



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

Abivax, a late-stage clinical biotech company

October 22, 2020



Forward looking statements (1/2)

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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

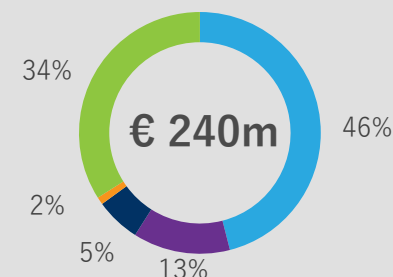


Head Office
Paris

**Cooperative
Lab with CNRS**
Montpellier



Shareholder structure¹ and market cap²



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

Operations



27
Employees



Cash³
€ 12.1m



21
in R&D



6
in Support

- 1) Undiluted – as of 31.03.2020
- 2) As of 16.09.2020 EOB
- 3) Actual June 2020

Abivax: A strong and diversified pipeline



Abivax Financing

Q3 2020

Q4 2021

ABX464
Manufacturing scale-up

ABX464
Preclinical

ABX464
Regulatory clinical
studies

Abivax
New research

Abivax
G&A

Funding Need
€ 100m+

ABX464 in UC: Phase 2a M & Phase 2b I+M*
Phase 3 preparation

ABX464 in CD: Phase 2b/3 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
- Société Générale PGE € 5m
- Kreos new funding € 15m+
- Kepler Cheuvreux Equity Line € 11m

→ Cash runway until Q2 2021

€ 67m+

€ 28m+

TO BE COMPLETED by end 2020

Core plan

- Non-dilut. public funding
- Capital raise

→ Cash runway until Q4 2021

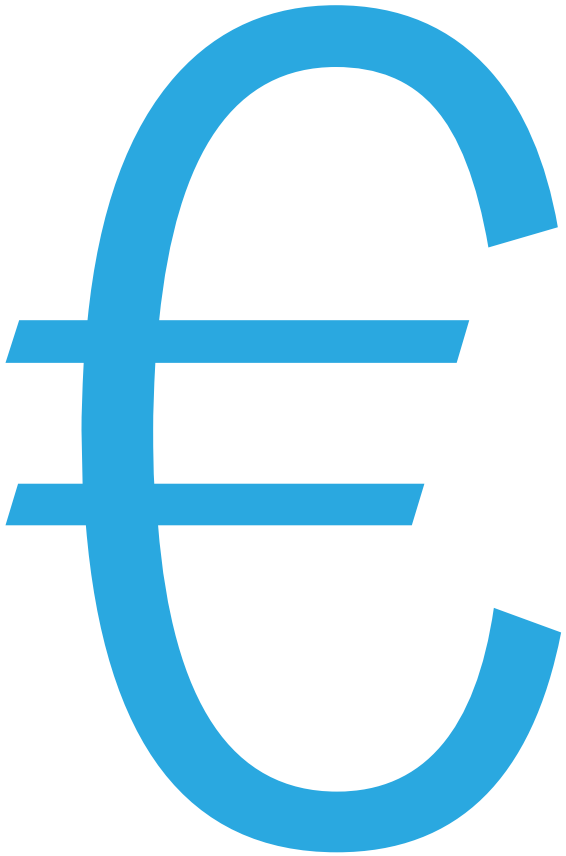
Upside plan

- Partnering
- ABX464 COVID-19 commercialization

Next planned funding milestone: Abivax partnering after ABX464 UC Phase 2b read out in Q2 2021

* I: Induction phase; M: Maintenance phase

Bpifrance € 36m funding



▶ The amount of € 36m will be paid by BPI until June 2021 (so far € 14.4m paid).

Total amount of € 36m is made of € 20.1m grant (non-refundable) and € 15.9m loan (refundable):

- ▶ → Either € 15.9m loan refundable over time when ABX464 is reaching commercial stage in COVID-19,
- Or € 15.9m loan refundable over 5 years starting in 2023 if ABX464 COVID-19 indication is not successful and other indications are successfully pursued.

▶ Total amount of € 36m is funding miR-AGE study (€ 16m) as well as additional costs (€ 20m) for all indications (incl. UC and RA) of ABX464 development and manufacturing scale up.

Details of Kreos Capital € 15m funding

€ 15m straight bonds in two tranches

Tranche A	Tranche B	Tranche C
€ 10m drawn at the signature of the agreement on October 15, 2020	€ 5m to be drawn down before November 1, 2020	€ 5m mutual option between Kreos Capital and Abivax before end 2020



Loan Conditions

- **No dilution:** No convertible bonds, no warrants attached
- **5 years maturity,** with first year repayment of interests only

Evolving financial conditions based on potential accelerated repayment of debt

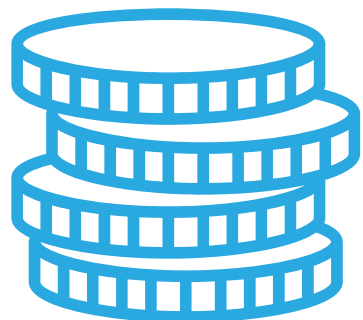
Year 1	Years 2 and 3	Years 4 and 5
<ul style="list-style-type: none">• 8% interest rate• No transaction fees• Repayment of remaining capital only	<ul style="list-style-type: none">• 9.75% interest rate• 2% transaction fees• Repayment of remaining capital +4%/year penalty	<ul style="list-style-type: none">• 9.75% interest rate• 4% transaction fees• Repayment of remaining capital +4%/year penalty

