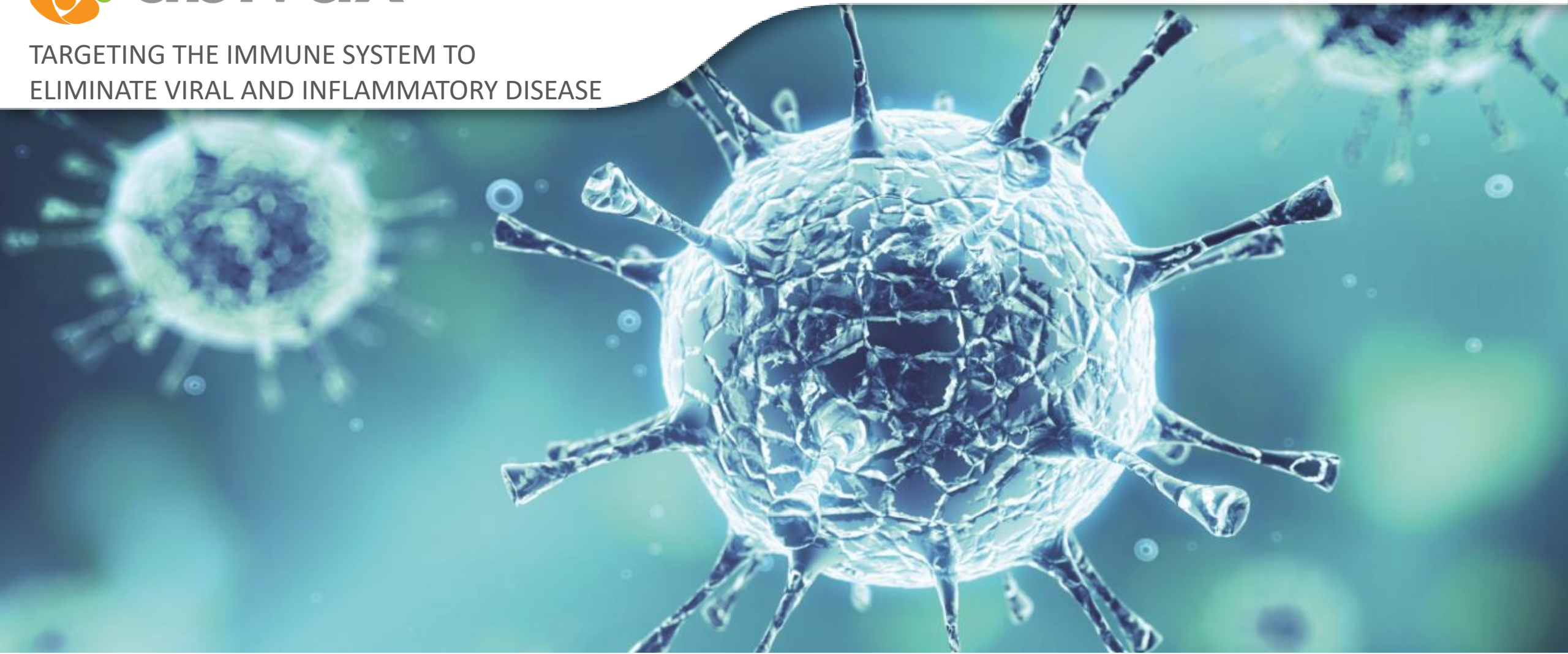




TARGETING THE IMMUNE SYSTEM TO
ELIMINATE VIRAL AND INFLAMMATORY DISEASE



Top-line results of the phase IIa study with ABX464 in ulcerative colitis

October 2018

Forward looking statements

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Abivax core management team

Today's presenters



Prof. Hartmut Ehrlich, M.D.

Chief Executive Officer

Baxter

Lilly

SANDOZ

*Ex-Head of Global R&D,
Baxter BioScience*



Didier Blondel

*Chief Financial Officer &
Board Secretary*

sanofi pasteur MSD
vaccines for life

SANOFI



Jean-Marc Steens, M.D.

Chief Medical Officer

ViiV
Healthcare

gsk
GlaxoSmithKline

Abivax has three key core pillars of value

			ABX464 Targets CBC 80/20 complex, thereby inducing enhanced RNA splicing	ABX196 Targets and activates invariant natural killer T immune cells
1	Ulcerative Colitis	2	HIV	3 Hepatocellular Carcinoma
• Upregulation of miRNA124 resulting in reduced inflammation in colon tissue • Strong therapeutic potential in UC as demonstrated in phase 2a clinical trial, as well as Crohn's disease and RA as demonstrated in preclinical models • Today: Results from phase 2a study in 30 UC patients in Europe • Q1 2019: Start phase 2B in UC • Q2 2019: Start ph 2a in Crohn's and RA		• Long-lasting HIV viral suppression, as shown in humanized mice • Decrease in HIV DNA in reservoir containing cells, as shown in patients • A potential functional cure to HIV, having already shown an up to 50% viral reservoir reduction in the blood of patients¹ • Today: Three months results of ongoing phase IIa study • H1 2019: Start phase IIb study		• Specific enhancer of cellular immune responses in cancer • Strong therapeutic potential in Hepatocellular Carcinoma (HCC) and other cancers in combination with checkpoint inhibitor • Q1 2019: Start of US phase 1/2 study in HCC patients
Multiple drug discovery platforms to drive drug candidate pipeline				
• <u>Antiviral platform</u>: novel antiviral drugs for Respiratory Syncytial Virus, Influenza, Dengue • <u>Immune Enhancer platform</u>: novel anti-cancer drugs • <u>Polyclonal Antibodies platform</u>: novel polyclonal antibodies for Ebola				

1: As demonstrated in phase IIa clinical studies after 28 days of ABX464 treatment

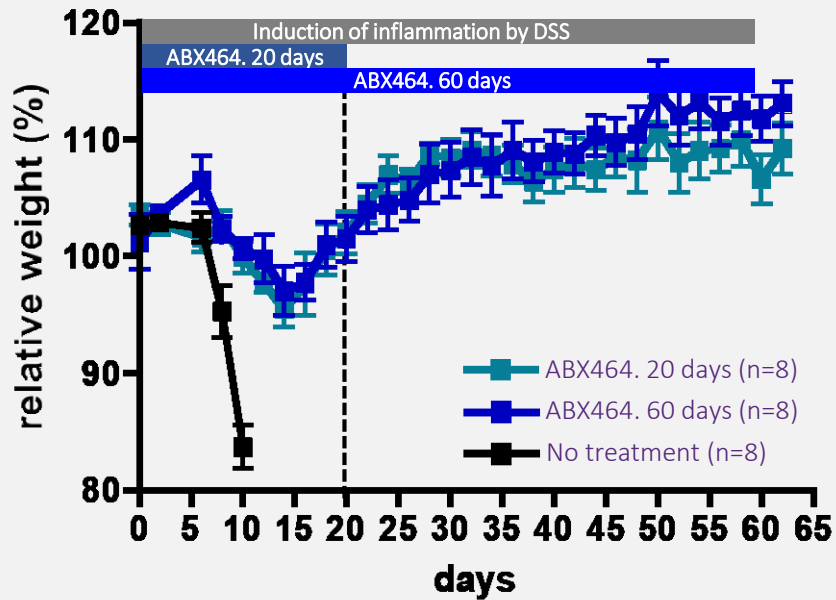
Anti-Inflammatory properties of ABX464

An oral drug with Novel Mechanism of Action

Invention ABX464

- **2015:** Recognition of ABX464 having strong anti-inflammatory properties through an increase of miRNA124 expression

