A Turning Story Towards Inflammatory Diseases

Targeting the immune system to eliminate inflammatory and viral diseases as well as cancer

June 2019

abivax

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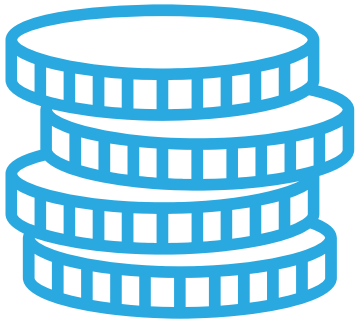
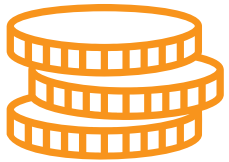
ABX464: A promising candidate addressing attractive markets



Total market size
in inflammatory diseases

greater than
USD 70 B



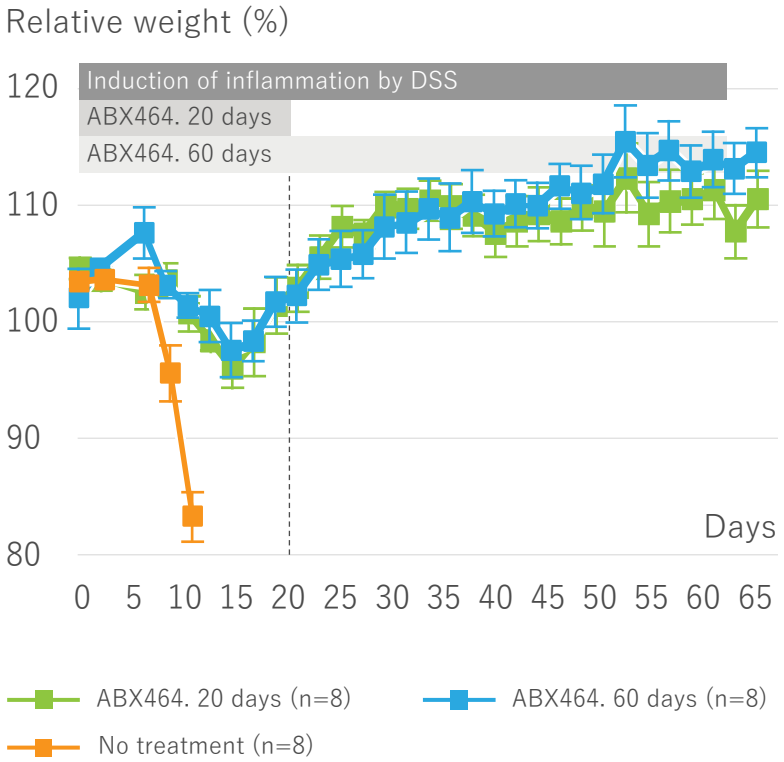
Market size
in first indication (ulcerative colitis)

around
USD 5.7 B

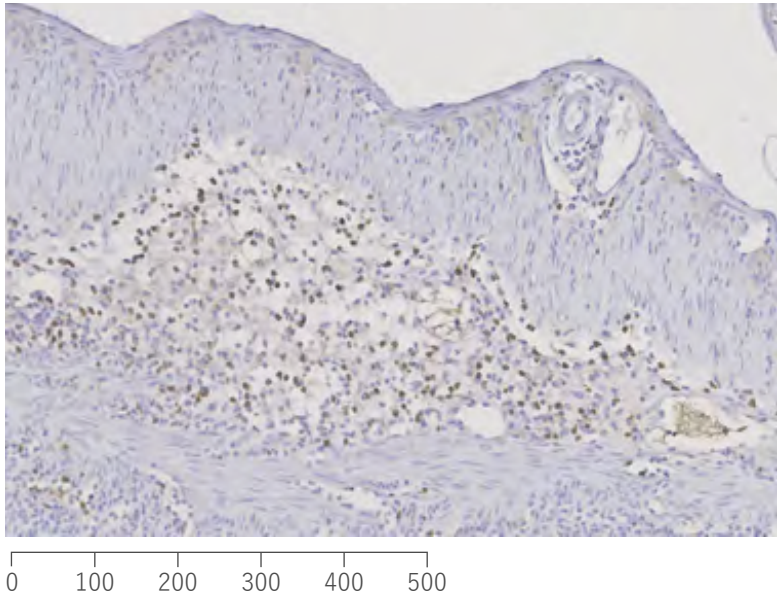
- Coming from the proprietary Abivax library of compounds, biased to **modulate RNA biogenesis** (>2000 molecules)
- **Small molecule** (quinoline), administered as an oral capsule (once a day)
- **First-in-Class, novel mechanism of action:** Selective upregulation of anti-inflammatory microRNA miR-124
- 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*

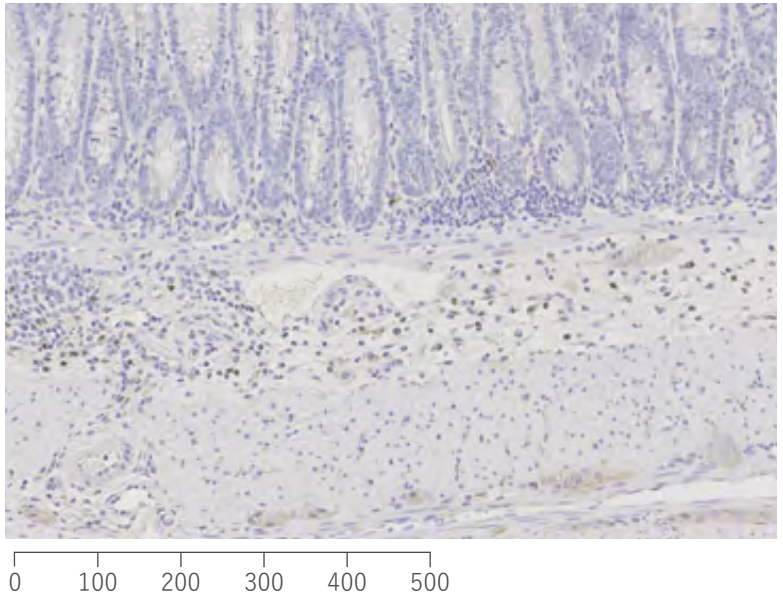
ABX464 protects mice from death in the DSS mouse model



