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

## Abivax, a late-stage clinical biotech company

**June, 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

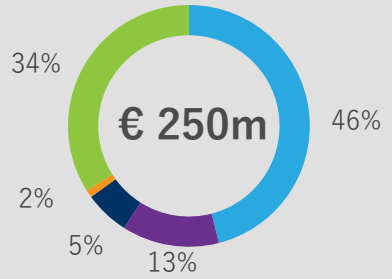
**Cooperative Lab with CNRS**
Montpellier

abivax

**BREAKING NEWS**

**€ 36m in non-dilutive funding from Bpifrance**

## Shareholder structure[1] and market cap[2]




## Operations

**26** Employees

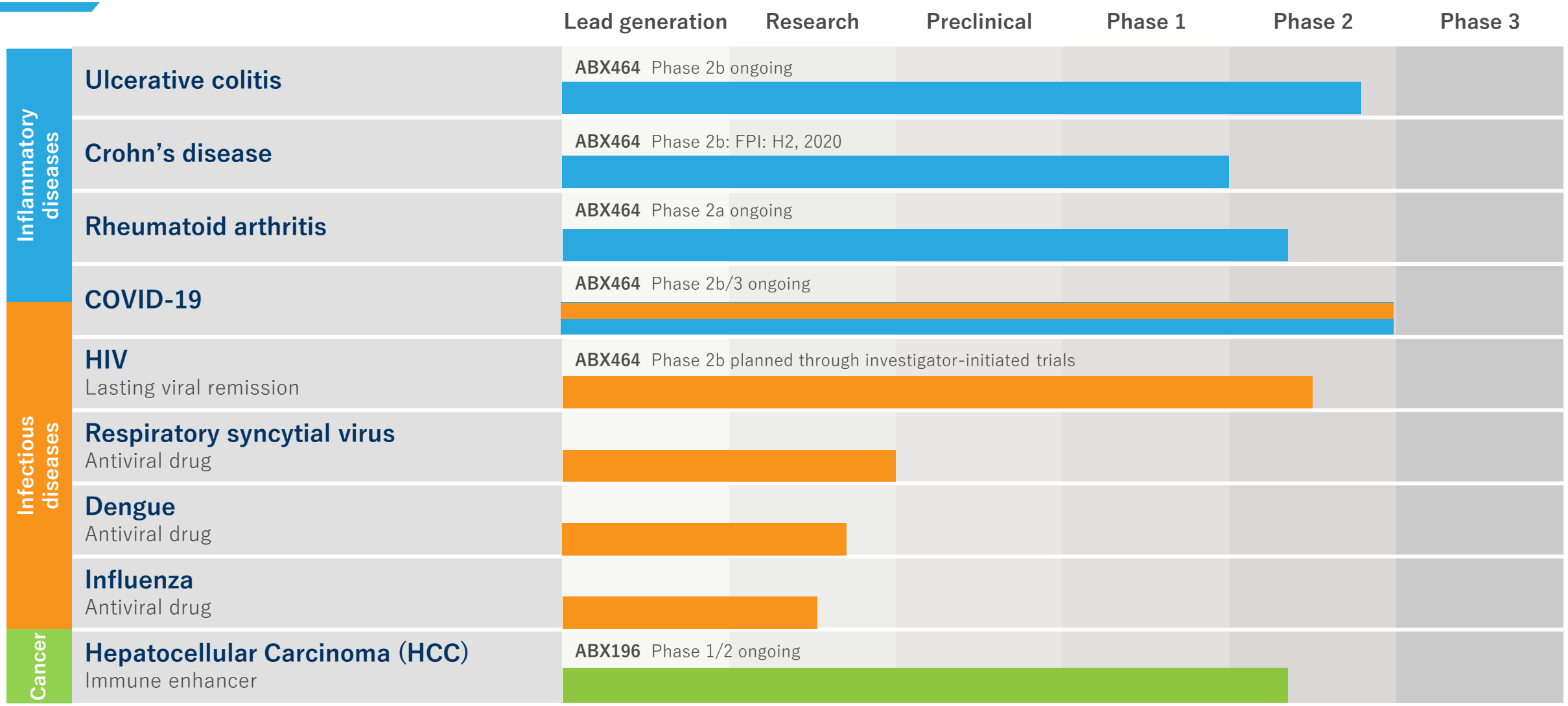
Cash[3] **€ 9.8m**

**20** in R&D

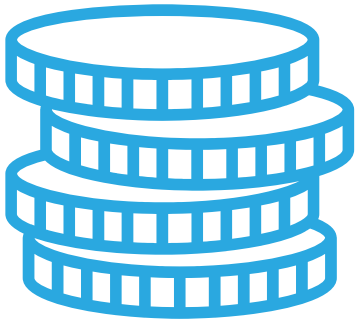
**6** in Support

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

# Abivax: A strong and diversified pipeline

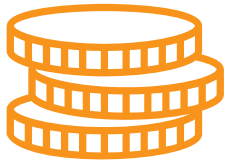


# ABX464: A promising candidate addressing attractive markets



**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 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 |

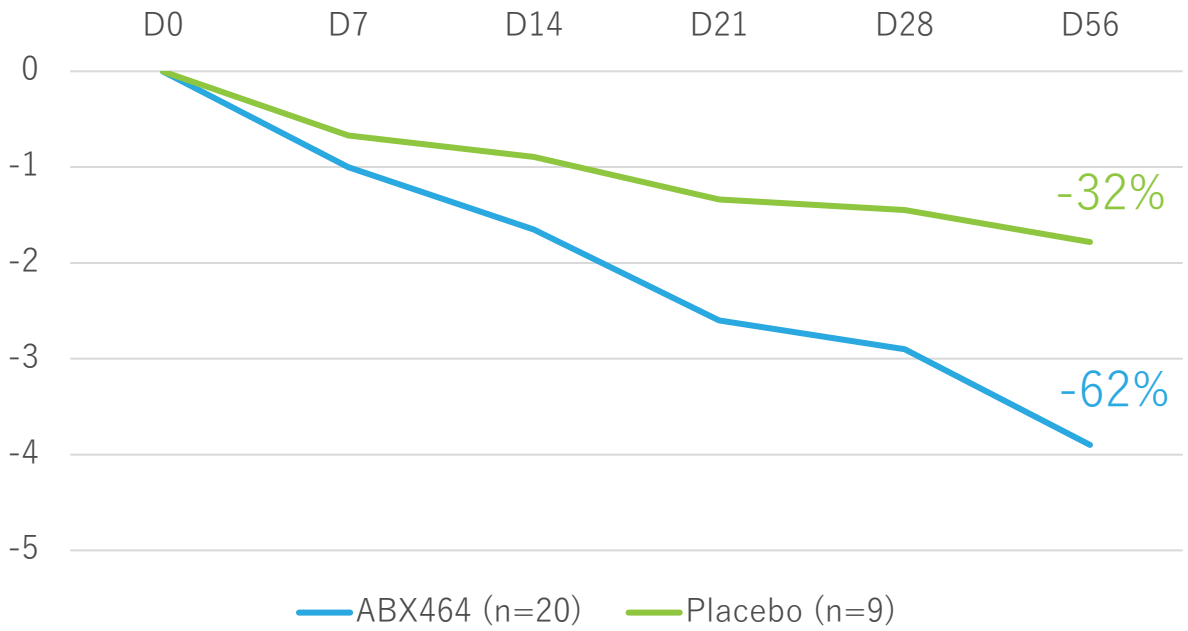
*Clinical remission according to previous FDA definition. With application of most recent FDA definition (excluding physician assessment), clinical remission rate was 40% in ABX464 group and remained at 11% with placebo

# ABX464-101 Partial Mayo Score Results

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

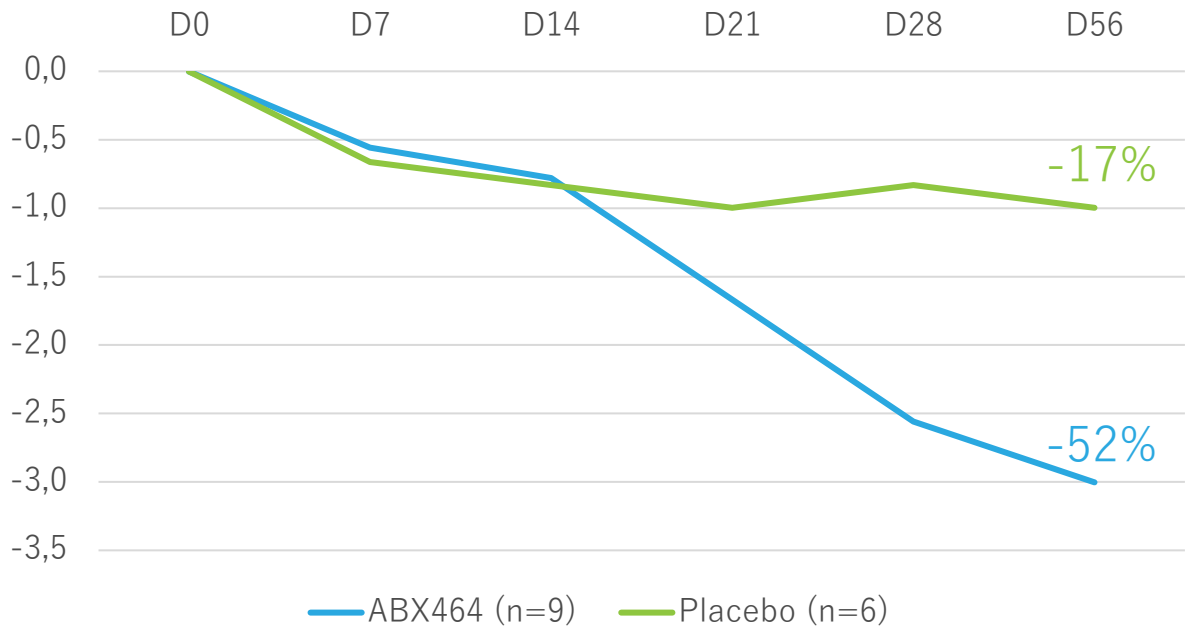
