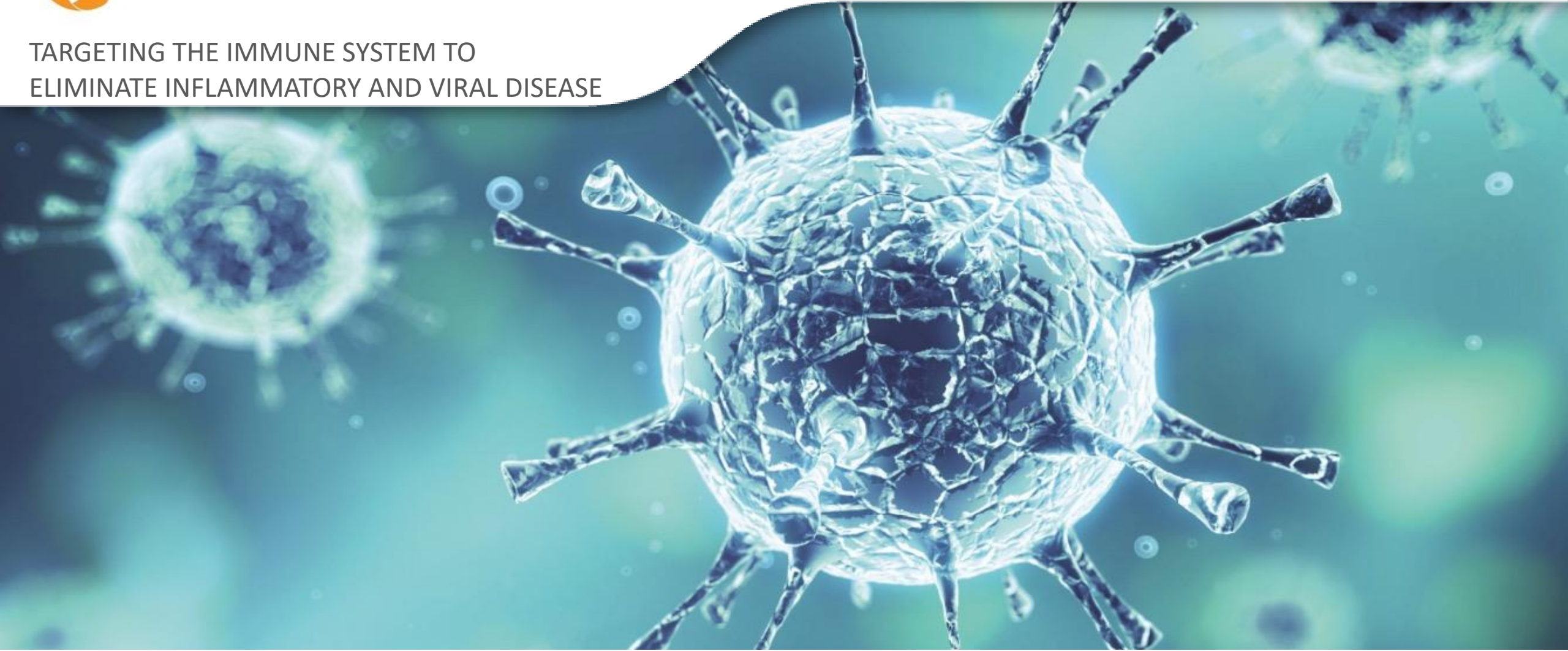




TARGETING THE IMMUNE SYSTEM TO  
ELIMINATE INFLAMMATORY AND VIRAL DISEASE



## A Turning Story Towards Inflammatory Diseases

April 2019



# Forward looking statements

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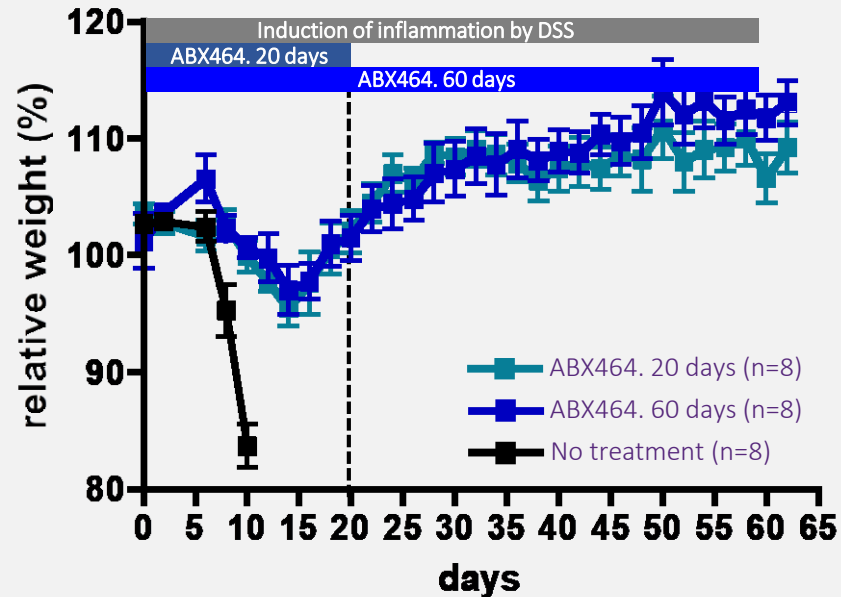
# ABX464 - Background