DSS without ABX464 leads to intestinal damage



ABX464 protects intestinal structure



ABX464 reduced the expression of pro-inflammatory cytokines in colon tissue: IL-6 (2x), TNF (7.5x) and MCP-1 (6x)

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

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

Induction study (ABX464-101)
8 weeks of treatment (completed)

Open label extension (ABX464-102)
52 weeks (ongoing), now extended for 2. year

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 α, 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, miR-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

	ABX-464 (n=23) n (%)	Placebo (n=9) n (%)
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:
Total Mayo Score (TMS) equal or lower than 2 + no sub-score >1

Endoscopic improvement:
Endoscopy sub-score 0 or 1

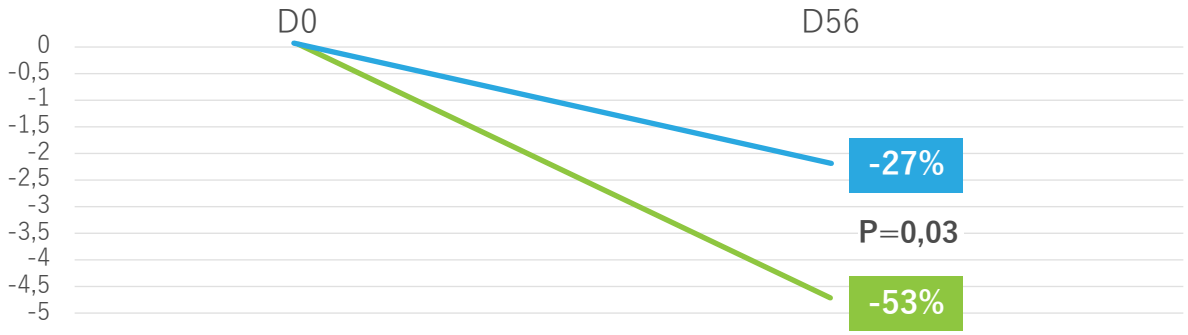
Clinical response:
TMS decrease of min 3 points and 30% from baseline + decrease of bleeding sub-score of min 1 point or absolute baseline of 0 or 1

	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**
Faecal calprotectin decrease > 50 %	75%	50%	na
miR-124 expression in rectal biopsies (fold increase)	7.69	1.46	0.004

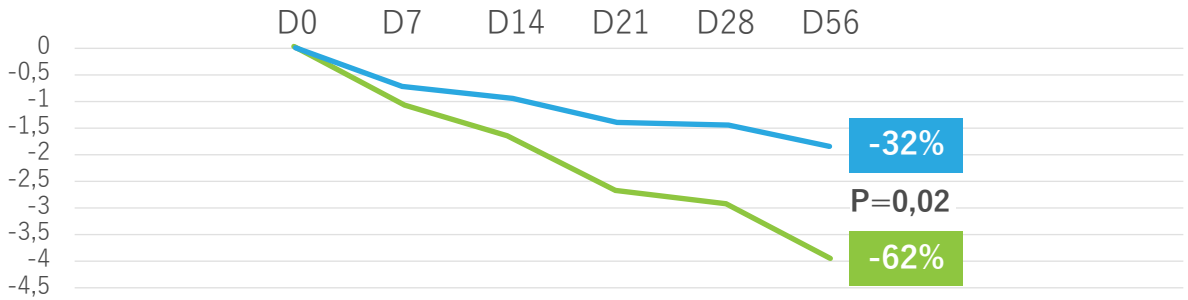
ABX464-101:
Impressive Mayo Score results

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

Change from baseline Total Mayo Score

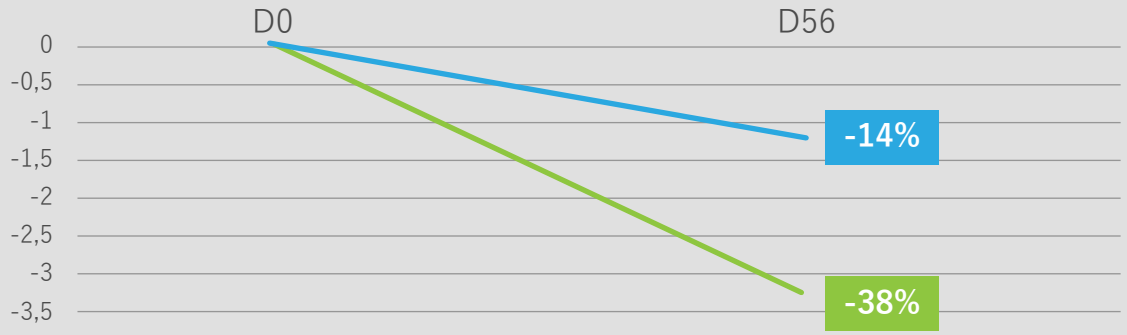


Change from baseline Partial Mayo Score

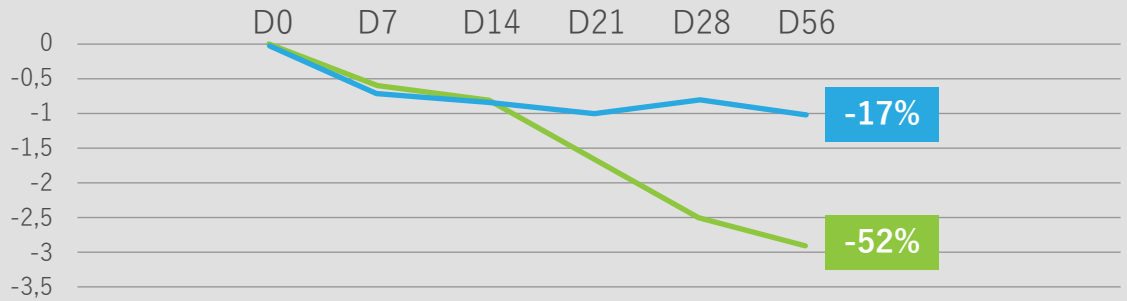


ABX464 (n=20) Placebo (n=9)

