

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

Abivax, a late-stage clinical biotech company

May 14, 2020



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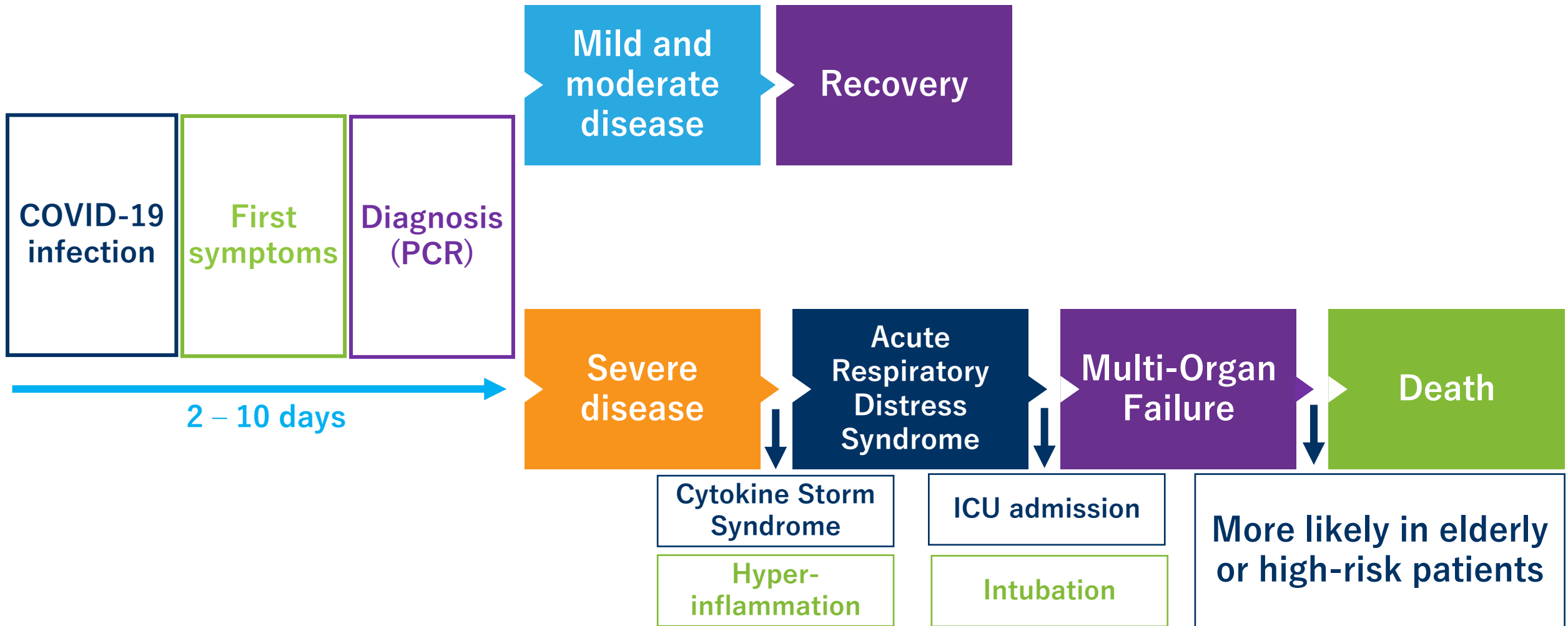
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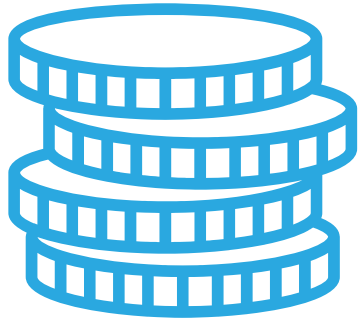
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COVID-19 disease



ABX464: A promising candidate addressing inflammatory and COVID-19 markets



Total market size⁽¹⁾
in inflammatory
diseases

greater than
USD 90 B



Market size^(1,2)
for therapeutic
(COVID-19)