Abivax Analyst Reports Overview

Analyst	Country	Last update	Target Price	Recommendation
Bryan, Garnier & Co	France	03/09/2020	€ 37.50	Buy
Degroof Petercam	Belgium	25/09/2020	€ 29.00	Buy
goetzpartners securities	UK/Germany	14/05/2020	€ 40.00	Buy
Kepler Cheuvreux	France	25/09/2020	€ 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		

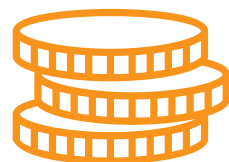
For full access to the reports, please directly contact the respective analysts listed on [Abivax's website](#).

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 **~375 patients and volunteers**

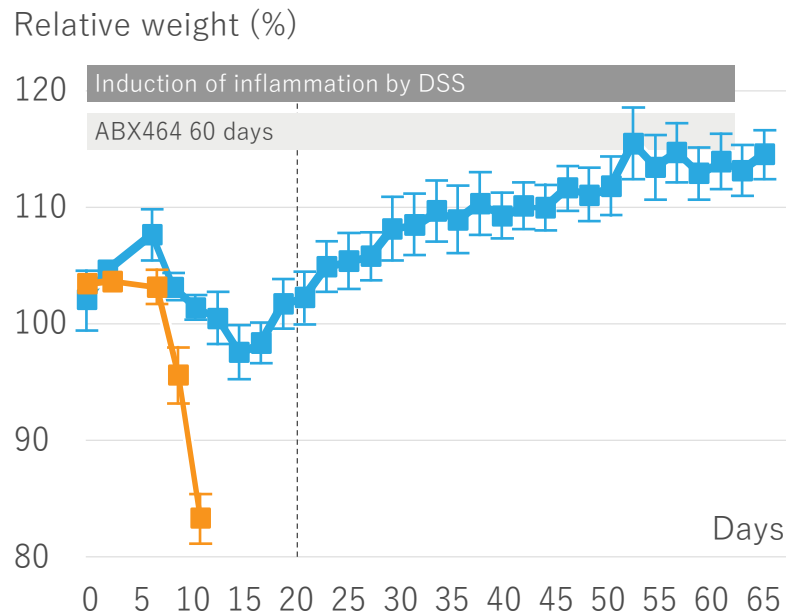
Anti-inflammatory effect confirmed in DSS mouse model of IBD as well as in Phase 2a induction and maintenance studies in ulcerative colitis. Phase 2b study in UC ongoing in 232 Patients, as well as Phase 2a in rheumatoid arthritis in 60 patients

High medical need for novel safe and efficacious drugs in inflammatory diseases

* For Europe G5, U.S. and Japan

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

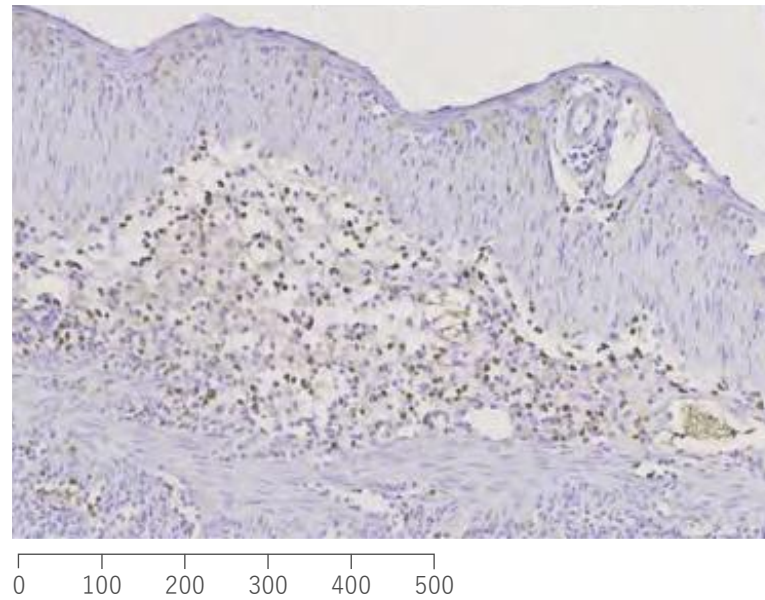
ABX464 protects mice from death in the DSS mouse model