Total Mayo Score (Biologic refractory pts)



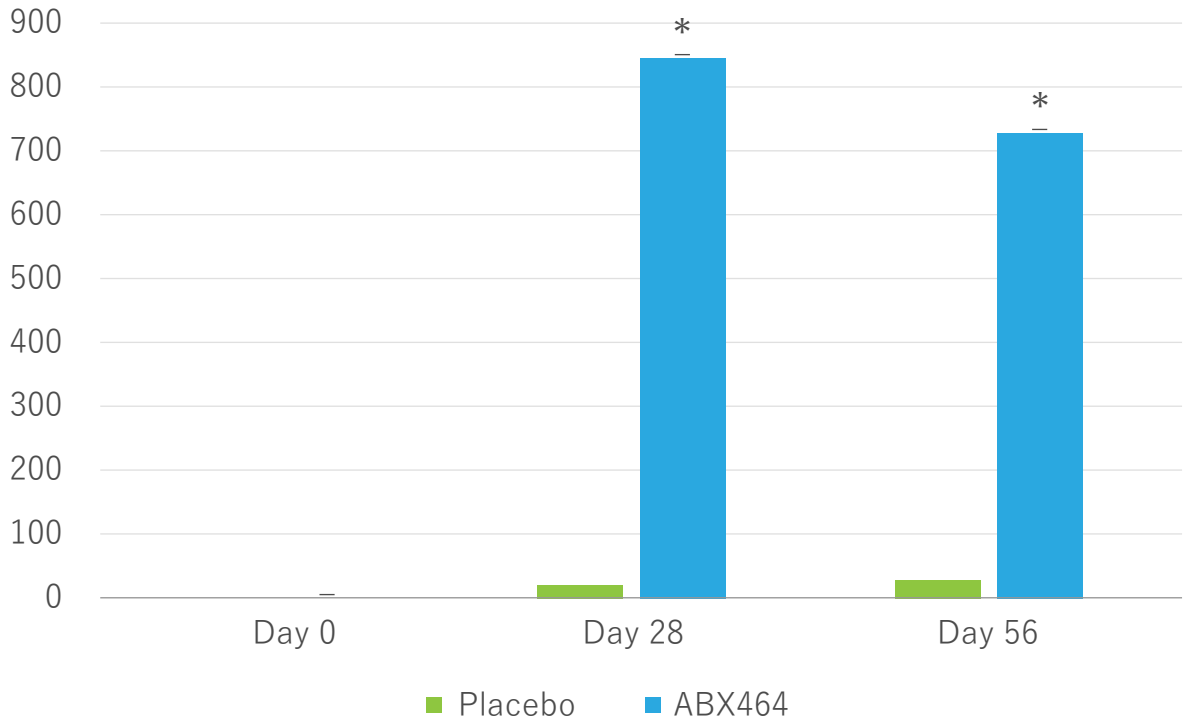
Partial Mayo Score (Biologic refractory pts)



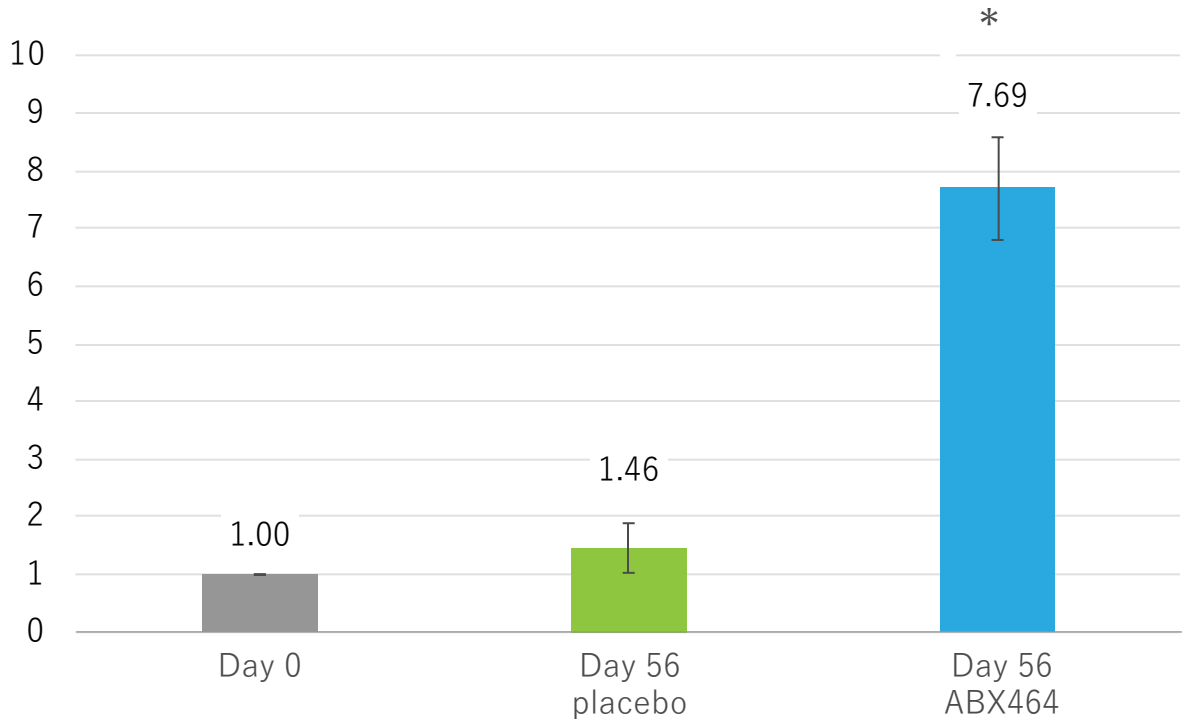
ABX464 (n=9) Placebo (n=6)