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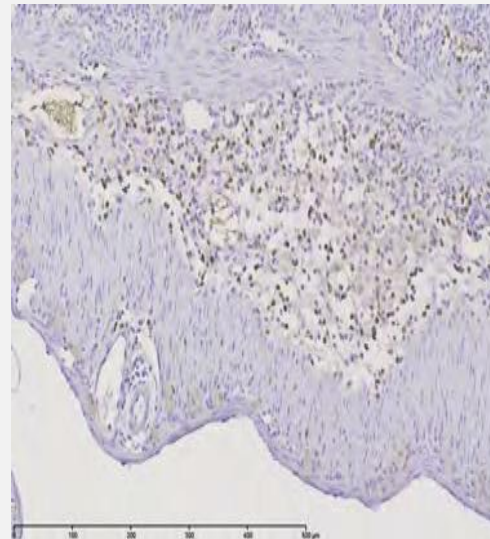
- Coming from the proprietary Abivax library of compounds, biased to modulate RNA biogenesis (>2000 molecules)
- Small molecule (quinoline), administered as an oral capsule (once a day)
- First-in-Class, novel mechanism of action: Selective upregulation of anti-inflammatory microRNA miR124
- Good safety profile after administration to >200 subjects
- Anti-inflammatory effect confirmed in phase 2a POC study in ulcerative colitis
- High level of medical need in inflammatory diseases
- Market size in first indication (ulcerative colitis) is around USD 5.7 B
- Total market size in inflammatory diseases is greater than USD 70 B

# ABX464 showed efficacy in DSS Mice Model\*

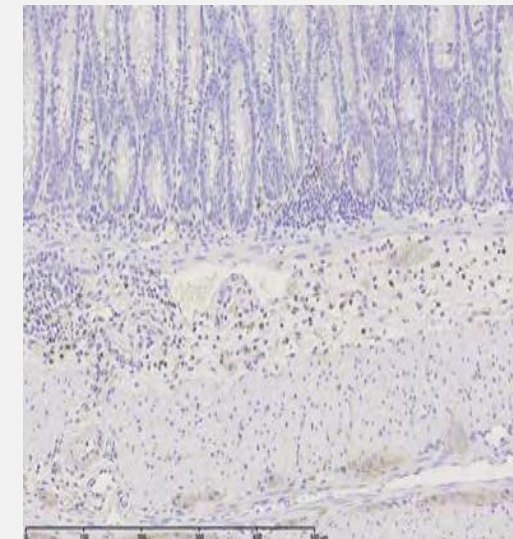
ABX464 protects mice from death in the DSS mouse model



DSS without treatment leads to intestinal damage



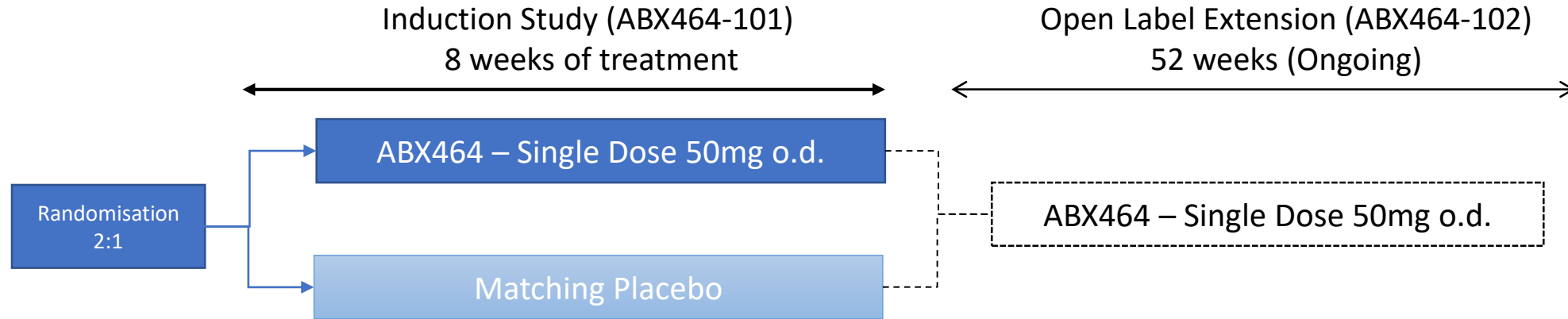
ABX464 protects intestinal Structure



\*Chebli et al, Nature Scientific Reports 7: 4860 (2017)

# Study Design

*Randomized, double-blind, placebo controlled, multi-national study*



- Study Population = Moderate to Severe Active UC patients who failed or were intolerant to immunomodulators, Anti-TNF $\alpha$ , vedolizumab and/or corticosteroids
  - Confirmed UC for at least 3 months with a Total Mayo Score of 6-12 with endoscopic sub-score of 2 or 3
  - Central reading of endoscopies
- Study Endpoints
  - Primary = Safety
  - Secondary : Mayo Score and Endoscopy, Faecal calprotectin levels , Geboes score, miRN-124 expression, microbiome, Quality of Life (SF-36) and Pharmacokinetics

# Good Safety Profile

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- Very consistent with previous clinical studies
- No deaths, no malignancies, no opportunistic infections, no significant changes in the laboratory parameters including WBC
- No Serious Adverse Reaction, all AE's of mild to moderate intensity

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Patients with at least one Treatment Emergent Adverse Events (>15%) regardless of causality	ABX-464 (N=23)	Placebo (N=9)
	N (%)	N (%)
<b>Any Treatment-Emergent Adverse Events</b>	<b>18 (78.3%)</b>	<b>5 (55.6%)</b>
<i>Gastrointestinal disorders (mainly Upper Abdominal Pain)</i>	8 (34.8%)	2 (22.2%)
<i>Infections and infestations</i>	4 (17.4%)	1 (11.1%)
<i>Nervous system disorders (mainly Headache)</i>	5 (21.7%)	0 (0.0%)

