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

Abivax, a late-stage clinical biotech company

**November 19, 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

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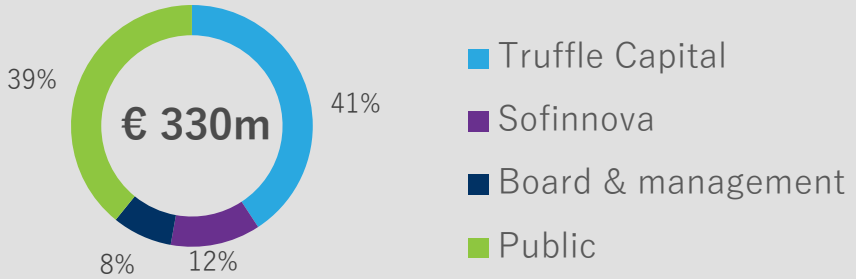
**BREAKING NEWS**

**Abivax receives "Best Technology Award" at the European Mediscience Awards 2020**

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




## Operations

**27** Employees

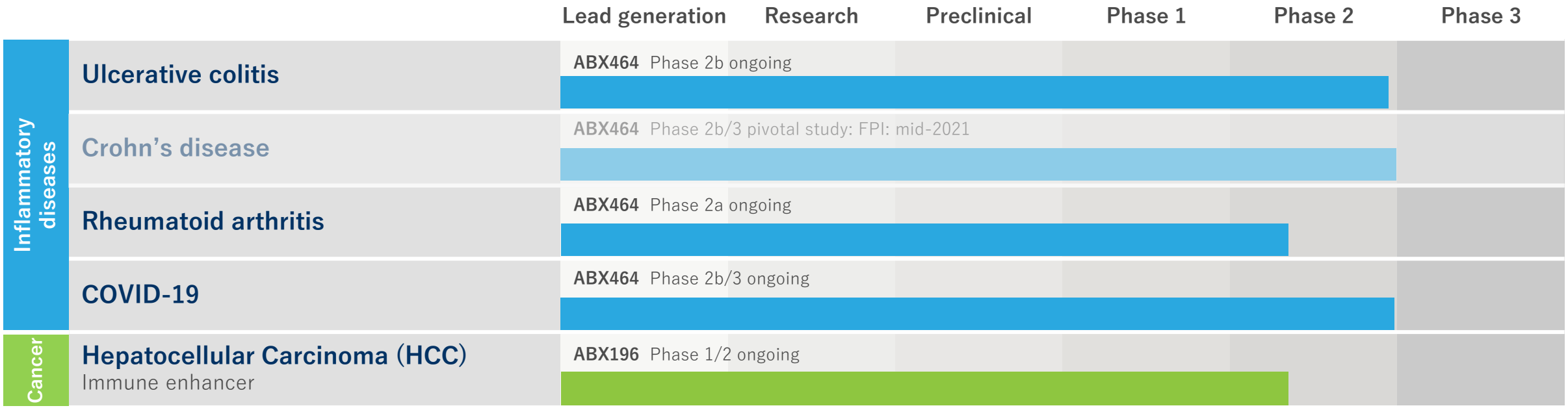
Cash[3] **€ 12.1m**

**21** in R&D

**6** in Support

1) Undiluted – as of 02/11/2020
2) As of 18/11/2020 EOB
3) Actual June 2020

# Abivax: A strong and diversified clinical pipeline



# Financing completed to extend cash runway until Q4 2021

## 2020 Funds Raised

*(As of November 2, 2020)*

- **Bpifrance funding € 36m**
- **Société Générale PGE € 5m**
- **Kreos new funding € 15m**

→ **NEW: € 28m Private Placement towards institutional investors on October 29, 2020**

→ **TOTAL: € 84m in 2020 (€ 56m non-dilutive and € 28m dilutive)**

## Cash Runway Extended Until Q4 2021

- **Financing to be used for:**
  - **ABX464 in ulcerative colitis (UC):** Completion of the Phase 2b induction phase, pursuance of the maintenance phase and preparation of Phase 3
  - **ABX464 in rheumatoid arthritis (RA):** Completion of the Phase 2a induction phase and pursuance of the maintenance phase
  - **ABX464 in COVID-19:** Completion of Phase 2b/3indication and preparation for regulatory filings, market access and commercialization, if clinical data are positive
  - **ABX464 in Crohn's disease (CD):** Preparation of Phase 2b/3
  - **General corporate purposes**

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

# In Focus: October 29, 2020, € 28m institutional private placement (1/2)

## Transaction Overview

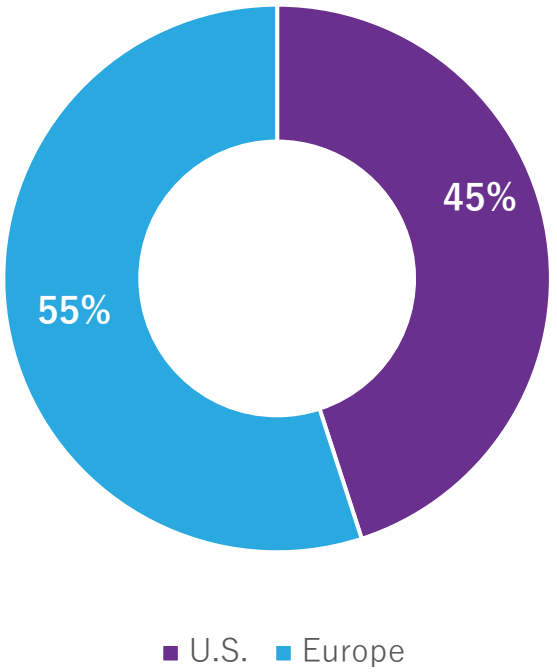
**Widely oversubscribed capital increase at market price, led by Abivax and Bryan, Garnier & Co.:**