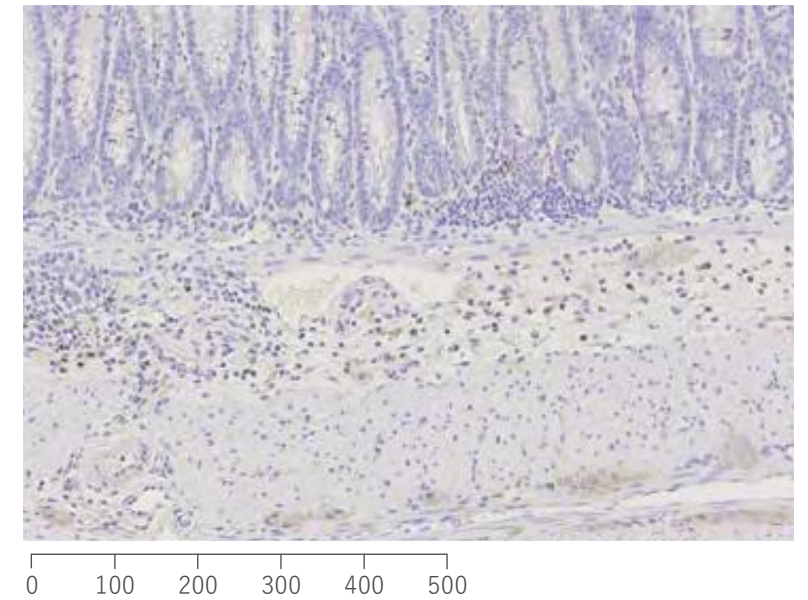
— No treatment (n=8)

— 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)

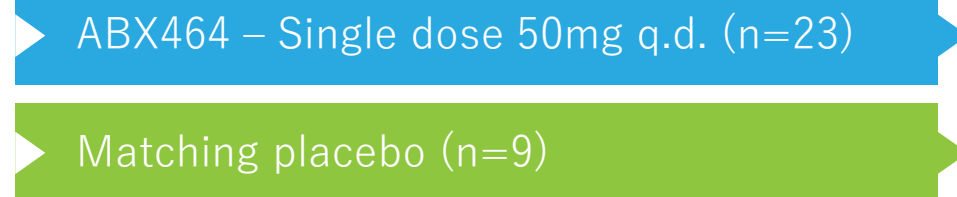
ABX464-101/102 study design: Phase 2a in ulcerative colitis

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

Induction study (ABX464-101)

8 weeks of induction treatment (completed)

Randomisation
2:1 (n=32)



Open label extension (ABX464-102)

Two years completed, with 16 patients on continued treatment in third year



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 (for induction and 2nd year maintenance study)

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



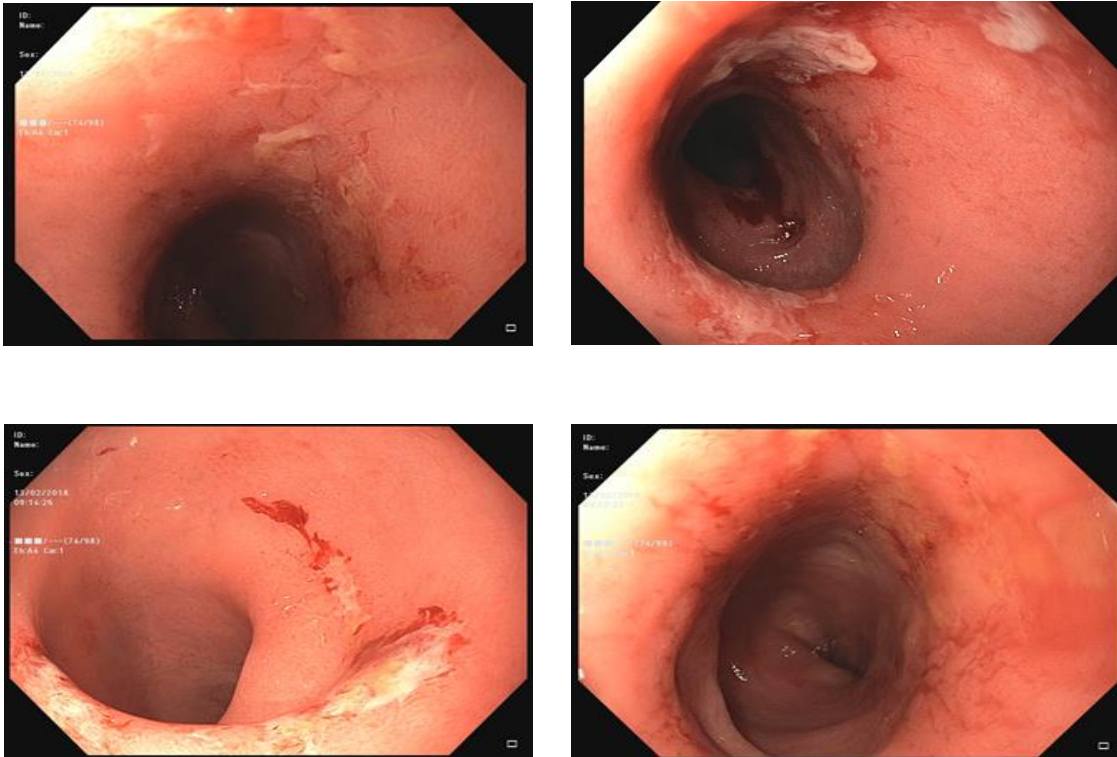
	ABX464 (n=20/23) PP/ITT	Placebo (n=9/9) PP/ITT	p value (PP)
Clinical remission*	35%/30%	11%/11%	0.16
Endoscopic improvement	50%/43%	11%/11%	0.03
Clinical response	70%/61%	33%/33%	0.06
Total Mayo Score reduction	-53%	-27%	0.03
Partial Mayo Score reduction	-62%	-32%	0.02
miR-124 expression in rectal biopsies (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

