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

Abivax, a late-stage clinical biotech company

February, 2021

abivax

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Abivax in a nutshell: A phase 3 biotech

Milestones

Founded in 2013 by Truffle Capital

IPO (ABVX) on Euronext Paris in June 2015, raising € 57.7m

Sept. 2018: Focus ABX464 on chronic inflammation

May 2020: ABX464 to prevent severe Covid-19 disease

Location

Head Office
Paris

Cooperative Lab with CNRS
Montpellier

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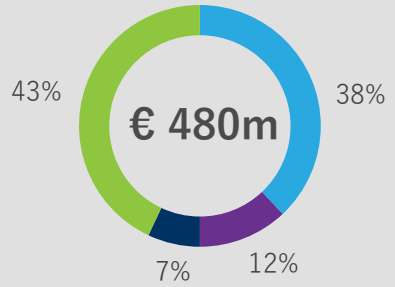
Shareholder structure[1] and market cap[2]



- Truffle Capital
- Sofinnova
- Board & management
- Public

Operations

27
Employees

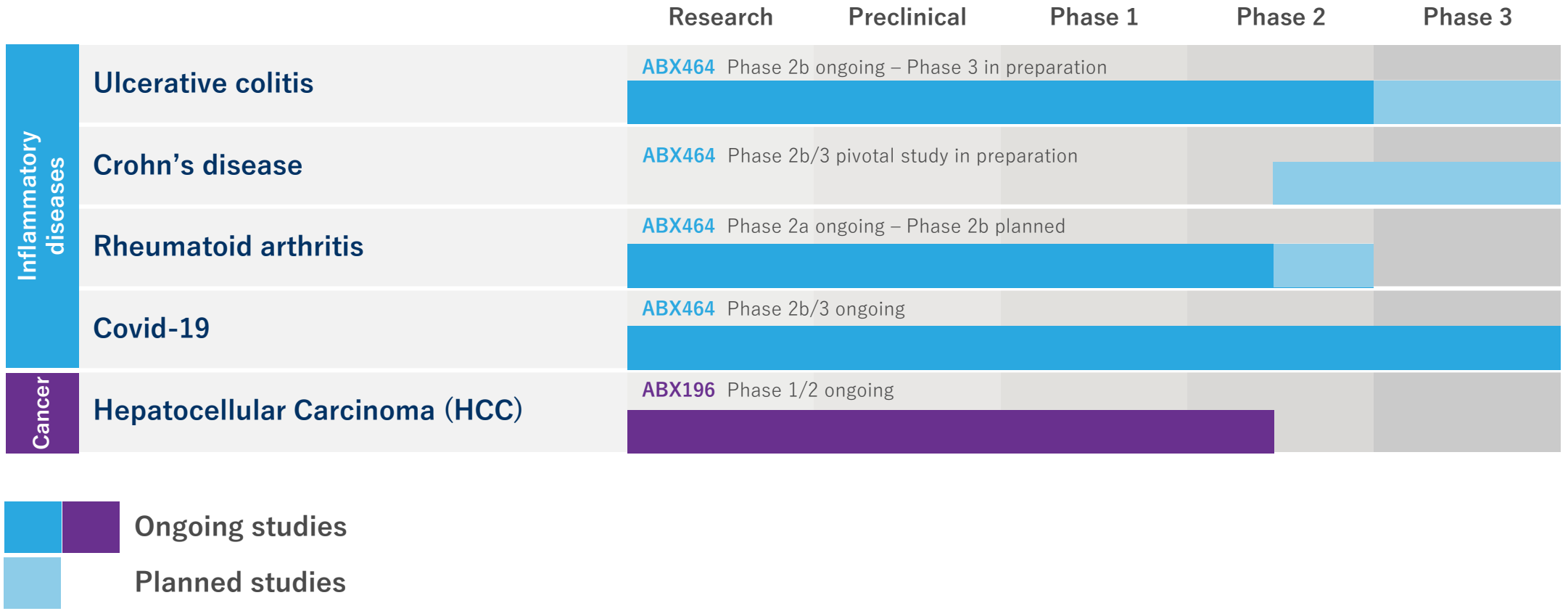
Cash[3]
€ 29.3m
Cash runway until Q4 2021