Very large Market

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 subjects**

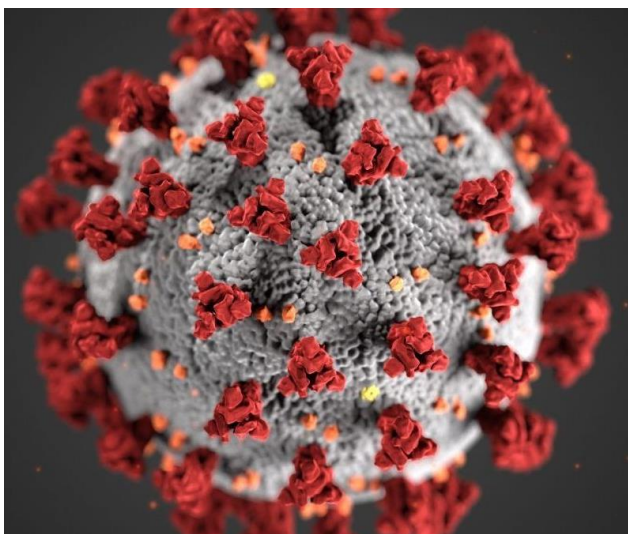
Anti-inflammatory effect confirmed in DSS mouse model of IBD as well as in Phase 2a induction and maintenance studies in ulcerative colitis. Phase 2b study in UC ongoing in 232 Patients, as well Phase 2a in rheumatoid arthritis in 60 patients

High medical need for novel safe and efficacious drugs in “classical” inflammatory diseases as well as Covid-19

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

(2) Abivax estimates

ABX464 COVID-19 Development Rationale



ABX464 showed the capacity to **reduce or eliminate the viral HIV reservoirs**; new data show that ABX464 **inhibits the replication of SARS-CoV-2** (COVID-19 virus) in an in vitro reconstituted human respiratory epithelium model

COVID-19 infection can induce a **cytokine storm** (including increased MCP1, IL-1 β , TNF α , IL-17, G-CSF and IL-6)*, leading to **acute respiratory distress syndrome** (ARDS), multiple organ failure and death

ABX464 has demonstrated in several *in-vivo* models and in patients **potent anti-inflammatory properties** thanks to its unique mechanism of action mediated by a specific upregulation of a single micro-RNA (miR-124)

