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

Abivax, a late-stage clinical biotech company

July, 2020

abivax

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Key company facts

Milestones

Founded in 2013 by Truffle Capital

Sept. 2018: Focus ABX464 on chronic inflammation

Abivax went public in June 2015, raising € 57.7m

May 2020: ABX464 to treat acute viral and inflammatory diseases

Location

Head Office
Paris

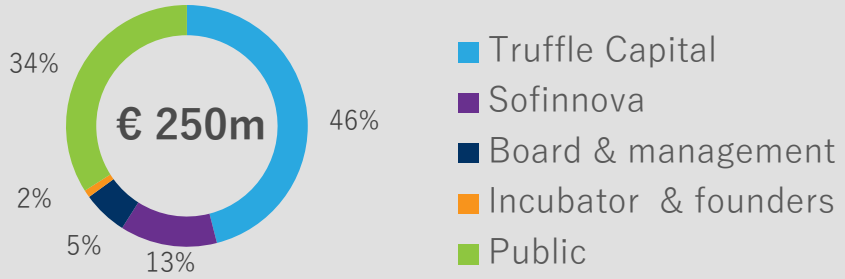
Cooperative Lab with CNRS
Montpellier

abivax

BREAKING NEWS

Abivax treats first patient in Phase 2b/3 ABX464 COVID-19 clinical trial

Shareholder structure[1] and market cap[2]



Operations

26 Employees

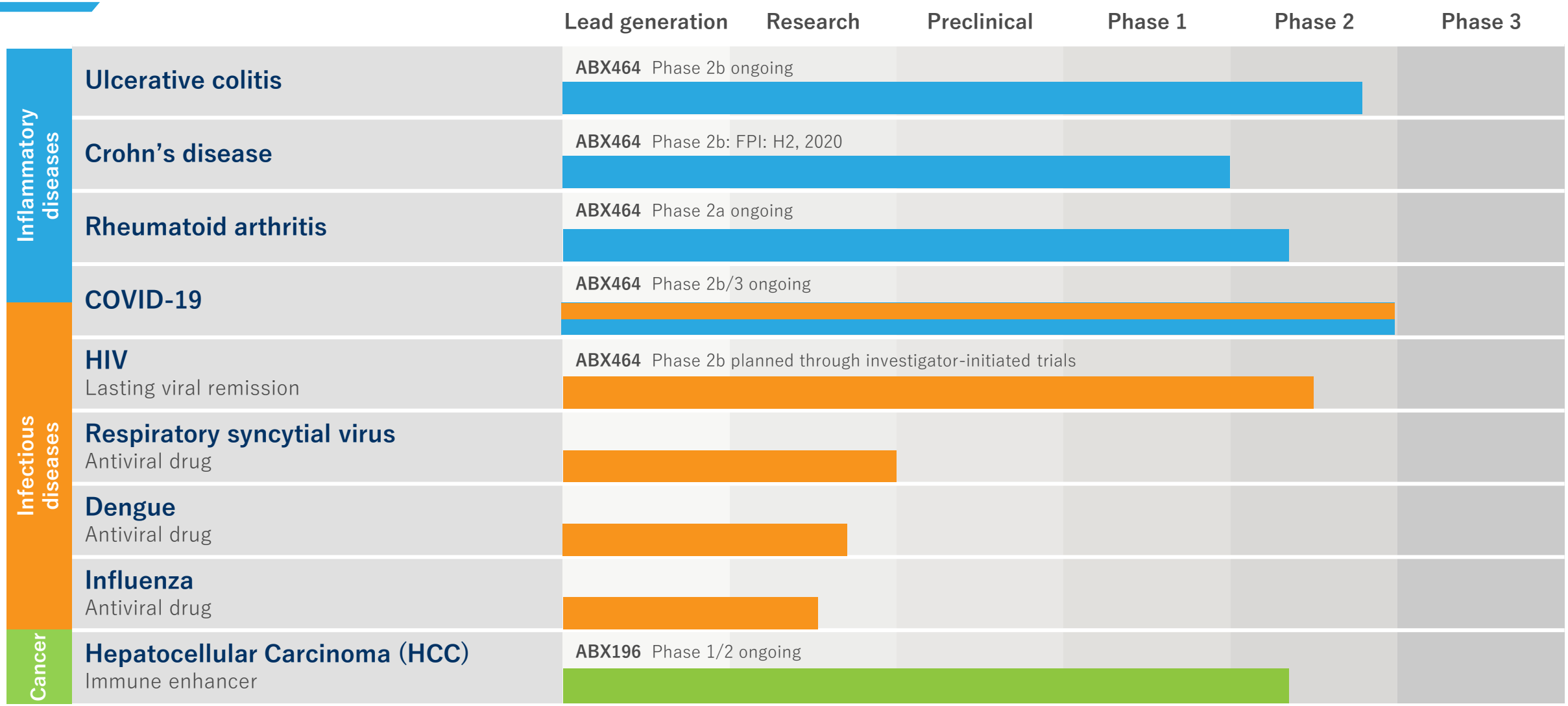
Cash[3] **€ 9.8m**

20 in R&D

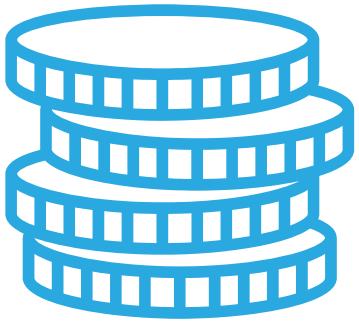
6 in Support

1) Undiluted – as of 31.03.2020
2) As of 22.05.2020 EOB
3) Actual December 2019

Abivax: A strong and diversified pipeline

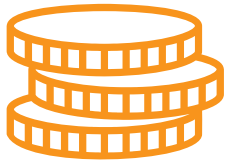


ABX464: A promising candidate addressing attractive markets



Total market size* in inflammatory diseases

greater than **USD 90 B**



Market size* in first indication (ulcerative colitis)

around **USD 5.8 B**

- Coming from the **proprietary** Abivax library of compounds, biased to **modulate RNA biogenesis** (>2200 molecules); Close collaboration with EVOTEC
- **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 >**300 patients and volunteers**
- **Anti-inflammatory effect** confirmed in DSS mouse model of IBD as well as in Phase 2a induction and maintenance studies in ulcerative colitis. Phase 2b study in UC ongoing in 232 Patients, as well as Phase 2a in rheumatoid arthritis in 60 patients
- **High medical need** for novel safe and efficacious drugs in inflammatory diseases

* For Europe G5, U.S. and Japan

ABX464-101/102 study design: Phase 2a in ulcerative colitis

- **Randomized, double-blind, placebo controlled, multi-national study followed by an open-label maintenance study**