- With **high interest coming from multiple geographies (US and Europe)** allowing the Company to select a limited number of 12 high-quality investors
- **€ 28m raised**, representing **11.70% of its share capital** pro-forma for the capital increase
- **Investor allocation selection process** mainly driven by Abivax's objective to bring in **biotech-specialized and renowned investors** into the Company's share capital
- Given **strong demand**, Abivax, advised by Bryan, Garnier & Co., opted for a **club deal** in order **to foster investment of large institutions**
- **Subscribed at market price** (no discount on October 28, 2020 closing price on Euronext Paris) despite challenging market conditions (Healthcare and small- and mid-caps indexes fell by 10% over the 5 days prior to pricing)
- **Since 2015, Abivax is the only company in the healthcare sector to execute a capital raise on Euronext Paris without share price discount**

# In Focus: October 29, 2020, € 28m institutional private placement (2/2)

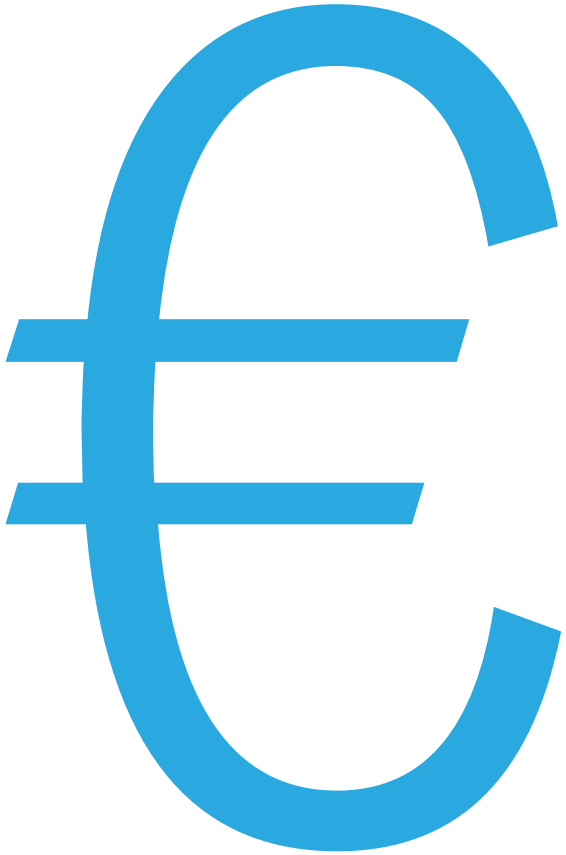
## Allocation

- **Subscribed by top-tier U.S. and European biotech investors** including[(1)]:
  - **Perceptive** (US)
  - **Life Science Partners** (the Netherlands)
  - **Invus** Public Equities (US / France)
  - **Sofinnova** Partners (Europe)
- The Funds of **Truffle Capital** remain the largest shareholder with 40.61%.




(1) Investors mentionned represent 71% of total raise

# 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

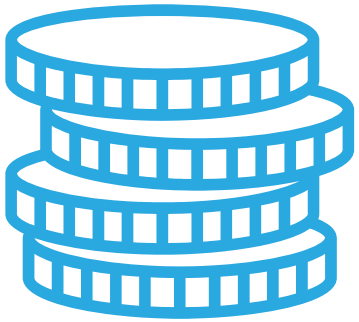
| Year 1 | Years 2 and 3 | Years 4 and 5 |
|---|---|---|
| • 8% interest rate<br>• No transaction fees<br>• Repayment of remaining capital only | • 9.75% interest rate<br>• 2% transaction fees<br>• Repayment of remaining capital +4%/year penalty | • 9.75% interest rate<br>• 4% transaction fees<br>• Repayment 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 | 11/11/2020 | € 50.00 | Buy |
| Kepler Cheuvreux | France | 25/09/2020 | € 40.00 | Buy |
| LifeSci Capital Alpha Series | US | 14/05/2020 | € 41.00 | Buy |
| Portzamparc | France | 30/10/2020 | € 27.50 | Buy |
| General recommendation: Buy | | Average target price: € 37.50 | | |

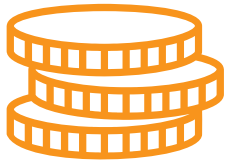
For full access to the reports, please directly contact the respective analysts listed on Abivax's website.

# 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** (>2,200 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 **~400 patients and volunteers**

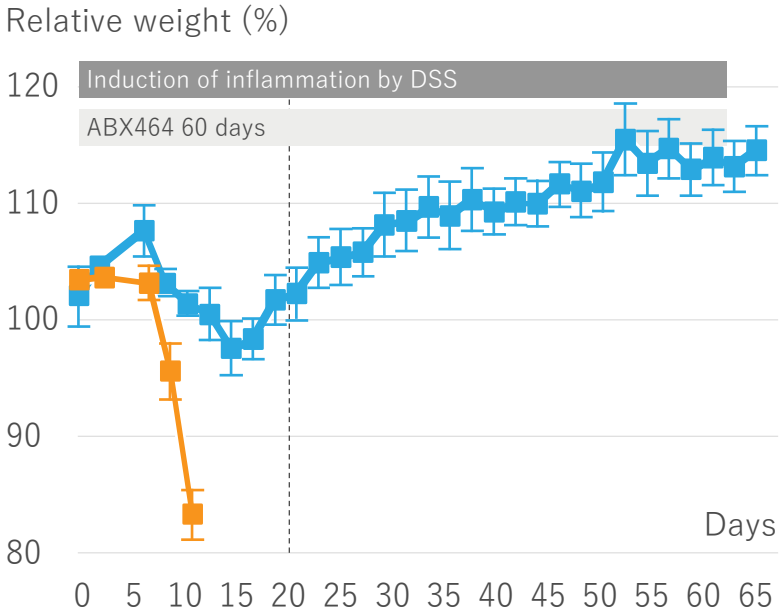
**Anti-inflammatory effect** confirmed in DSS mouse model of IBD as well as in Phase 2a induction and maintenance studies in ulcerative colitis. Phase 2b study in UC ongoing in 232 Patients, as well as Phase 2a in rheumatoid arthritis in 60 patients