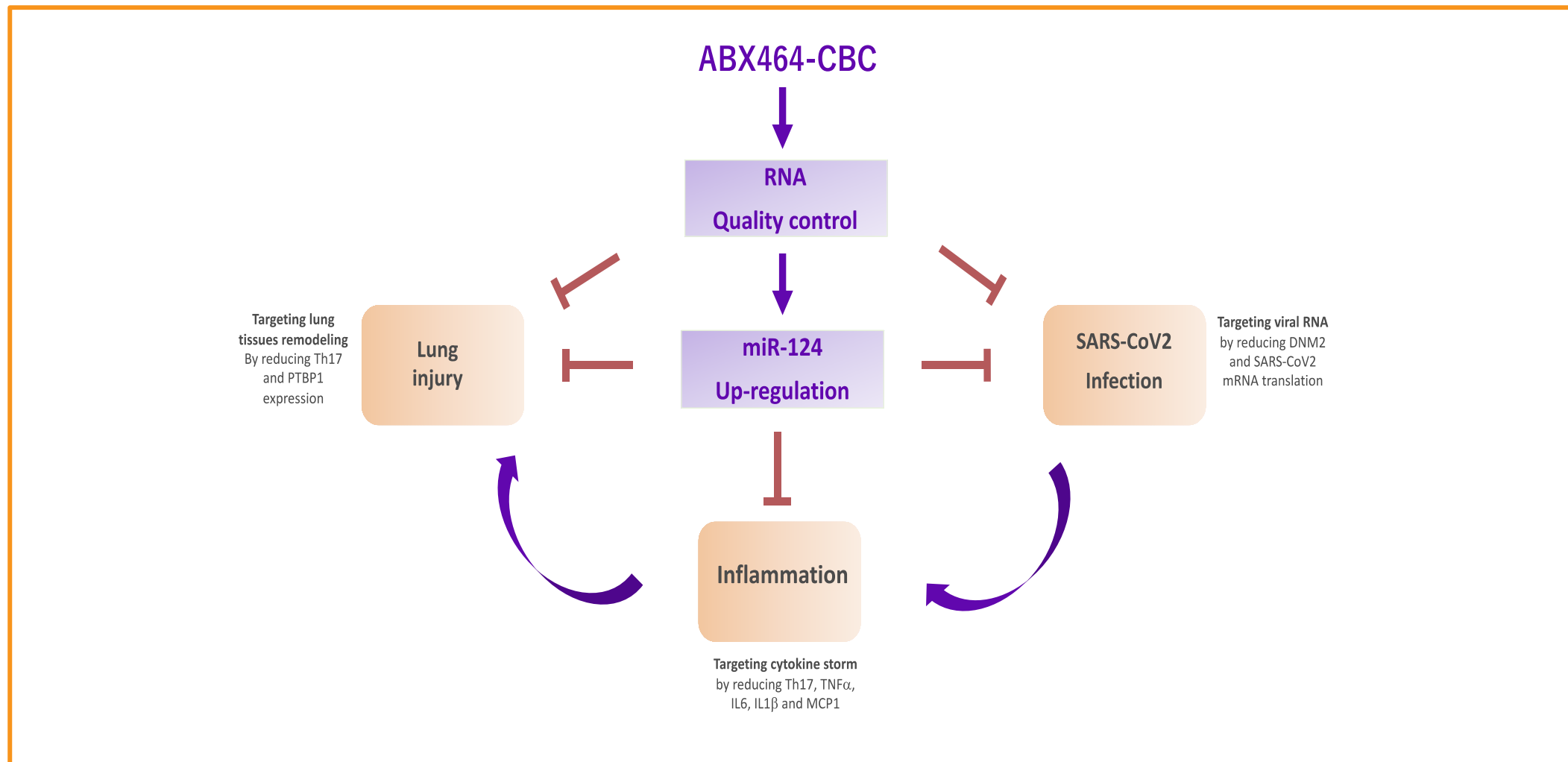
Abivax is conducting a **randomized, double-blind and placebo-controlled Phase 2b/3 clinical trial** in Europe with ABX464 in 1,034 COVID-19 patients – Clinical trial already fully approved in France