**Overall Patient Population**

Change from Baseline Partial Mayo Score




**Patients previously treated with biologics**

Change from Baseline Partial Mayo Score



# ABX464-102 Maintenance study, one-year interim analysis
# Patient disposition

ABX464 -101 Induction study

ABX464 Evaluable patients at Week 8
N = 20

Placebo Evaluable patients at Week 8
N = 9

Full regulatory clearance in 4/6 countries:
22/23 eligible patients enrolled into the maintenance study

ABX464-102 Maintenance study
All patients receive
ABX464 50mg QD Oral Caps

ABX464 50mg QD N=15

1 lack of efficacy at M1
1 loss to Follow-Up

ABX464 Evaluable
Patients at week 52
N=13

3 drop outs:

ABX464 50mg QD N=7

1 grade 2 headache at M4

ABX464 Evaluable
Patients at week 52
N=6

**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)**

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

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

| | Day 0 Maintenance | Month 12 |
|---|---|---|
| **Clinical remission (TMS)** | 6/19 (31.6%) | 12/16 (75.0%)* |
| **Clinical Response** | 14/19 (73.7%) | 15/16 (93.7%) |
| **Endoscopic Improvement**** | 11/19 (57.9%) | 16/16 (100.0%) |
| **Endoscopic remission***** | 2/19 (10.5%) | 13/16 (81.2%) |