Key R&D and manufacturing partners

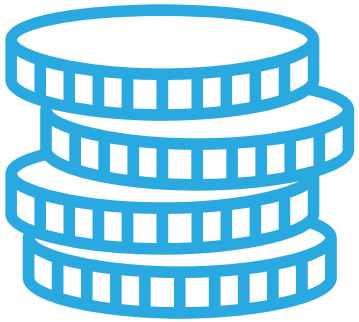
IQVIA · parexel BIOTECH · SEQENS · DELPHARM · evotec

1) Undiluted – as of 31/01/2021
2) As of 13/01/2021 noon (Share price EUR 33.55 | Outstanding shares 14.3m)
3) December 2020 estimate

Abivax: A late-stage biotech with a strong and diversified clinical pipeline addressing major medical needs and markets

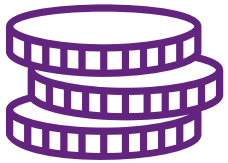


ABX464: A promising candidate addressing large unmet medical needs



Total market size* in inflammatory diseases

greater than
USD 90 B



Market size* in ulcerative colitis

around
USD 6.1 B**

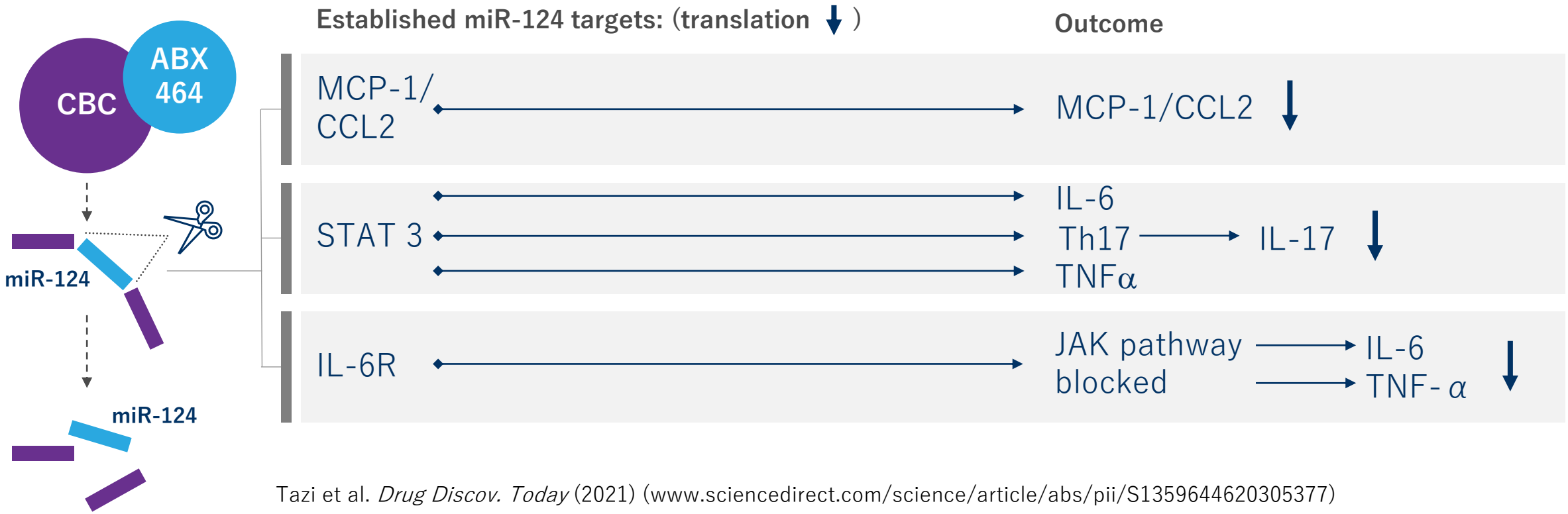
* 2019 data for Europe G5, U.S. and Japan
** 1st, 2nd and 3rd line