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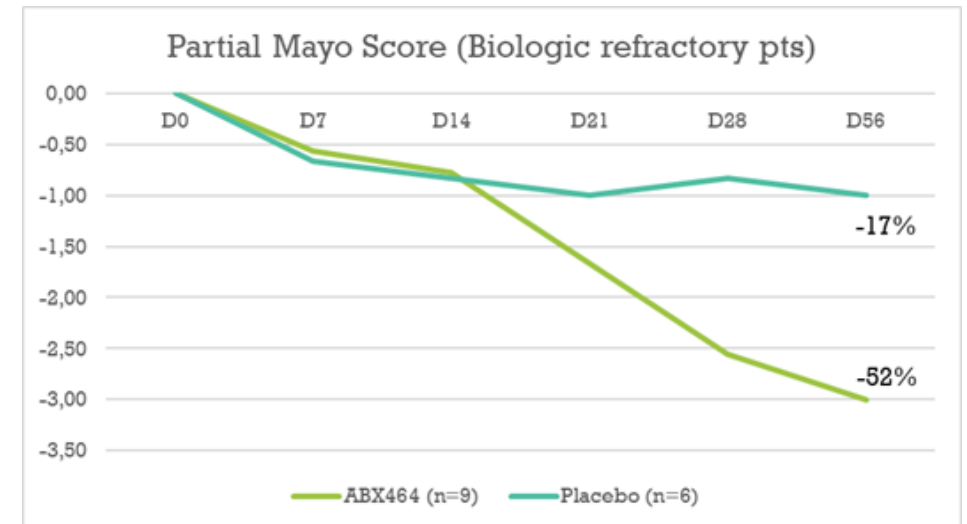
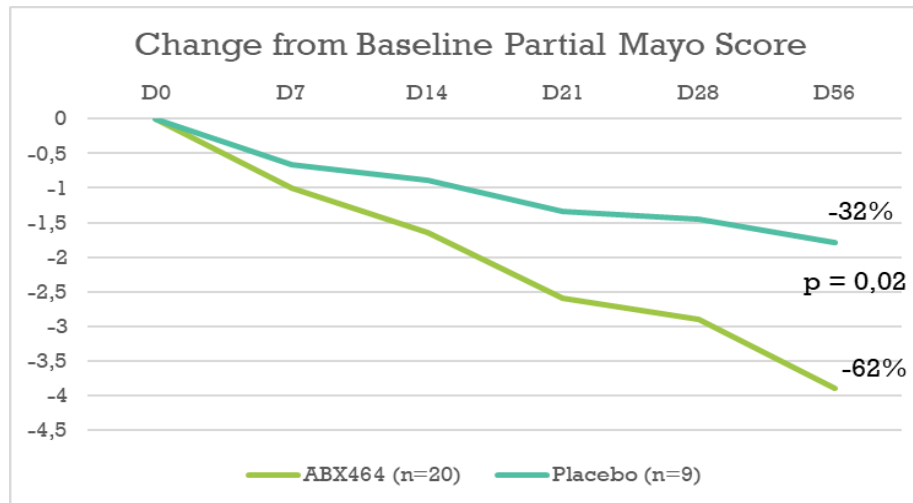
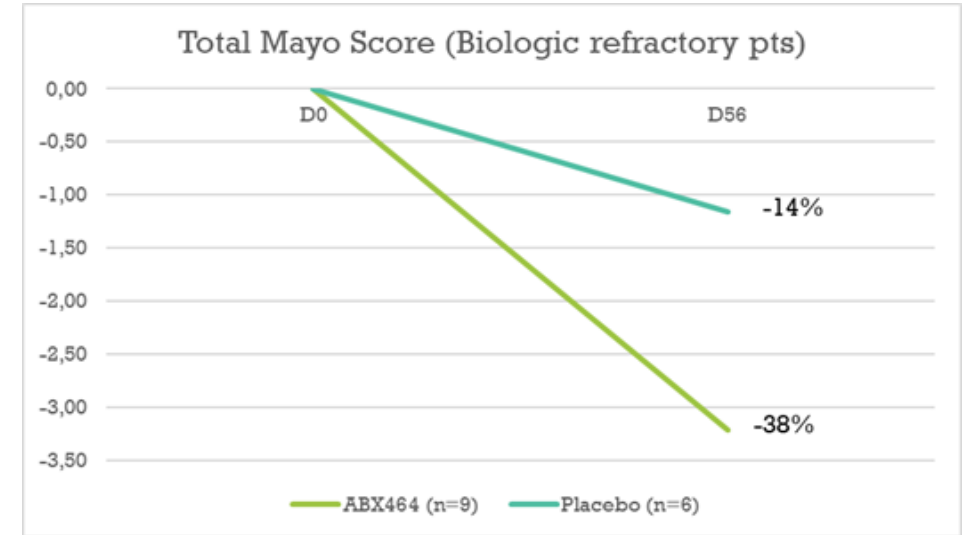
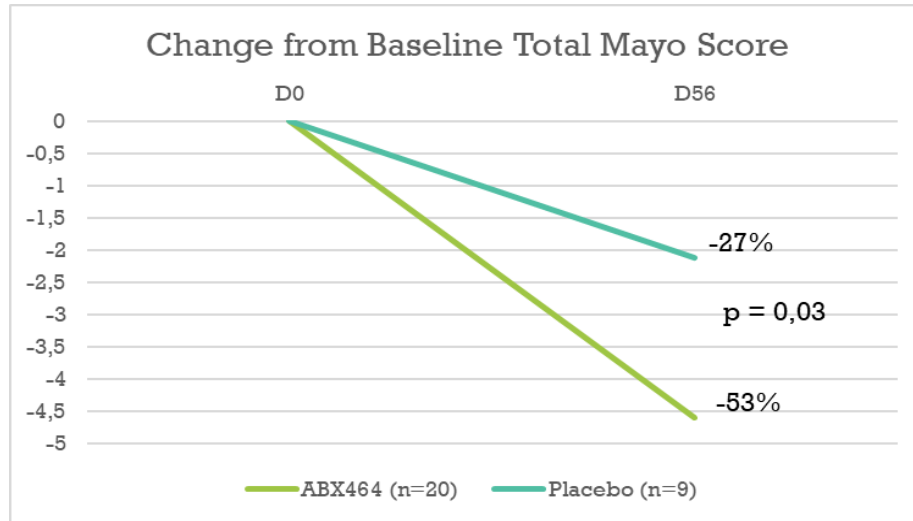
# Efficacy data (Day 56)