Randomisation 2:1 (n=32)

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

- ABX464 – Single dose 50mg q.d. (n=23)
- Matching placebo (n=9)

Open label extension (ABX464-102)
First year completed, second year completing by end of January 2020 and going into third year

- ABX464 – Single dose 50mg q.d. (n=22)

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 (Induction)

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**
miR-124 expression in rectal biopsies (fold increase)	7.69	1.46	0.004

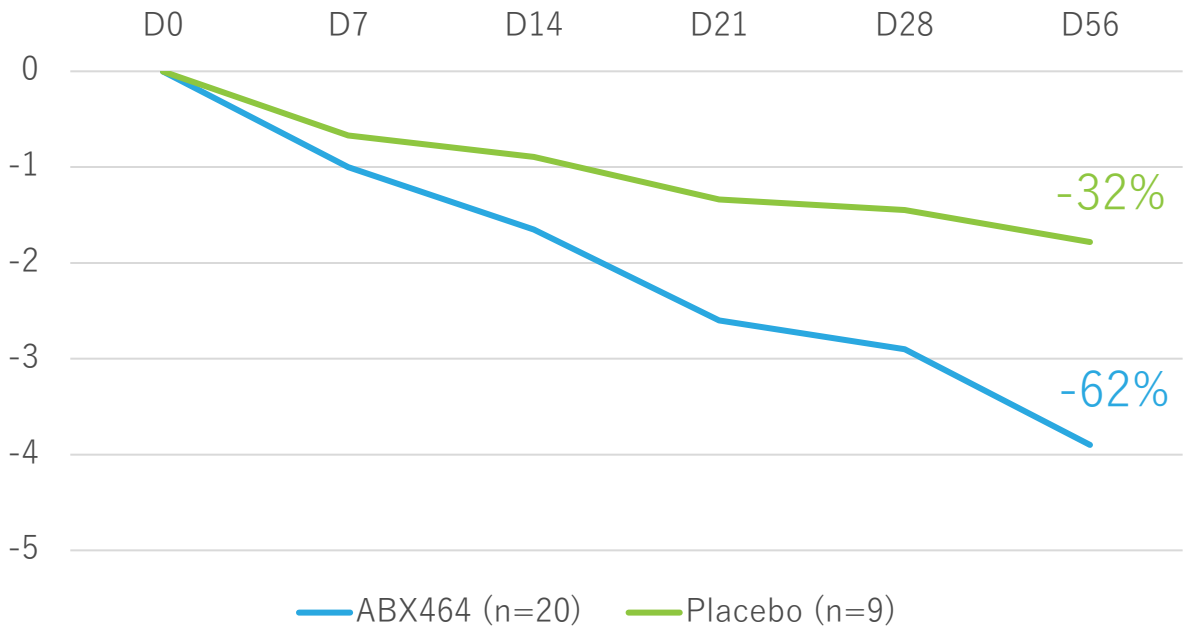
*Clinical remission according to previous FDA definition. With application of most recent FDA definition (excluding physician assessment), clinical remission rate was 40% in ABX464 group and remained at 11% with placebo

ABX464-101 Partial Mayo Score Results

Fast onset of action and clear responses in patients previously treated with biologics

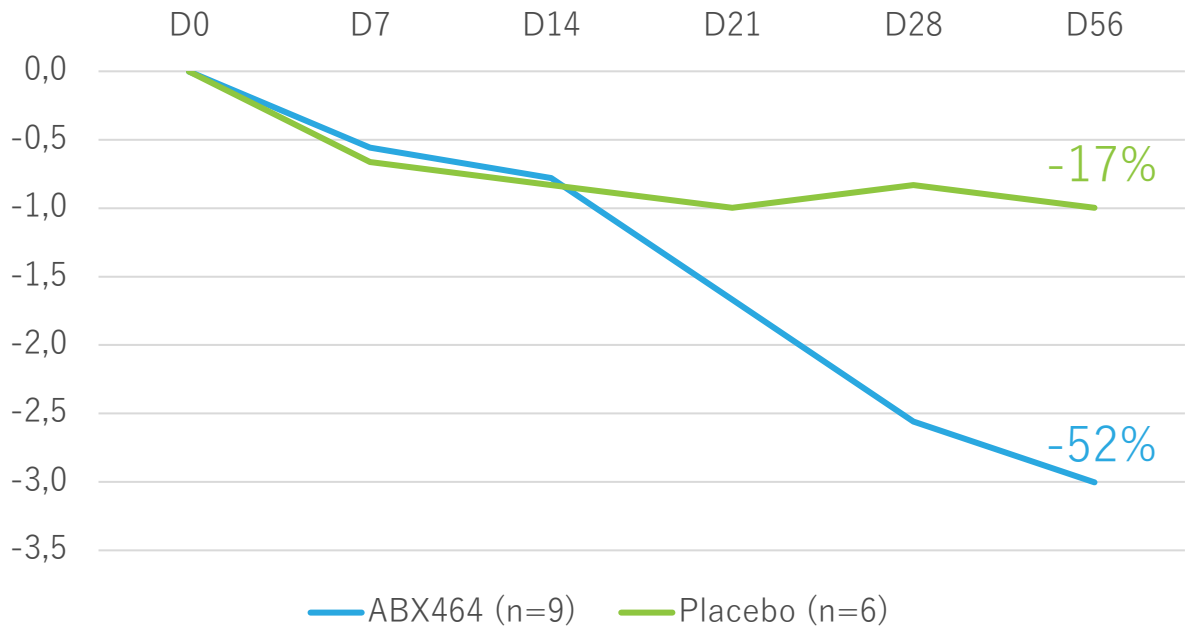
Overall Patient Population

Change from Baseline Partial Mayo Score



Patients previously treated with biologics

Change from Baseline Partial Mayo Score



ABX464-102:
Efficacy further amplified by 12-months maintenance study

29/32	4/6	22/23
Patients completed the induction study	Countries granted regulatory approval for maintenance study	Eligible patients enrolled in the maintenance study, 19 completed first year