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)



* p value < 0.05 (Treatment and time point)

ABX464-102 maintenance phase: Month 9 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 CTA submission)

Cumulative exposure (in months) as of May 20, 2019:

Mean	**13.6**
Median	13.1
Max	17.8
Min	10.5

One due to lack of efficacy at M1, initially on ABX464

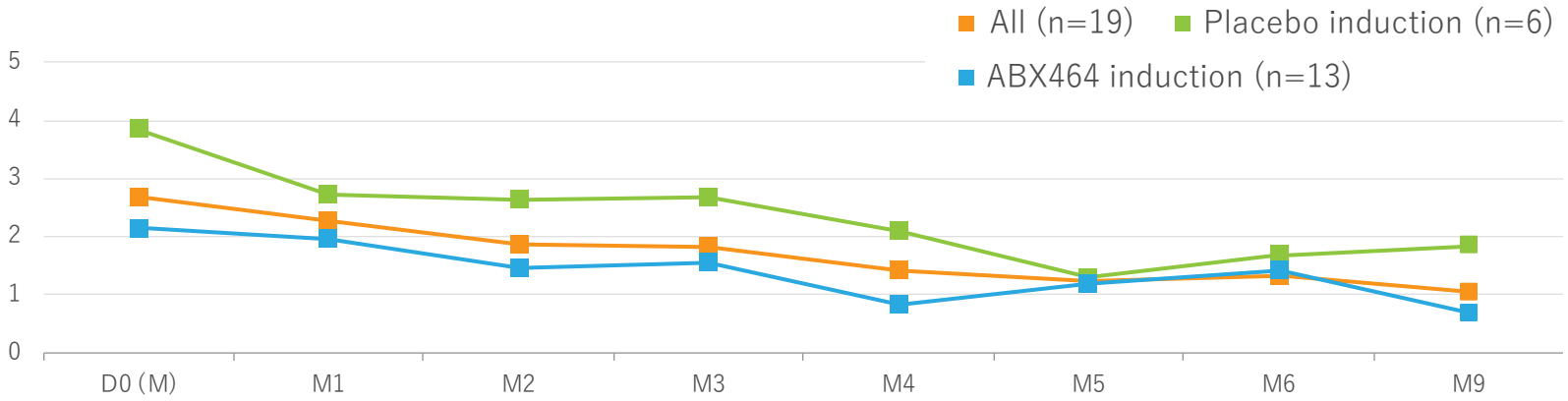
One due to subject's decision despite clinical response at M4, initially on ABX464

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

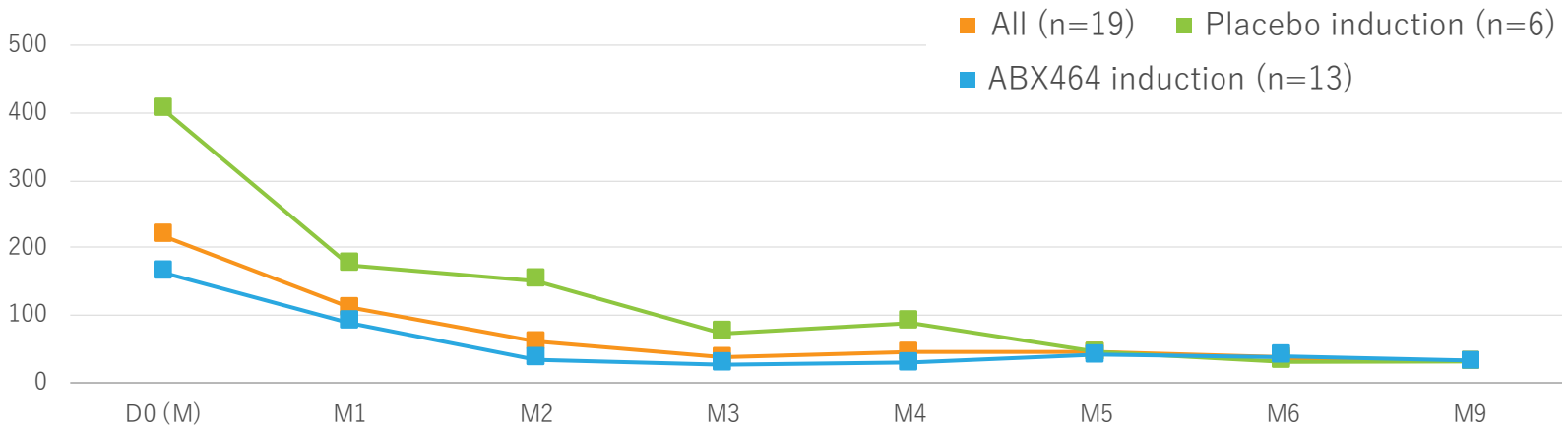
ABX464-102 maintenance phase: Month 9 interim-analysis confirms strong potential

Results presented at U.S. Digestive Disease Week (DDW) on May 21st

Partial Mayo Score (n=19)



Faecal calprotectin level (µg/g) (n=19)



Safety profile remains very good with no severe adverse reactions.