ABX464 protects mice from death in the DSS mouse model

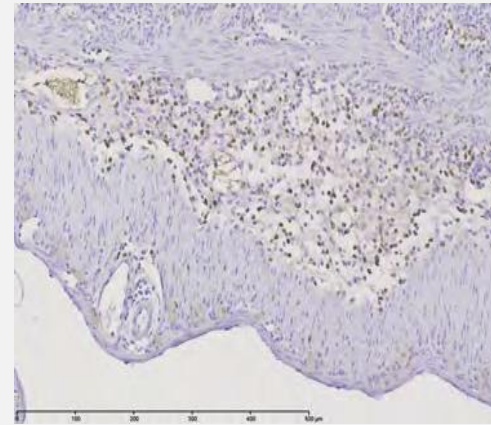


Preclinical validation in Ulcerative Colitis (UC) mouse model

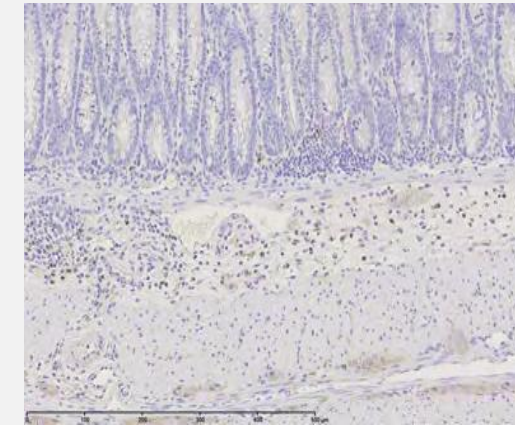
- **July 2017:** Nature scientific reports publication of compelling anti-inflammatory efficacy in a DSS¹ mouse model

SCIENTIFIC REPORTS
OPEN The Anti-Hiv Candidate Abx464 Dampens Intestinal Inflammation by Triggering IL-22 Production in Activated Macrophages
Received: 9 January 2017
Accepted: 19 May 2017

DSS without treatment leads to intestinal damage



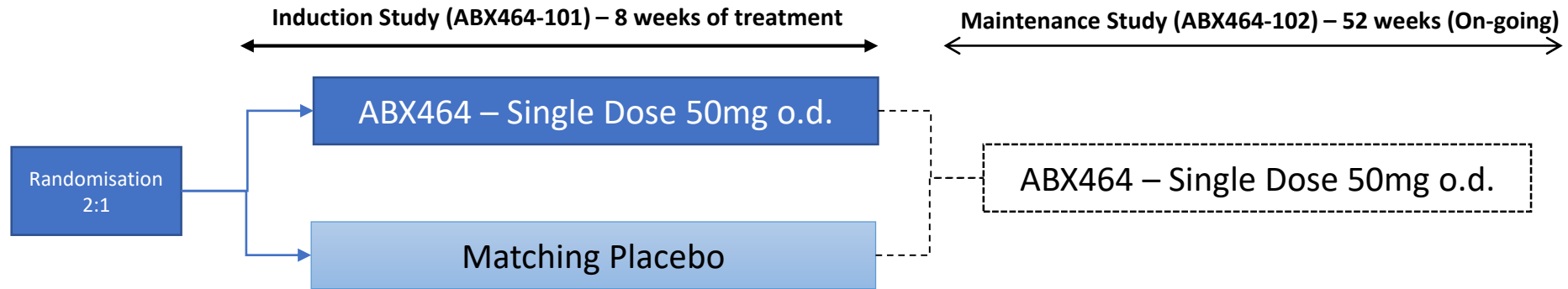
ABX464 protects intestinal Structure



In the DSS model, ABX464 leads to reduced expression of pro-inflammatory cytokines: IL-6 (2x), TNF (7.5x) and MCP-1 (6x) and increased expression of the anti-inflammatory IL22

Phase IIa Study Design (ABX464-101)

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



- Study Population = Patients with Moderate to Severe Active UC who have failed or are intolerant to immunomodulators, Anti-TNF α , vedolizumab and/or corticosteroids
 - Confirmed diagnosis of UC for at least 3 months with a Total Mayo Score (TMS) of 6 to 12 with endoscopic sub-score of 2 or 3
 - Previous Treatment Failure to : Salicylates, corticoids, immunomodulators or biologics
- Key Study Endpoints
 - Safety - Adverse Events
 - Mayo Score and Endoscopy (Central reading)
 - Fecal Calprotectin level, Geboes Score (histopathology), miRNA-124 expression, Microbiome
 - Quality of Life (SF-36)
 - Pharmacokinetics (Optional procedure; N=4)

- Coordinator : Prof Séverine Vermeire (Univ. Leuven)
- Countries involved : Belgium, France, Germany, Austria, Poland, Hungary, Czech Republic and Spain *
- Robust study methodology using central reading of the endoscopies & Central lab for all biological endpoints

* Underlined = Inactive countries

Patient demographics and baseline disease characteristics

Groups generally well-balanced; comparable with competition

		ABX-464 N = 23	Placebo N = 9	Total N = 32
Age (years)	Mean (Min-Max)	42.96 (20.0 – 73.0)	44.11 (20.0 – 64.0)	43.28 (20.0 – 73.0)
Sex	Male	12 (52.2%)	8 (88.9%)	20 (62.5%)
BMI (kg/m ²) at Screening	Mean	25.63 (17.6 – 38.6)	25.96 (20.3 – 32.9)	25.72 (17.6 – 38.6)
CRP (mg/L)	Mean / Median	7.4 / 2.5	4.5 / 1.8	6.6 / 2.3
	Min-Max	0.4– 66.8	0.4–19.2	0.4– 66.8
Fecal Calprotectin (µg/g)	Geometric Mean (N)	958.9 (23)	786,01 (8)	910,9 (31)
	Min-Max	78.7 – 19109.0	39.2 – 5150.3	39.2 – 5150.3
Disease Duration (years)	Mean / Median	7.60 / 5.76	6.47 / 5.17	7.28
	Min-Max	0.3– 26.0	2.9– 13.0	0.3– 26.0
Previous Biologics Exposure		10/23 (43.5%)	6/9 (66.6%)	16/32 (50%)
	Refractory to anti-TNF & Vedo	5/10 (50%)	4/6 (67%)	9/16 (56%)
	Refractory to anti-TNF	5/10 (50%)	2/6 (33%)	7/16 (44%)
Total Mayo Score	Mean (Min-Max)	8.65 (6 – 11)	7.89 (4 – 11)	8.44 (4 – 11)
Partial Mayo Score	Mean (Min-Max)	6.17 (4 – 8)	5.56 (2 – 8)	6,0 (2 – 8)

Topline Results : Phase IIa (ABX464-101) in Ulcerative Colitis

Strong Efficacy signal observed

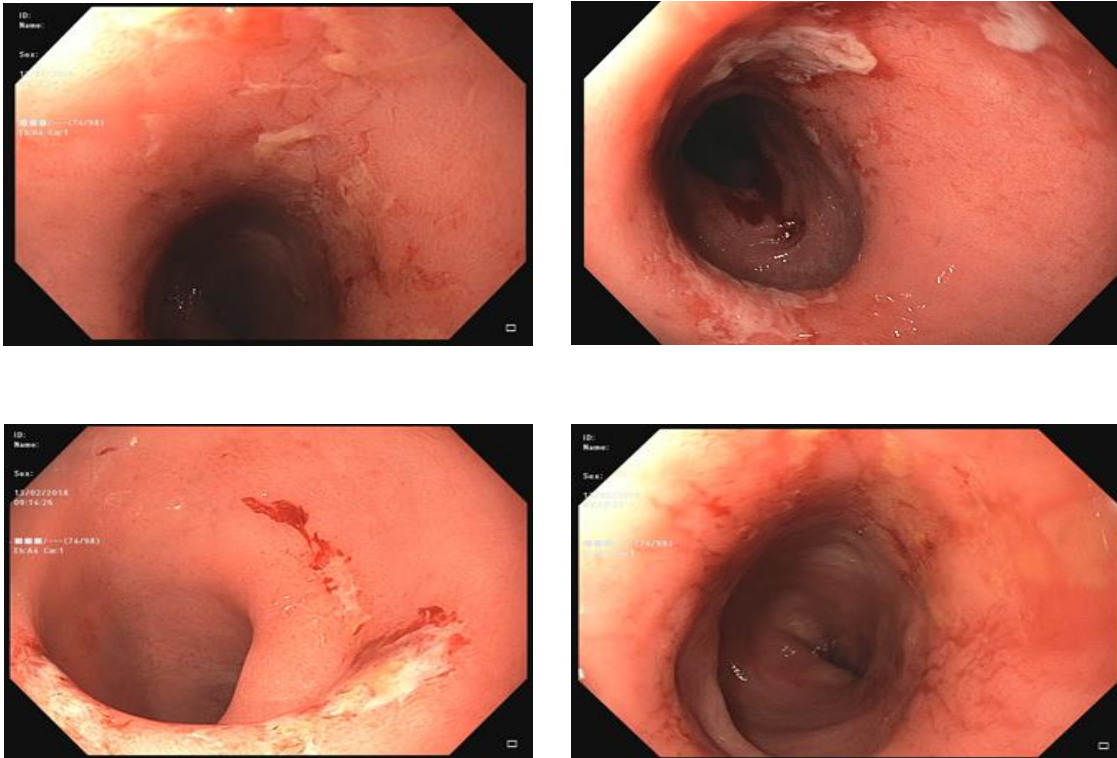
- Clinical Remission rate (i.e. Primary endpoint for registration)
 - **35.0 %** of ABX464 patients in Clinical Remission (Placebo = 11.1%)
- Mucosal Healing rate
 - **50.0 %*** of ABX464 patients with Mucosal Healing (Placebo = 11.1%)
- Clinical Response rate
 - **70.0 %** of ABX464 patients with a Clinical Response (Placebo = 33.0%)
- Good Safety profile, consistent with previous ABX464 studies
 - No Severe, nor Serious Adverse Drug Reaction reported
 - One patient (3%) dropped out due to an Adverse Event