	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%	<b>0.03</b>
Clinical response	70% / 61%	33% / 33%	0.06
Total Mayo Score Reduction	-53%	-27%	<b>0.03</b>
Partial Mayo score Reduction	-62%	-32%	<b>0.02</b>
Faecal Calprotectin decrease > 50 %	75%	50%	na
miR-124 expression in rectal biopsies (fold increase)	7.69	1.46	0.004

- *Clinical remission : TMS equal or lower than 2 + no sub-score >1*
- *Endoscopic improvement : Endoscopy sub-score 0 or 1*
- *Clinical response : TMS decrease of min 3 points and 30% from baseline + decrease of bleeding sub-score of min 1 point or absolute baseline of 0 or 1*

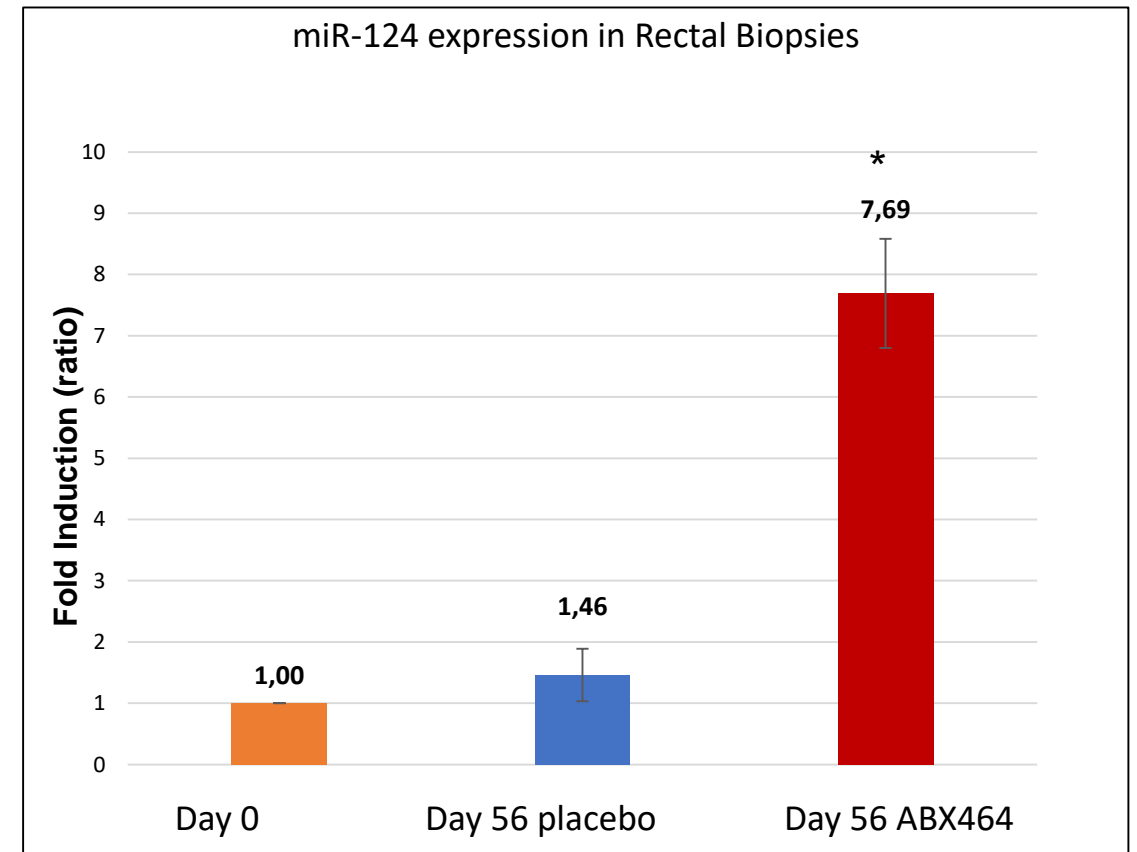
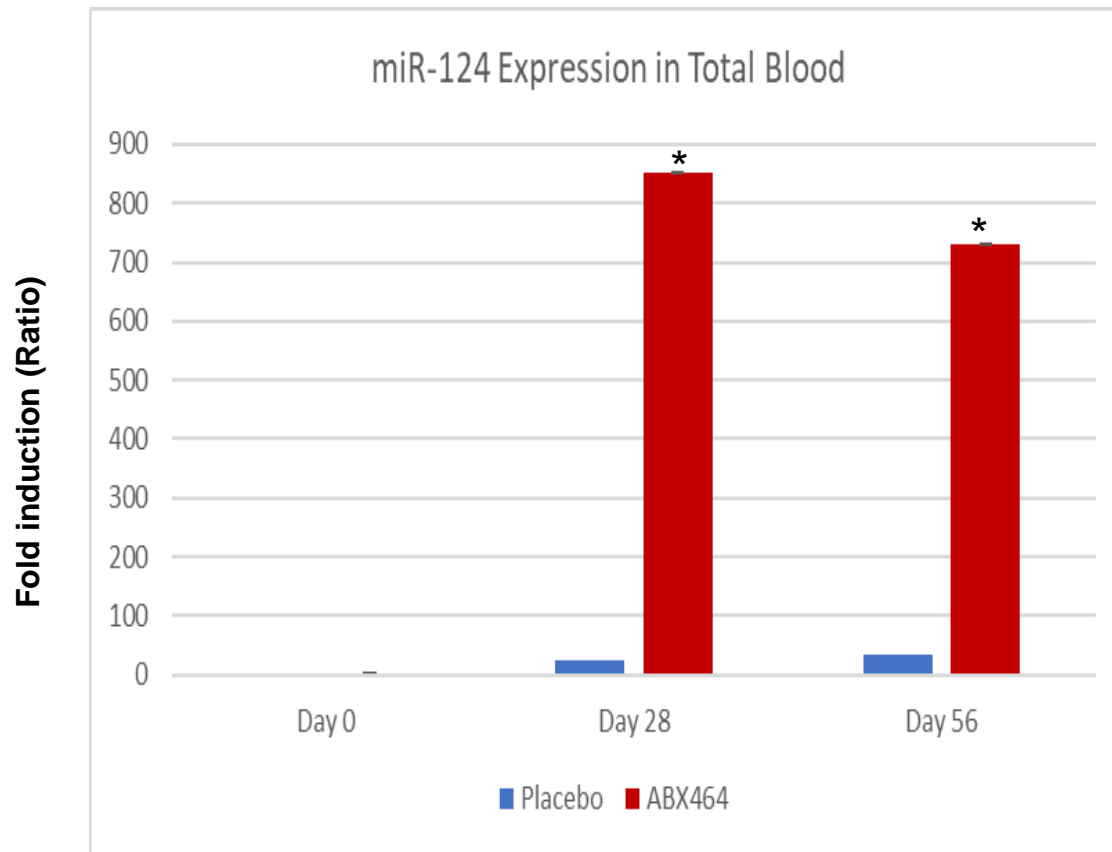
# Mayo Score Results

