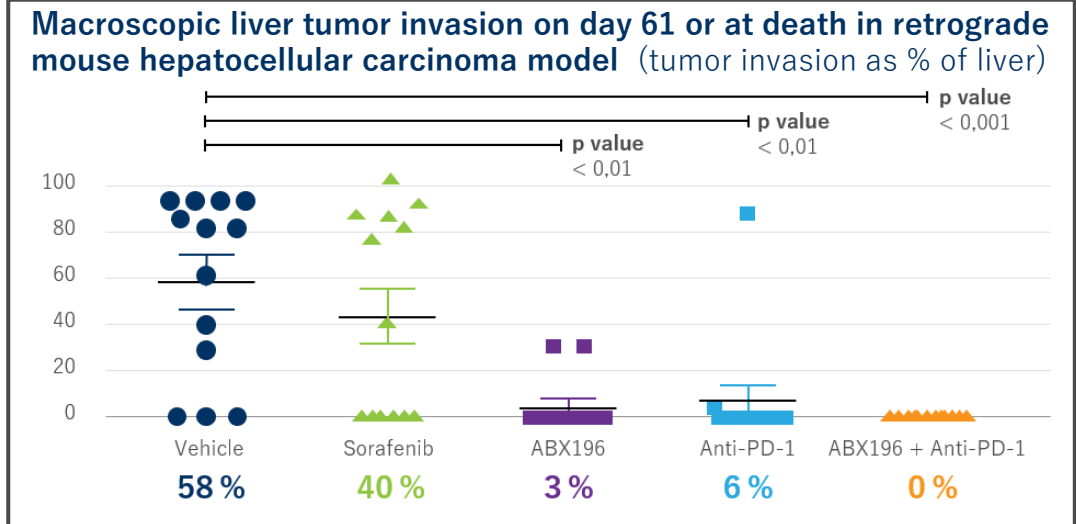
Licensed from Scripps Research, University of Chicago, Brigham-Young University

Synthetic glycolipid agonist of iNKT (invariant Natural Killer T) cells in liposomal formulation

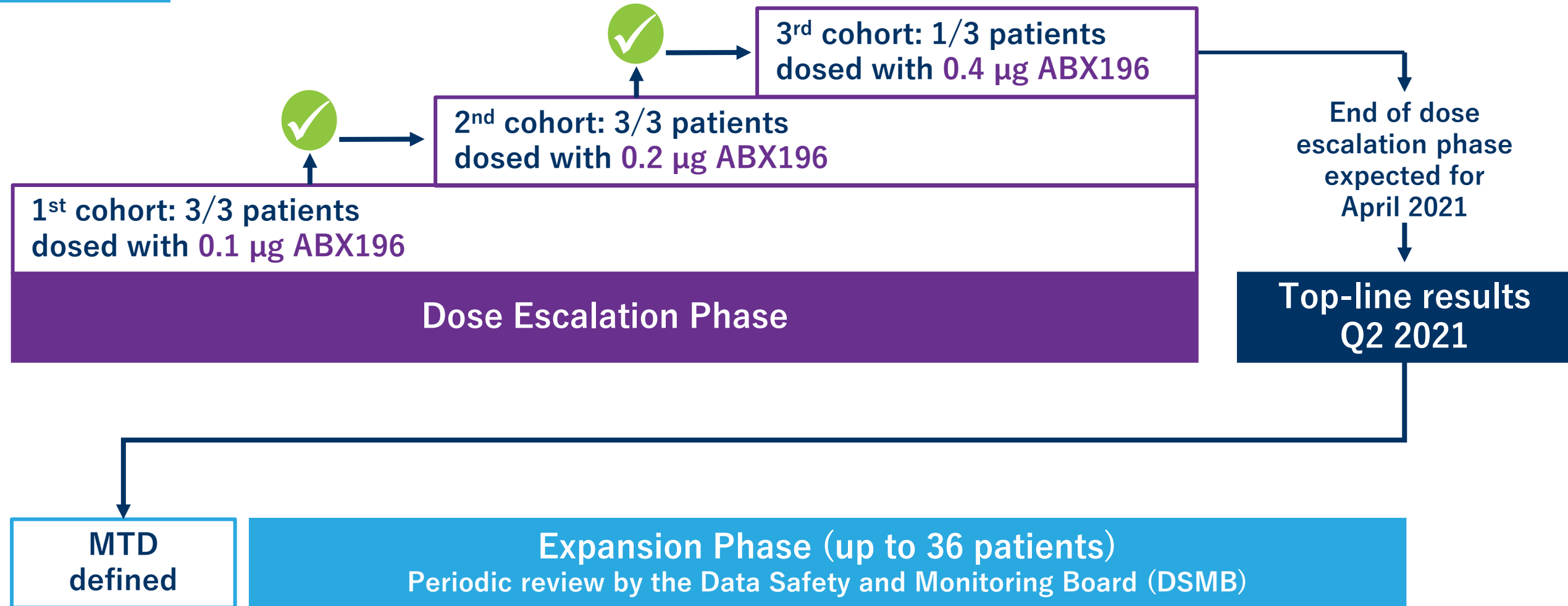
Strong preclinical data in liver cancer and melanoma