Good safety profile of ABX464 demonstrated in >300 volunteers and patients

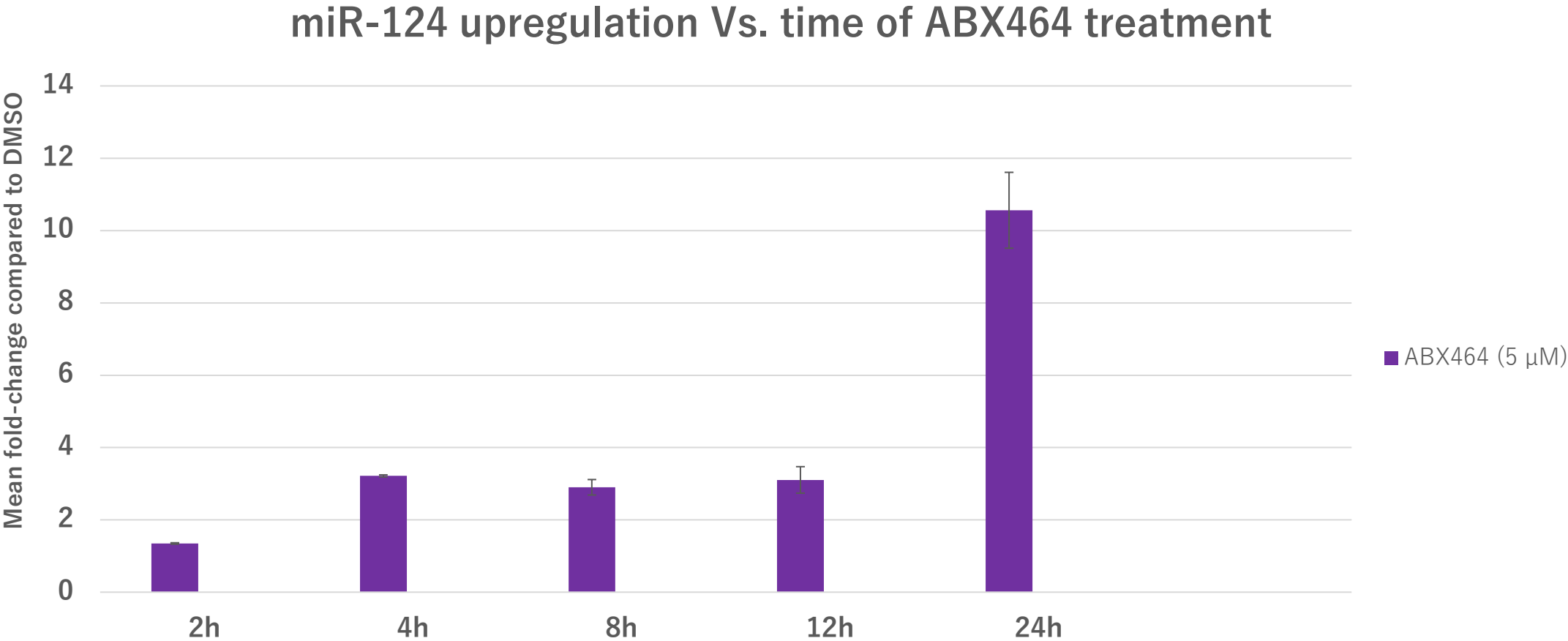
Abivax has already **manufacturing capacities in place** (drug substance, finished product and packaging) to supply the investigational drug **for large clinical trials** as well as to ramp up quickly to **large scale commercial production**

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

Rationale for testing ABX464 in patients infected with COVID-19

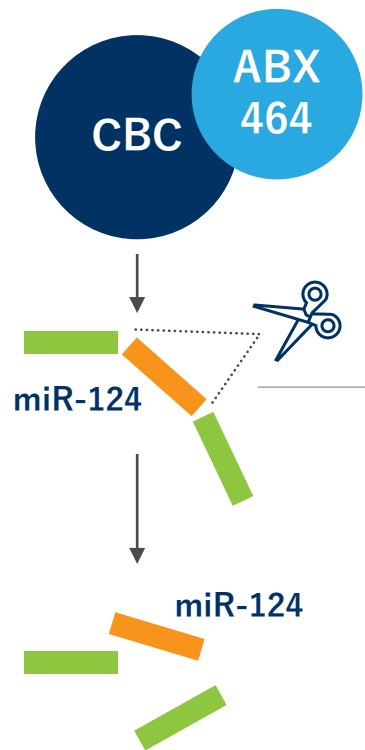


ABX464 specifically and rapidly upregulates miR-124
10-fold within 24 hours in human PBMCs (*in vitro* results)



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



Established miR-124 targets:
(translation ↓)

Outcome

MCP-1/
CCL2

MCP-1/CCL2



STAT 3

IL-6

IL-17

TNF α



IL-6R

JAK pathway
blocked

IL-6

TNF- α



ABX464 reduced MCP1, IL-1 β , TNF α and IL-6 within 4 days of treatment of primary human monocyte-derived macrophages

Within four days of treatment ABX464 reduced relevant chemokines and cytokines in primary human monocyte-derived macrophages

MCP1
(-50 to -60%)