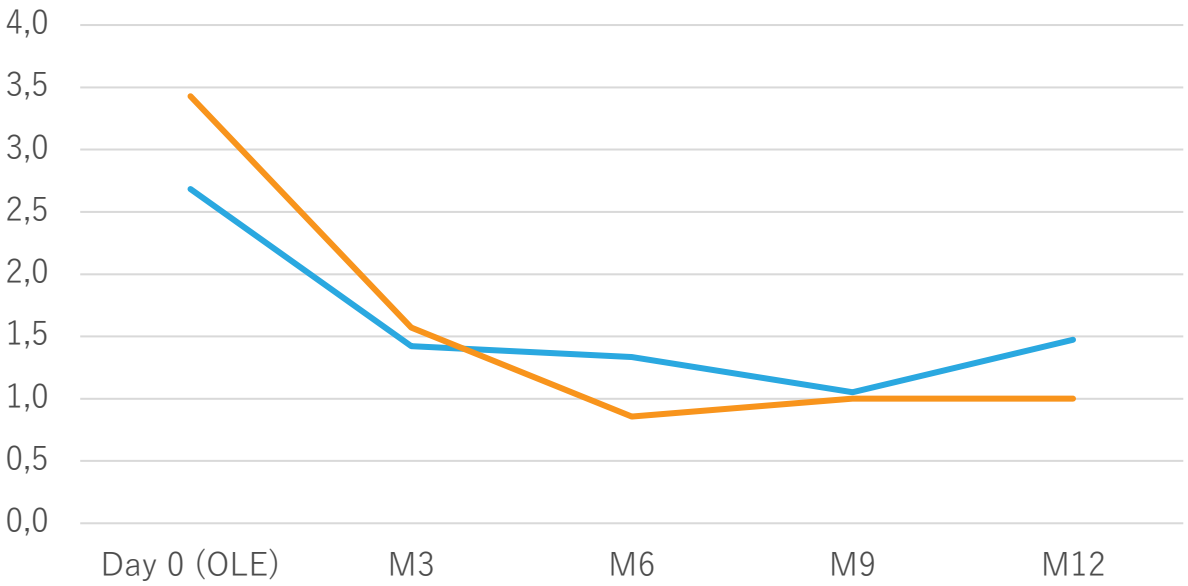
Fast onset and **durable efficacy** with **impressive 12 months data.**

	Day 0 Maintenance	Month 12
Clinical remission (TMS) (no loss of clinical remission)	6/19 (31.6%)	12/16 (75.0%)*
Clinical Response	14/19 (73.7%)	15/16 (93.7%)
Endoscopic Improvement** (sub-score 0 or 1)	11/19 (57.9%)	16/16 (100.0%)
Endoscopic remission*** (sub-score 0)	2/19 (10.5%)	13/16 (81.2%)

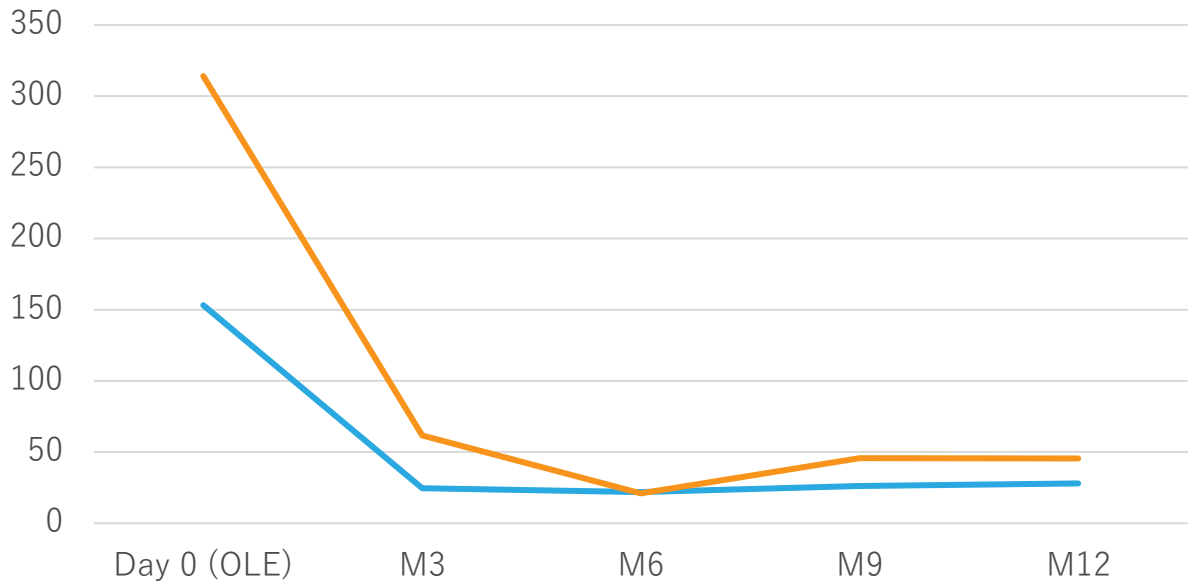
As of June, 2020: Mean cumulative exposure to ABX464 in maintenance study is over two years with ABX464-102 UC maintenance patients N=16 (mean: 25.6 months; min.: 23.3 months; max: 30.5 months)

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

Partial Mayo Score – Mean



Fecal calprotectin µg/g – Median



All patients (N=19) Patients previously treated with biologics (N=7)

→ **Partial Mayo Score continued to decrease**

→ **Fecal calprotectin levels went down to normal values (< 50 µg/g)**

ABX464, Vedolizumab, Tofacitinib and Filgotinib efficacy in induction and maintenance clinical trials

	Vedoluzimab Phase 3			Tofacitinib Phase 3			Filgotinib* Phase 3			ABX464 Phase 2a		
INDUCTION	Active	Placebo	Delta	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	11,5-26,1**	4,2-15,3	7,3-10,8	35	11	24
Mucosal Healing (%)	40,9	24,8	16,1	28,4-31,3	11,6-15,6	16,8-15,7	n/a	n/a	n/a	50	11	39
MAINTENANCE												
Clinical Remission (%)	41,8	15,9	25,9	34,3-40,6	11,1	23,2-29,5	37,2	11,2	26	75		
Mucosal Healing (%)	51,6	19,8	31,8	37,4-45,7	13,1	24,3-32,6	n/a	n/a	n/a	100		

* For patients treated with 200mg

** Biologic experienced vs. biologic naïve patients

Phase 2a study ABX464-102 maintenance study allowed all patients irrespective of treatment assignment or clinical response during induction to be included in open label ABX464 50mg open label

ABX464 showed a good safety profile during clinical development of the 50 mg dosage form

Safety profile consistent with previous and ongoing clinical studies

(>300 healthy volunteers and patients exposed to ABX464)

- **Overall: Generally well tolerated** with no deaths, no malignancies, no severe infections, no significant changes in the laboratory parameters including blood cell counts
- **No Serious Adverse Reactions,** most AEs were of mild to moderate intensity
- **Most frequently reported AEs:** Headache and epigastric pain; occurring mainly during the first days of treatment
- N=16 patients from UC ABX464-102 maintenance study are on **continuous daily treatment with ABX464 with a mean of 26 months**