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

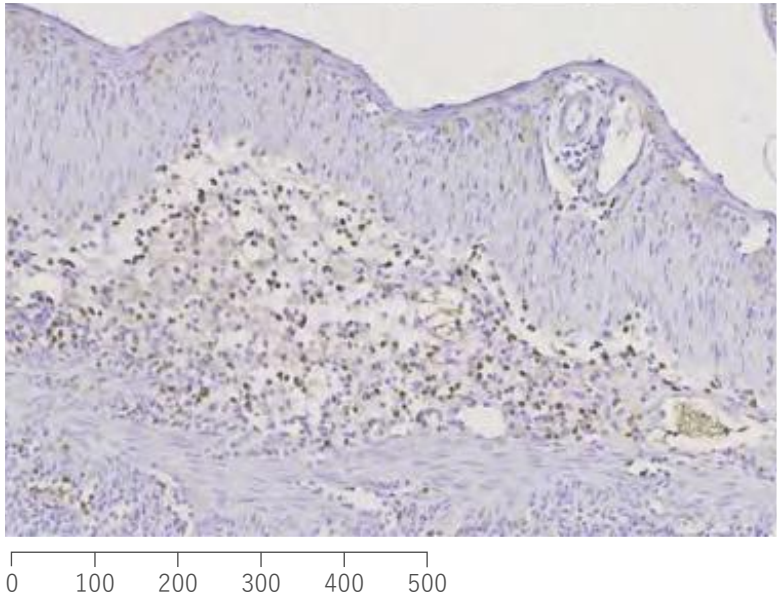
* For Europe G5, U.S. and Japan

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

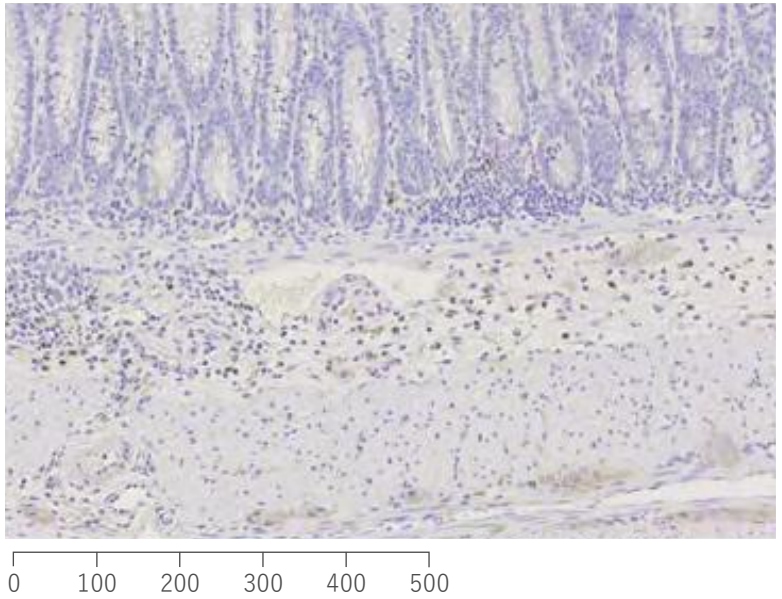
## ABX464 protects mice from death in the DSS mouse model




## 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**

**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)**
Two years completed, with 16 patients on continued treatment in 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** (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

