Establishing ABX464's anti-inflammatory, antiviral and tissue repair properties to prevent and treat COVID-19

Abivax, a late-stage clinical biotech company

May 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

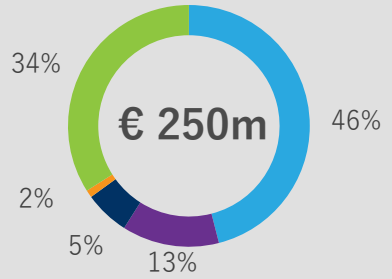
Cooperative Lab with CNRS
Montpellier

abivax

BREAKING NEWS

€ 36m in non-dilutive funding from Bpifrance

Shareholder structure[1] and market cap[2]



Operations

26 Employees

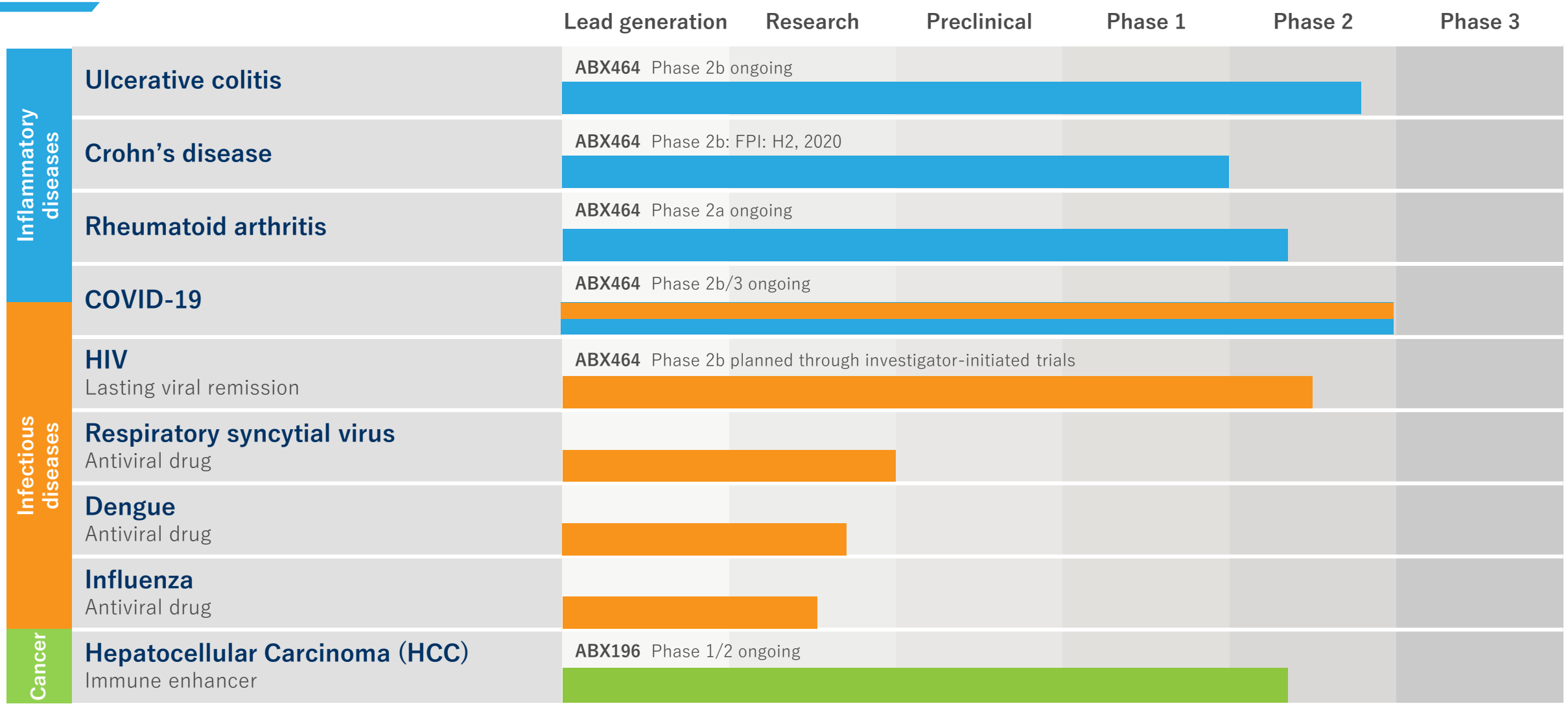
Cash[3] **€ 9.8m**

20 in R&D

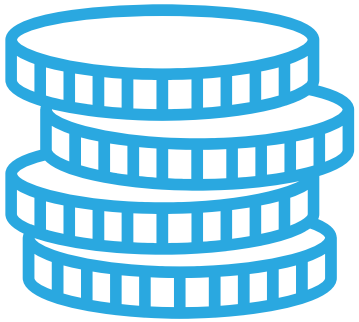
6 in Support

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

Abivax: A strong and diversified pipeline

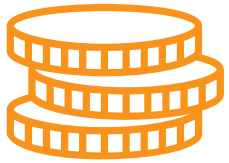


ABX464: Targeting inflammatory diseases and COVID-19 markets



Inflammatory disease market size(1)