Reduction of Partial Mayo Score to <2

Biomarker faecal calprotectin reduced to normal values (<50 ug/g)

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 16 months on ABX464).

ABX464 in Ulcerative colitis Summary

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)

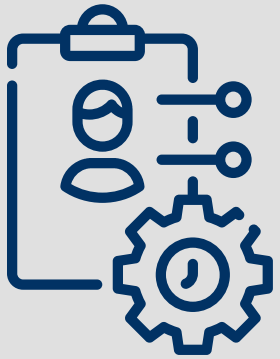
Confirmed preliminary efficacy in phase 2a UC study

- All endpoints favourable to ABX464
- Fast onset of action

Durability of effect: maintenance 9-month interim data

- Partial Mayo Score continued to decrease
- Faecal calprotectin levels reduced to normal values

ABX464 development plan



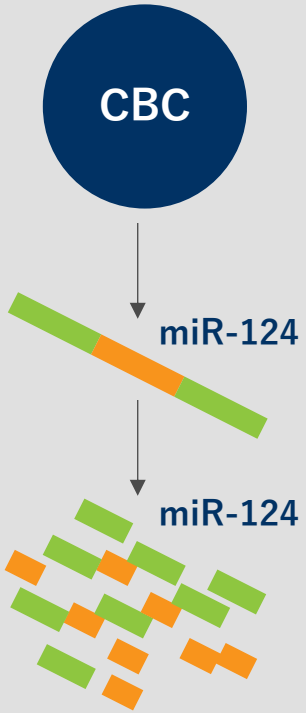
1 **Phase 2b study protocol in 232 patients** with moderate to severe ulcerative colitis was approved by regulatory agencies in first countries in EU and Canada

2 Phase 2a studies are being submitted in **Rheumatoid Arthritis** (CTA already fully approved in France) **and Crohn's disease**

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

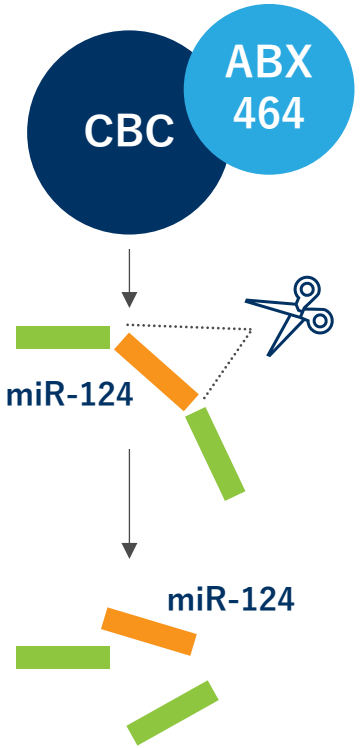
ABX464 novel mechanism of action-1: Generation of miR-124, a potent anti-inflammatory micro-RNA*

Normal CBC Function



1. **CBC** binds to the majority of **RNAs** generated in the **nucleus** and **recruits factors** necessary for RNA processing
2. CBC **binds weakly** to a long non-coding (lnc) **RNA** (carrying **anti-inflammatory** microRNA **miR-124:** However, lncRNA is not **edited**
3. lncRNA is degraded and **miR-124 is not released**

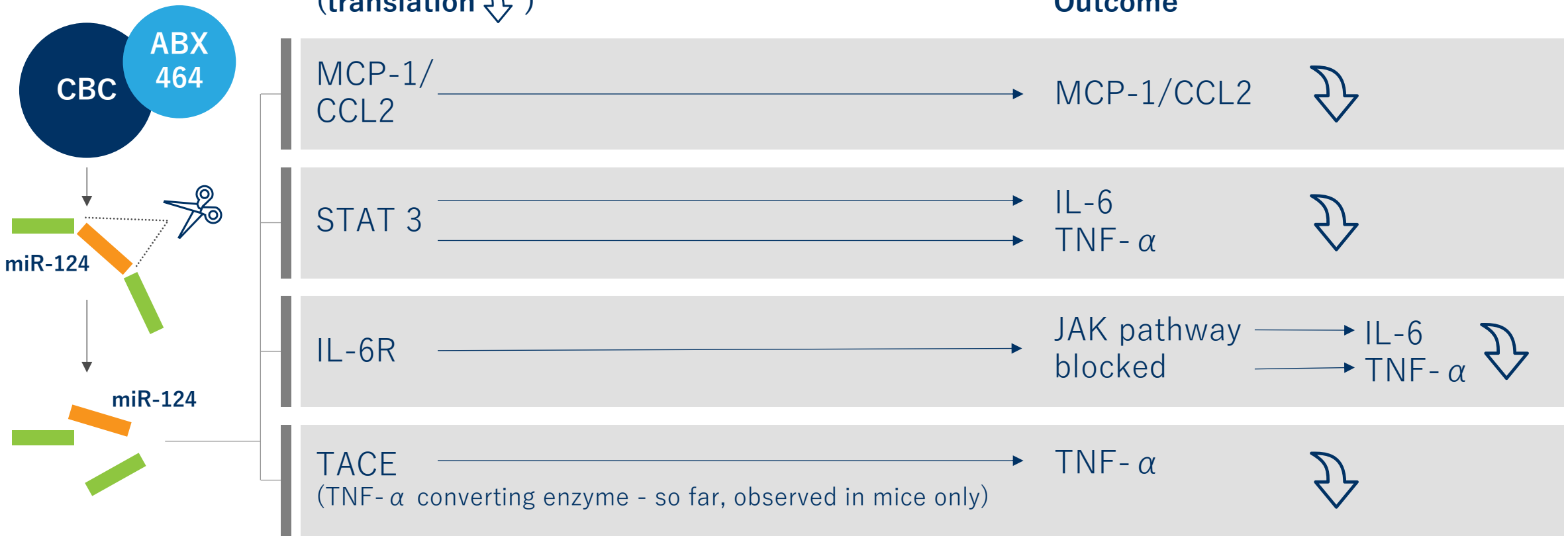
ABX464 and CBC Function



1. **ABX464** acts on the CBC to **increase long non-coding RNA (containing miR-124) binding**
2. **Increased** binding **promotes** long non-coding RNA **splicing**
3. Expression of **miR-124** is **increased, inducing an anti-inflammatory response**