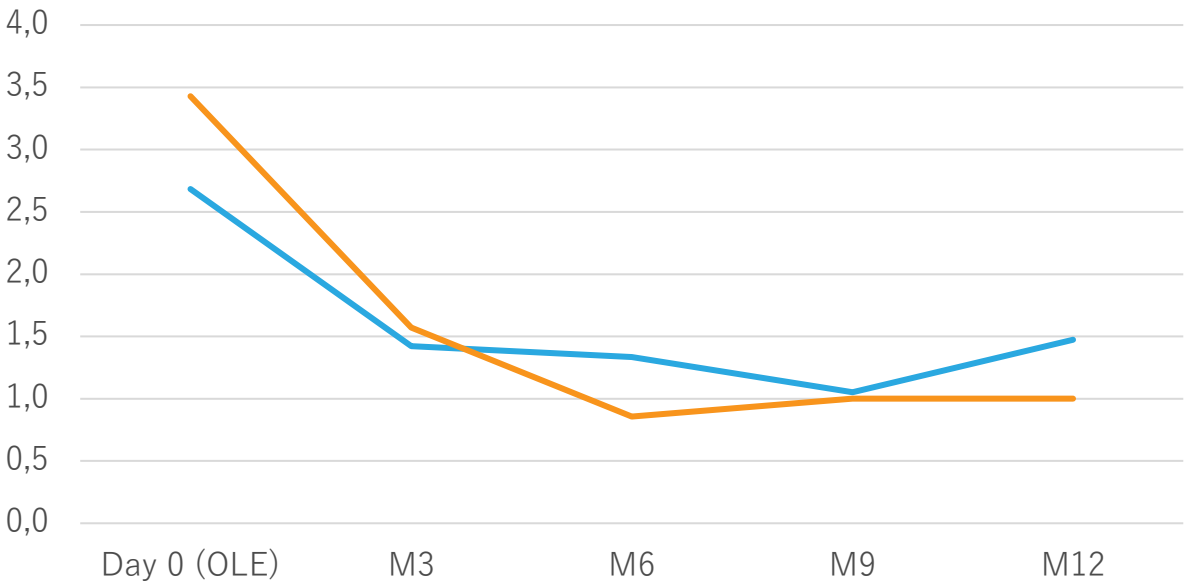
* No loss of clinical remission

** Endoscopy sub-score 0 or 1

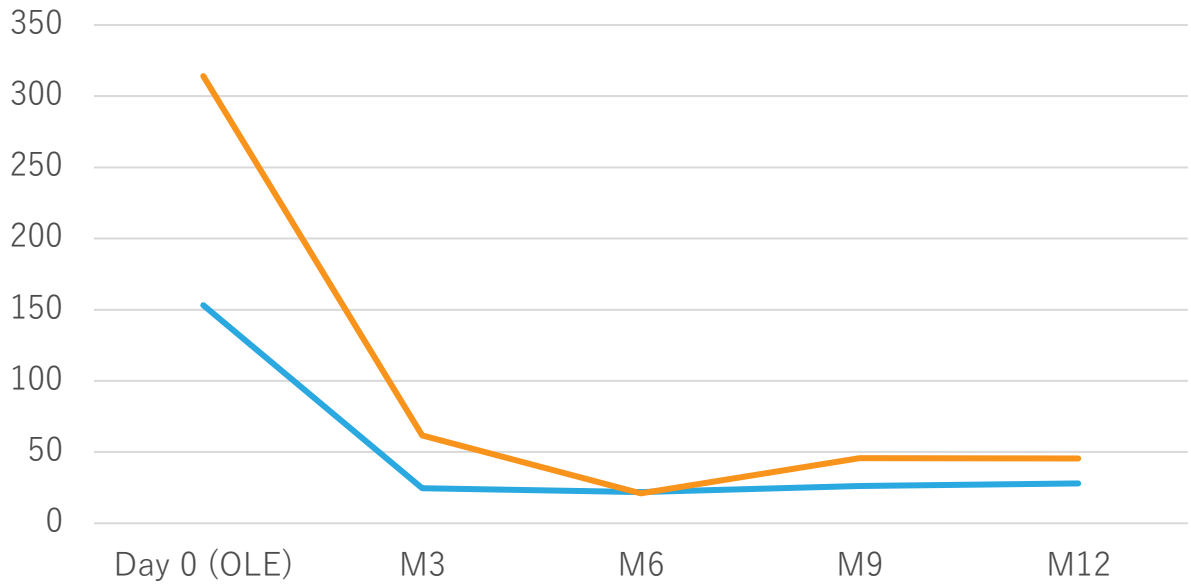
*** Endoscopy sub-score 0

# 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

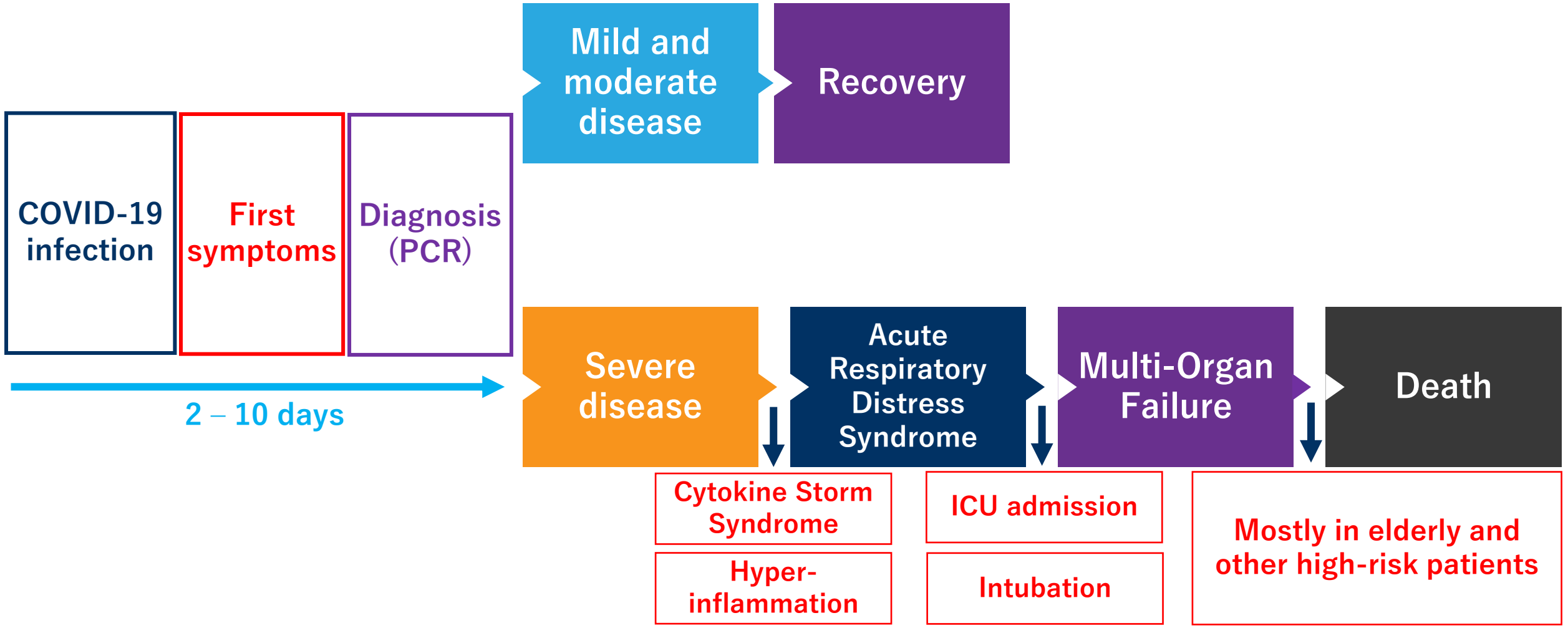
**Phase 2b study in 232 patients with moderate to severe ulcerative colitis is currently ongoing in Canada and Europe and the US (with FDA clearance of IND on 19/01/20)**

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

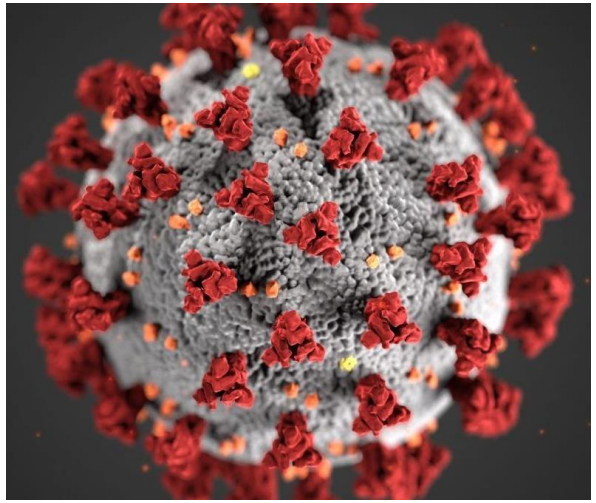
**Phase 2b study planned in app. 200 patients with Crohn's disease – FPI planned for end of 2020**