* Statistically significant (p=0.03)

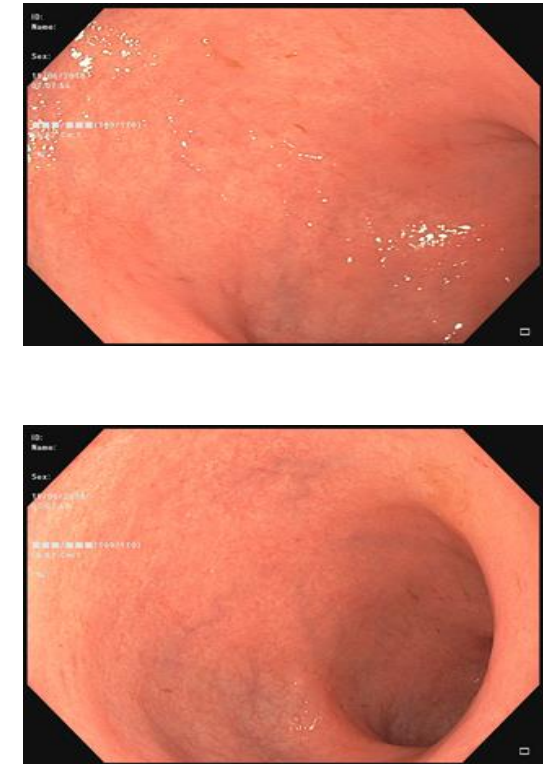
Mucosal healing in an ABX464 treated patient

Courtesy of Prof. Severine Vermeire

Before ABX464



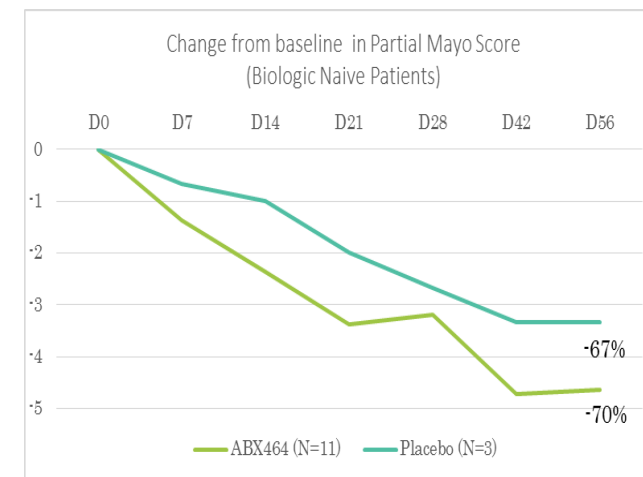
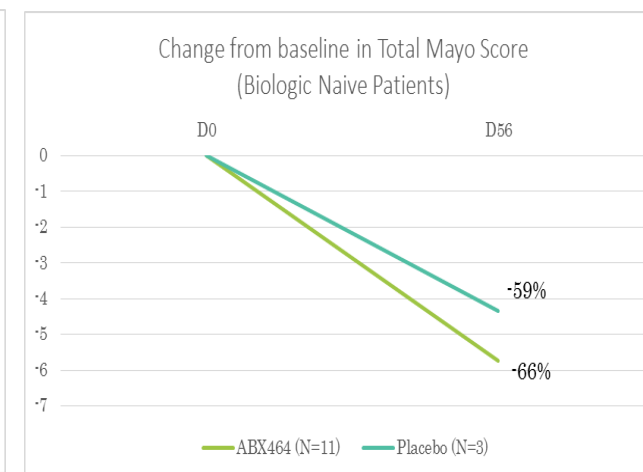
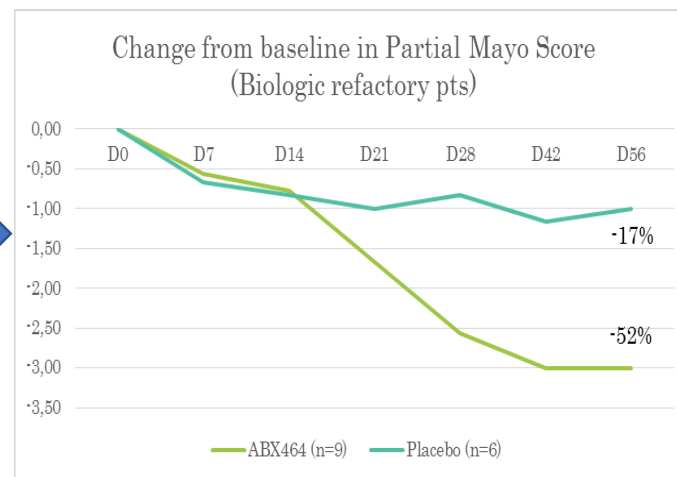
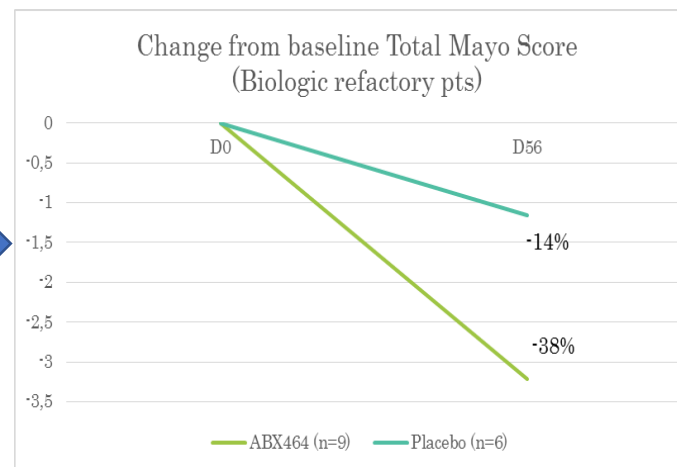
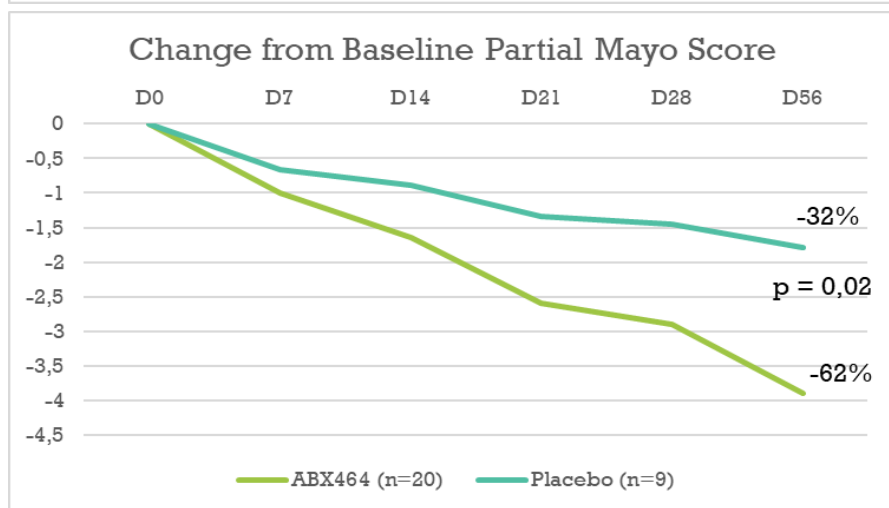
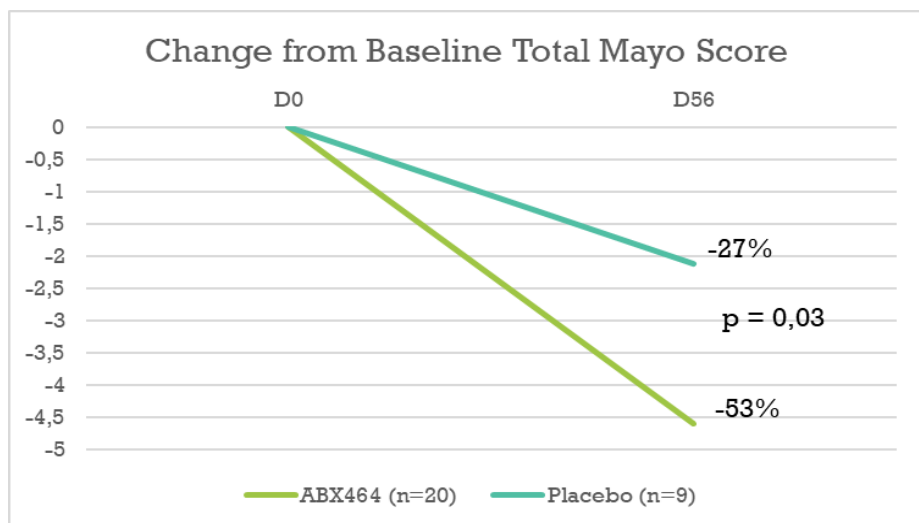
After ABX464