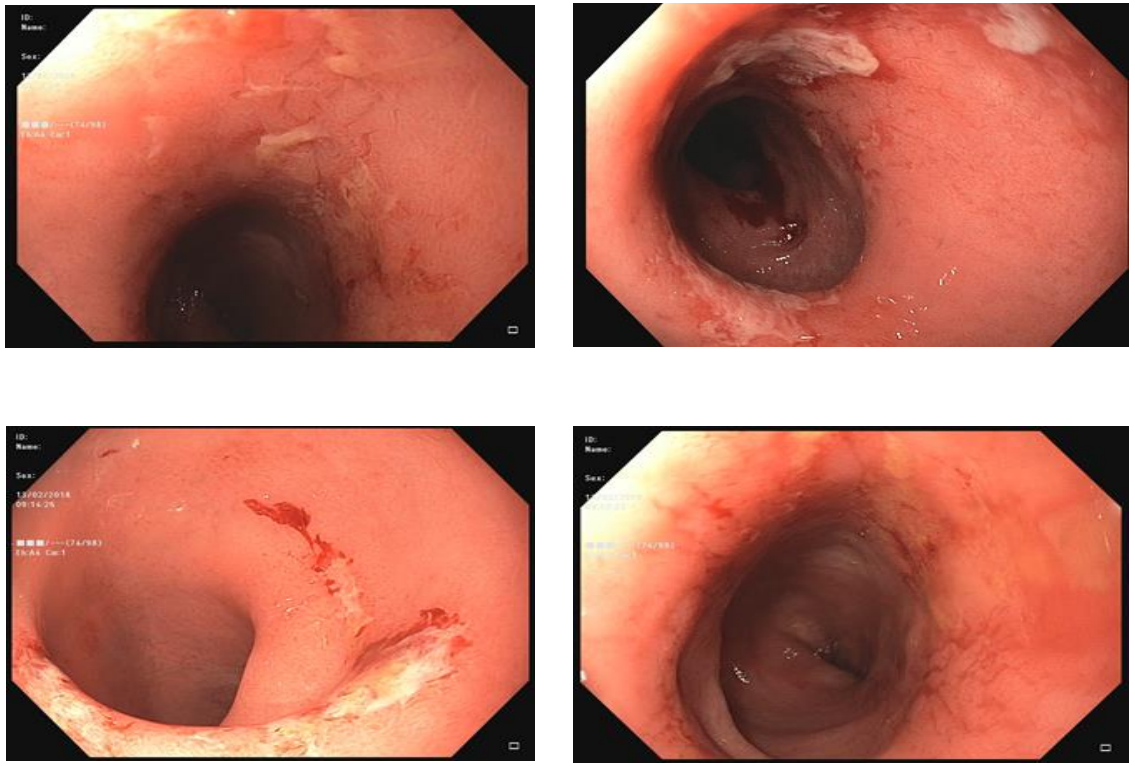
| | **ABX464 (n=20/23)** PP/ITT | **Placebo (n=9/9)** PP/ITT | **p value** (PP) |
|---|---|---|---|
| Clinical remission* | 35%/30% | 11%/11% | 0.16 |
| Endoscopic improvement | 50%/43% | 11%/11% | **0.03** |
| Clinical response | 70%/61% | 33%/33% | 0.06 |
| Total Mayo Score reduction | -53% | -27% | **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

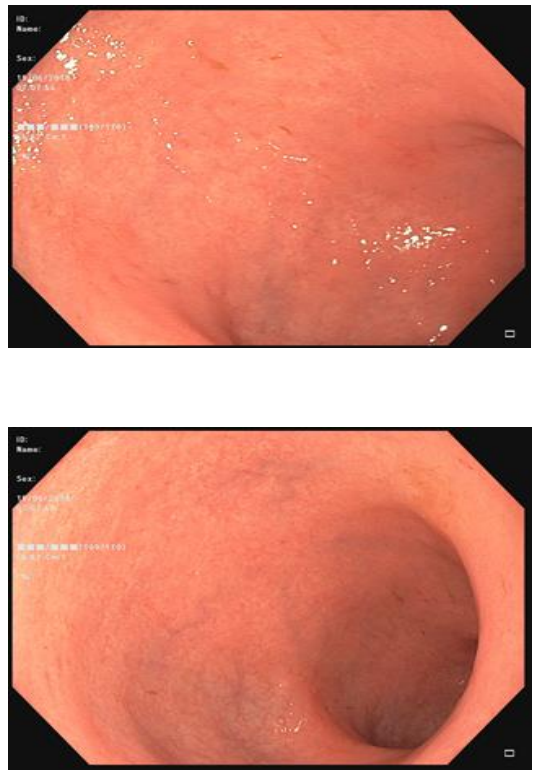
# Tissue repair in an ABX464 treated UC patient