Conclusions

ABX464 oral 50mg QD drug candidate for moderate to severe UC patients

Good safety and tolerability of chronic treatment with ABX464 50mg QD in patients with UC

Conclusion is supported by safety analysis in more than 300 healthy volunteers and patients (no serious adverse reactions, no severe infections, no lymphopenia, no neutropenia)

Most frequently reported adverse events were transient and mild headache, nausea, gastro-intestinal pain

Confirmed efficacy in Phase 2a UC induction study

- All endpoints favorable to ABX464, with statistical significance in endoscopic improvement, TMS and PMS reductions, and clear trends for clinical remission and clinical response
- Fast onset of action
- Active in both biologics naive and biologics refractory patients

Efficacy signal further amplified during 12-months maintenance study

- Continued very good safety profile
- Durability of clinical efficacy with further improvement and increased clinical remission with longer treatment
- Normalized fecal calprotectin levels
- Significant endoscopic improvement
- Continued over expression of miR-124

ABX464 ongoing and planned studies

Phase 2b in ulcerative colitis:

- Conducted with IQVIA as CRO
- 232 patients, 17 countries, 150+ study sites
- 4 study arms (placebo, 25, 50, 100 mg QD)
- Central blinded reading of endoscopies
- Top-line data for induction phase expected for Q2 2021

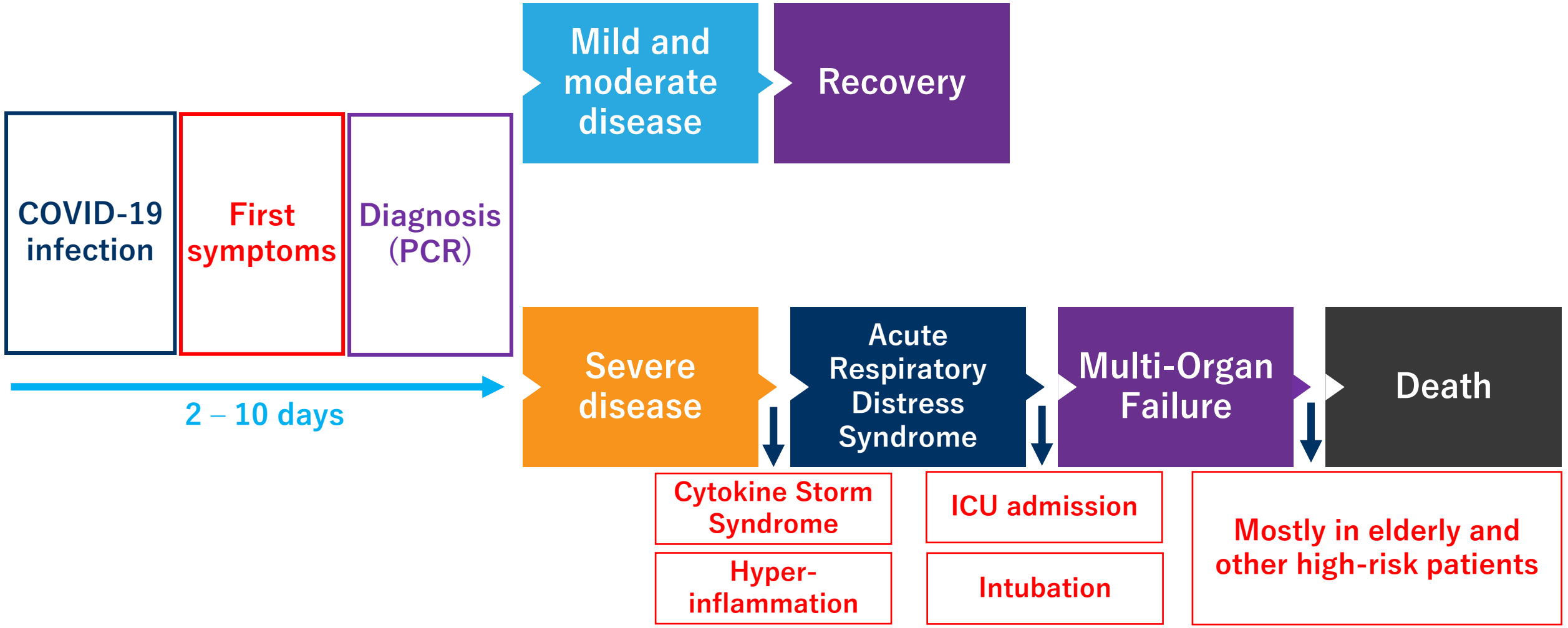
Phase 2b study in 232 patients with moderate to severe ulcerative colitis is currently ongoing in Canada and Europe and the US (with FDA clearance of IND on 19/01/20)

Phase 2a study ongoing in 60 patients with rheumatoid arthritis in 5 European countries

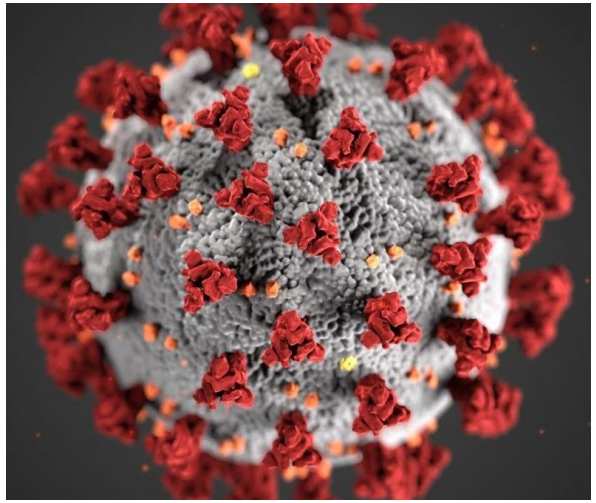
Phase 2b study planned in app. 200 patients with Crohn's disease – FPI planned for end of 2020

Phase 2b/3 study in COVID-19 ongoing – FPI 01/07/2020, 2020, 1.034 patients in total