Mayo Score Results

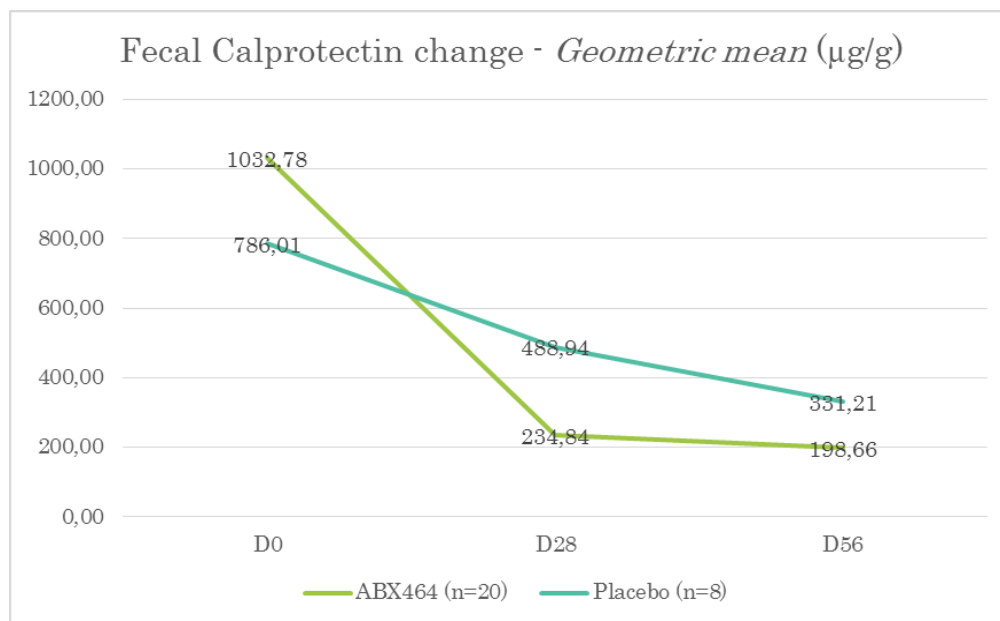
Statistically significant signal observed in TMS and PMS

Fast onset of action – Greater difference over Placebo observed in Biologics refractory Patients



Calprotectin level

Trend of greater reduction despite high placebo response – Consistent with TMS results



% of patients with at least a 50% reduction from Baseline in Fecal Calprotectin

ABX464 (n=20)

75.0%

Placebo (n=8)

50.0%

Safety Profile

Good safety profile – Consistent with previous studies

Patients experiencing at least one TEAEs (Treatment Emergent Adverse Events) by SOC and PT (>5%) regardless of causality		ABX-464 (N=23)	Placebo (N=9)
		N (%)	N (%)
Any Treatment-Emergent Adverse Events		18 (78.3%)	5 (55.6%)
Gastrointestinal disorders		8 (34.8%)	2 (22.2%)
	Abdominal pain	4 (17.4%)	1 (11.1%)
	Abdominal pain upper	3 (13.0%)	0 (0.0%)
	Diarrhoea	0 (0.0%)	1 (11.1%)
	Nausea	2 (8.7%)	0 (0.0%)
General disorders and administration site conditions		3 (13.0%)	0 (0.0%)
	Chest pain	2 (8.7%)	0 (0.0%)
	Influenza like illness	2 (8.7%)	0 (0.0%)
Hepatobiliary disorders		0 (0.0%)	1 (11.1%)
	Cholestasis	0 (0.0%)	1 (11.1%)
Infections and infestations		4 (17.4%)	1 (11.1%)
	Nasopharyngitis	1 (4.3%)	1 (11.1%)
Investigations		1 (4.3%)	1 (11.1%)
	Glutamate dehydrogenase increased	0 (0.0%)	1 (11.1%)
Metabolism and nutrition disorders		2 (8.7%)	2 (22.2%)
	Hypophosphataemia	1 (4.3%)	2 (22.2%)
Nervous system disorders		5 (21.7%)	0 (0.0%)
	Headache	4 (17.4%)	0 (0.0%)
Renal and urinary disorders		0 (0.0%)	1 (11.1%)
	Nephrolithiasis	0 (0.0%)	1 (11.1%)
	Renal colic	0 (0.0%)	1 (11.1%)

Conclusions

- Results show statistically significant efficacy based on both clinical and endoscopic endpoints
- Rapid onset of efficacy with 3.2-fold improvement in clinical remission rate and 4.5-fold in mucosal healing
- ABX464 was safe and well tolerated
- Convenient once a day oral regimen for chronic disease
- First-in-class mechanism of action

Phase IIa results support continuation of ABX464 in UC as well as clinical exploration in other inflammatory indications

- Full study results (incl. Geboes score, miRNA, Microbiome, QoL) expected by October
 - Study results Communication (ECCO, DDW, ACG,...) and Publication planned
- Clinical results warrant the conduct of **Phase IIb Study**
 - Patients with moderate to severe Ulcerative Colitis refractory to conventional and/or biological therapies
 - 25mg, 50mg, 100mg or placebo – daily dosing / 8 weeks + 52 weeks (Maintenance Phase)
 - 180 patients (70- 100 centres) – Coordinator: Prof. Severine Vermeire
 - First Clinical Trial Application planned by Q4/2018
- Planning of Phase IIa Proof of Concept studies in inflammatory conditions such as Crohn's disease, rheumatoid arthritis

ABX464 Mechanism of Action

Molecular target :

Activity :

Biological effects:

Outcome :

Observed outcome

In vitro

In vivo

CBC 80/20

Conformational change of CBC complex

enhanced RNA splicing

1. Enhanced splicing of a long, non-codingRNA, leading to miR124 upregulation
2. Cytokine modulation

UC and other inflammatory indications:
Dampening of inflammation

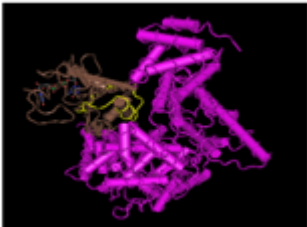
Enhanced viral RNA splicing and prevention of
REV mediated export of long viral RNA

HIV
Reduction of viral load*

Hypotheses being investigated :

1. *Generation of neoantigens and initiation of immune response*
2. *Cytotoxicity for reservoir cells by peptides related to viral RNA*
3. *Generation of deficient virus*