greater than
$ 90 B



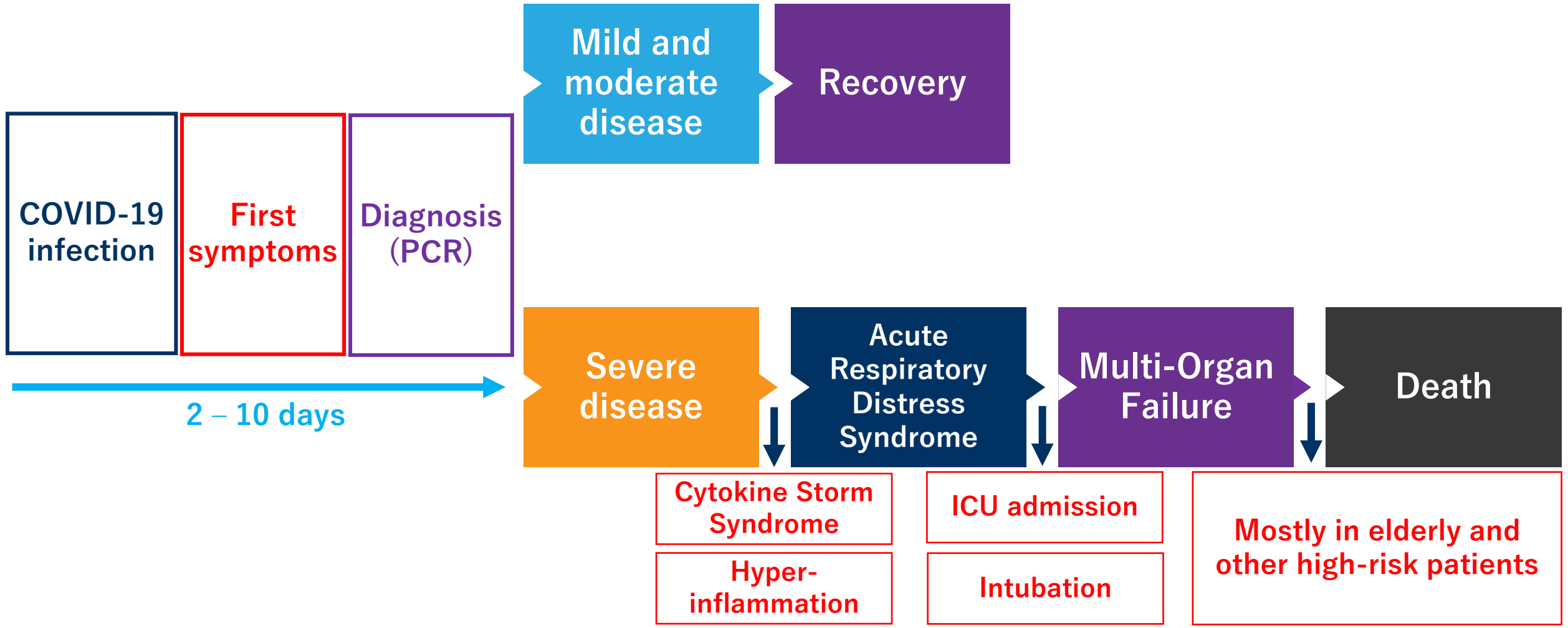
COVID-19 market size

Multi billion $ market

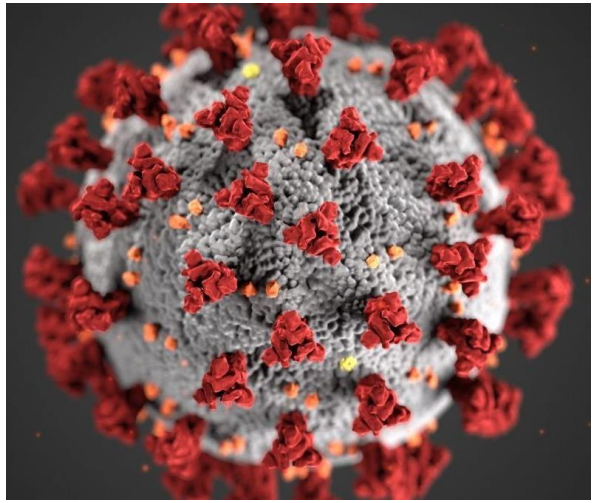
- Discovered in **proprietary** Abivax compound library, biased to **modulate RNA biogenesis**; Close collaboration with EVOTEC
- **Small molecule** (quinoline), administered as an **oral capsule** (once-daily)
- **First-in-Class, novel mechanism of action:** Selective upregulation of microRNA miR-124 puts the brakes on inflammation, anti-viral
- **Good safety profile** after administration to >**300 subjects**
- **Anti-inflammatory and tissue healing effects** confirmed in DSS mouse model of IBD and Phase 2a induction and maintenance studies in ulcerative colitis patients
- **High medical need** for novel safe and efficacious drugs in “classical” inflammatory diseases and to treat or prevent severe COVID-19 infection

