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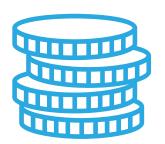
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### ABX464: A promising candidate addressing attractive markets



Total market size in inflammatory diseases

greater than USD 70 B



Coming from the proprietary Abivax library of compounds, biased to **modulate RNA biogenesis** (>2000 molecules)



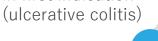
**Small molecule** (quinoline), administered as an oral capsule (once a day)



**First-in-Class, novel mechanism of action:** Selective upregulation of anti-inflammatory microRNA miR-124



Market size in first indication (ulcarative colitis





Good safety profile after administration to >200 subjects





Anti-inflammatory effect confirmed in phase 2a POC study in ulcerative colitis



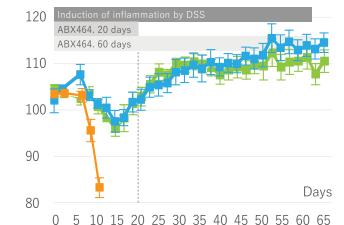
**High medical need** in inflammatory diseases



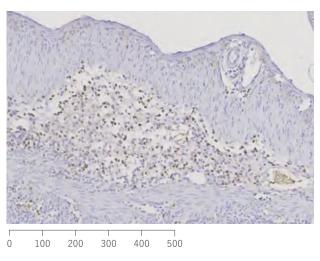
### ABX464 showed efficacy in DSS mouse model\*

## ABX464 protects mice from death in the DSS mouse model

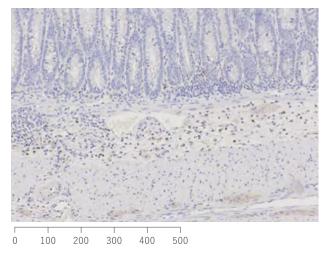
# Relative weight (%)



## DSS without treatment leads to intestinal damage



## ABX464 protects intestinal structure



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

ABX464. 60 days (n=8)



ABX464. 20 days (n=8)

No treatment (n=8)

## Study design: Randomized, double-blind, placebo controlled, multi-national study

#### Induction study (ABX464-101)

8 weeks of treatment

Open label extension (ABX464-102)

52 weeks (ongoing)

Randomisation 2:1

ABX464 - Single dose 50mg o.d.

Matching placebo

ABX464 – Single dose 50mg o.d.

#### 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



# ABX464-101: Good safety profile

**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 Patients with at least one treatment emergent adverse events (>15%) regardless of causality

	<b>ABX-464 (n=23)</b> n (%)	Placebo (n=9)
Any treatment- emergent adverse events	18 (78.3%)	5 (55.6%)
Gastrointestinal disorders (mainly upper abdominal pain)	8 (34.8%)	2 (22.2%)
Infections and infestations	4 (17.4%)	1 (11.1%)
Nervous system disorders (mainly headache)	5 (21.7%)	0 (0.0%)



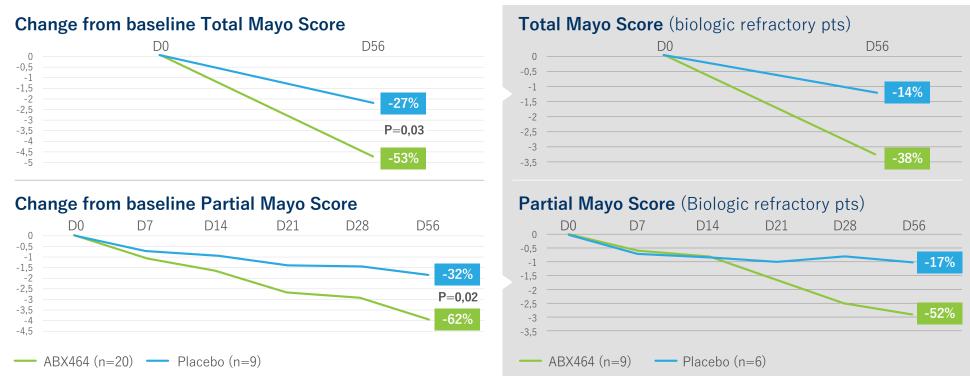
## ABX464-101: Statistically significant efficacy achieved for major endpoints (day 56)