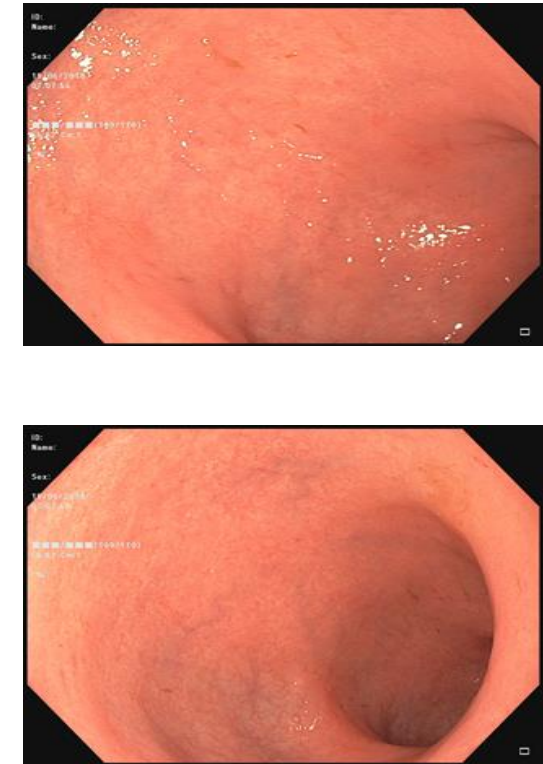
Tissue repair in an ABX464 treated UC patient

Courtesy of Prof. Severine Vermeire

Before ABX464



After ABX464

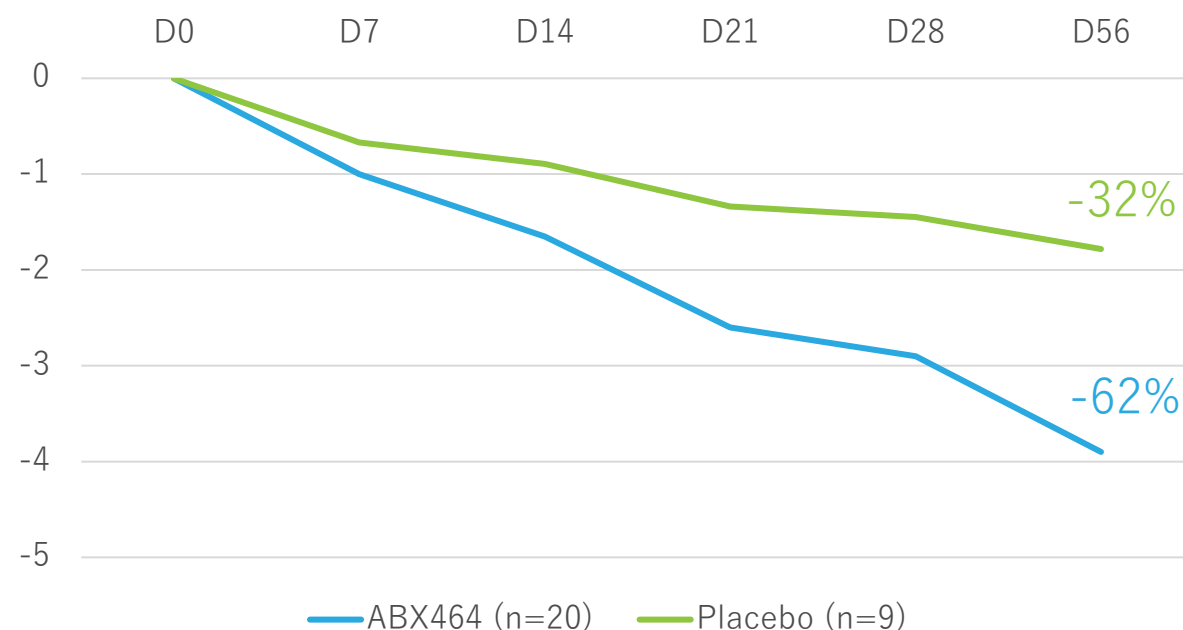


ABX464-101 Partial Mayo Score Results

Fast onset of action and comparable efficacy in both biologics naïve and experienced patients