**Phase 2b/3 study in COVID-19 ongoing – FPI expected in June 2020, 1.034 patients in total**

# COVID-19 infection and pathology

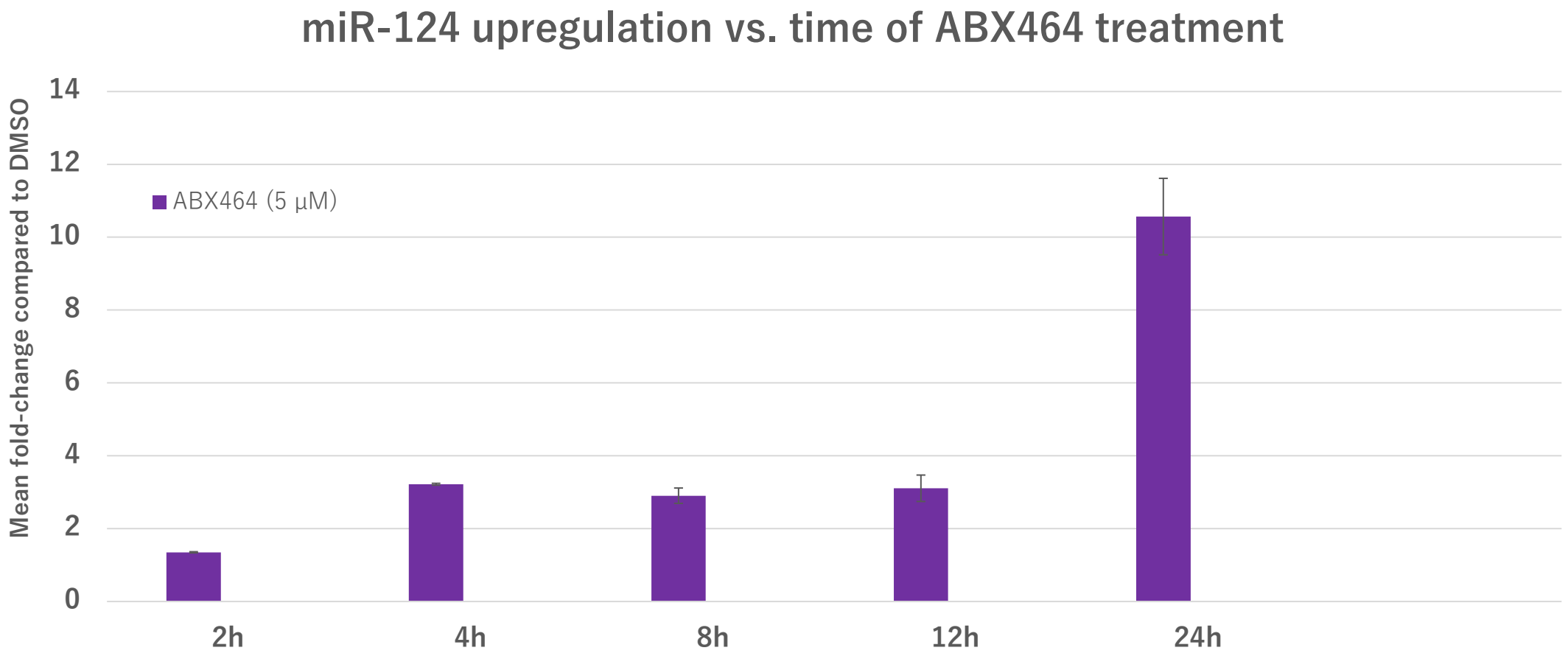


# ABX464 COVID-19 Development Rationale



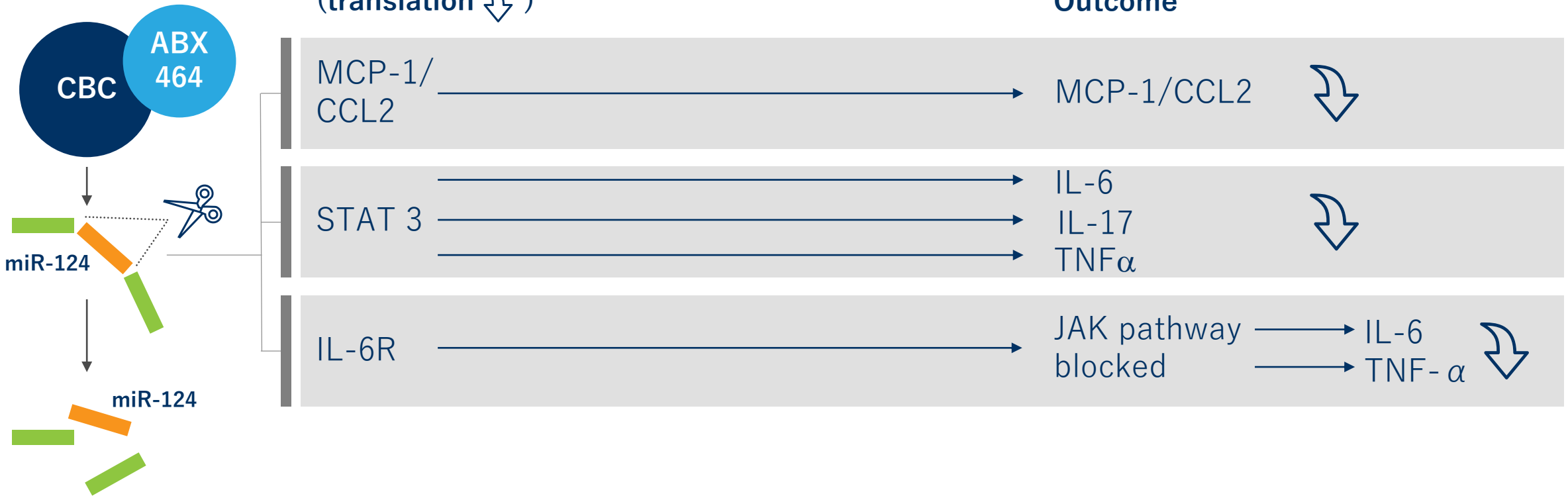
- **Antiviral:** ABX464 inhibits SARS-CoV-2 (COVID-19 virus) *in vitro* replication in human respiratory epithelium: Inhibition of COVID-19 viral replication comparable to Remdesivir
- **Anti-inflammatory:** ABX464 has demonstrated potent anti-inflammatory properties in several *in-vivo* models and in 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)



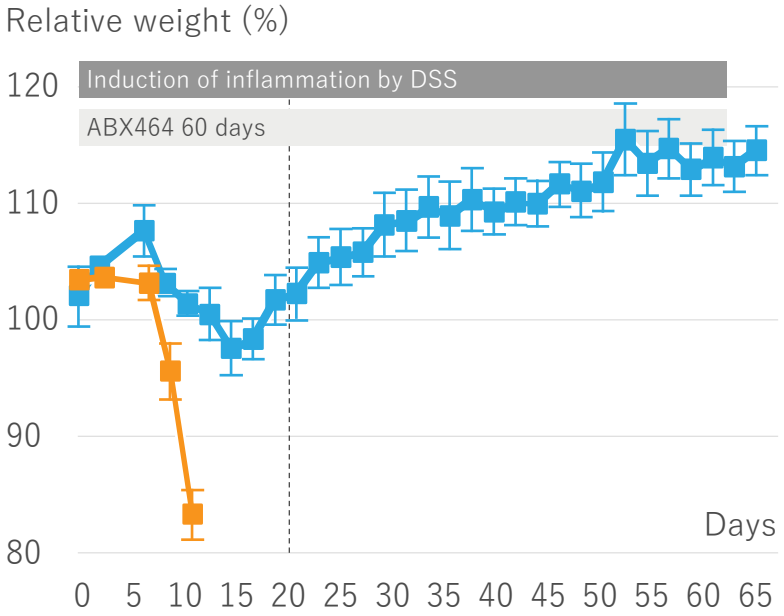
# ABX464 novel mechanism of action: Potent and specific upregulation of miR-124 leads to reduction of pro-inflammatory cytokines