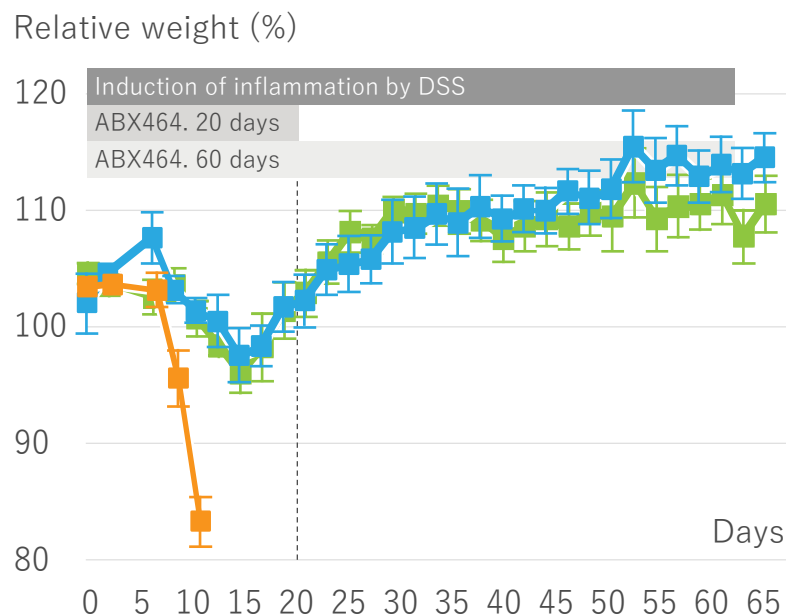
IL-6
(-20%)

TNF α
(-25%)

IL-1 β
(-25%)

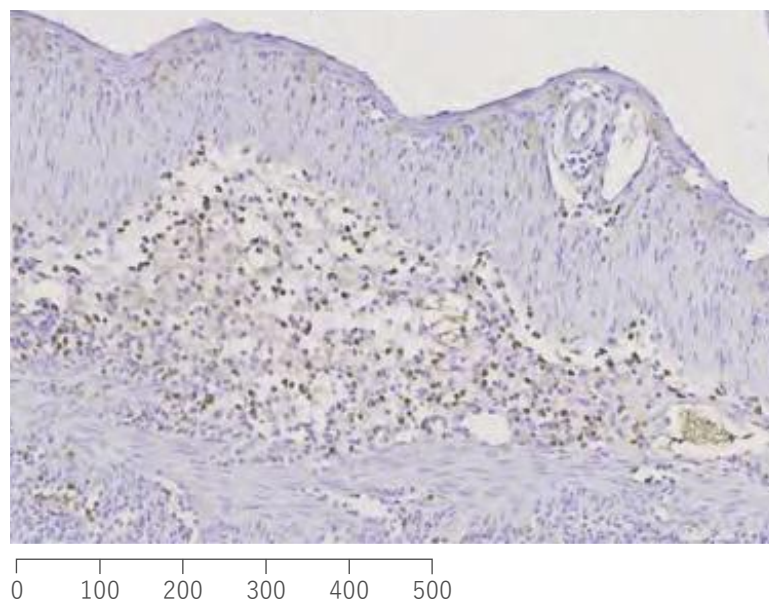
ABX464 showed efficacy in the DSS mouse model*