Source: Informa

- Coming from the **proprietary Abivax library of compounds**, designed to **modulate RNA biogenesis** (>2,200 molecules); Collaboration with EVOTEC
- **Small molecule**, administered as an **oral capsule** (once a day) ABX464 tablet form under development
- **First-in-Class, novel mechanism of action:** Selective upregulation of anti-inflammatory microRNA, miR-124
- **Good safety profile** after administration to >**750 patients and volunteers**
- **Strong anti-inflammatory effect** confirmed in phase 2a studies in ulcerative colitis
- **Antiviral effect** ABX464 inhibits SARS-CoV-2 *in vitro* replication in human respiratory epithelium: Inhibition of Covid-19 viral replication comparable to Remdesivir
- **High unmet medical need and commercial opportunities** for novel safe and efficacious drugs for inflammatory diseases as well as Covid-19

ABX464 novel mechanism of action: Potent and specific upregulation of miR-124, activating a “physiological brake” of inflammation

- **First-in-class mechanism of action related to intracellular upregulation of miR-124.**
- **microRNAs work by down-regulating the translation of their respective target genes.**



Tazi et al. *Drug Discov. Today* (2021) (www.sciencedirect.com/science/article/abs/pii/S1359644620305377)

Poholek et al. *J Exp Med* (2020) 217 (10): e20191761

ABX464 phase 2a POC induction study in ulcerative colitis: Impressive efficacy achieved for all endpoints (day 56)

Study Design:

PI: Prof. Severine Vermeire, Leuven, BE

32 patients with moderate to severe UC: randomized (2:1), double blind, placebo controlled study

Active and placebo groups well balanced re demographics

8-weeks treatment

Moderate to severe UC patients who failed/were intolerant to immunomodulation/steroids (50%) and/or biologics (50%)

Central blinded reading of endoscopies (induction, 2nd and 3rd year maintenance)

Followed by open-label maintenance study (now in 4th year)