(1) For Europe G5, U.S. and Japan

COVID-19 infection and pathology



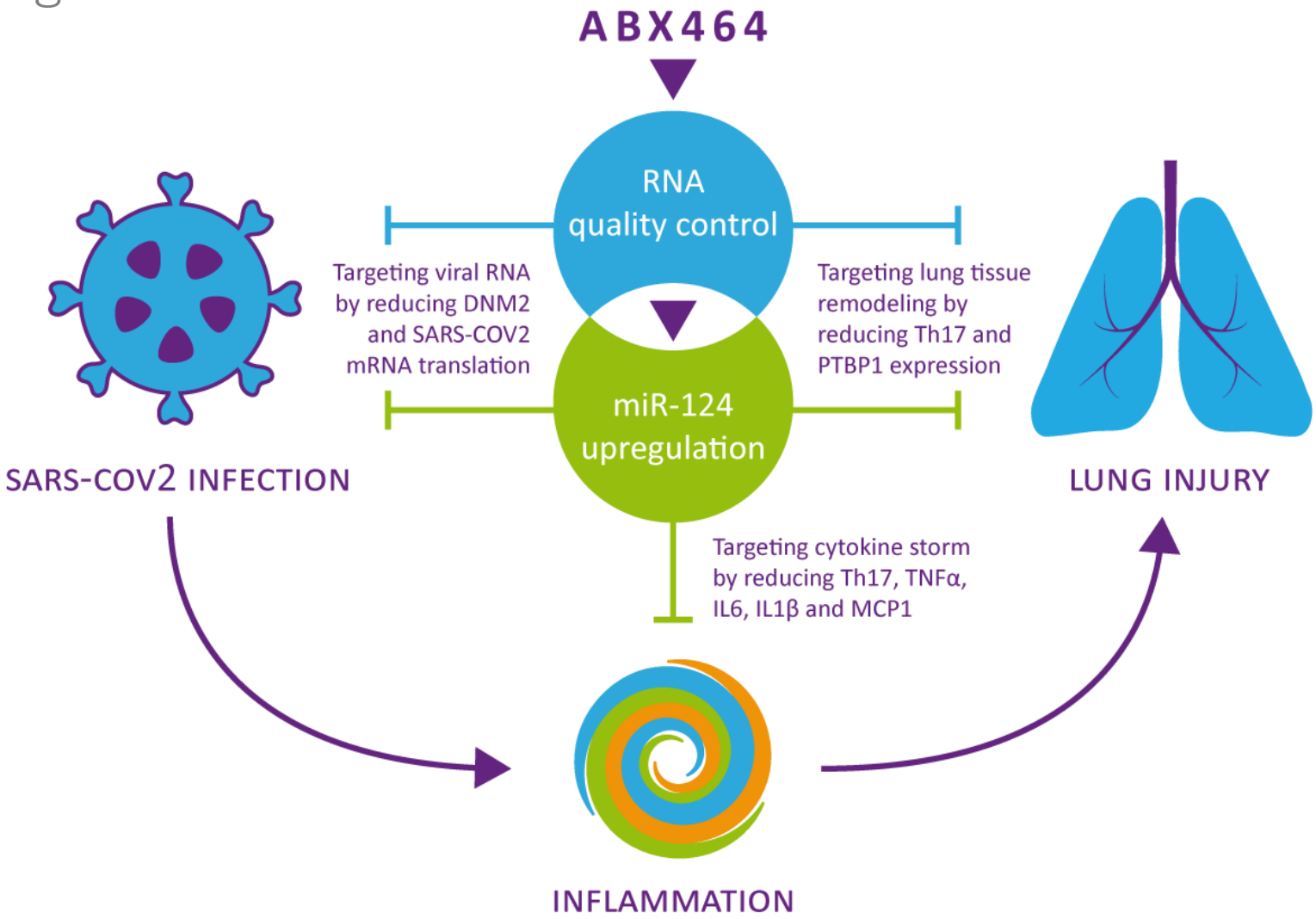
ABX464 COVID-19 Development Rationale



- **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
- **Tissue repair** observed in DSS model of inflammatory bowel disease (IBD) and in patients in Phase 2 ulcerative colitis trial
- Ongoing randomized, double-blind and placebo-controlled **Phase 2b/3 clinical trial** of ABX464 in 1,034 severe COVID-19 patients; Trial authorized in France & Germany
- **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