## Both systemic and local inflammatory sites

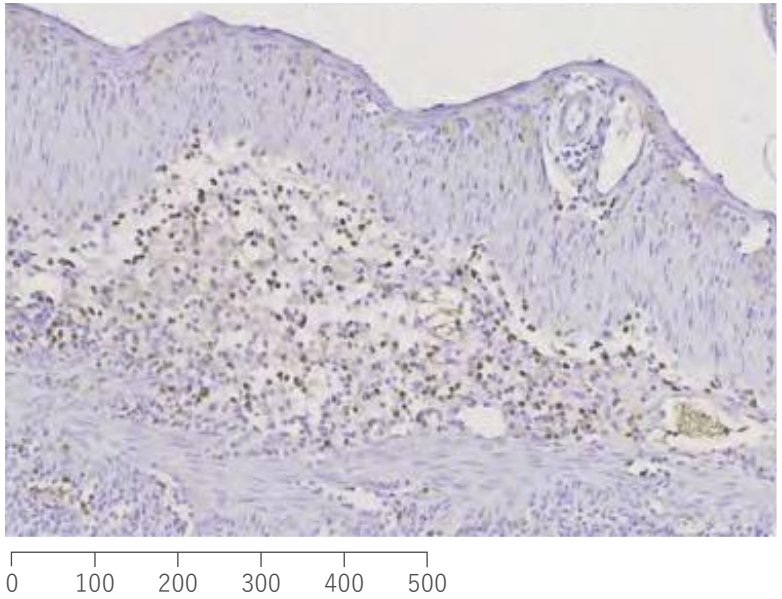


# Anti-inflammatory effect:
# ABX464 showed efficacy in the DSS mouse model*

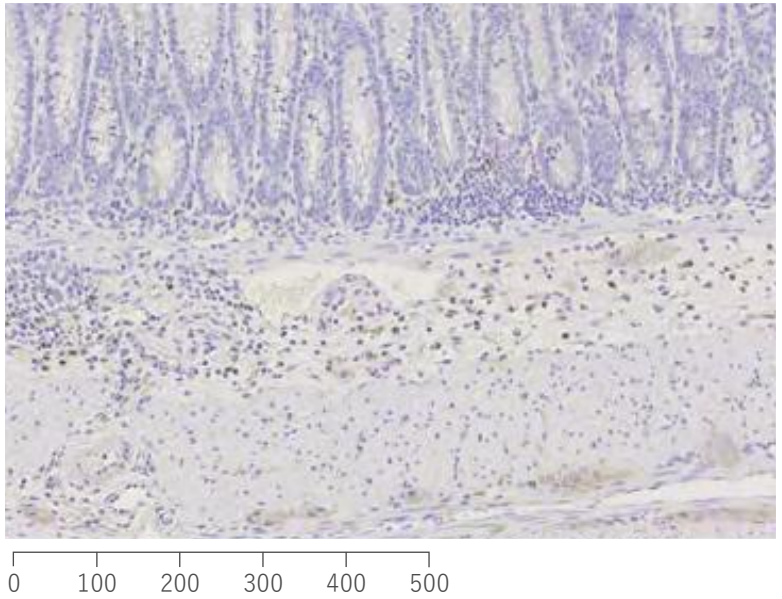
## ABX464 protects mice from death in the DSS mouse model