ABX464: Fast onset of action and clinical responses in patients who failed on biologics



# Statistically significant increase in miR-124 expression

## Total blood and Rectal tissue



\*  $p$  value < 0.05 (Treatment and time point)

# Maintenance Phase: 6-months interim analysis

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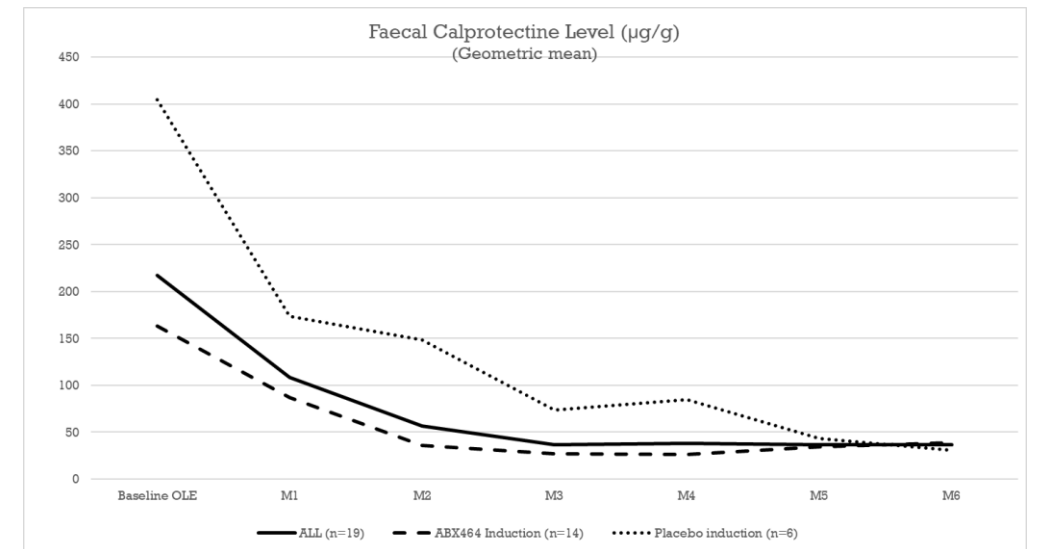
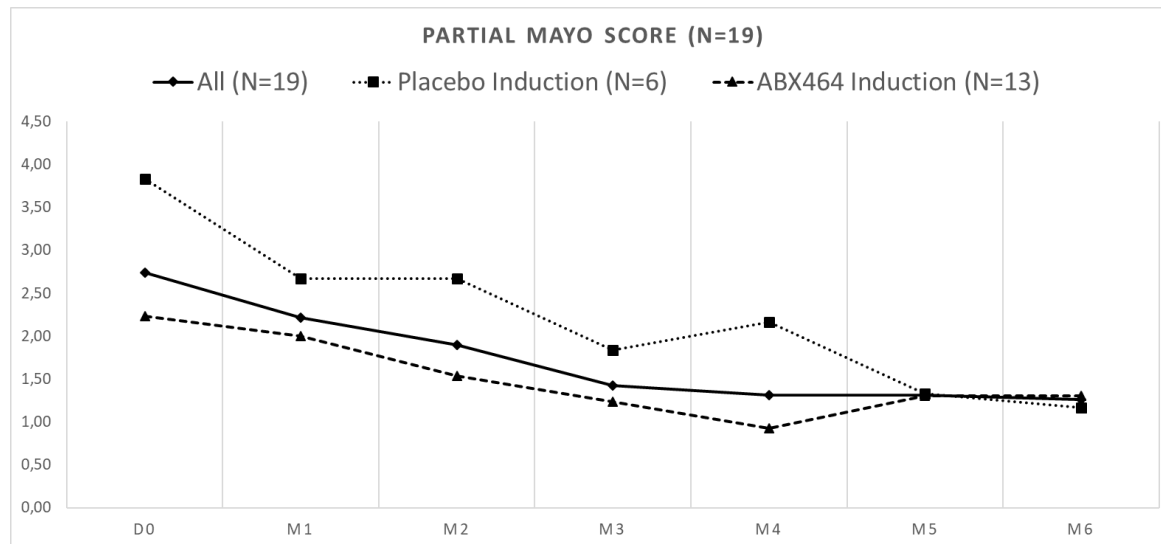
- 22/23 patients including 7 patients initially on placebo enrolled in the induction phase (2 countries did not grant regulatory clearance because of lack of efficacy data at the time of submission)
- 3 patients dropped out
  - One Lack of Efficacy at M1, initially on ABX464
  - One due to subject's decision despite clinical response at M4, initially on ABX464
  - One due to TEAE (Headache, grade 2, drug related according to PI) occurring 4 months after first dosing at M5, initially on placebo
- All other 19 patients ongoing
- As of March 8, 2019 the cumulative exposure is the following;