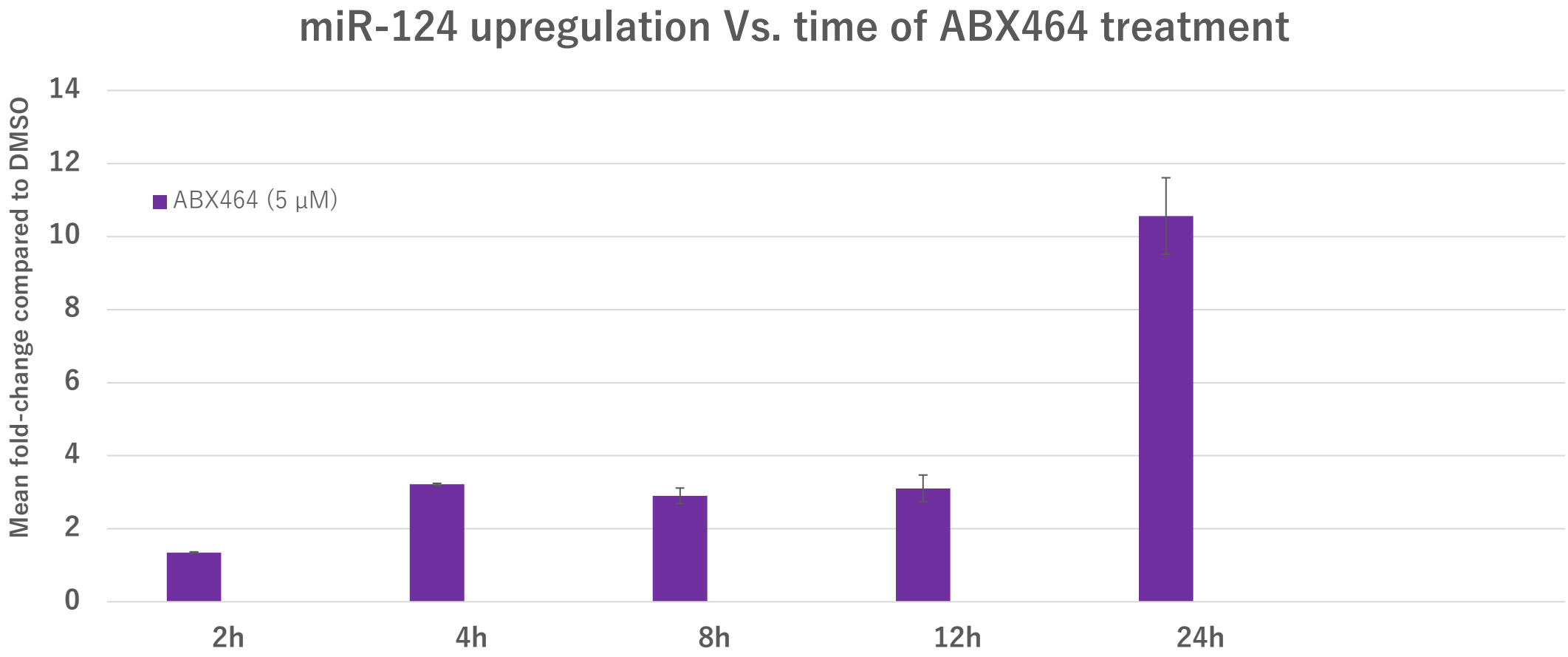
Mechanistic rationale for ABX464 to treat COVID-19 infection

Three shots on goal



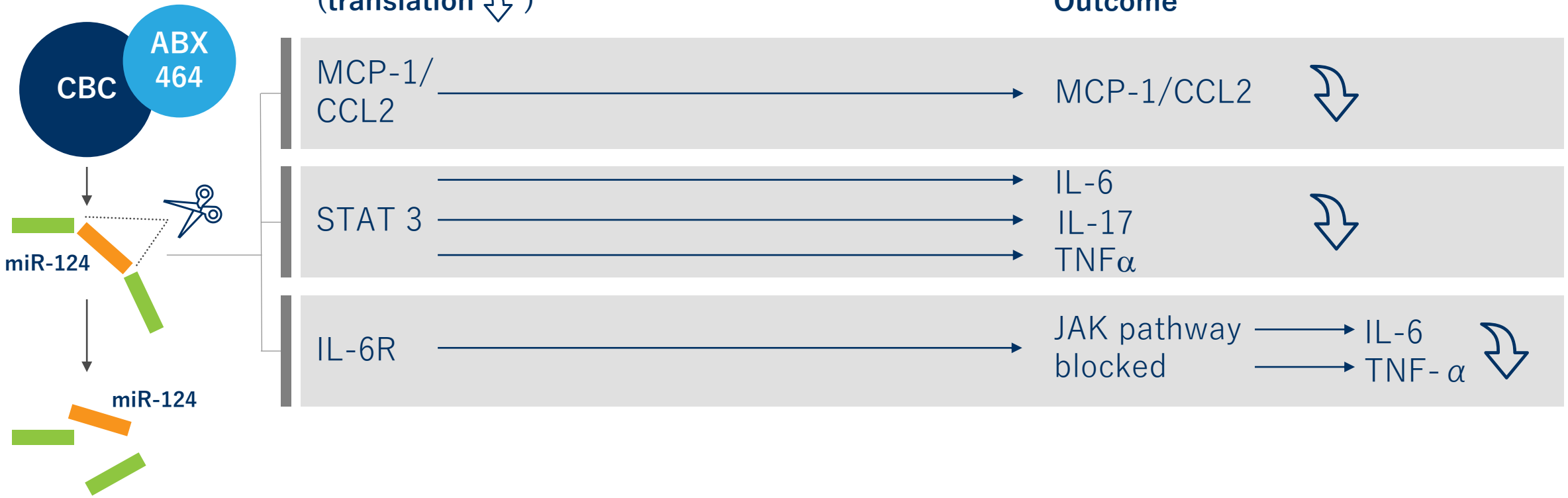
* The Lancet, March 16, 2020
Puja Mehta et al.