## DSS without ABX464 leads to intestinal damage




## ABX464 protects intestinal structure



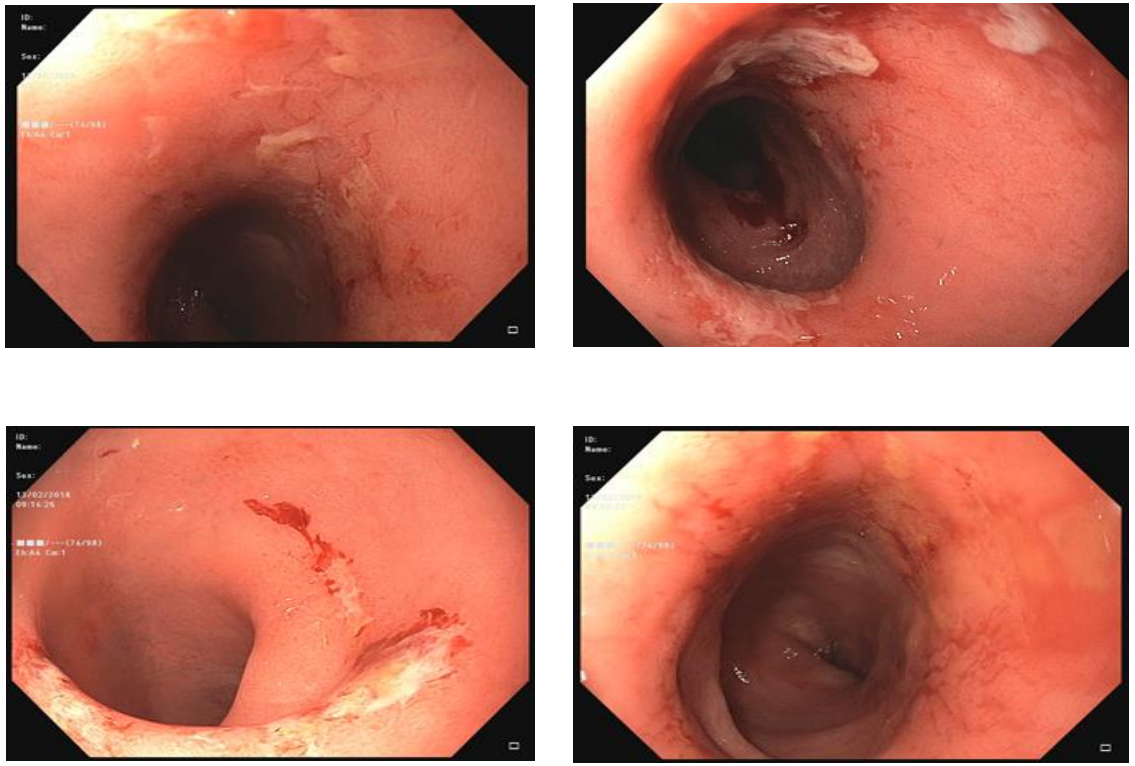

→ **ABX464 reduced the expression of pro-inflammatory cytokines in colon tissue:**
IL-6 (2x), TNF (7.5x) and MCP-1 (6x)

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

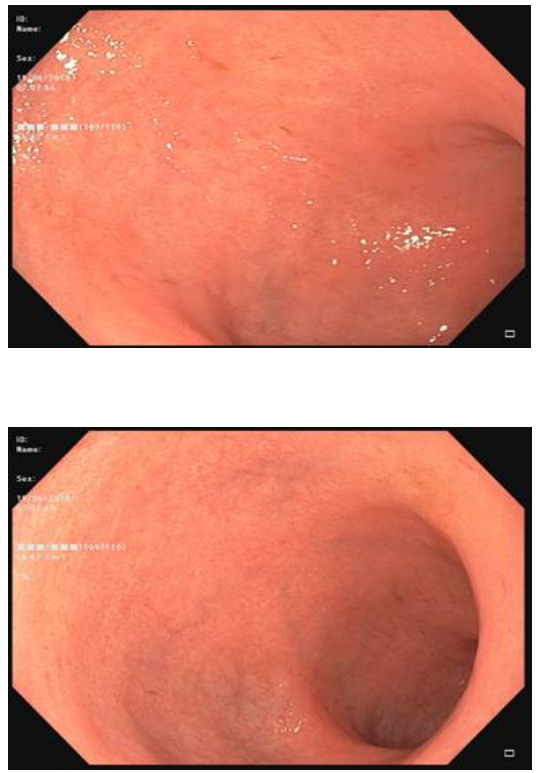
# Tissue repair in an ABX464 treated UC patient