COVID-19 infection and pathology

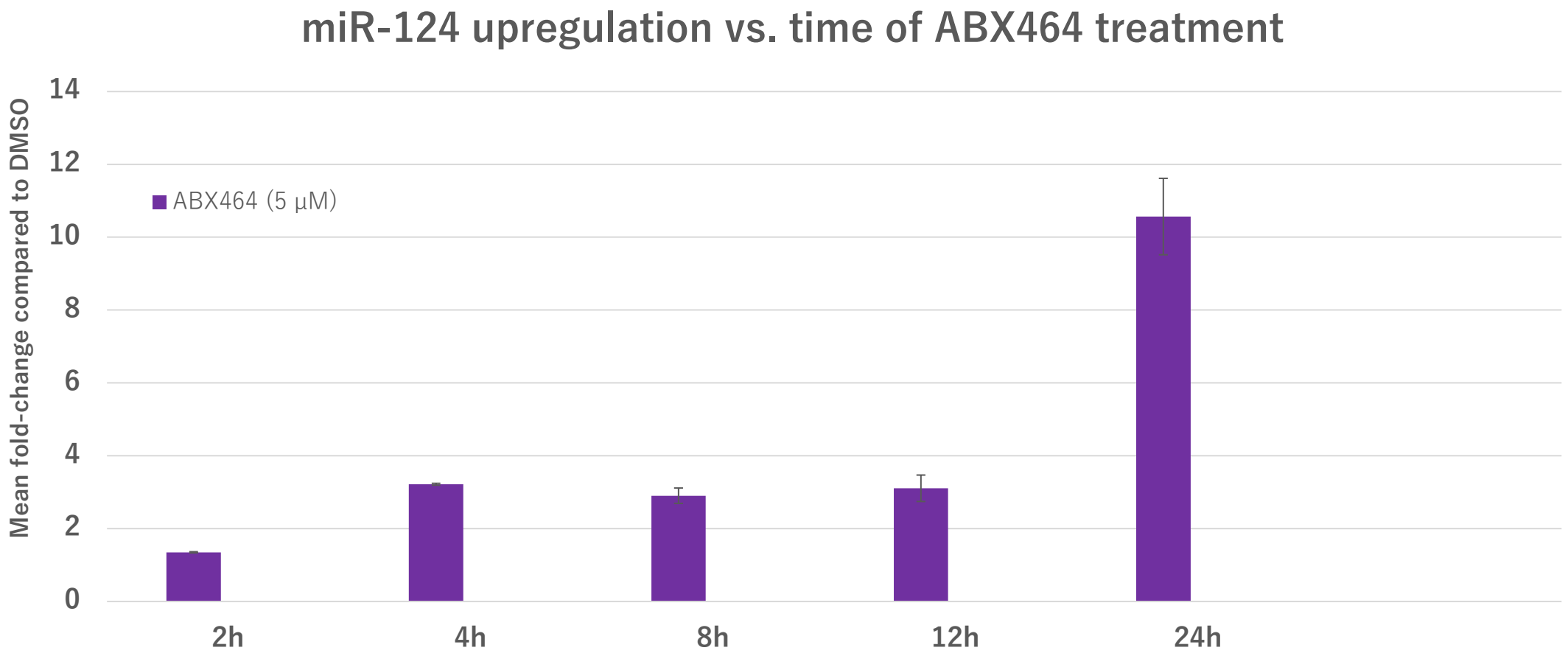


ABX464 COVID-19 Development Rationale



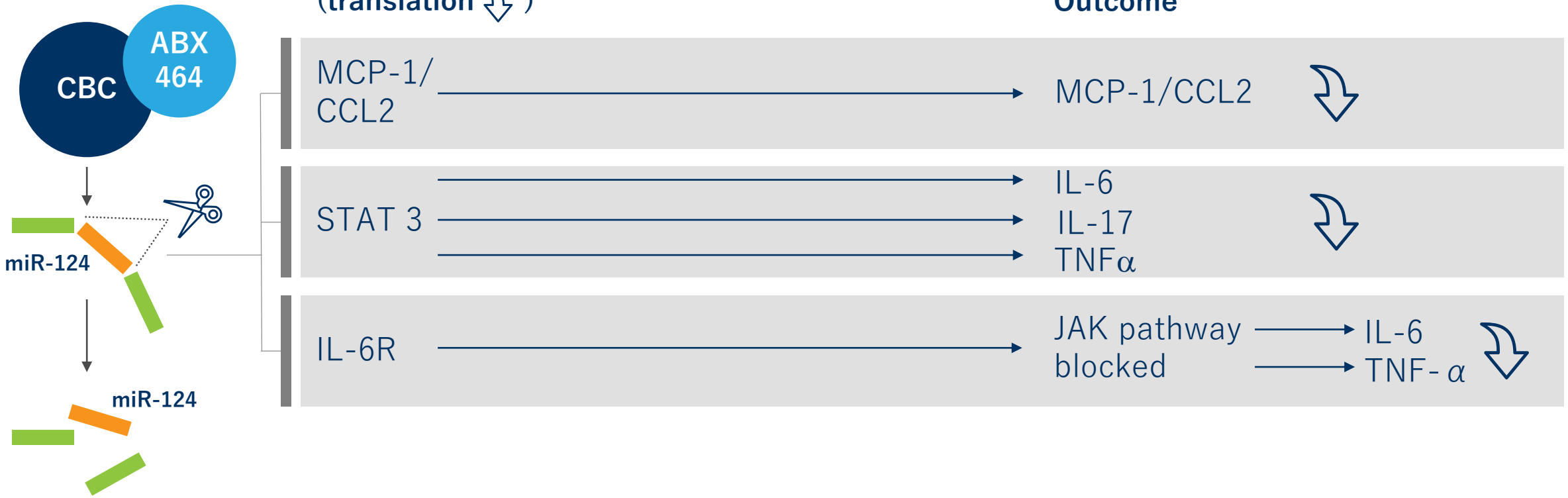
- **Antiviral:** ABX464 inhibits SARS-CoV-2 (COVID-19 virus) *in vitro* replication in human respiratory epithelium: Inhibition of COVID-19 viral replication comparable to Remdesivir
- **Anti-inflammatory:** ABX464 has demonstrated potent anti-inflammatory properties in several *in-vivo* models and in patients with moderate to severe ulcerative colitis
- **Tissue repair** observed in DSS model of inflammatory bowel disease (IBD) and in patients in Phase 2 ulcerative colitis trial
- **Good safety** profile of ABX464 demonstrated in >300 patients and volunteers
- **Manufacturing capacity in place** (drug substance, finished product and packaging) to supply the investigational drug for large clinical trials and rapidly scale for commercial production

ABX464 rapidly upregulates miR-124 (10-fold) within 24 hours in human PBMCs (*in vitro* results)