## Courtesy of Prof. Severine Vermeire

### Before ABX464



### After ABX464

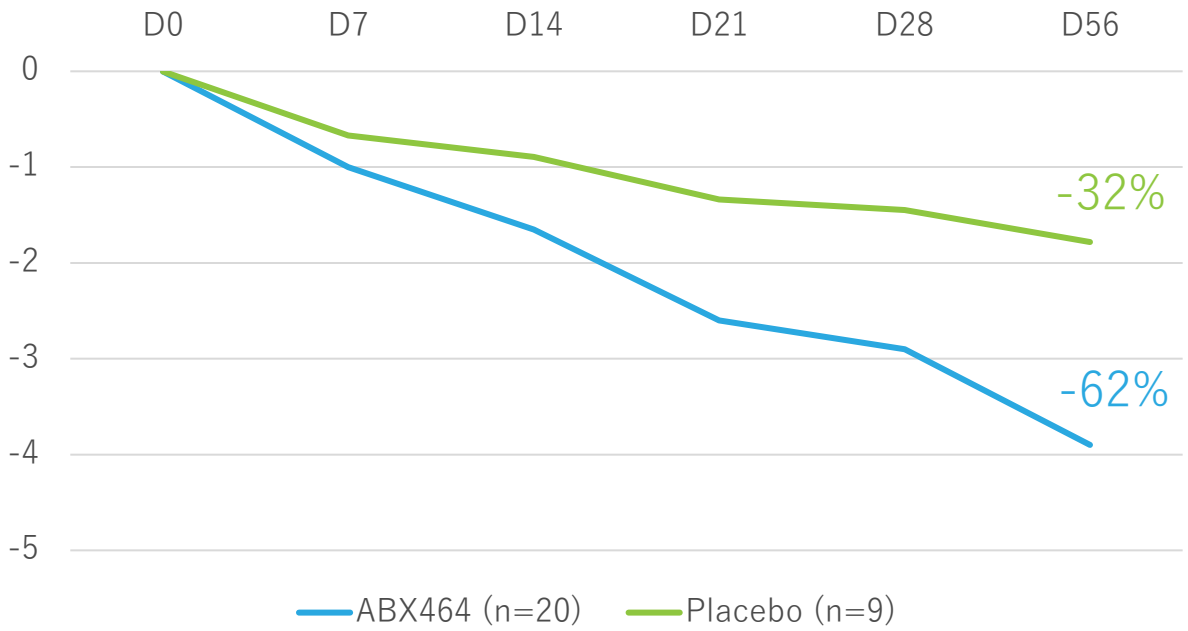


# ABX464-101 Partial Mayo Score Results

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

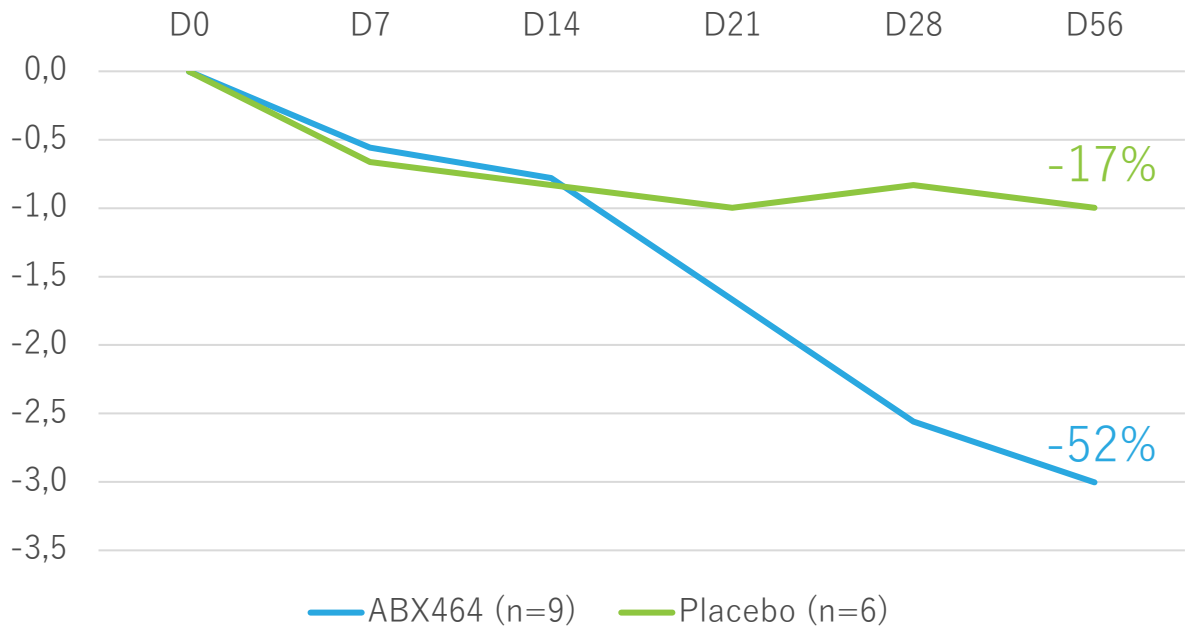
**Overall Patient Population**

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.**

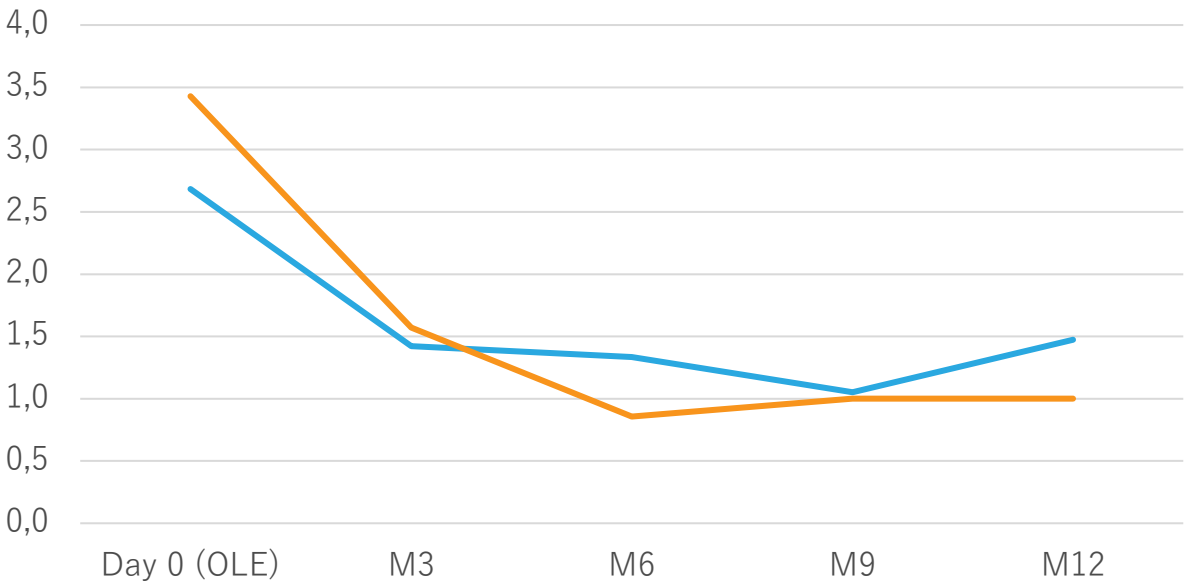
| | Day 0 Maintenance | Month 12 | Month 24 |
|---|---|---|---|
| **Clinical remission** (TMS including endoscopy) | 6/19 (31.6%) | 12/16* (75.0%) | 11/16 (68.8%) |
| **Clinical response** | 14/19 (73.7%) | 15/16* (93.8%) | 15/16 (93.8%) |