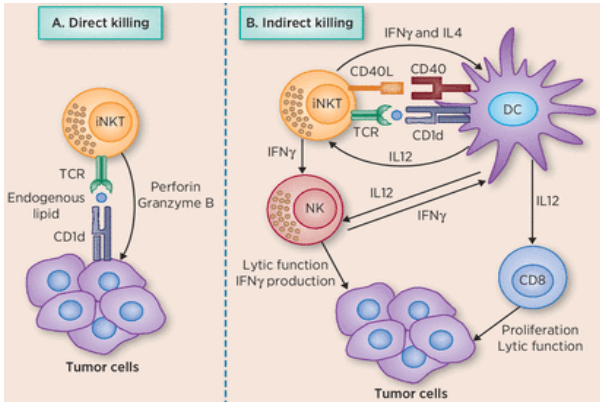
*Vautrin et al., Nature Scientific Reports 9 (2019); Source: Goetzpartners Securities Research

ABX464 novel mechanism of action-2: miR-124 suppresses pro-inflammatory cyto– and chemokines



ABX196 – Background

Mechanism of Action



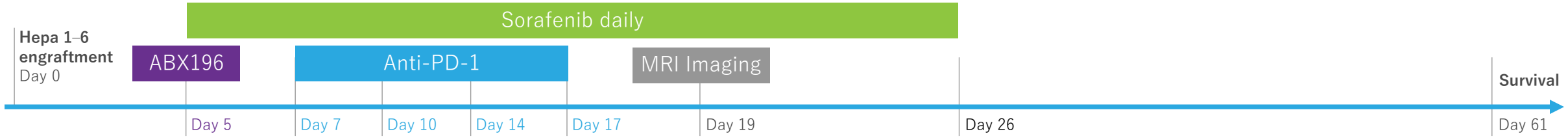
© 2015 American Association for Cancer Research

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

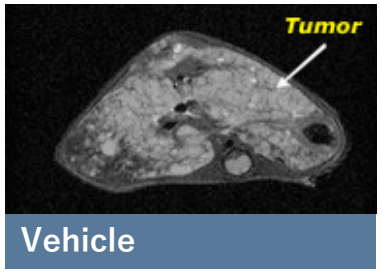
USD 616 M

- **Synthetic glycolipid agonist** of iNKT (invariant Natural Killer T) cells in liposomal formulation
- **Licensed from Scripps Research**, University of Chicago, Brigham-Young University
- **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)

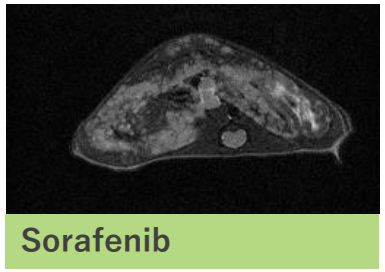
ABX196 controls tumor growth in orthotopic HCC mouse model…