<b>Mean (Days)</b>	<b>330</b>
Median (Days)	316
Max (Days)	462
Min (Days)	246

# ABX464 - 102 Maintenance Phase

## Month 6 interim analysis Maintenance Phase

- Safety profile remains very good with no severe adverse reactions.
- Further improvement of Partial Mayo Score ( down by 76 % ) in patients who received ABX464 during induction study
- 68 % reduction of Partial Mayo Score in patients who received Placebo during induction study
- Biomarker Faecal Calprotectin reduced to reach close to normal values



- Results presented at the ECCO Conference on March 8<sup>th</sup> ; 9 months will be presented in May at DDW ( San Diego )
- Amendment to extend the maintenance study to 2 years approved in all countries.
- First patient entered the extension of the maintenance study on Jan 24, 2019 (now more than 15 months on ABX464).

# Summary

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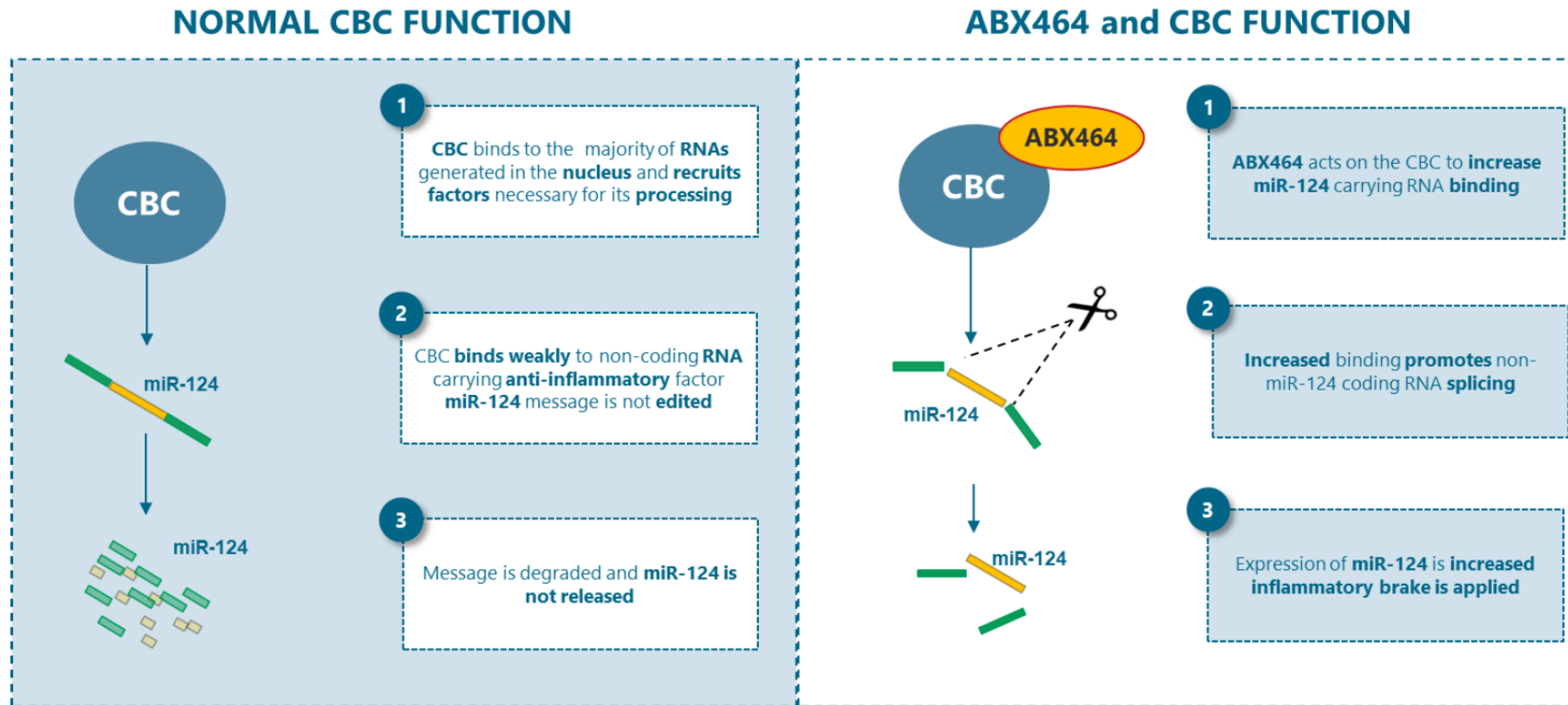
- New mechanism of action ORAL drug ABX464
- Promising preclinical data in IBD model
- Good Safety and tolerability of ABX464 in UC patients and HIV program in more than 200 subjects treated (No Serious Adverse Reactions, no severe infections, no lymphopenia, no neutropenia)
- Confirmed preliminary efficacy in Phase 2a UC study
  - All endpoints favorable to ABX464
  - Fast onset of action
- Durability of effect : maintenance 6-month interim data
  - Partial Mayo Score continued to decrease
  - Faecal Calprotectin levels went down to values approaching normal values