ABX464 protects mice from death in the DSS mouse model

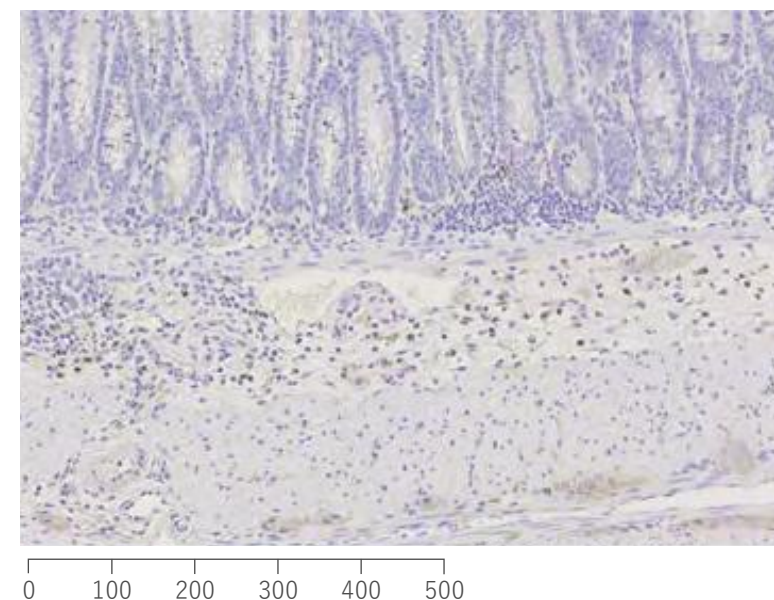


- ABX464. 20 days (n=8)
- No treatment (n=8)
- ABX464. 60 days (n=8)

DSS without ABX464 leads to intestinal damage



ABX464 protects intestinal structure



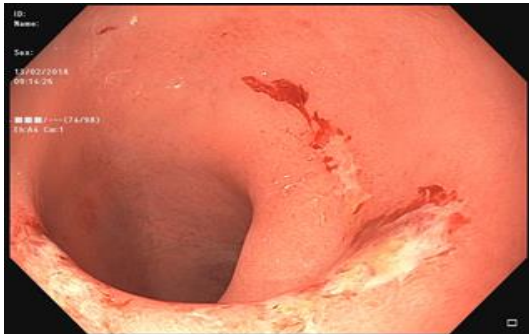
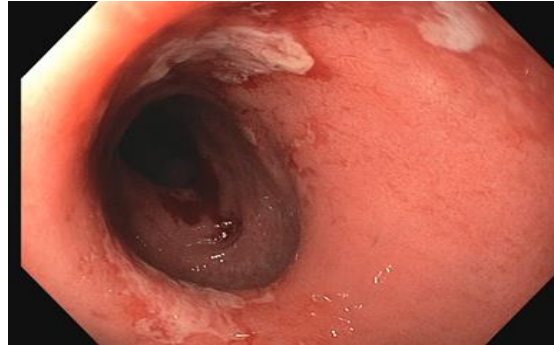
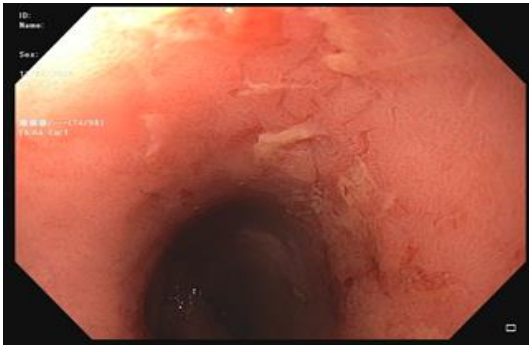
→ **ABX464 reduced the expression of pro-inflammatory cytokines in colon tissue:**
IL-6 (2x), TNF (7.5x) and MCP-1 (6x)