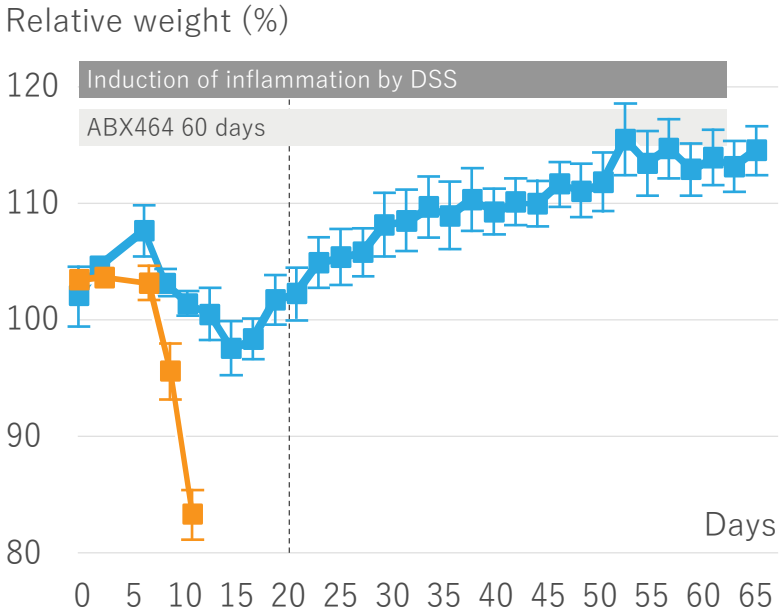
ABX464 novel mechanism of action: Potent and specific upregulation of miR-124 leads to reduction of pro-inflammatory cytokines

Both systemic and local inflammatory sites

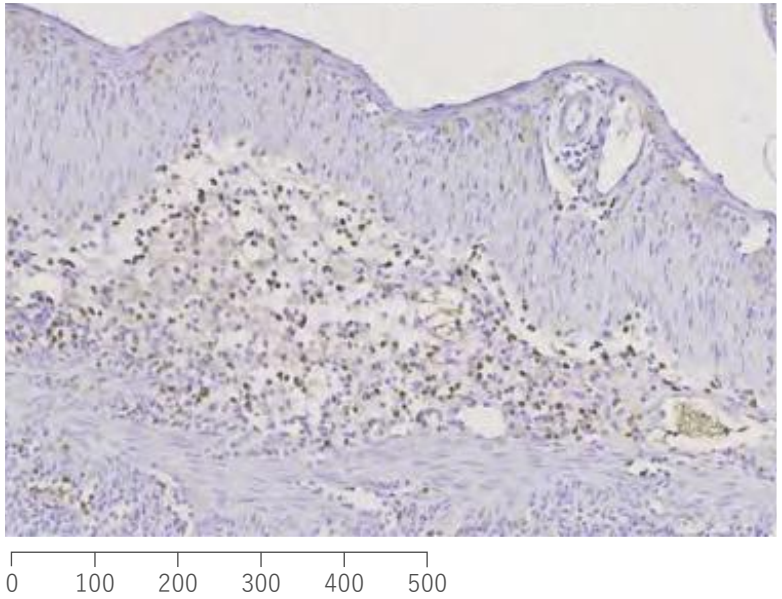


Anti-inflammatory effect:
ABX464 showed efficacy in the DSS mouse model*

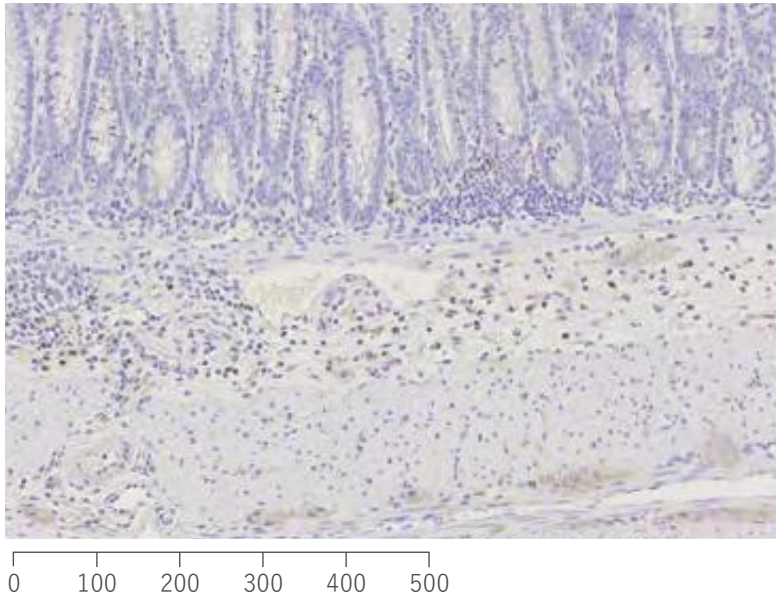
ABX464 protects mice from death in the DSS mouse model



DSS without ABX464 leads to intestinal damage



ABX464 protects intestinal structure



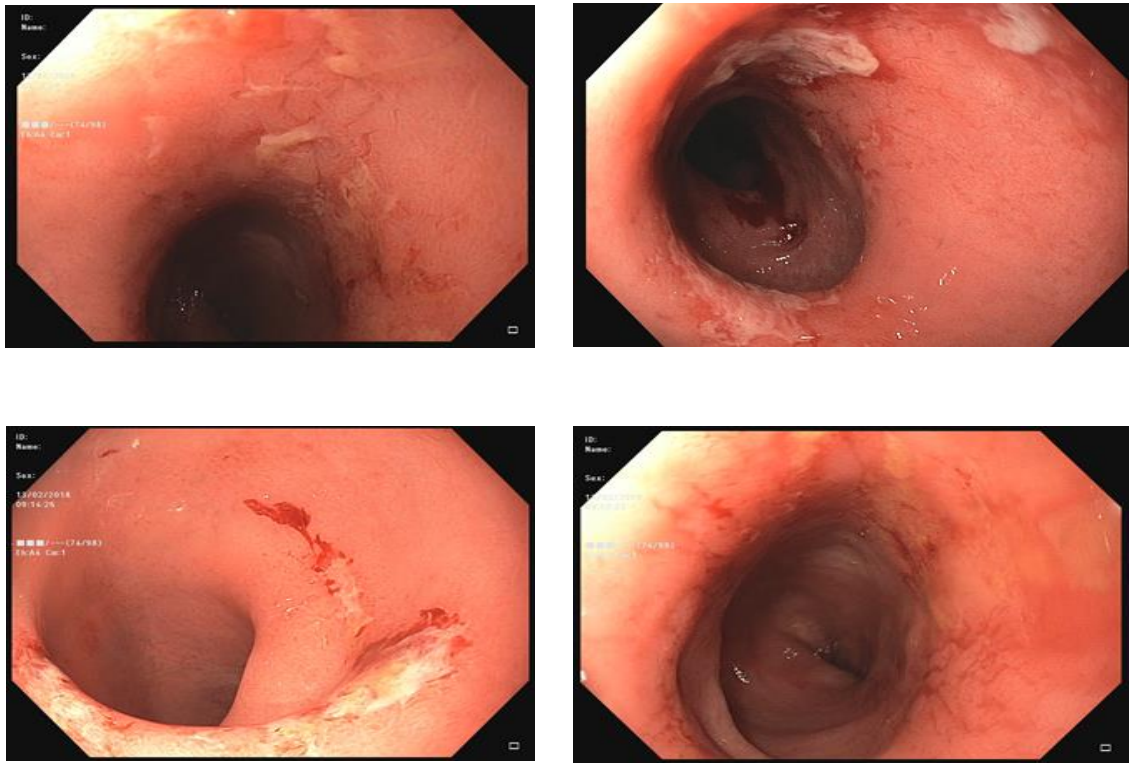
→ **ABX464 reduced the expression of pro-inflammatory cytokines in colon tissue:**
IL-6 (2x), TNF (7.5x) and MCP-1 (6x)