## *ABX464 current activities*

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- Phase 2b study protocol in 232 patients with moderate to severe ulcerative colitis was submitted to regulatory agencies in first countries in EU and Canada
- Phase 2a studies are being submitted in Rheumatoid Arthritis and Crohn's disease
- Pre-clinical models in Multiple Sclerosis , Parkinson's disease and Psoriasis ongoing

# CBC-mediated effects of ABX464 on inflammation\*



Source: Goetzpartners Securities Research

\*Vautrin et al., Nature Scientific Reports 9 (2019)

# High unmet medical need in HCC: Response Rates with Nivolumab (Checkmate 040 Study)

	Uninfected Untreated/ Intolerant (N=56)	Uninfected Sorafenib Progressors (N=57)	HCV (N=50)	HBV (N=51)	All (N=214)
ORR	21%	20%	20%	14%	20%
Med DOR	8.4 mo	NR	9.9 mo	NR	9.9 mo

ORR: Objective Response Rate; DOR: Duration of Response

FDA accelerated approval obtained for nivolumab Opdivo (BMS) on September 22, 2017 for HCC previously treated with sorafenib based on objective response rate and duration of response

El-Khoueiry et al. Lancet 2017

# ABX196 shows anti-cancer effects in mouse models

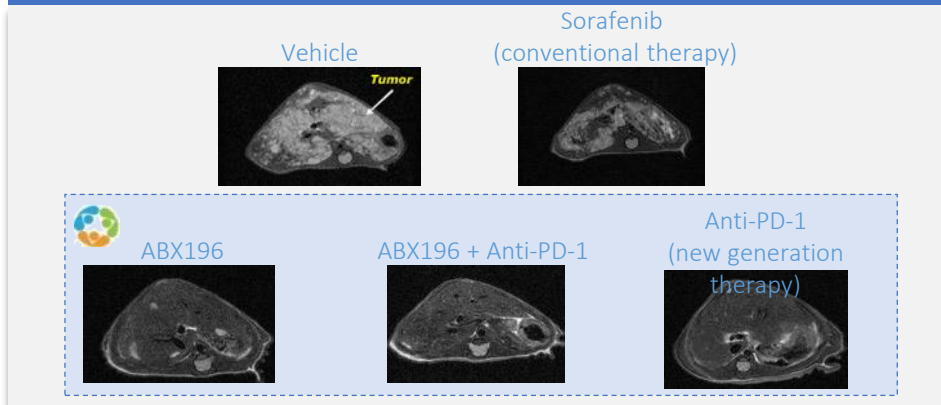
## Liver cancer is a devastating disease with rapid mortality

Region	2017 HCC prevalence <sup>1</sup>	2017 HCC new annual cases <sup>1</sup>	2017 HCC sales <sup>1</sup>
EU (G5 <sup>2</sup> ) + US	77k	65k	USD 0.4b
China	265k	328k	n.a.

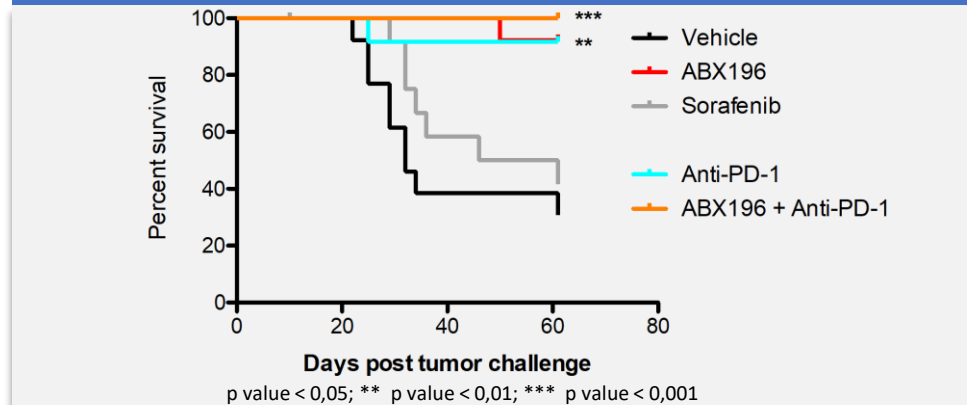
## ABX196 shows to be a potent immune response activator

- Reduces tumor progression in Hepatocellular Carcinoma (HCC) and B16 melanoma models
- Shows survival benefit as stand-alone treatment and in combination with a PD-1 checkpoint inhibitor
- Strong immune response observed
- Preliminary results indicate the ability of ABX196 to sensitize the tumor micro-environment for checkpoint inhibitors
- Clinical trial with ABX196 and Nivolumab in HCC to start Q2, 2019 in US (Scripps Clinic plus 3 additional US sites)