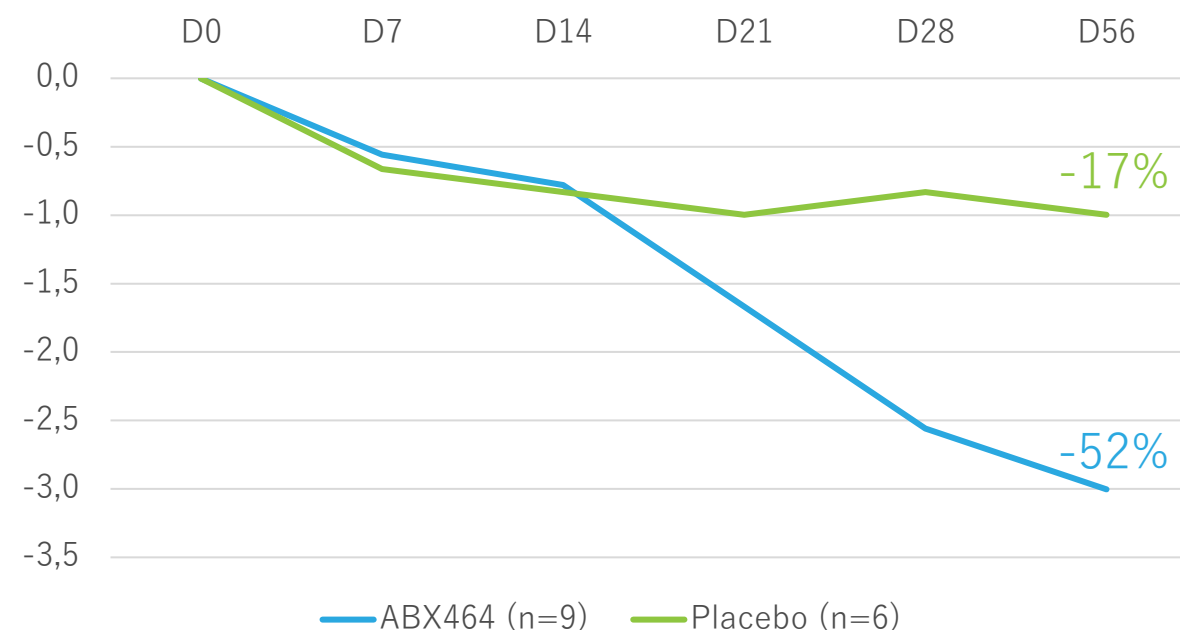
Overall Patient Population

Change from Baseline Partial Mayo Score



Patients previously treated with biologics

Change from Baseline Partial Mayo Score



ABX464-102:

Durable efficacy confirmed by 24-months maintenance study

29/32
 Patients completed the induction study

4/6
 Countries granted regulatory approval for maintenance study

22/23
 Eligible patients enrolled in the maintenance study, 19 completed first year

16/19
 16 out of 19 patients completed the second year of treatment

Durable and improved efficacy with impressive 12 and 24 months data.

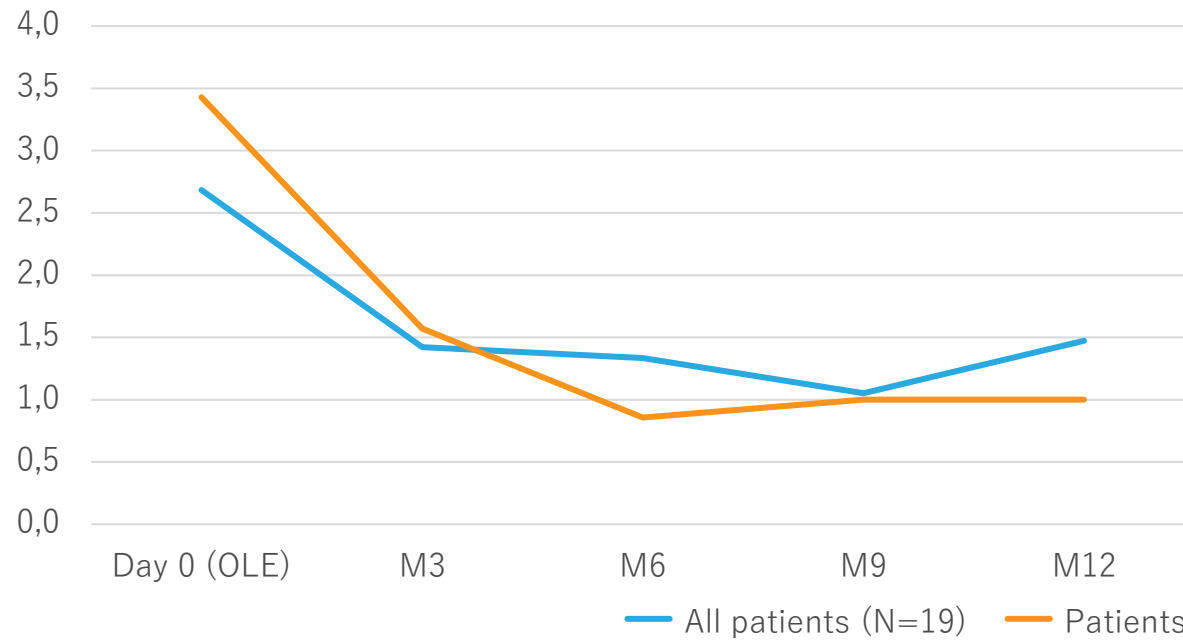
	Day 0 Maintenance	Month 12	Month 24
Clinical remission (TMS including endoscopy)	6/19 (31.6%)	12/16* (75.0%)	11/16 (68.8%)
Clinical response	14/19 (73.7%)	15/16* (93.8%)	15/16 (93.8%)