* 16 out of 19 patients had endoscopy

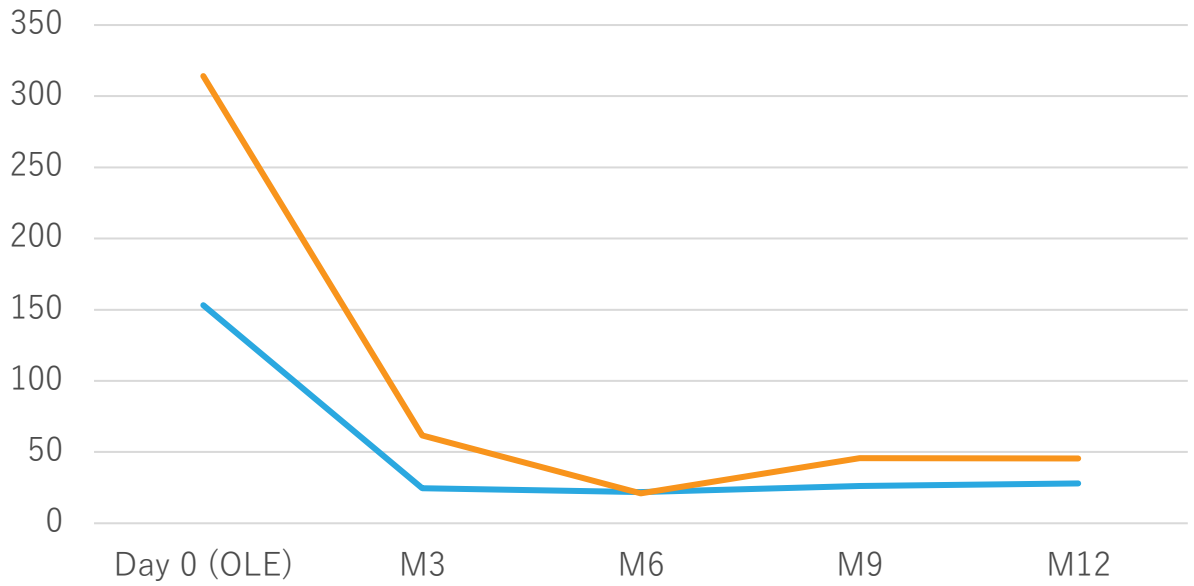
**As of October 21, 2020, all ongoing ABX464-102 patients (N=15) have completed at least 27 months of continuous daily treatment with ABX464, with the longest treated patient being on product for 35 months.**

# 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 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 )**

**Median fecal calprotectin remained in normal range after two years (31.6 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 |
| 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. 400 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
- Top-line data for induction phase expected for Q2, 2021

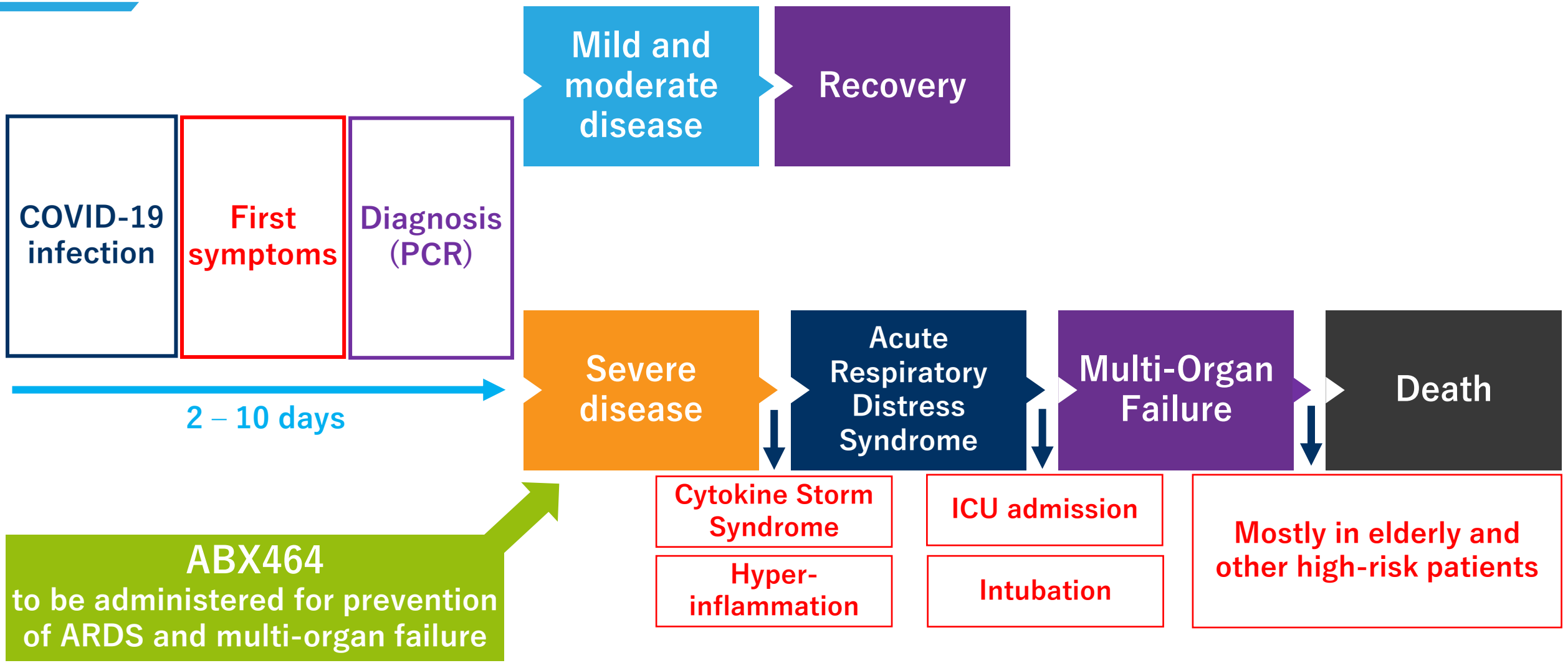
→ **Phase 2b study in 232 patients with moderate to severe ulcerative colitis is currently ongoing in Canada and Europe and the US (with FDA clearance of IND on 19/01/20). Recruitment to be completed before year end.**