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



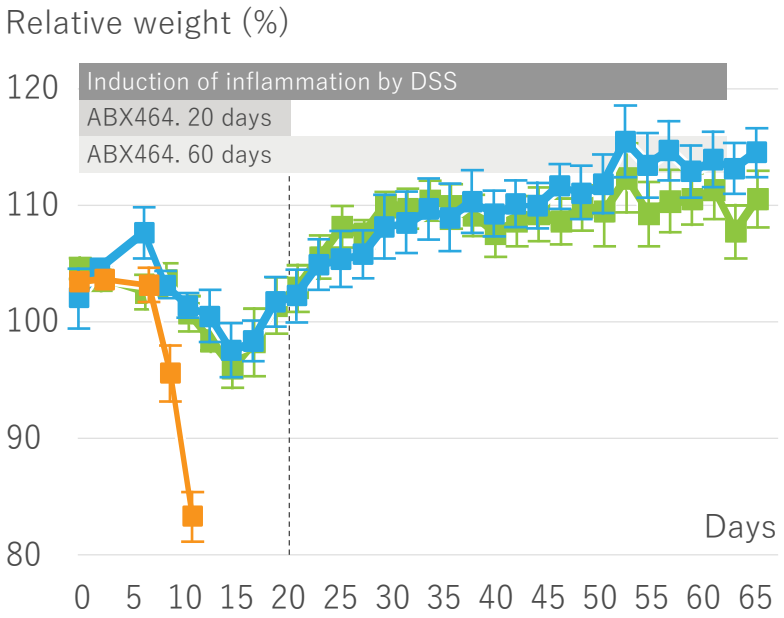
ABX464 novel mechanism of action: Potent and specific upregulation of miR-124 leads to reduction of pro-inflammatory cytokines

Both systemic and local inflammatory sites

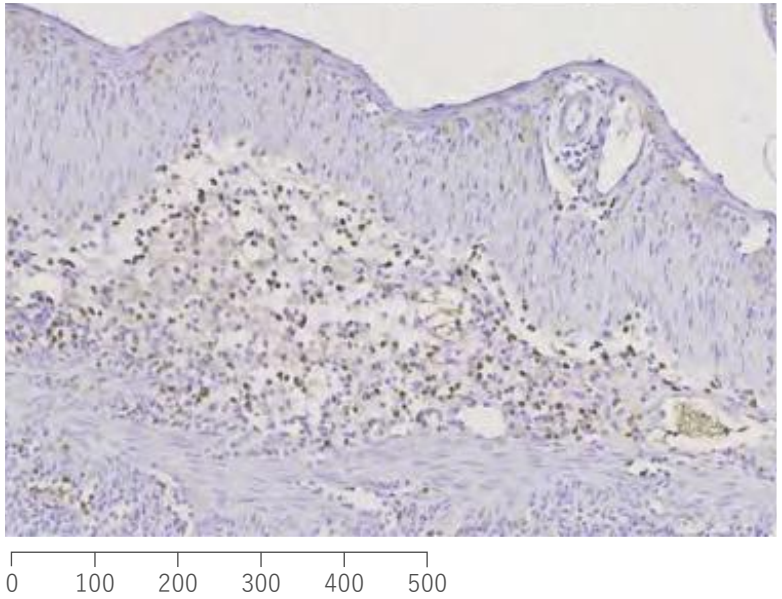


ABX464 showed efficacy in the DSS mouse model*

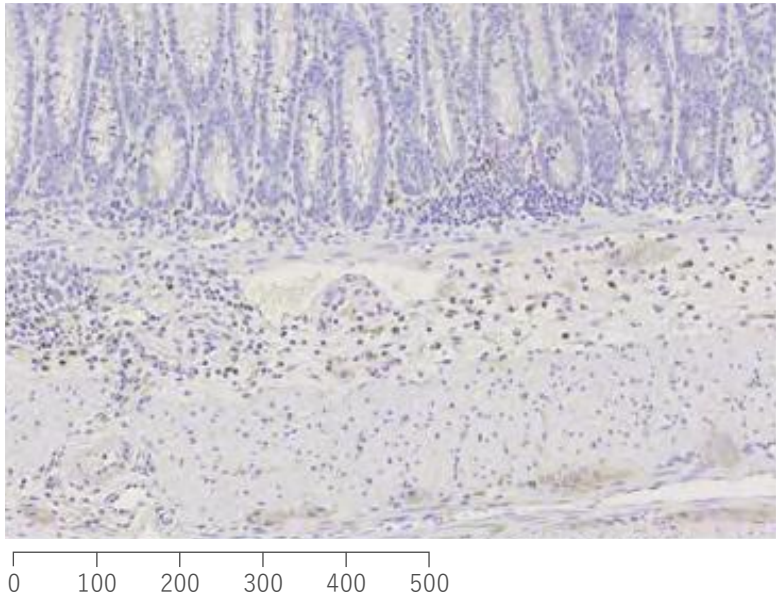
ABX464 protects mice from death in the DSS mouse model