* 16 out of 19 patients had endoscopy

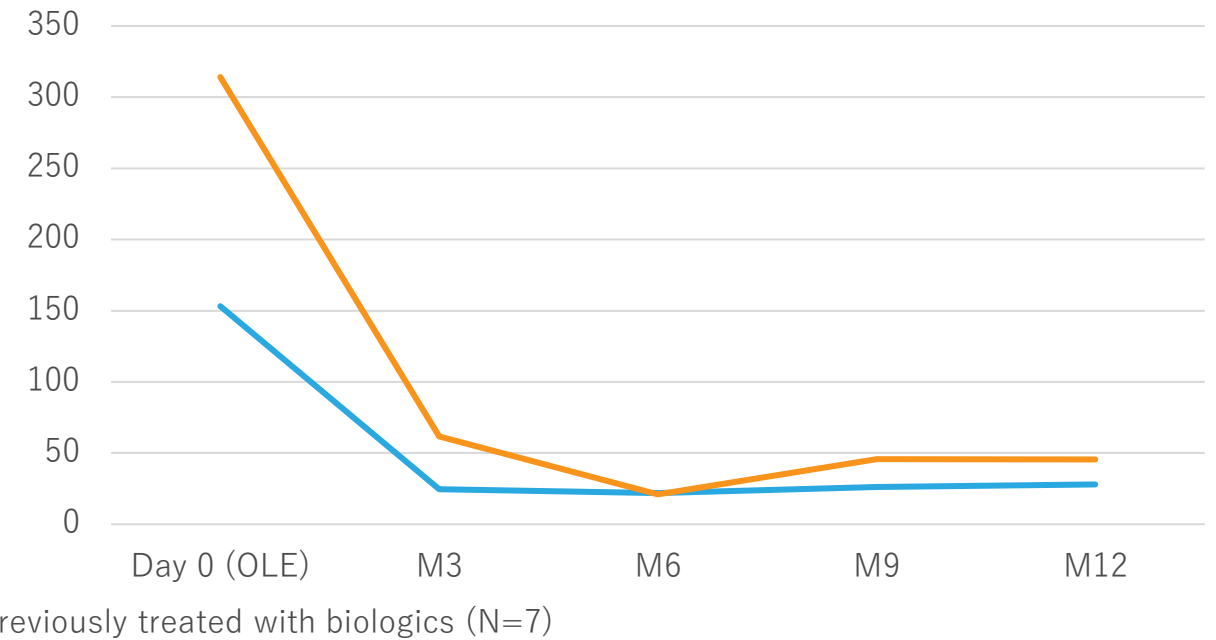
As of October 21, 2020, all ongoing ABX464-102 patients (N=15) have completed at least 27 months of continuous daily treatment with ABX464, with the longest treated patient being on product for 35 months.

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 $\mu\text{g/g}$ – Median



→ Partial Mayo Score continued to decrease

→ Fecal calprotectin levels went down to normal values ($< 50 \mu\text{g/g}$)

Median fecal calprotectin remained in normal range after two years ($31.6 \mu\text{g/g}$).

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
Endoscopic improvement (%)	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		
Endoscopic improvement (%)	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 maintenance study

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 app. 375 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
- 24-months data confirm good and durable safety and efficacy

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
- End of recruitment expected in December 2020
- 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). Status: 206 patients randomized



Phase 2a study ongoing in 60 patients with rheumatoid arthritis in 5 European countries.
Status: 53 patients randomized