HIV
Substained biological control of viral load

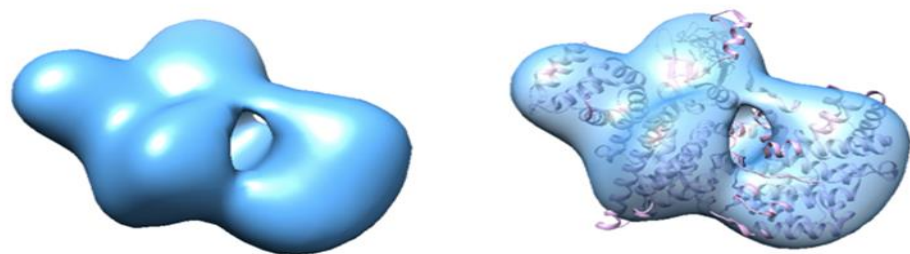


Note : *italic* characters = hypotheses

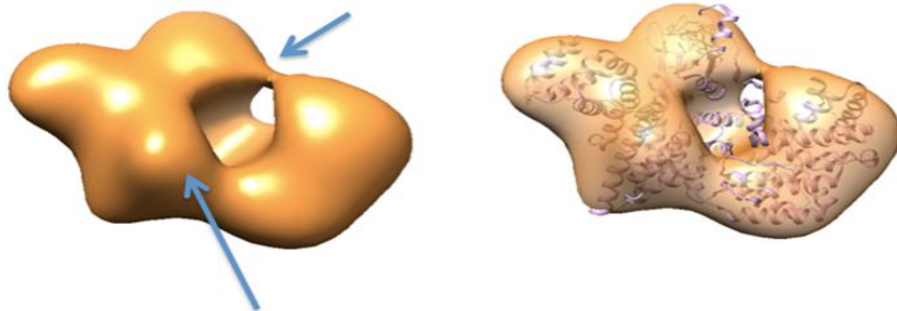
*Campos N et al. Retrovirology 2015; 12:1-15

Cryo-EM of the ABX464-CBC complex structure

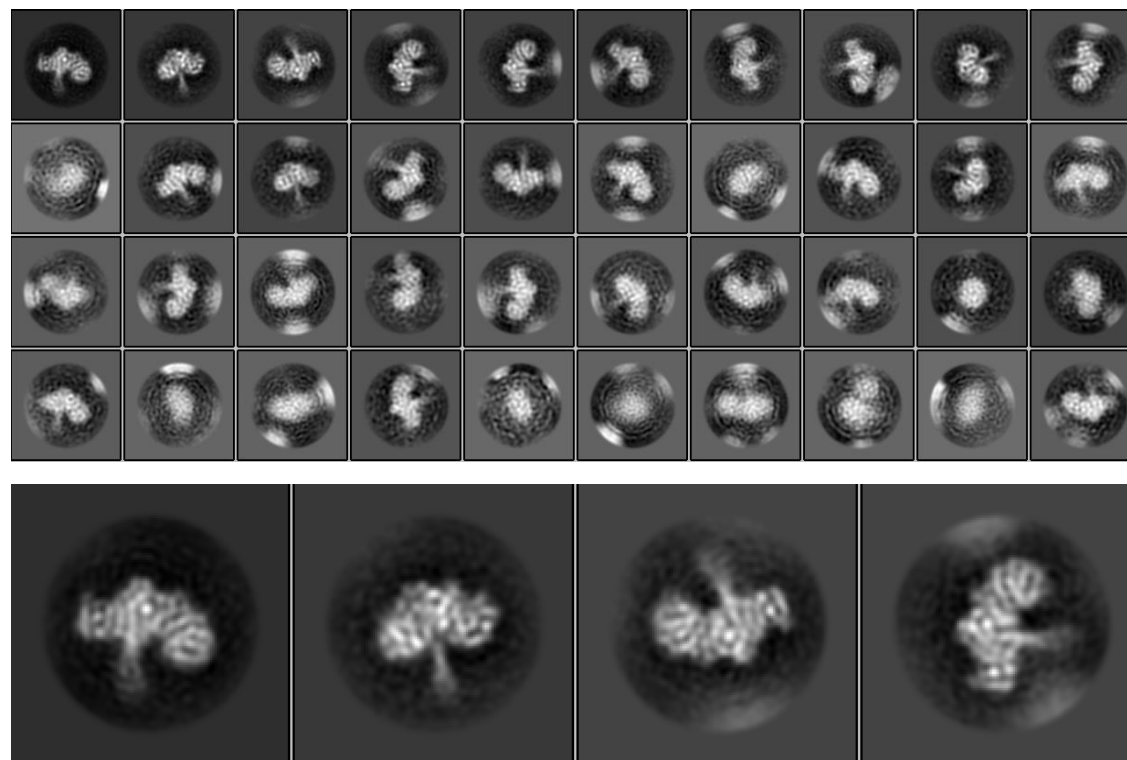
CBC



CBC-ABX464



Images of higher resolution have been produced for CBC alone and CBC-464 and are currently being analyzed



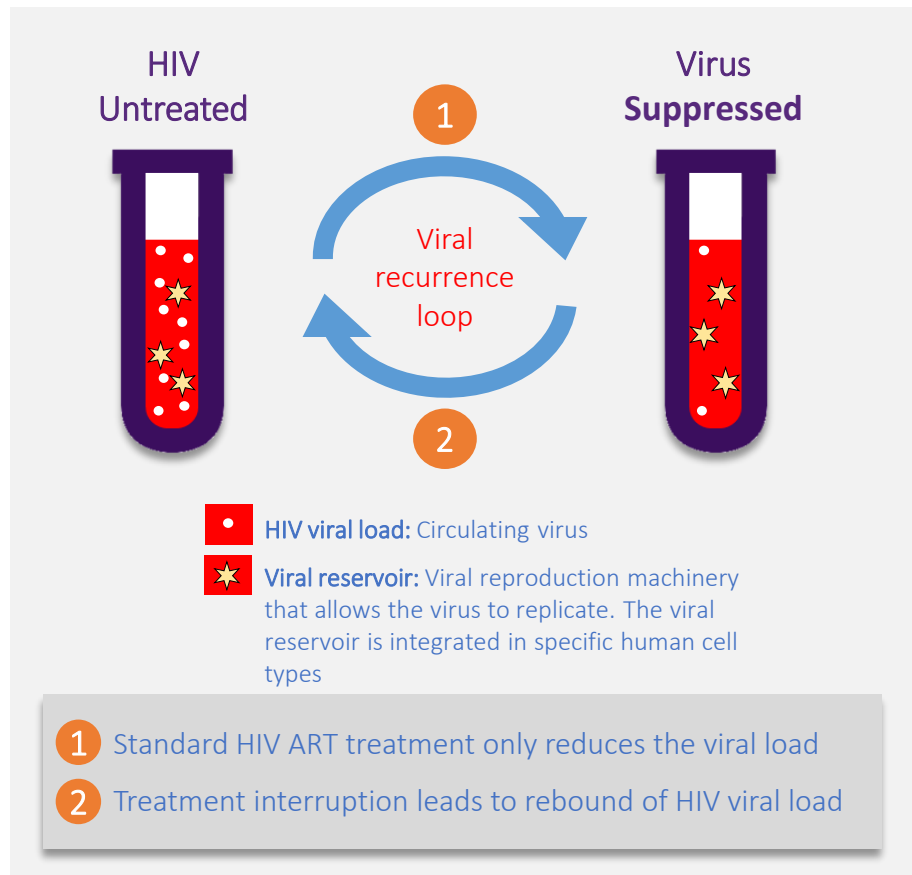
Abivax has three key core pillars of value

 ABX464 Targets CBC 80/20 complex, thereby inducing enhanced RNA splicing			ABX196 Targets and activates invariant natural killer T immune cells
	1 Ulcerative Colitis	2 HIV	3 Hepatocellular Carcinoma
What:	Upregulation of miRNA124 resulting in reduced inflammation in colon tissue	- Long-lasting HIV viral suppression, as shown in humanized mice - Decrease in HIV DNA in reservoir containing cells, as shown in patients	Specific enhancer of cellular immune responses in cancer
Promise:	Strong therapeutic potential in UC as demonstrated in phase 2a clinical trial, as well as Crohn's disease and RA as demonstrated in preclinical models	A potential functional cure to HIV, having already shown an up to 50% viral reservoir reduction in the blood of patients¹	Strong therapeutic potential in Hepatocellular Carcinoma (HCC) and other cancers in combination with checkpoint inhibitor
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Multiple drug discovery platforms to drive drug candidate pipeline			
<u>Antiviral platform</u>: novel antiviral drugs for Respiratory Syncytial Virus, Influenza, Dengue <u>Immune Enhancer platform</u>: novel anti-cancer drugs <u>Polyclonal Antibodies platform</u>: novel polyclonal antibodies for Ebola			