→ **Phase 2b/3 pivotal study planned in app. 900 patients with Crohn's disease – FPI planned for mid-2021**

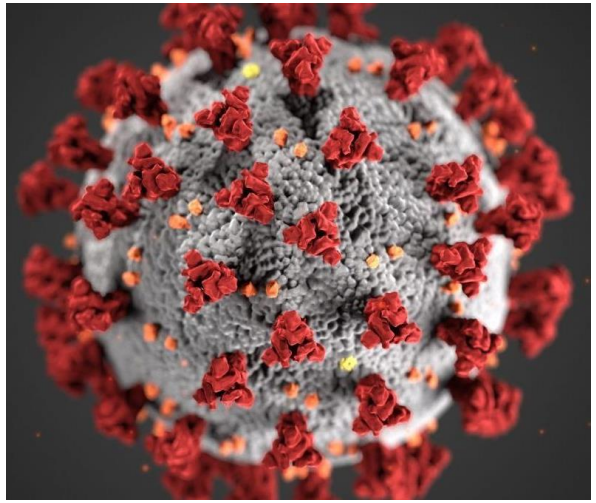
→ **Phase 2a study ongoing in 60 patients with rheumatoid arthritis in 5 European countries. Recruitment to be completed before year end.**

→ **Phase 2b/3 study in COVID-19 ongoing – 1.034 patients in total. Recruitment to be completed in Q1 2021, dependent on the dynamics of the pandemic.**