Phase 1 completed in volunteers: ABX196 was safe and well tolerated, and triggered both humoral and iNKT responses


Phase 1/2 dose escalation study ongoing: Combination therapy with checkpoint inhibitors at Scripps MD Anderson Cancer Center (San Diego, CA) and MD Anderson Cancer Center (Houston, TX)



# ABX196 study design and recruitment status



# Newsflow through end of 2021

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



# 2020 financing completed to extend cash runway until Q4 2021

## 2020 Financing

- Private Placement towards institutional investors € 28m
  - Bpifrance funding € 36m  
(to be tailored following ABX464 Covid-19 stop on March 5, 2021)
  - Société Générale PGE € 5m
  - Kreos new funding € 15m
  - **TOTAL: € 84m raised in 2020**  
(€ 56m non-dilutive and € 28m dilutive)
- In addition, available remainder of Equity Line with Kepler Cheuvreux (612 k shares, around € 12m)

## Cash Runway Until Q4 2021

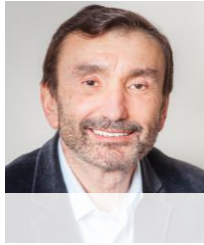
- **Financing to be used for:**
  - **ABX464 in ulcerative colitis (UC):** Completion of the phase 2b induction phase, pursuance of the maintenance phase, and preparation of Phase 3 program for Q4 2021
  - **ABX464 in Crohn's disease (CD):** Preparation of phase 2b/3 for Q4 2021
  - **ABX464 in rheumatoid arthritis (RA):** Completion of the phase 2a induction phase and pursuance of the maintenance phase, preparation of phase 2b for Q1 2022
  - **ABX464 in Covid-19:** Program stopped on March 5, 2021
  - **General corporate purposes**

## Abivax analyst reports overview (after Covid-19 stop)

Analyst	Country	Last update	Target Price	Recommendation
Bryan, Garnier & Co	France	04/03/2021	€ 39.40	Buy
Degroof Petercam	Belgium	08/03/2021	€ 29.00	Buy
goetzpartners securities	UK/Germany	09/03/2021	€ 43.00	Buy
Kepler Cheuvreux	France	08/03/2021	€ 40.00	Buy
LifeSci Capital Alpha Series	US	14/05/2020	€ 41.00	Buy
Portzamparc	France	08/03/2021	€ 39.40	Buy
<b>General recommendation: Buy</b>		<b>Average target price (after Covid-19 stop): € 38.60</b>		

For full access to the reports, please directly contact the respective analysts listed on [Abivax's website](#).

# Highly experienced Executive Committee



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



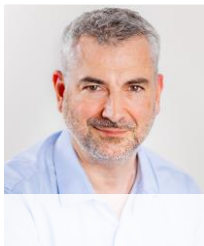
**Didier Blondel**  
Chief Financial Officer & Board Secretary



**Sophie Biguenet, M.D.**  
Chief Medical Officer



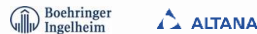
**Jean-Marc Steens, M.D.**  
Chief Medical Advisor



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



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



**Jérôme Denis, Ph.D.**  
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**Regina Jehle**  
Director Communications



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