DSS without ABX464 leads to intestinal damage



ABX464 protects intestinal structure



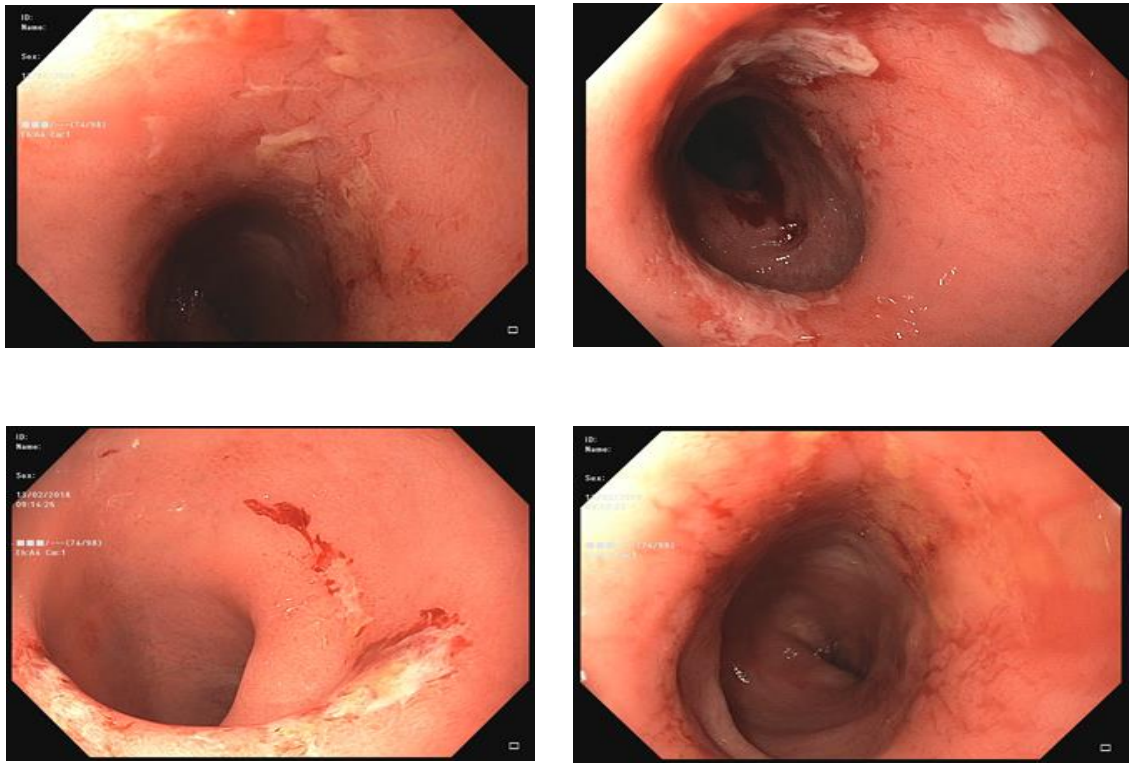
→ **ABX464 reduced the expression of pro-inflammatory cytokines in colon tissue:**
IL-6 (2x), TNF (7.5x) and MCP-1 (6x)

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

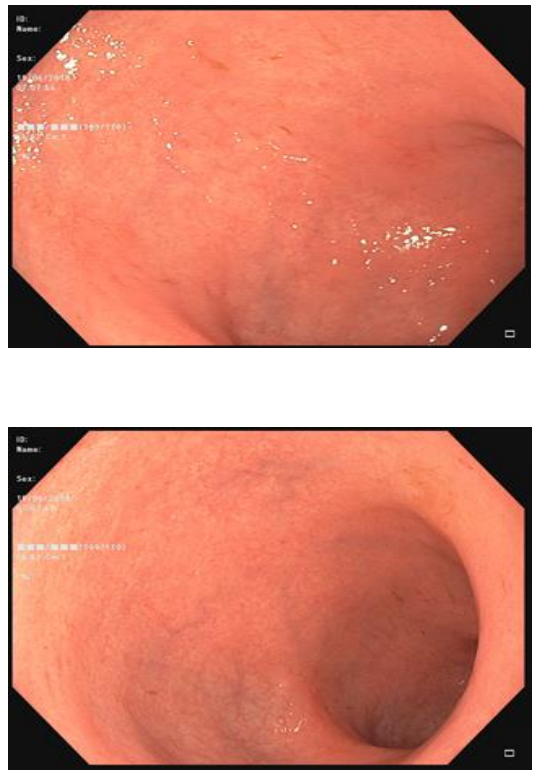
Tissue repair in an ABX464 treated UC patient