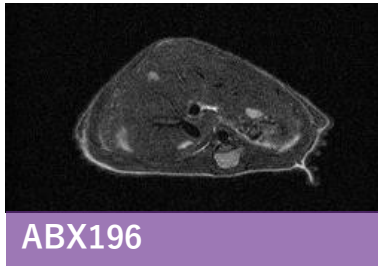
All MRI Imaging Done on day 19



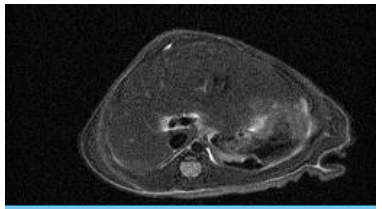
Vehicle



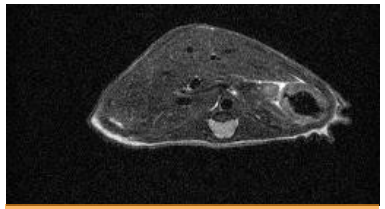
Sorafenib



ABX196

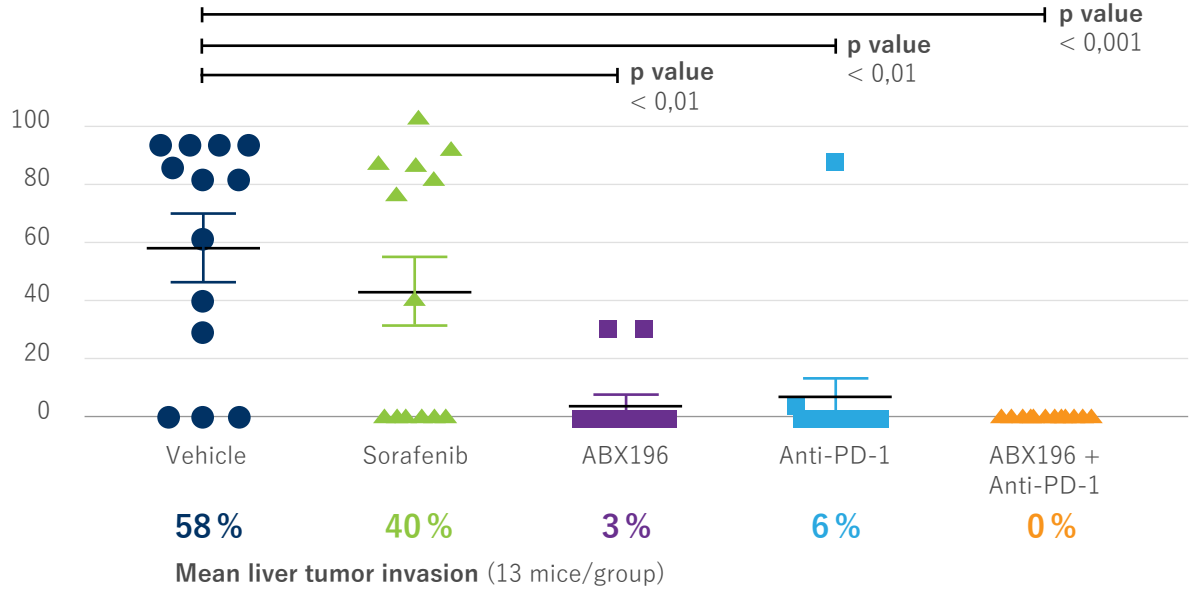


Anti-PD-1



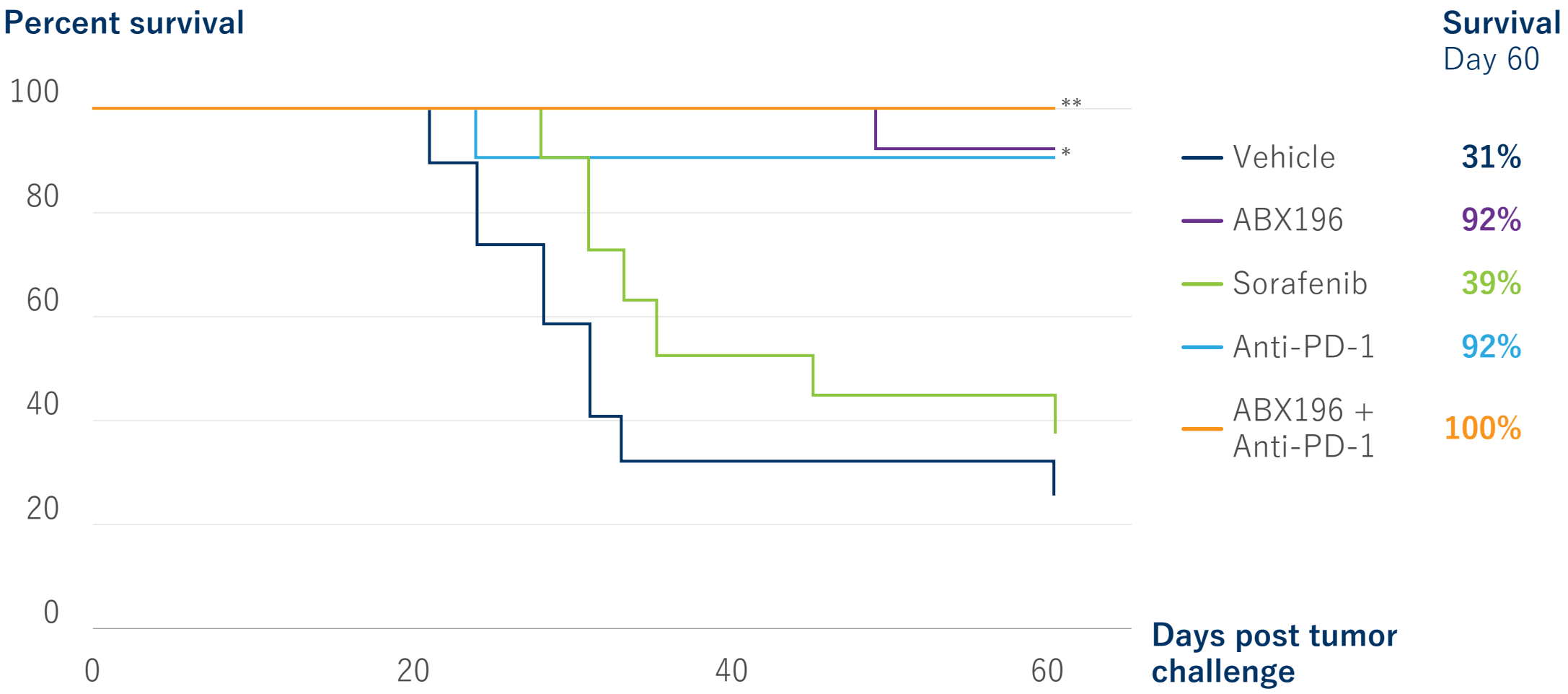
ABX196 + Anti-PD-1

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



Mean liver tumor invasion (13 mice/group)

… and increases survival



*p value <0.01; **p value <0.001

ABX196: Rationale for use in HCC therapy

The liver is a tolerogenic, immunosuppressed organ

Very high 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

High unmet medical need in HCC

Low response rates with nivolumab (Checkmate 040 Study)