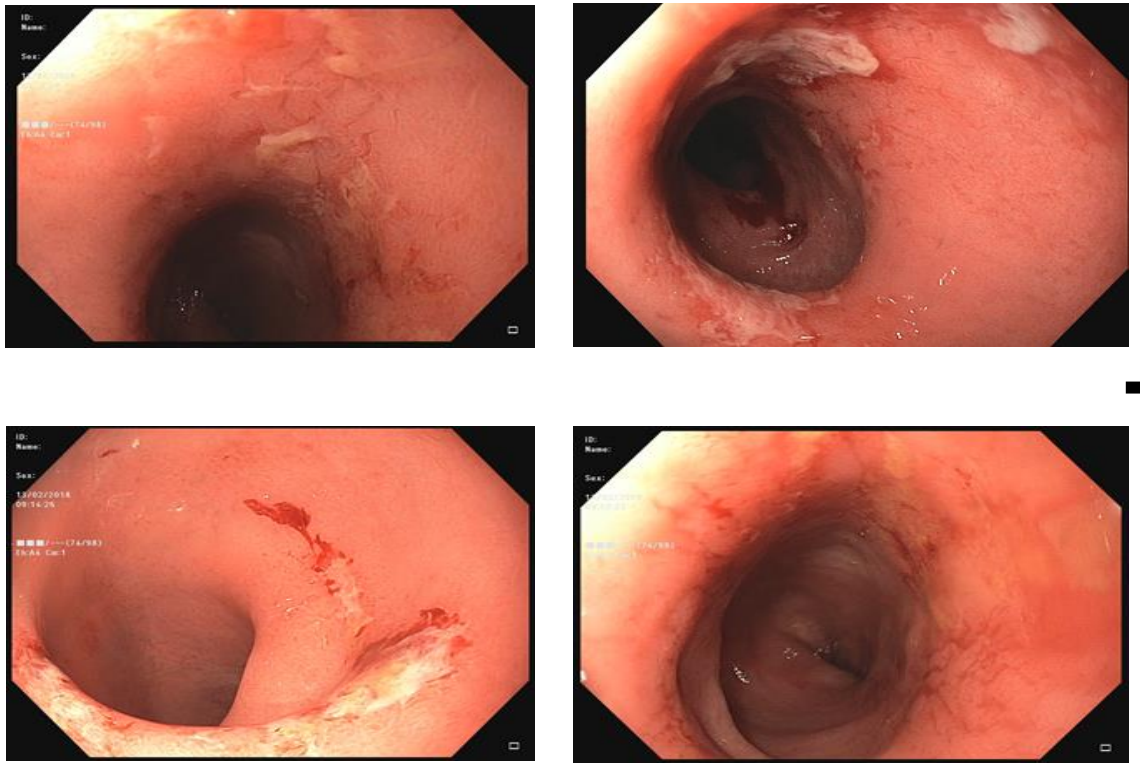
	ABX464 (n=20/23) PP/ITT**	Placebo (n=9/9) PP/ITT	p value (PP)
Clinical remission*	35%/30%	11%/11%	0.16
Endoscopic improvement	50%/43%	11%/11%	0.03
Clinical response	70%/61%	33%/33%	0.06
Total Mayo Score reduction	-53%	-27%	0.03
Partial Mayo Score reduction	-62%	-32%	0.02
miR-124 expression in rectal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

** PP: Per protocol / ITT: Intent to treat

Complete resolution of UC lesions in an ABX464 treated (vedolizumab, infliximab and adalimumab resistant) patient