Clinical remission: TMS equal or lower than 2 + no sub-score >1		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: Endoscopy sub-score 0 or 1	Endoscopic improvement	50%/43%	11%/11%	0.03
	Clinical response	70%/61%	33%/33%	0.06
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	Total Mayo Score reduction	-53%	-27%	0.03
	Partial Mayo Score reduction	-62%	-32%	0.02
	Faecal calprotectin decrease > 50 %	75%	50%	na
	miR-124 expression in rectal biopsies (fold increase)	7.69	1.46	0.004



# ABX464-101: Impressive Mayo Score results

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

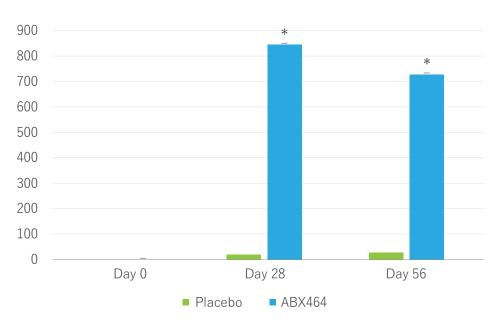




# ABX464-101: Statistically significant increase in miR-124 expression

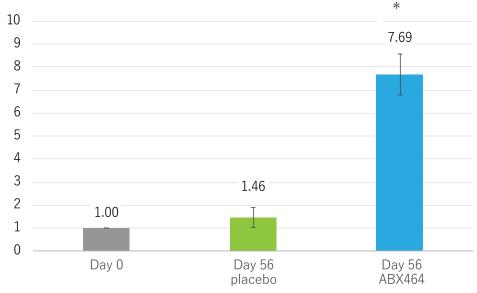
#### miR-124 expression in total blood

Fold induction (ratio)



#### miR-124 expression in rectal biopsies

Fold induction (ratio)





<sup>\*</sup> p value < 0.05 (Treatment and time point)

# ABX464-102 maintenance phase: Month 6 interim analysis

**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)





# As of March 8, 2019 the cumulative exposure is the following:

Mean (Days)	330
Median (Days)	316
Max (Days)	462
Min (Days)	246

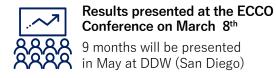
One lack of efficacy at M1, initially on ABX464

One due to subject's decision despite clinical response at M4, initially on ABX464

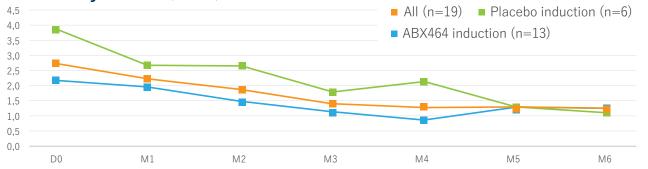
One due to TEAE (Headache, grade 2, drug related according to PI) occurring 4 months after first dosing at M5, initially on placebo



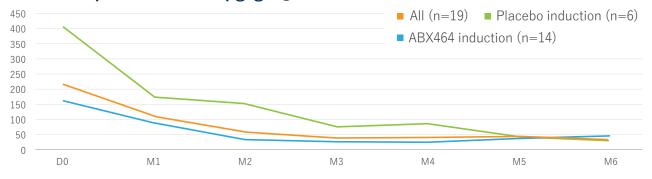
# ABX464-102 maintenance phase: Month 6 interim-analysis confirms strong potential







#### Faecal calprotectin level (µg/g) (geometric mean)



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

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).