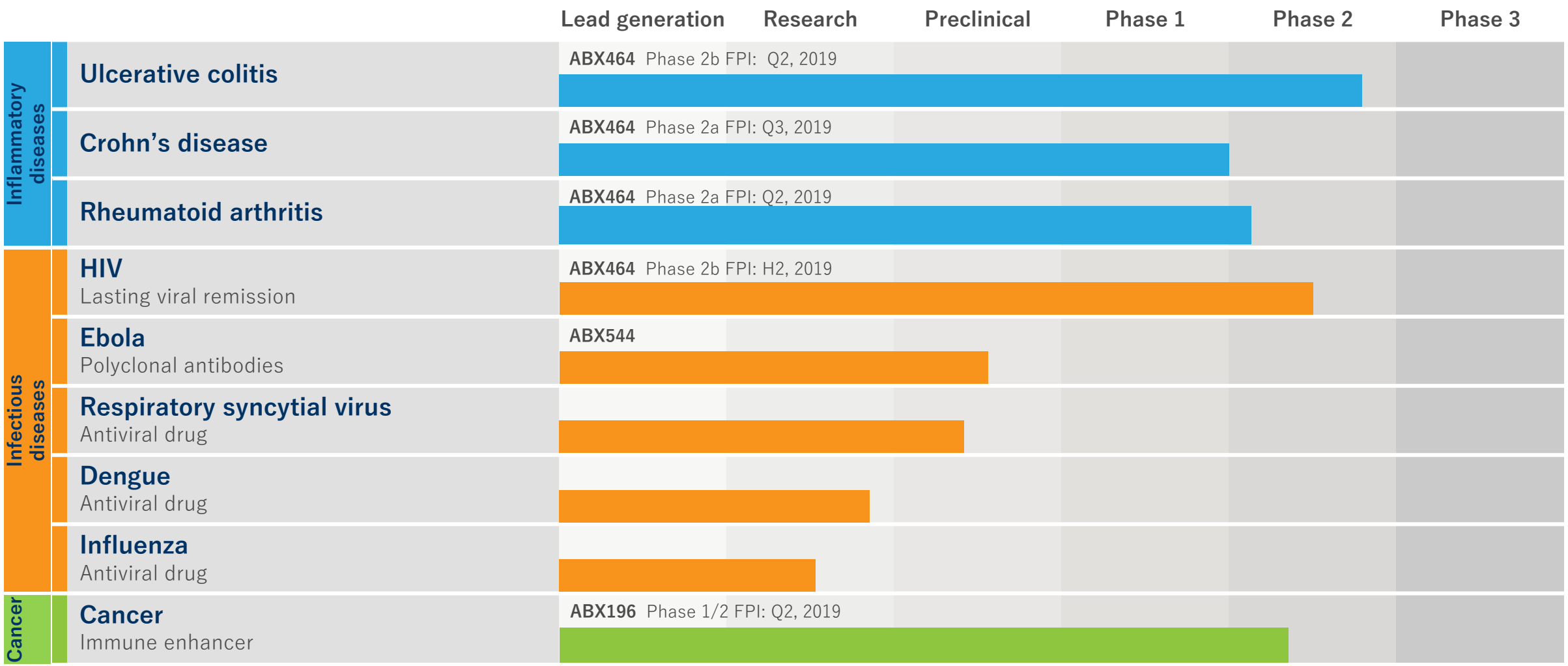
	Uninfected untreated/ intolerant (n=56)	Uninfected sorafenib progressors (n=57)	HCV (n=50)	HBV (n=51)	All (n=214)
ORR	21%	20%	20%	14%	20%
Med DOR	8.4 mo	NR	9.9 mo	NR	9.9 mo

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

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

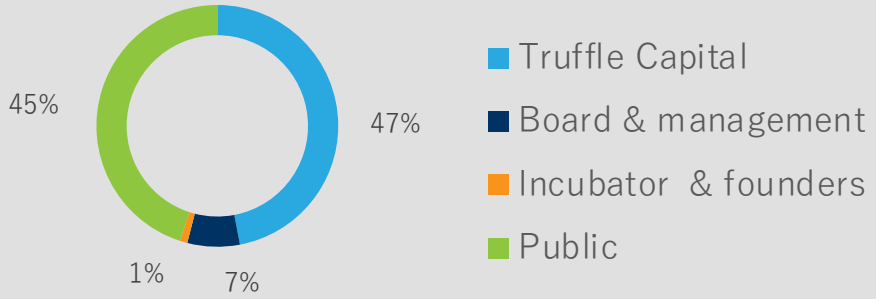
Primary listing: Euronext (Paris)
ABVX: FR0012333284
Liquidity: 27K shares/day in 2018[1]

Location

Head office
Paris

Cooperative lab with CNRS
Montpellier

Shareholder structure 2 (undiluted)



Operations

25
Employees[2]

Cash[2]
€ 13,0m

19
in R&D

6
in Support

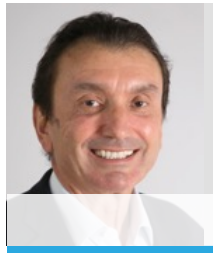
[1]TSAF report as of Dec. 31st, 2018; [2]Actual Dec. 31st, 2018

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



Prof. Hartmut Ehrlich, M.D.

Chief Executive Officer
Ex-Head of Global R&D, Baxter BioScience

Baxter · SANDOZ · Lilly

Didier Blondel

Chief Financial Officer & Board Secretary

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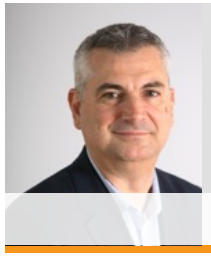

Pierre Courteille Pharmacist, MBA

Chief Commercial Officer & VP, BD

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Jérôme Denis Ph.D.

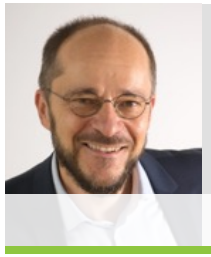
VP, Process Dev. & Manufacturing

iMabio · LYONBIOPOLE

Alexandra Pearce Ph.D.

VP, Regulatory Affairs, Quality, PV

AMGEN · Pfizer



Paul Gineste Pharm.D.

VP, Clinical Operations

Boehringer Ingelheim · ALTANA

Didier Scherrer Ph.D.

VP, R&D

AstraZeneca

Jean-Marc Steens M.D.

Chief Medical Officer

ViiV Healthcare · gsk GlaxoSmithKline

Prof. Jamal Tazi Ph.D.

CNRS Director & Founder of antiviral platform

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→ **Competencies from discovery to global commercialization**