## Significantly reduced tumor growth in HCC (liver cancer)

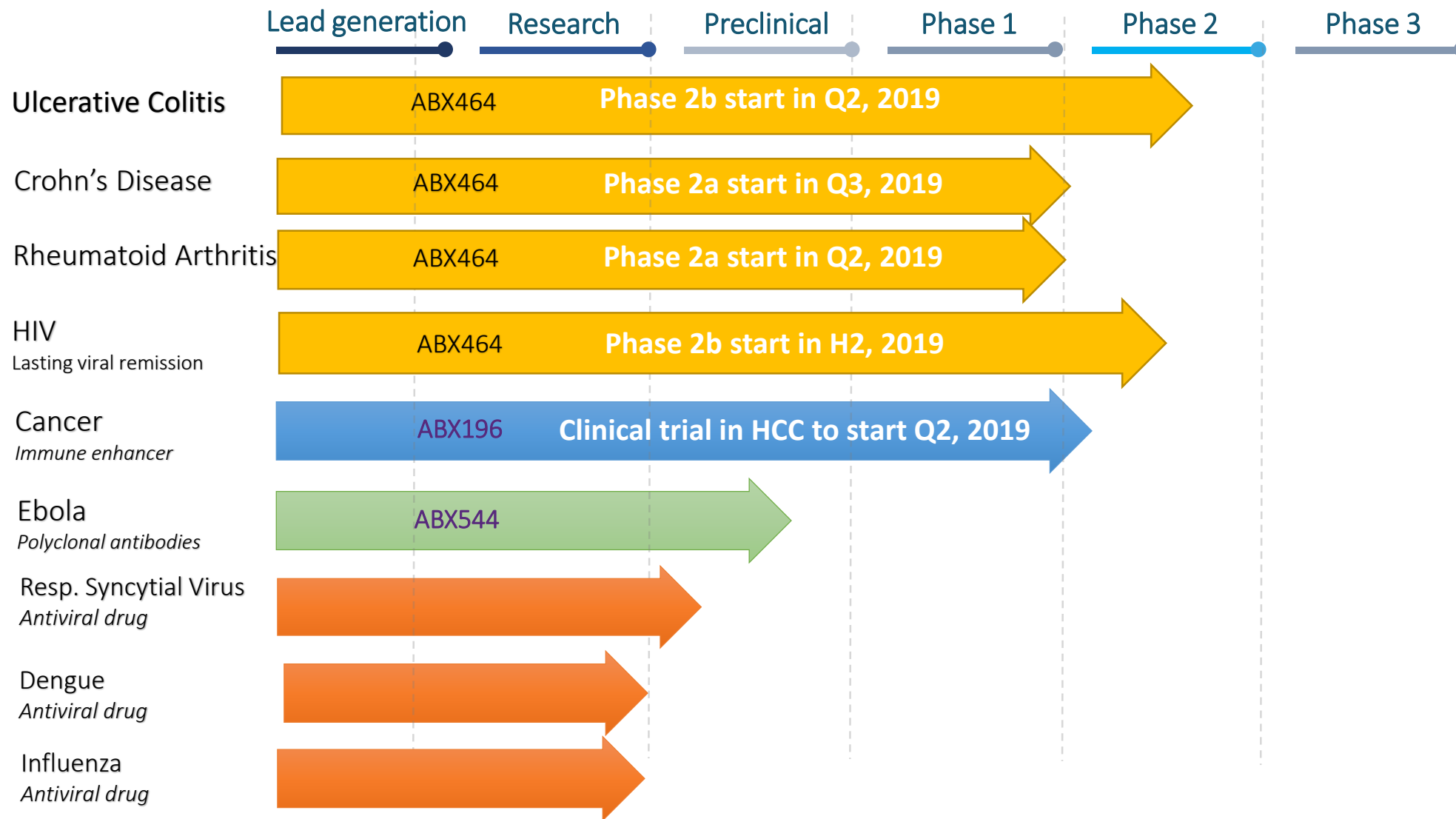


## ABX196 shows significant overall survival benefit in mice



ABX196 will be evaluated in combination with a checkpoint inhibitor in HCC patients starting Q2, 2019

# Abivax: A strong and diversified pipeline



# Key company facts

## Overview



Founded in 2013 by Truffle Capital



Abivax went public in June 2015, raising EUR 57.7m



Primary listing: Euronext (Paris)

ABVX : FR0012333284

Liquidity: 27K shares/day in 2018<sup>1</sup>

## Shareholder Structure 2 (undiluted)



■ Truffle Capital 1,0% ■ Board & Management 7,0%  
■ Incubator & Founders 45,0% ■ Public 47,0%

## Location



## Operations



25 Employees<sup>2</sup>



19 in R&D



6 in Support



Cash<sup>2</sup> € 13,0m



1: TSAF report as of Dec. 31<sup>st</sup>, 2018

2: Actual Dec. 31<sup>st</sup>, 2018

# Actuals 2018 - Key Figures

		2018 FY m€	2017 FY m€	Variation	
				m€	%
Costs	<b>Administrative Costs</b>	-4,1	-3,7	-0,4	-11%
	<i>% of Oper. Costs</i>	20%	25%		
	<b>R&amp;D Costs</b>	-15,9	-10,8	-5,0	-46%
	<i>% of Oper. costs</i>	80%	75%		
	<b>Operating Costs</b>	-19,9	-14,5	-5,4	-37%
	Other costs	-0,9	-0,2	-0,7	-318%
	Revenues	5,0	3,5	1,5	42%
	<b>Net Income</b>	-15,8	-11,2	-4,6	-41%
Headcount	Administrative	6,0	6,0	0,0	0%
	R&D	19,0	18,0	1,0	6%
	Total	25,0	24,0	1,0	4%
Cash	End of period	13,0	17,0	-4,0	-24%

Available funding, up to 35 m€, sustains operations for 12 months until Q1 2020

# Highly experienced Executive Committee



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

Ex-Head of Global R&D, Baxter BioScience



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



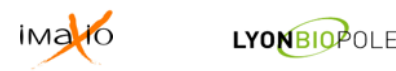
**Pierre Courteille**  
Pharmacist, MBA  
Chief Commercial Officer & VP, BD



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



**Alexandra Pearce, Ph.D.**  
VP, Regulatory Affairs, Quality, PV



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



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



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



**Prof. Jamal Tazi, Ph.D.**  
CNRS Director & Founder of antiviral platform



Competencies from discovery to global commercialization