# COVID-19 infection and pathology

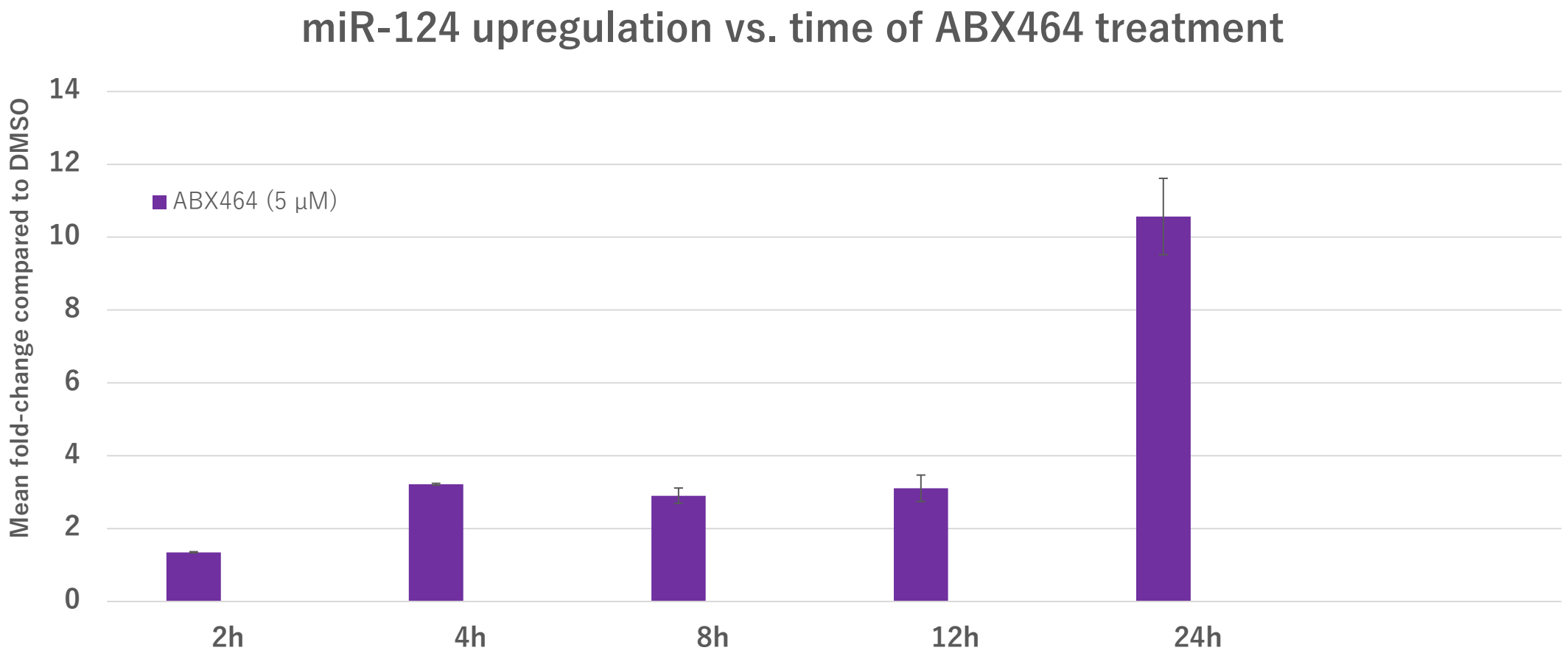


# ABX464 COVID-19 Development Rationale



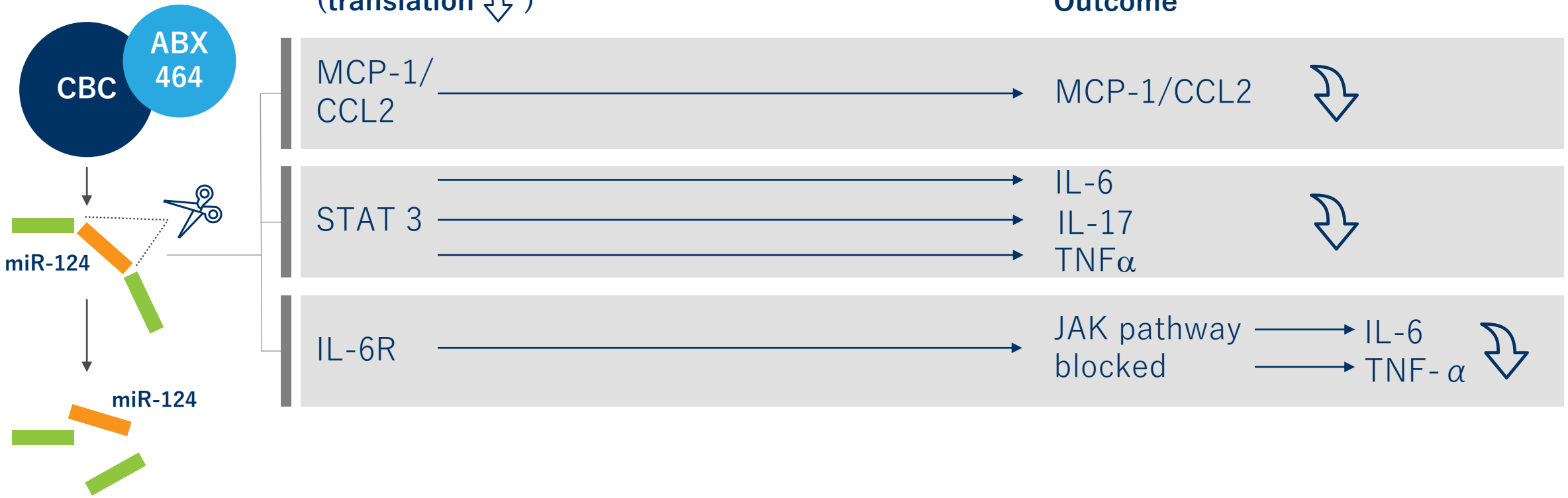
- **Antiviral:** ABX464 inhibits SARS-CoV-2 (COVID-19 virus) *in vitro* replication in human respiratory epithelium: Inhibition of COVID-19 viral replication comparable to Remdesivir
- **Anti-inflammatory:** ABX464 has demonstrated potent anti-inflammatory properties in several *in-vivo* models and in 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 ~400 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)



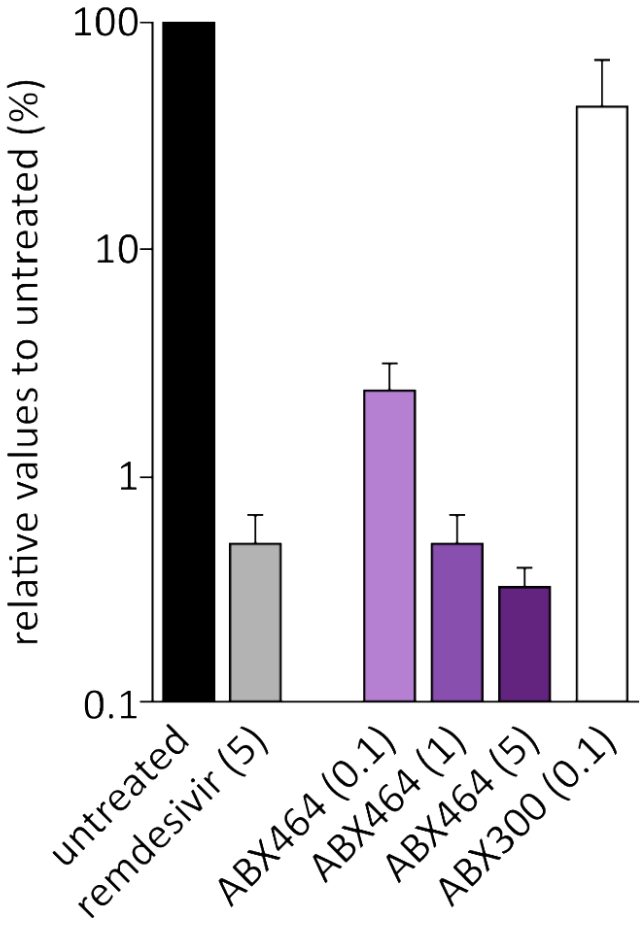
# ABX464 novel mechanism of action: Potent and specific upregulation of miR-124 leads to reduction of pro-inflammatory cytokines

## Both systemic and local inflammatory sites



# 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** ✓ | | **Interim analysis, completion of enrollment, top-line results & MAA/NDA submission, dependent on the dynamics of the pandemic** | | |
| **HCC** Phase 1/2 (ABX196) | | | **Enrollment completed** (Dose escalation) | **Top-line results Dose escalation phase** | |

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Chief Executive Officer

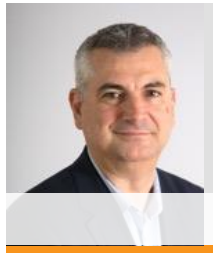
Former Head of Global R&D, Baxter BioScience

Baxter · SANDOZ · Lilly

**Didier Blondel**

Chief Financial Officer & Board Secretary

SANOFI · sanofi pasteur MSD vaccines for life



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iMaxio · LYONBIOPOLE

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