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

Tissue repair in an ABX464 treated UC patient

Courtesy of Prof. Severine Vermeire

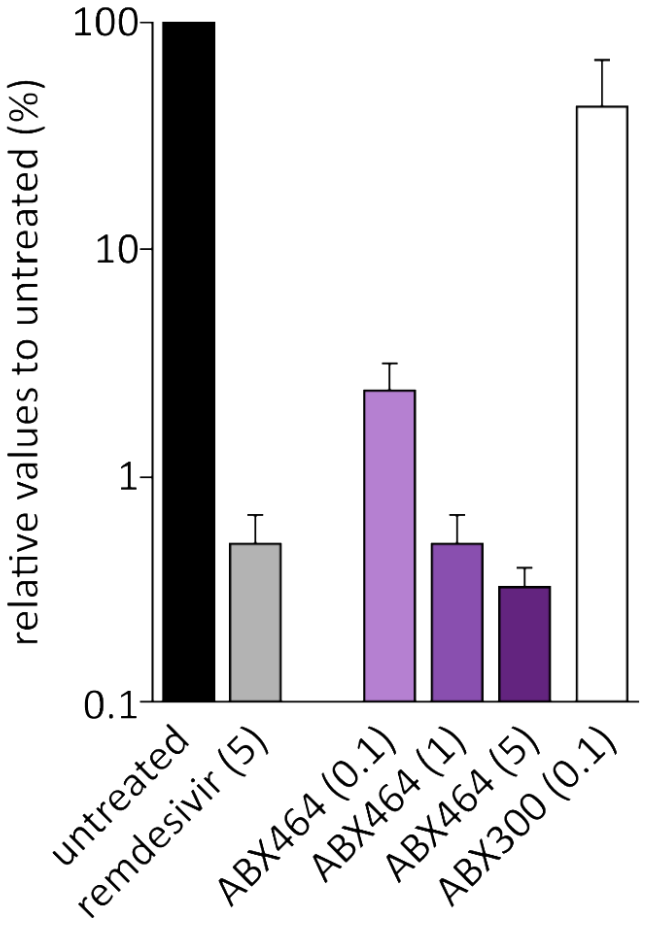
Before ABX464



After ABX464

Antiviral effect: Reduction of COVID-19 replication in an *in vitro* reconstituted human airway epithelial model

Infectious titrations TCID50 at 48 hours post infection



Comparable efficacy between Remdesivir and ABX464

ABX464 showed a good safety profile during clinical development of the 50 mg dosage form

Safety profile consistent with previous and ongoing clinical studies

(>300 healthy volunteers and patients exposed to ABX464)

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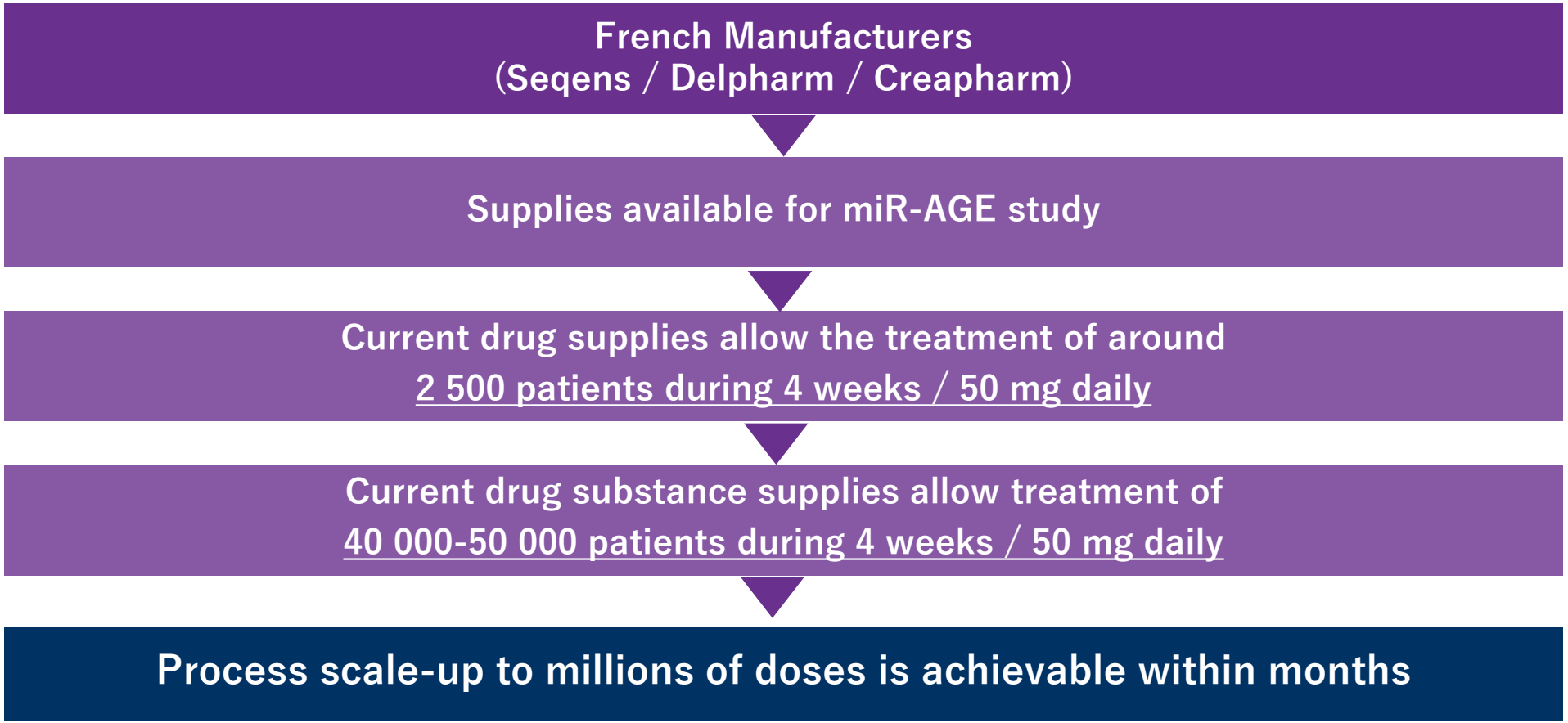
Phase 2b/3 clinical trial miR-AGE: High-risk patients, PRIOR to respiratory distress