# ABX464 in Ulcerative colitis Summary



New mechanism of action ORAL drug ABX464



**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)

Promising preclinical data in IBD model





Confirmed preliminary efficacy in phase 2a UC study

- All endpoints favourable 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 development plan



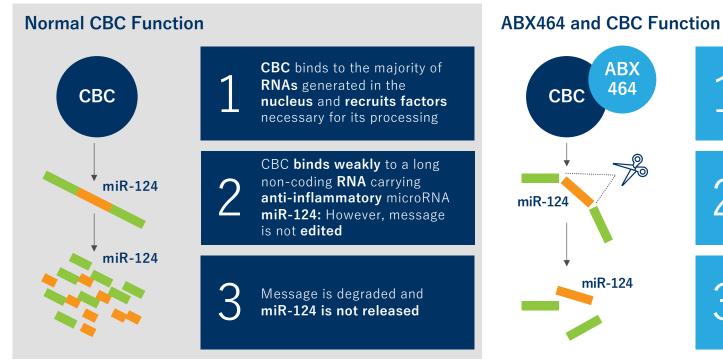
Phase 2b study protocol in 232 patients with moderate to severe ulcerative colitis was submitted to regulatory agencies in first countries in EU and Canada

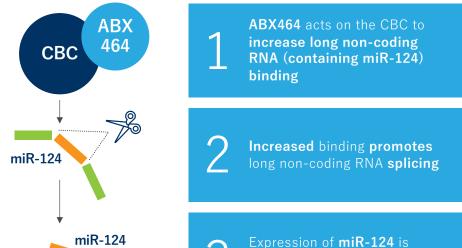
Phase 2a studies are being submitted in **Rheumatoid**Arthritis and Crohn's disease

3 Pre-clinical models in Multiple Sclerosis, Parkinson's disease, NASH and Psoriasis ongoing



# ABX464 novel mode of action: CBC-mediated effects on inflammation\*







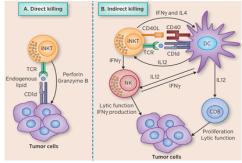


increased and inflammatory

brake is applied

### ABX196 - Background

#### **Mechanism of Action**



© 2015 American Association for Cancer Research

Market size (US/G5 EU/Japan) in first indication (hepatocellular cancer)







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

Strong preclinical data in liver cancer and melanoma

**IND** open in **US** for phase 1/2 in liver cancer: Combination treatment with checkpoint inhibitors

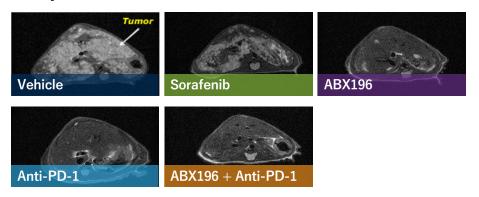
Clinical trial to start in summer 2019 at Scripps MD Anderson Cancer Center (San Diego, CA)



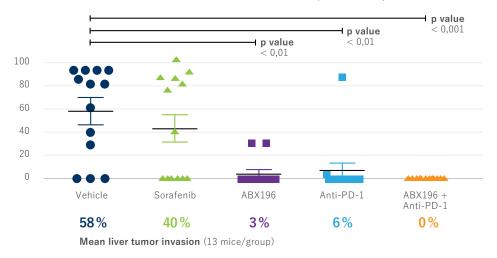
### ABX196 controls tumor growth in orthotopic HCC mouse model



## All MRI Imaging Done on day 19

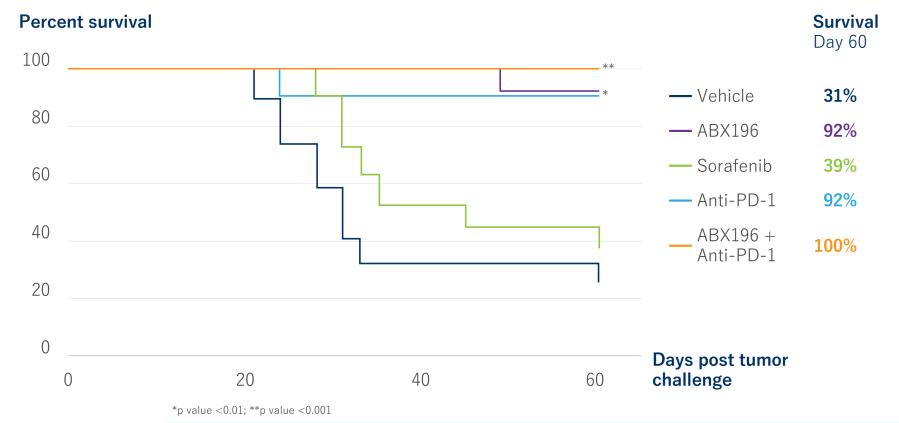


## Macroscopic Liver tumor invasion evaluation on day 61 or at death of the animals Tumor Invasion (% of liver)





#### ... and increases survival





### ABX196: Rationale for use in HCC therapy

## The liver is a tolerogenic organ

Enormous exposure to gut-borne pathogens and non-pathogenic molecules

Central role in host defense and self-tolerance:

- Largest concentration of immune effector cells in the body
- APCs express high levels of PD-L1 and low level of co-stimulatory molecules
- Limited ability to activate CD4 and CD8

## HCC arises in the setting of chronic inflammation

Inflamed microenvironment favors immune cell exhaustion/hypo-responsiveness

Upregulation of PD-1, CTLA-4, IL-10, TGF-beta, Tregs

## HCC is an immunogenic cancer

Strategies that overcome the immunosuppressive microenvironment may lead to enhanced clinical benefit

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.

#### High unmet medical need in HCC

Low response rates with nivolumab (Checkmate 040 Study)

	Uninfected untreated/ intolerant (n=56)	Uninfected sorafenib progressors (n=57)	<b>HCV</b> (n=50)	<b>HBV</b> (n=51)	<b>AII</b> (n=214)
ORR	21%	20%	20%	14%	20%
Med DOR	8.4 mo	NR	9.9 mo	NR	9.9 mo

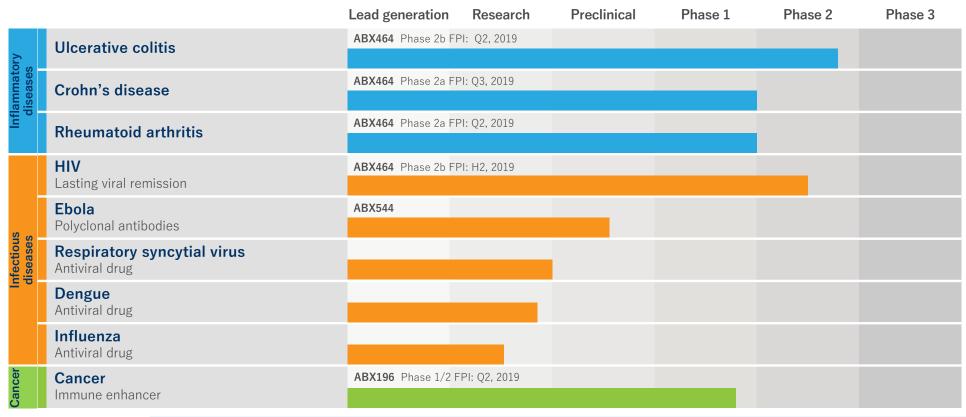
El-Khoueiry et al. Lancet 2017



ORR: Objective Response Rate; DOR: Duration of Response



## 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



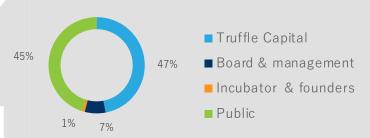
**Primary listing:** Euronext (Paris)

ABVX: FR0012333284

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

# abivax

#### **Shareholder structure 2 (undiluted)**



#### Location





#### **Operations**



**25** Employees<sup>2</sup>



Cash² **€ 13,0m** 





**6** in Support

<sup>1</sup>TSAF report as of Dec. 31st, 2018; <sup>2</sup>Actual Dec. 31st, 2018



## Actuals 2018: Key financial figures

		2018 FY m€	2017 FY m€	Variation m€ / %
Costs	Administrative Costs	-4,1	-3,7	-0,4 -11%
	% of Oper. Costs	20%	25%	
	R&D Costs	-15,9	-10,8	-5,0 -46%
	% of Oper. Costs	80%	75%	
	Operating Costs	-19,9	-14,5	-5,4 -37%
	Other Costs	-0,9	-0,2	-0,7 -318%
	Revenues	5,0	3,5	1,5 42%
	Net Income	-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



















→ Competencies from discovery to global commercialization