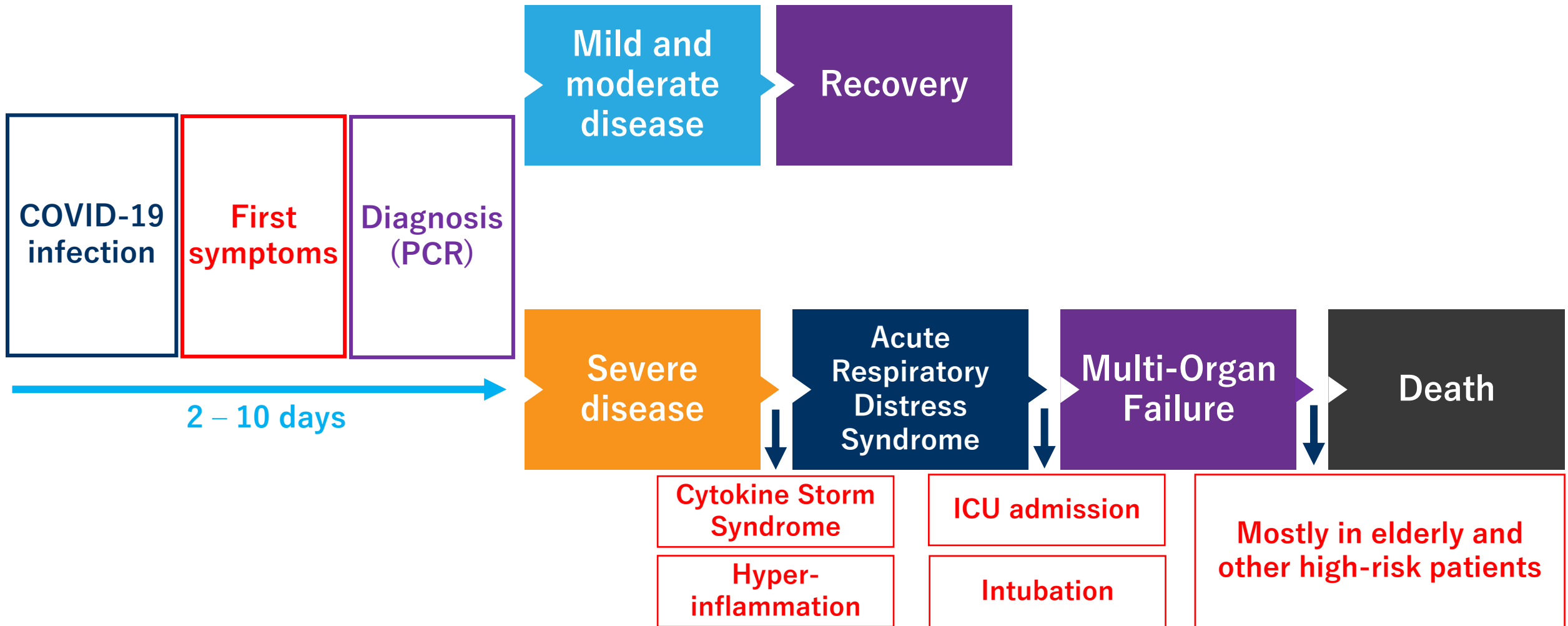


Phase 2b/3 pivotal study planned in app. 900 patients with Crohn's disease – FPI planned for Q2, 2021

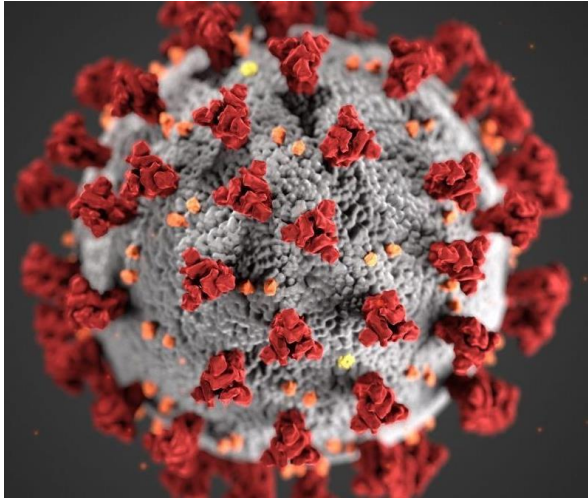


Phase 2b/3 study in COVID-19 ongoing – 1.034 patients in total.
Status: Recruitment in Europe and Brazil ongoing, 102 patients randomized

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

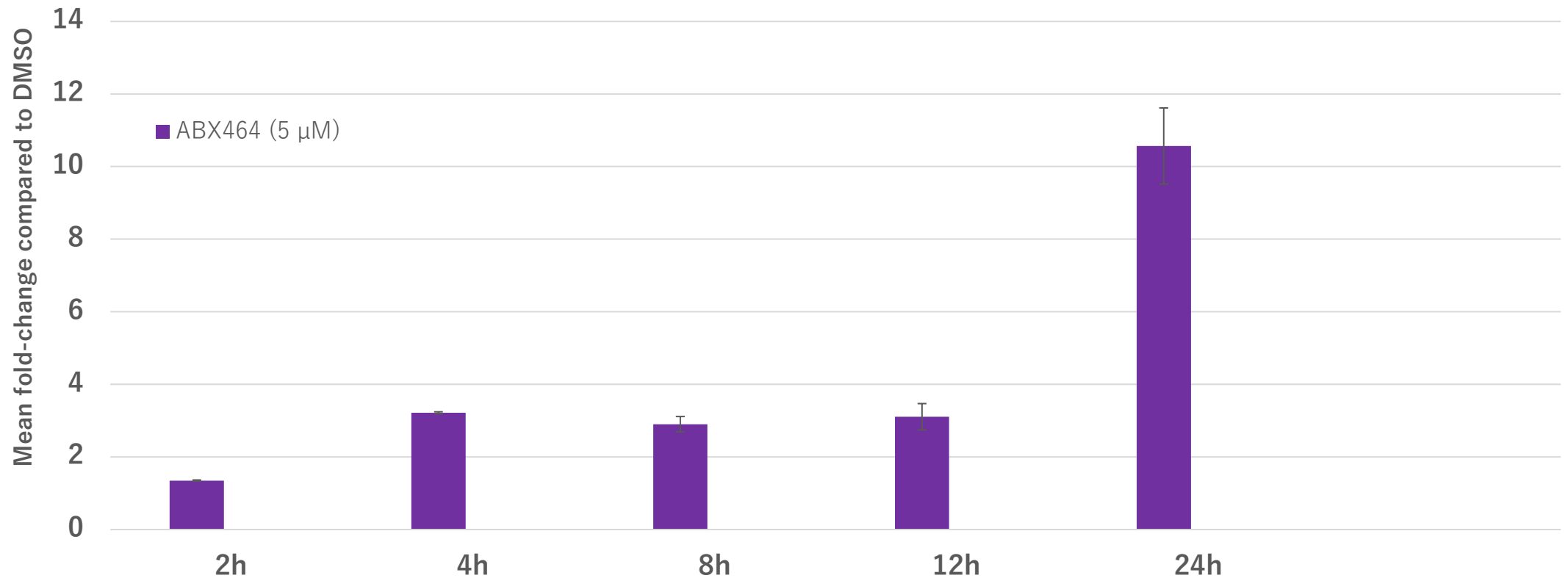
Tissue repair observed in DSS model of inflammatory bowel disease (IBD) and in patients in Phase 2 ulcerative colitis trial