- **Early treatment** of high-risk patients infected with COVID-19
- **Main objective**: A Phase 2b/3, randomized, double blind, placebo-controlled study of ABX464 to treat inflammation and prevent acute respiratory failure
- **Inclusion criteria:** COVID-19 patients aged ≥65 and aged ≥18 with at least one additional risk factor who are infected with SARS-CoV-2
- **Target population:** hospitalized and non-hospitalized patients
- **Main evaluation criterion:** Absence of high-flow oxygen (>3 l/min), assisted ventilation (positive pressure or intubation) and/or death after 28 days
- **Treatment duration:** 28 days
- **1,034 patients** will be included in **50 clinical study sites in Europe and South America**
  - Placebo + SOC group: 344 patients
  - ABX464 + SOC group: 690 patients (2 to 1 randomization)
  - Expected response rates: 75% on placebo, 83 % on ABX464 (alpha 0.05, beta 80%)
- **Parexel** selected as CRO; total study costs € 16m

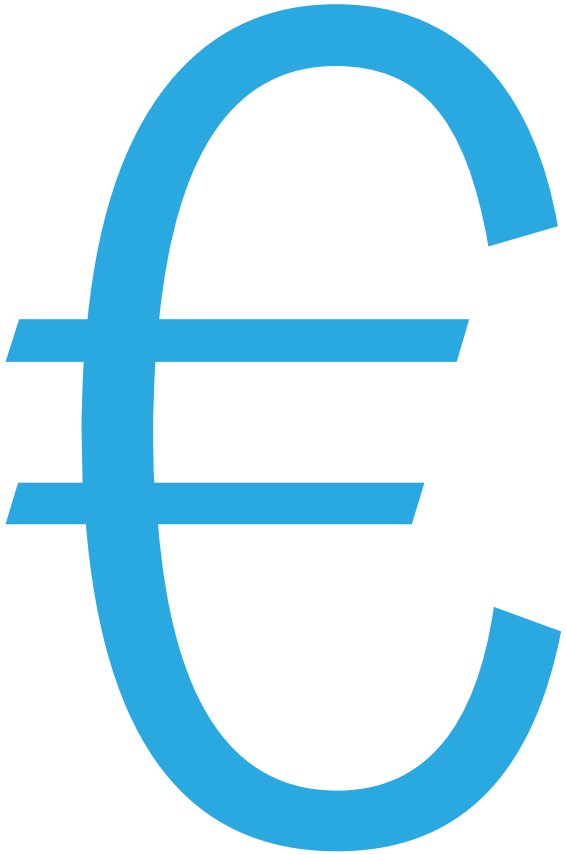
ABX464 supply available for COVID-19 clinical trials and scalable for commercialization



Abivax Communication Plan until mid-2021

	Q2 2020	Q3 2020	Q4 2020	Q1 2021	Q2 2021
UC Phase 2a (ABX464)			**2-years maintenance data**		
UC Phase 2b (ABX464)			**Enrollment completed**		**Top line results**
RA Phase 2a (ABX464)			**Enrollment completed**		**Top line results**
Crohn's Phase 2b (ABX464)			**FPI**		
COVID-19 Phase 2b/3 (ABX464)	**FPI**	**Enrollment completed**	**Top line results**		**MAA/NDA submission**
HCC Phase 1/2 (ABX196)			**Enrollment completed** (Dose escalation)	**Top line results Dose escalation phase**	

Abivax financial planning – Bpifrance € 36m funding first building block



- **The amount of € 36m will be paid within the next 12 months**
- **Total amount of € 36m is made of € 20,1m grant (non-refundable) and € 15,9m loan (refundable when ABX464 is reaching commercial stage)**
- **Total amount of € 36m is funding miR-AGE study as well as additional costs for ABX464 development and manufacturing scale up, required for potential ABX464 MAA (marketing authorization application) in COVID-19 by mid-2021**

Abivax Financing

07/2020 → 06/2021

ABX464 Manufacturing scale-up	ABX464 Preclinical	
ABX464 Regulatory clinical studies	Abivax New research	Abivax G&A

Funding Need
€ 80m

- ABX464 in UC: Phase 2a M & Phase 2b I+M*
- ABX464 in CD: Phase 2b I+M
- ABX464 in RA: Phase 2a I+M & Phase 2b I
- ABX464 in COVID-19: Phase 2b/3
- ABX196 in HCC: Phase 1/2

COMPLETED

- **Bpifrance funding € 36m**
- **Kepler Cheuvreux Equity line € 11m**
- **Société Générale PGE € 5m**

Cash runway until early 2021

€ 52m

€ 28m or more

TO BE COMPLETED by summer 2020

Core plan
- Non-dilut. Public funding
- Venture loan
- Capital raise

Cash runway > mid 2021

Upside plan
- Partnering
- ABX464 COVID-19 commercialization

Next funding milestone planned in Q2 2021: Abivax Partnering AND/OR Abivax Nasdaq listing

* I: Induction phase; M: Maintenance phase

Abivax Analyst Reports Overview

Analyst	Country	Last update	Target Price	Recommendation
Bryan, Garnier & Co	France	03/12/2019	€ 37.50	Buy
Degroof Petercam	Belgium	13/12/2019	€ 29.00	Buy
goetzpartners securities	UK/Germany	14/05/2020	€ 40.00	Buy
Kepler Cheuvreux	France	18/05/2020	€ 40.00	Buy
LifeSci Capital Alpha Series	US	14/05/2020	€ 41.00	Buy
Portzamparc	France	25/05/2020	€ 24.70	Buy
General recommendation: Buy		Average target price: € 35.50		

For full access to the reports, please directly contact the respective analysts listed on Abivax's website.

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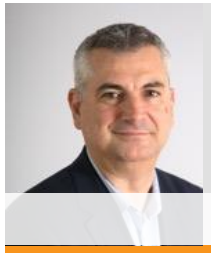

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→ Competencies from discovery to global commercialization