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

Tissue repair in an ABX464 treated UC patient

Courtesy of Prof. Severine Vermeire

Before ABX464

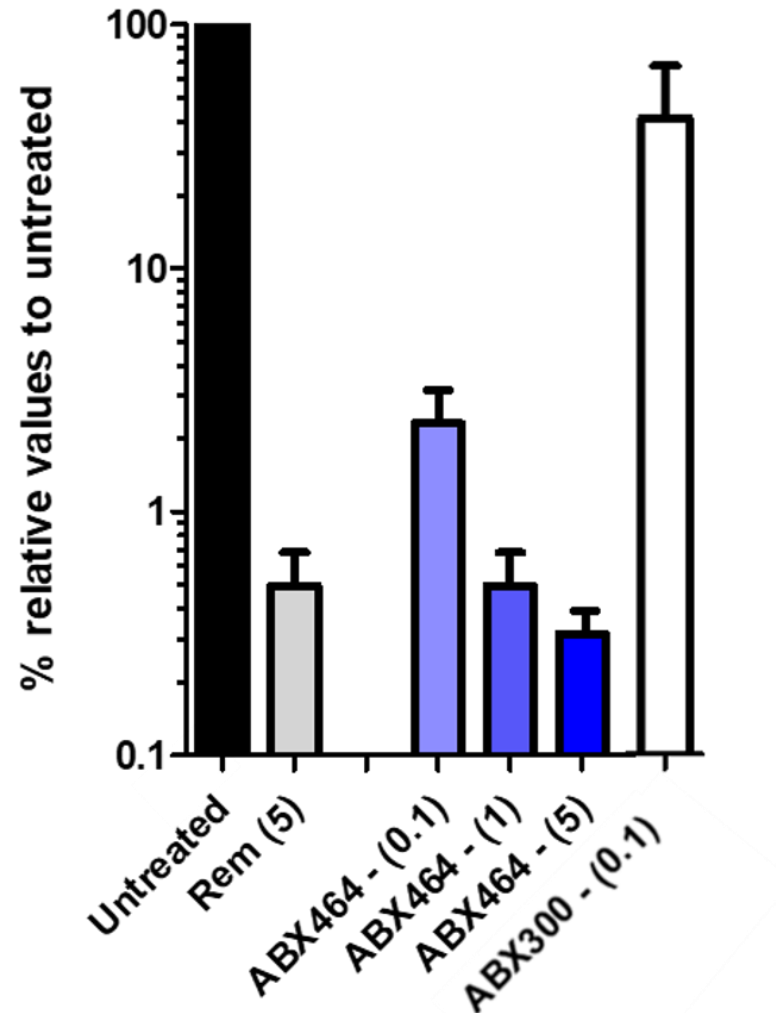


After ABX464



Reduction of Covid-19 replication in an in vitro reconstituted human airway epithelial model

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: 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 to evaluate the efficacy and the safety of ABX464 in treating inflammation and preventing acute respiratory failure in patients aged ≥ 65 and patients aged ≥ 18 with at least one additional risk factor who are infected with SARS-CoV-2 (the miR-AGE study).
- 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**
- Preliminary sample size estimate: Placebo + SOC group : 344 patients, ABX464 + SOC group : 690 patients (2 to 1 randomization). Expected response rate; 75% on placebo, 83 % on ABX464 (alpha 0.05, beta 80%).
- In total, **1,034 patients** will be included in **50 European clinical study sites**

ABX464 Supply available for COVID-19 clinical trials and scalable

French Manufacturers
(Seqens / Delpharm / Creapharm)