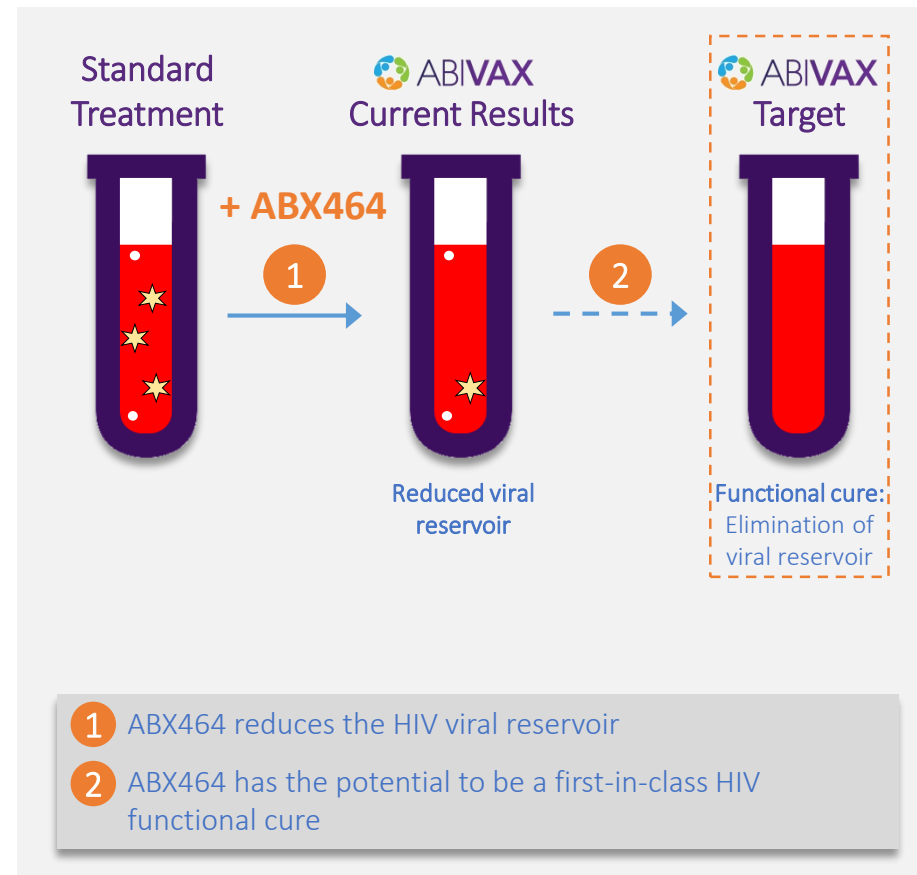
1: As demonstrated in phase IIa clinical studies after 28 days of ABX464 treatment

ABX464: a functional cure for HIV

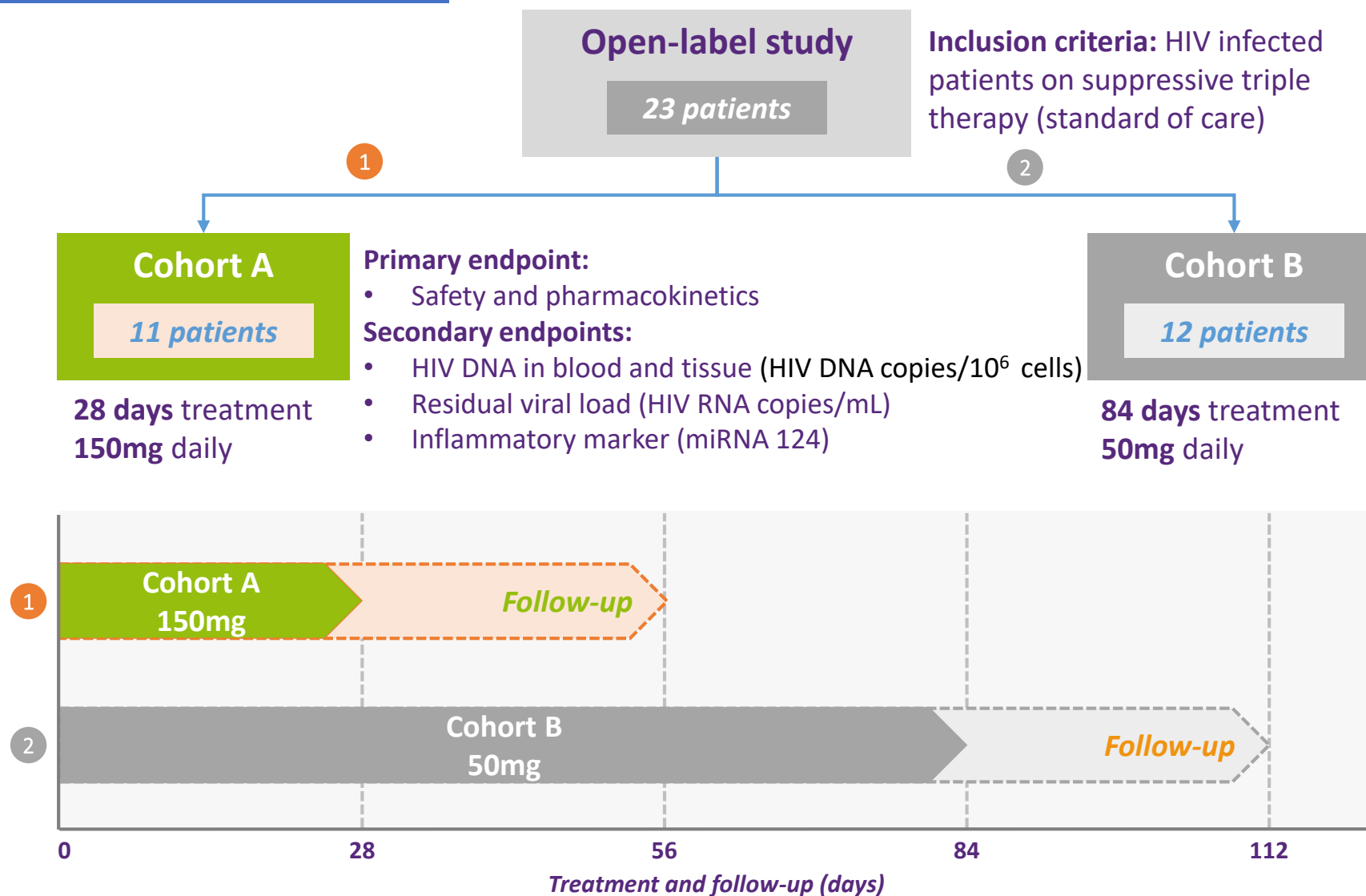
Standard ART¹ suppresses HIV as long as patients are compliant with treatment