Courtesy of Prof. Severine Vermeire

Before ABX464

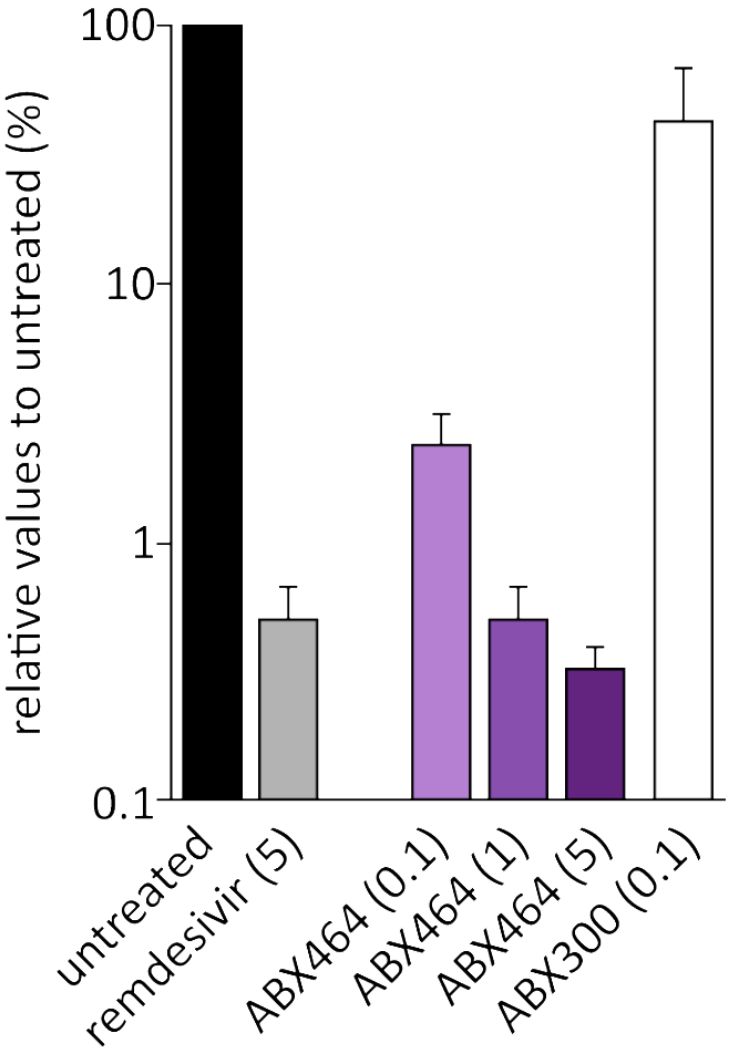


After ABX464



Reduction of COVID-19 replication in an *in vitro* reconstituted human airway epithelial model: Comparable efficacy between Remdesivir and ABX464