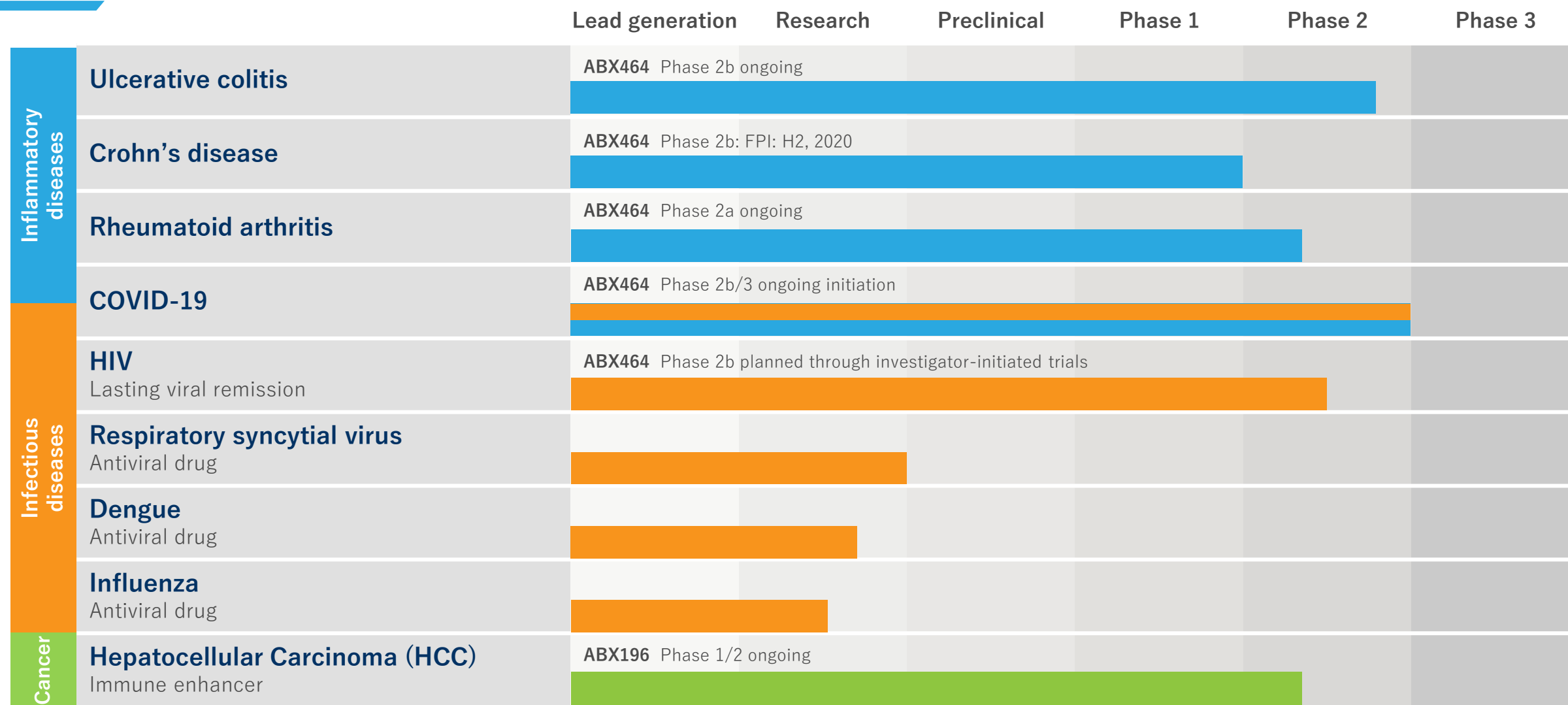
Supplies available for miR-AGE study

Current drug supplies allow the treatment of around 2 500 patients during 4 weeks / 50 mg daily

Current drug substance supplies allow treatment of 40 000-50 000 patients during 4 weeks / 50 mg daily

Process scale-up to millions of doses is doable within months

Abivax: A strong and diversified pipeline



Key company facts

Milestones



Founded in 2013
by Truffle Capital



Focus on chronic
inflammatory diseases with
ABX464 in Sept. 2018



Abivax went
public in June 2015,
raising € 57.7m



Acute viral and
inflammatory diseases
with ABX464 in May 2020

Location

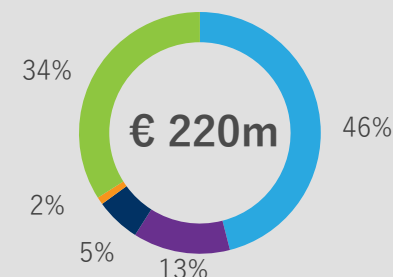


Head Office
Paris

**Cooperative
Lab with CNRS**
Montpellier



Shareholder structure¹ and market cap²



■ Truffle Capital
■ Sofinnova
■ Board & management
■ Incubator & founders
■ Public

Operations



26
Employees



Cash³
€ 9.8m



20
in R&D



6
in Support

- 1) Undiluted – as of 31.03.2020
- 2) As of 12.05.2020 EOB
- 3) Actual December 2019

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**
vaccines for life



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Officer & VP, BD

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Contrast for Life



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Manufacturing

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AMGEN **Pfizer**



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Prof. Jamal Tazi
Ph.D.
VP, Research & Director of
Cooperative Lab with CNRS

CIR **W**

→ Competencies from discovery to global commercialization