ABX464 aims to be a functional cure for HIV by reducing the viral reservoir



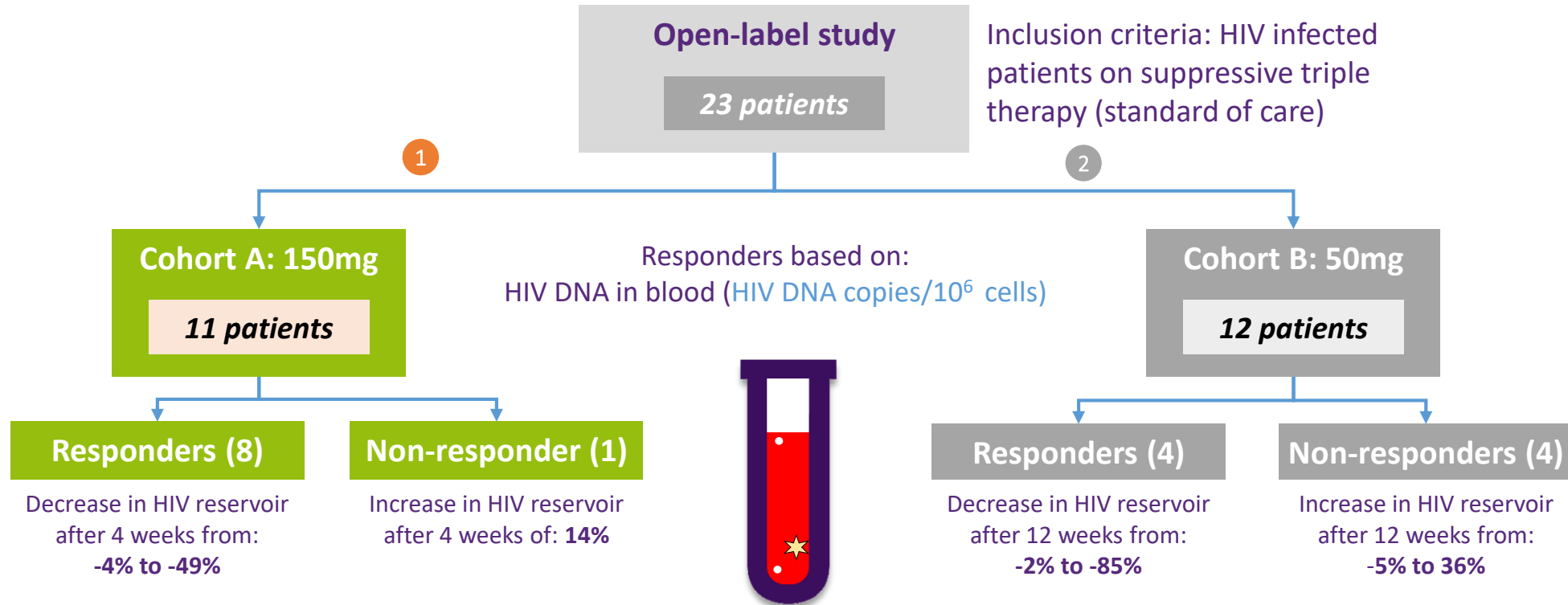
ABX464-005 Study design: assessing different dosing regimens



ABX464-005 :Treatment-emergent Adverse Drug Reactions*

	GRADE 1		GRADE 2	
	150mg (n=11)	50mg (n=13)	150mg (n=11)	50mg (n=13)
Any Treatment Emergent AE (Related) Number of patients (%) experiencing at least one TEAE	7 (63.6)	5 (38.5)	2 (18.2)	1 (7.7)
<i>Gastrointestinal Disorders</i>				
Abdominal pain	2 (18.2)	1 (7.7)		1 (7.7)
Epigastric pain	1 (9.1)	2 (15.4)		
Flatulence		1 (7.7)		
Nausea	4 (36.4)			
Diarrhea	1 (9.1)	2 (15.4)		
<i>Nervous system disorders</i>				
Headache / Migraine	7 (63.6)	4 (30.7)	1 (9.1)	
<i>Musculoskeletal and connective tissue disorders</i>				
Myalgia/ Lumbar Pain	6 (54.6)	1 (7.7)		
Cramps	1 (9.1)	1 (7.7)		
Chest Pain	1 (9.1)			
<i>Metabolism and nutrition disorders</i>				
Hyperamylasemia			1 (9.1)	
Hyperlipasaemia			1 (9.1)	
<i>Skin and subcutaneous tissue disorders</i>				
Folliculitis	1 (9.1)			
Rash erythematous	1 (9.1)			

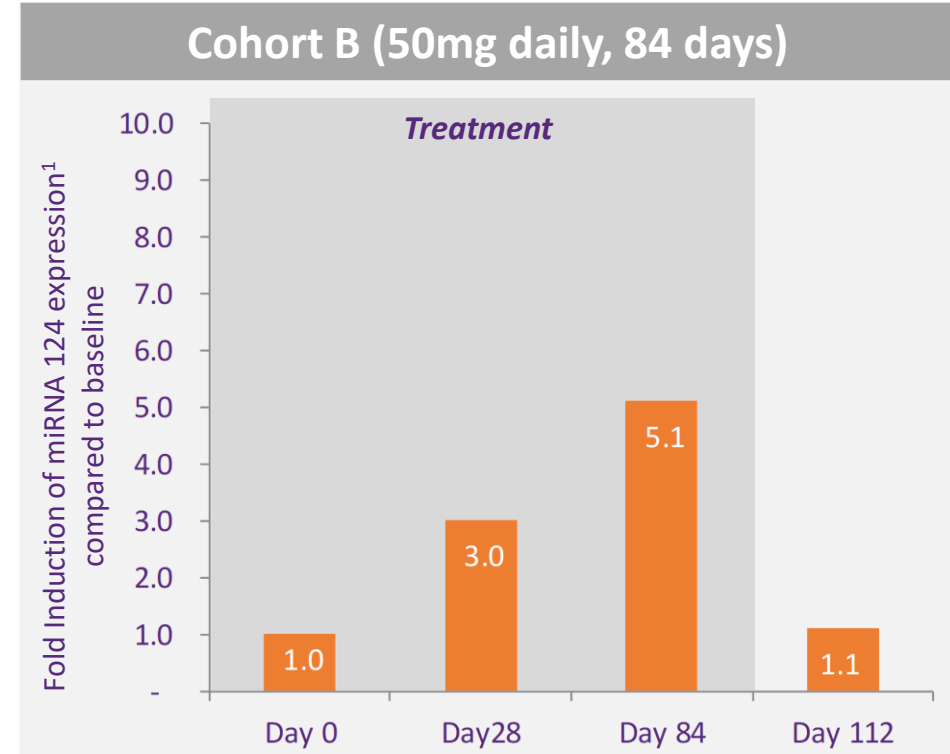
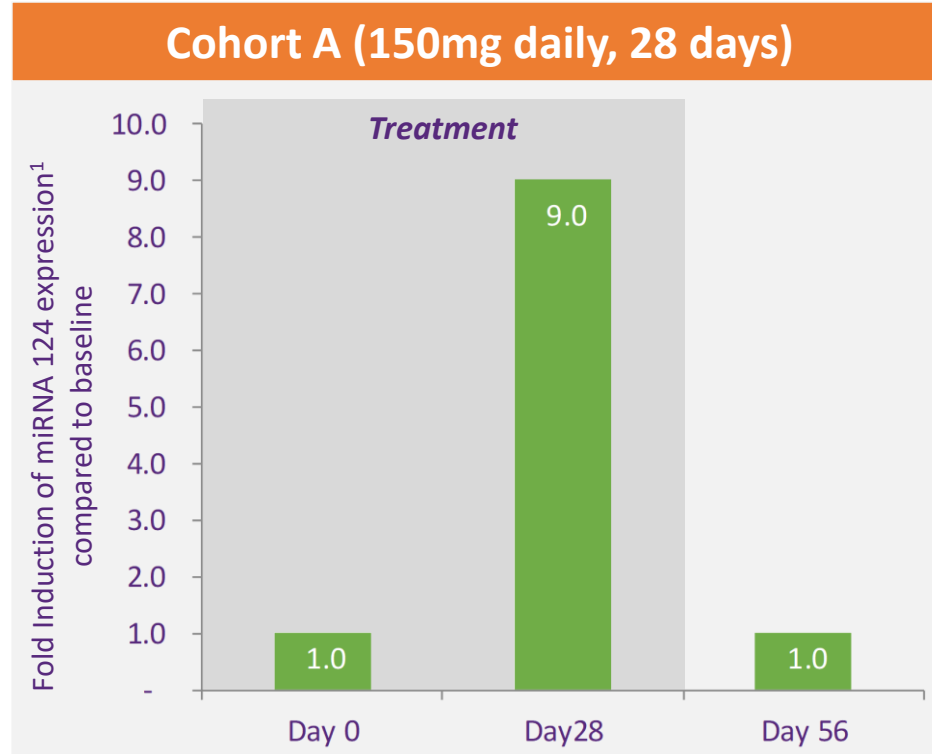
ABX464-005 Results: Summary



ABX464 is safe and reduces the viral reservoir

- HIV reservoir (HIV DNA) can be reduced in blood and tissue
- ABX464 activates the immune system in a dose-dependent manner
- Residual HIV viral replication activity (HIV RNA) can be reduced with 150mg ABX464

ABX464-005 both cohorts: dose dependent miR124 increase



Dose-dependent increase in miRNA 124 expression shows anti-inflammatory activity

Next steps: phase IIb study in Europe

1

Stratify HIV patient population

- Stratify HIV patients on baseline HIV viral reservoir (high vs low)
- Create two subgroups: a high and low baseline HIV viral reservoir arm (baseline < 200 DNA copies / million CD4⁺ cells)

2

Prove efficacy of ABX464

- Demonstrate ABX464 efficacy by comparing ABX464 + Standard of Care (Triple therapy) with Standard of Care alone (Placebo) in both subgroups
- Randomize patients in each HIV viral reservoir (high vs low) subgroup

3.