Infectious titrations TCID50 at 48 hours post infection



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

Safety profile consistent with previous and ongoing clinical studies

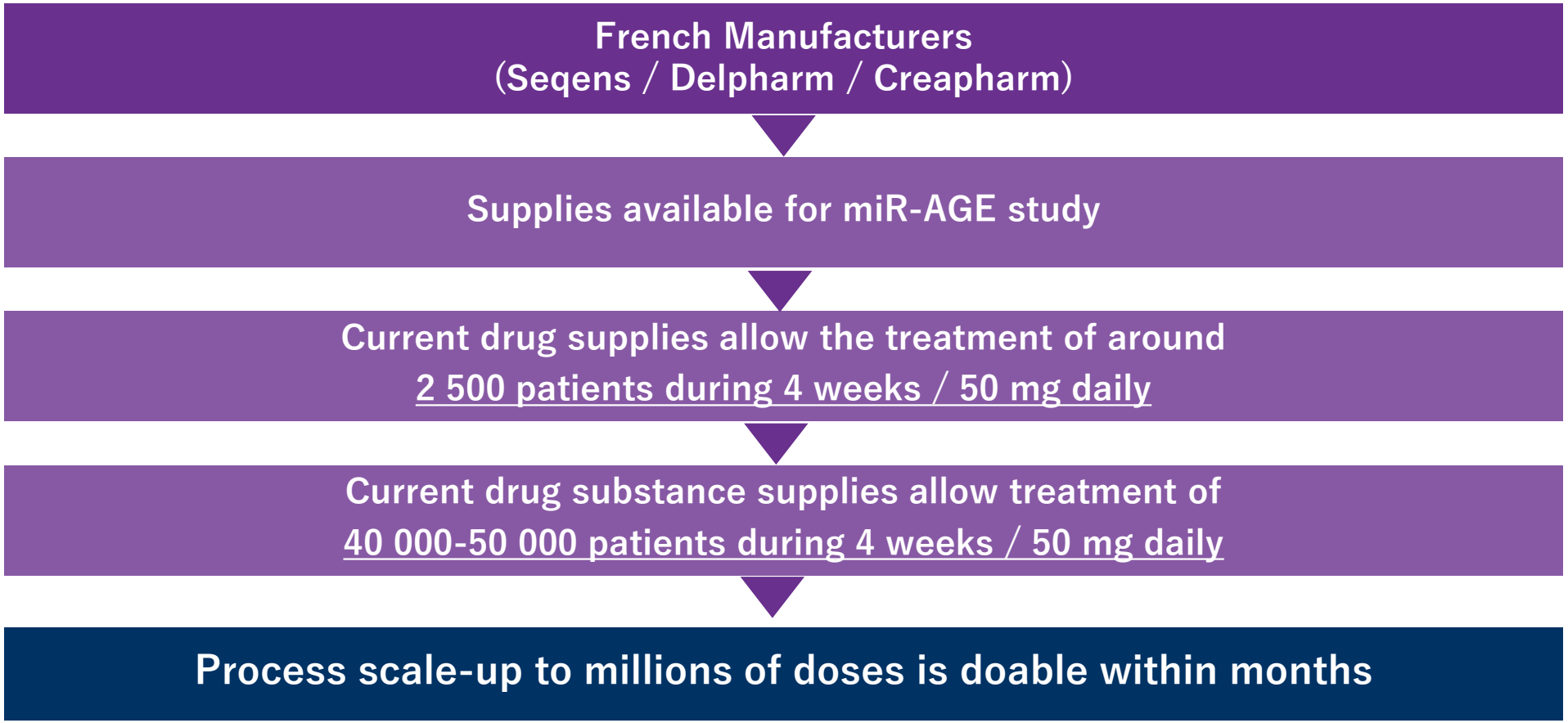
(>300 healthy volunteers and patients exposed to ABX464)

- **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
- Some patients are on **continuous daily treatment with ABX464 for >2 years**

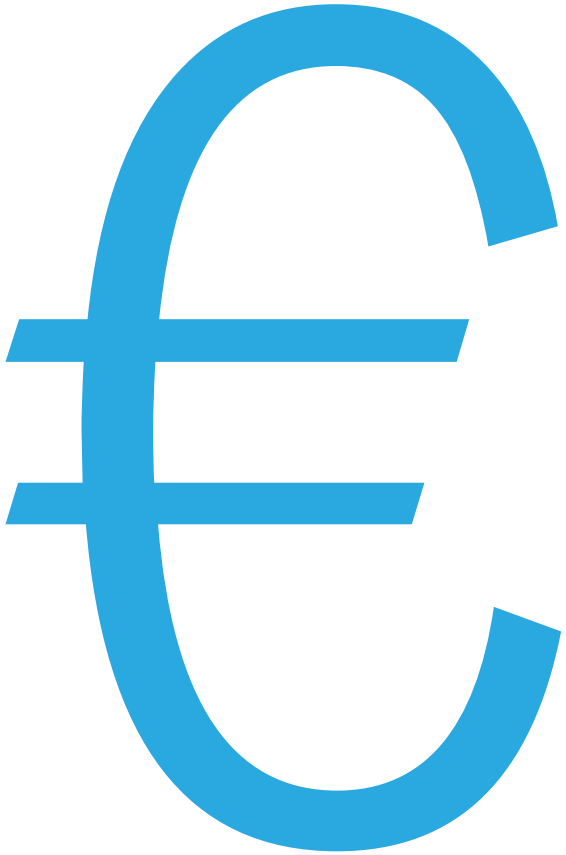
European Phase 2/3 clinical trial miR-AGE : High-risk patients, PRIOR to respiratory distress

- **Early treatment** of high-risk patients infected with COVID-19
- **Phase 2b/3 study**, placebo-controlled and randomized
- **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
- In total, **1,034 patients** will be included in **50 clinical study sites**
- **Preliminary sample size estimate:**
  - 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



ABX464 COVID-19 Bpifrance funding



- 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
- The amount of € 36m will be paid within the next 12 months
- 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

Prof. Hartmut Ehrlich, M.D.

Chief Executive Officer

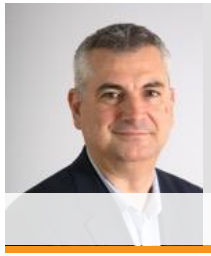
Former Head of Global R&D, Baxter BioScience

Baxter · SANDOZ · Lilly

Didier Blondel

Chief Financial Officer & Board Secretary

SANOFI · sanofi pasteur MSD



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Chief Commercial Officer & VP, BD

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imaXio · 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 · GlaxoSmithKline

Prof. Jamal Tazi Ph.D.

VP, Research & Director of Cooperative Lab with CNRS

→ Competencies from discovery to global commercialization