Good safety profile of ABX464 demonstrated in ~375 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-up for commercial production

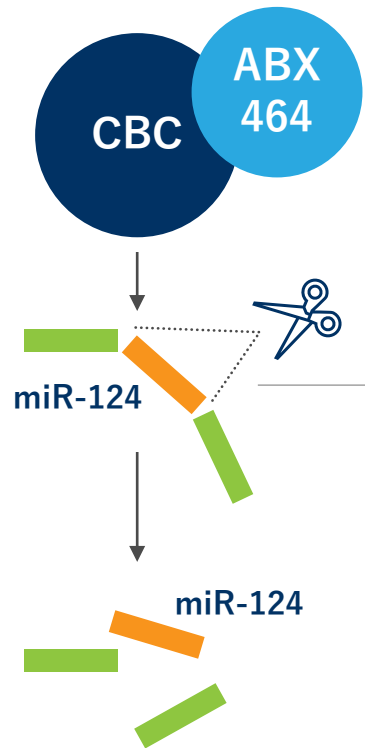
ABX464 rapidly upregulates miR-124 (10-fold) within 24 hours in human PBMCs (*in vitro* results)

miR-124 upregulation vs. time of ABX464 treatment



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

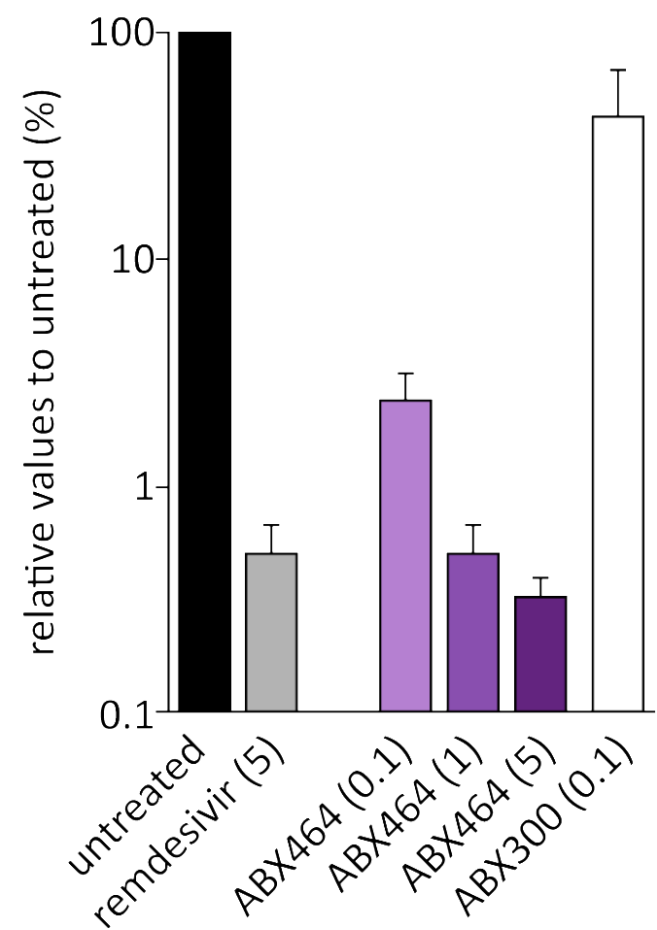
IL-6

TNF- α



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

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%)
- **Interim Analysis** to be performed after first 300 patients have been dosed for 28 days
- **Parexel** selected as CRO; total study costs € 16m

Newsflow 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/3 pivotal (ABX464)					FPI
COVID-19 Phase 2b/3 (ABX464)	FPI 		Completion of enrollment, top-line results & MAA/NDA submission, depend on the dynamics of the pandemic		
HCC Phase 1/2 (ABX196)			Enrollment completed (Dose escalation)	Top-line results Dose escalation phase	

Highly experienced Executive Committee



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Chief Executive Officer
Former Head of Global R&D,
Baxter BioScience

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→ Competencies from discovery to global commercialization