Maximize ABX464 treatment effect

- Treat patients once daily with 150mg ABX464 until maximum HIV DNA reduction is achieved with a minimum treatment duration of 112 days
- Measure patients once monthly to determine whether maximum reduction is achieved

Abivax has three key core pillars of value

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1: As demonstrated in phase IIa clinical studies after 28 days of ABX464 treatment

ABX196 shows anti-cancer effects in mouse models

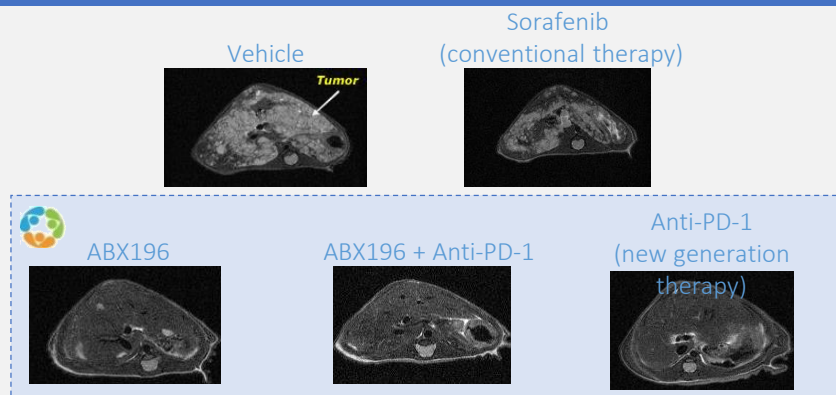
Liver cancer is a devastating disease with rapid mortality

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

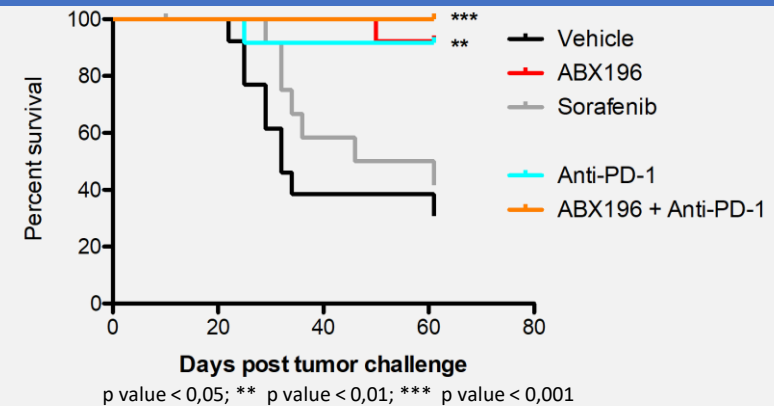
ABX196 shows to be a potent immune response activator

- 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

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 Q1, 2019

High unmet medical need in HCC:

Response Rates with Nivolumab (Checkmate 040 Study)

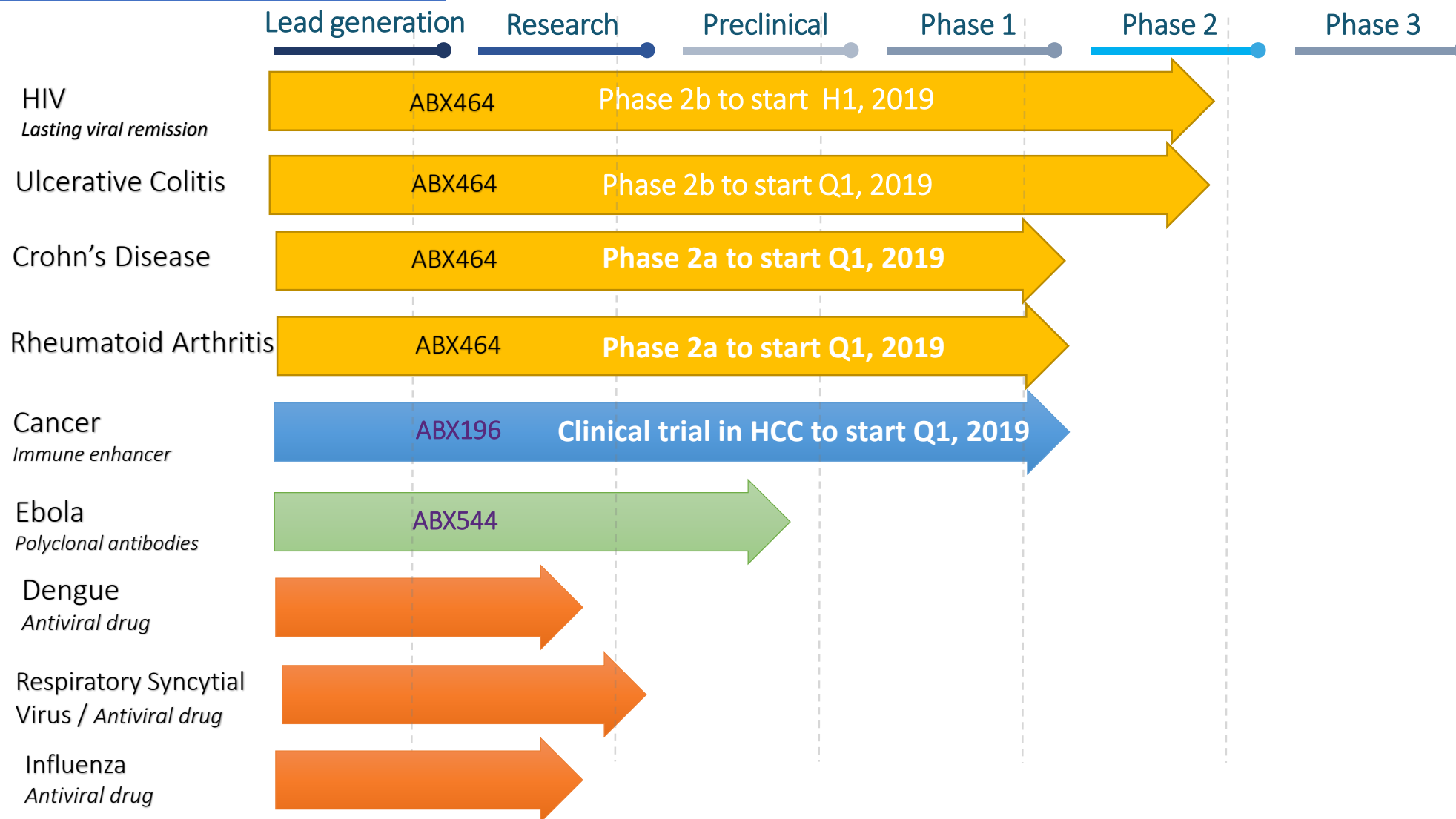
	Uninfected Untreated/ Intolerant (N=56)	Uninfected Sorafenib Progressors (N=57)	HCV (N=50)	HBV (N=51)	All (N=214)
ORR	21%	20%	20%	14%	20%
Med DOR	8.4 mo	NR	9.9 mo	NR	9.9 mo

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

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

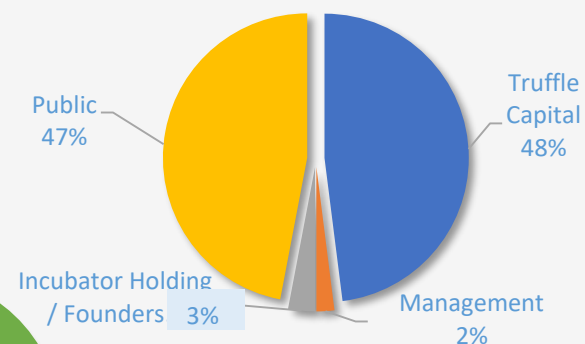


Primary listing: Euronext (Paris)

ABVX : FR0012333284

Liquidity: 30K shares/day in 2018¹

Shareholder structure² (undiluted)



Location



Operations



24
Employees²



18
in R&D



6
in Support



EUR 17.6m
Cash²



1: Boursorama

2: Actual as of June 30, 2018 plus Kreos Capital tranche 1 of € 10m paid in July 2018

Highly experienced Executive Committee



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

Ex-Head of Global R&D, Baxter BioScience
Baxter  **SANDOZ** 



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