## Courtesy of Prof. Severine Vermeire

### Before ABX464

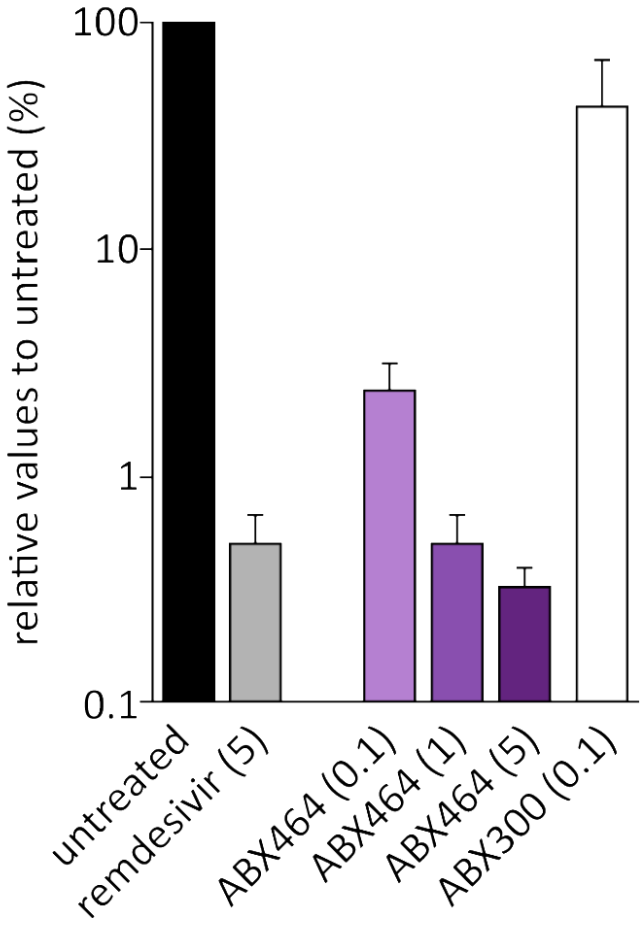


### After ABX464



# 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**

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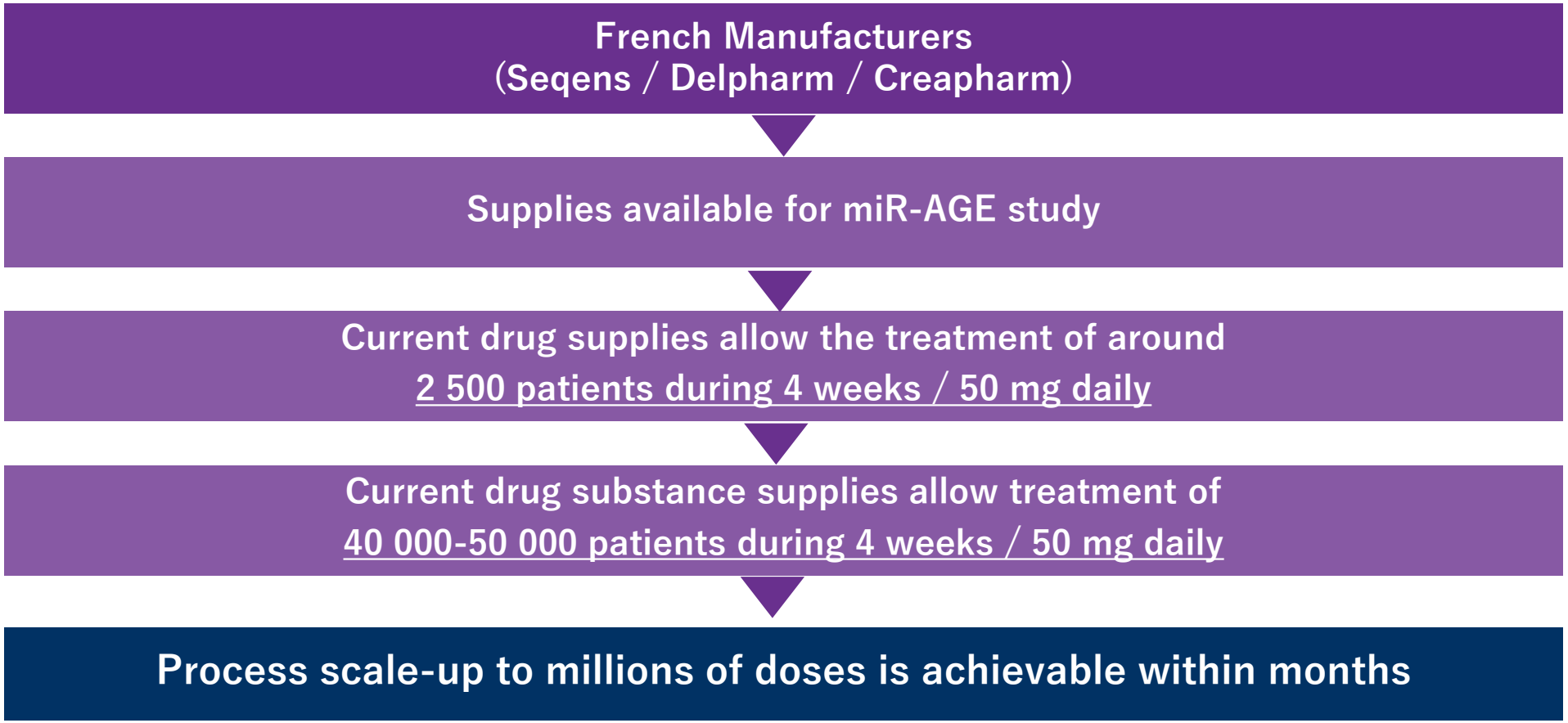
# Phase 2b/3 clinical trial miR-AGE: High-risk patients, PRIOR to respiratory distress

- **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

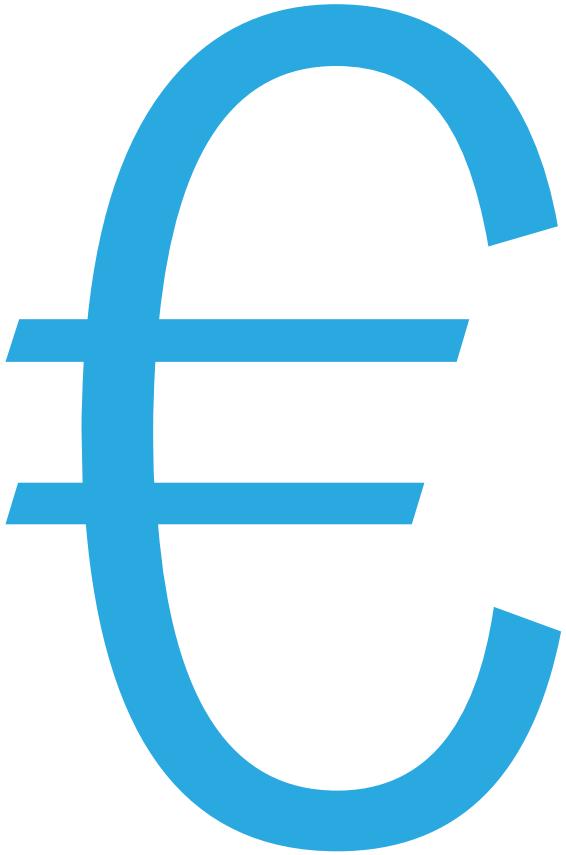
# ABX464 supply available for COVID-19 clinical trials and scalable for commercialization



# Abivax Communication Plan until mid-2021

| | Q2 2020 | Q3 2020 | Q4 2020 | Q1 2021 | Q2 2021 |
|---|---|---|---|---|---|
| **UC** Phase 2a | | | **2-years maintenance data** | | |
| **UC** Phase 2b | | | **Enrollment completed** | | **Top line results** |
| **RA** Phase 2a | | | **Enrollment completed** | | **Top line results** |
| **Crohn's** Phase 2b | | | **FPI** | | |
| **COVID-19** Phase 2b/3 | **FPI** | **Enrollment completed** | **Top line results** | | **MAA/NDA submission** |
| **HCC** Phase 1/2 | | | **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
- With this € 36m funding Abivax cash runway is extended to end of 2020; additional funding planned to extend cash runway until mid 2021, preferably non-dilutive

# Highly experienced Executive Committee

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Chief Executive Officer

Former Head of Global R&D, Baxter BioScience

Baxter · SANDOZ · Lilly

**Didier Blondel**

Chief Financial Officer & Board Secretary

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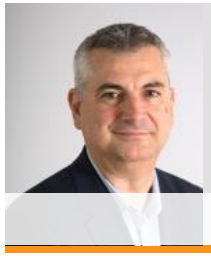

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Chief Commercial Officer & VP, BD

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**→ Competencies from discovery to global commercialization**