Endoscopy before ABX464



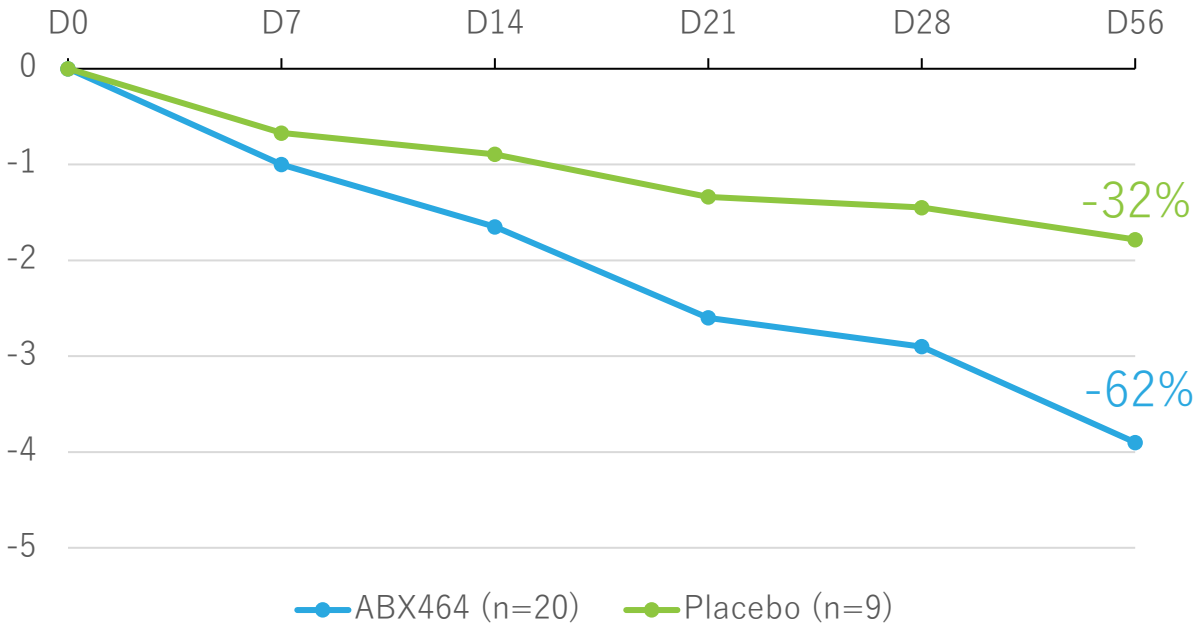
Endoscopy after ABX464

Courtesy of Prof. Severine Vermeire, Leuven, Belgium

ABX464 phase 2a UC induction study: Fast onset of action and comparable efficacy in both biologics naïve and refractory patients

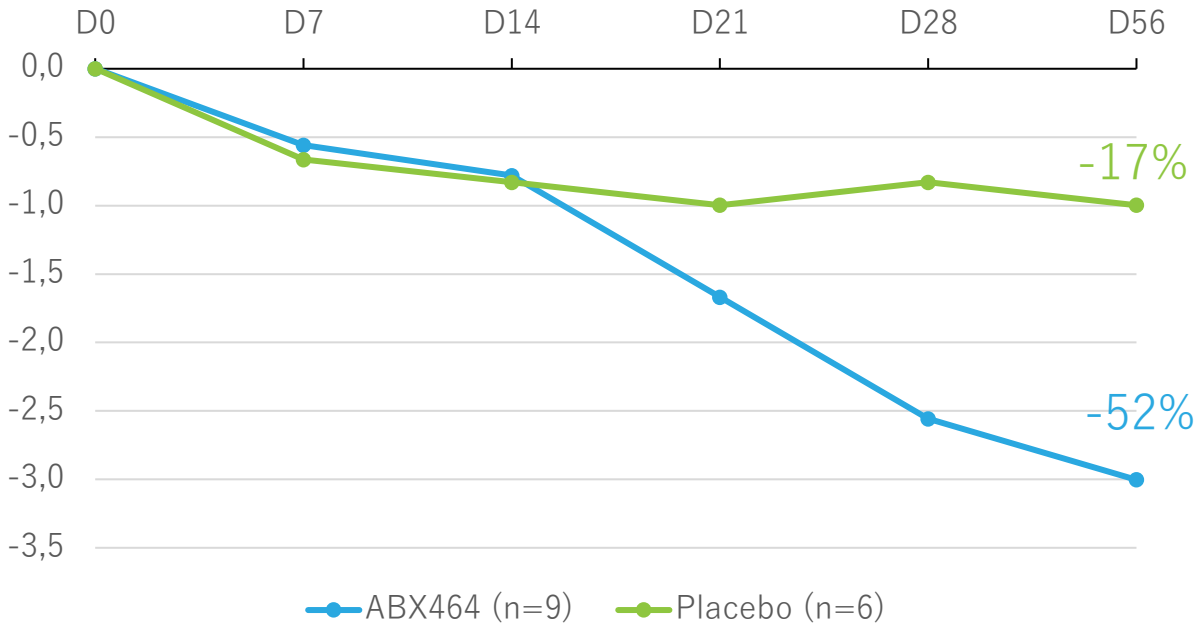
Overall Patient Population

Change from Baseline Partial Mayo Score



Patients previously treated with biologics

Change from Baseline Partial Mayo Score



Confirmed durable and improved long-term efficacy in UC maintenance study: Several patients in 4th year of ABX464 continuous treatment

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 out of 22 patients completed first year

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

	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 January 13, 2021, all ongoing phase 2a maintenance patients (N=15) have completed at least 29 months of continuous daily treatment with ABX464, with the longest treated patient being on ABX464 for over 37 months.

ABX464, Entyvio® and Xeljanz® efficacy in UC induction and maintenance clinical trials

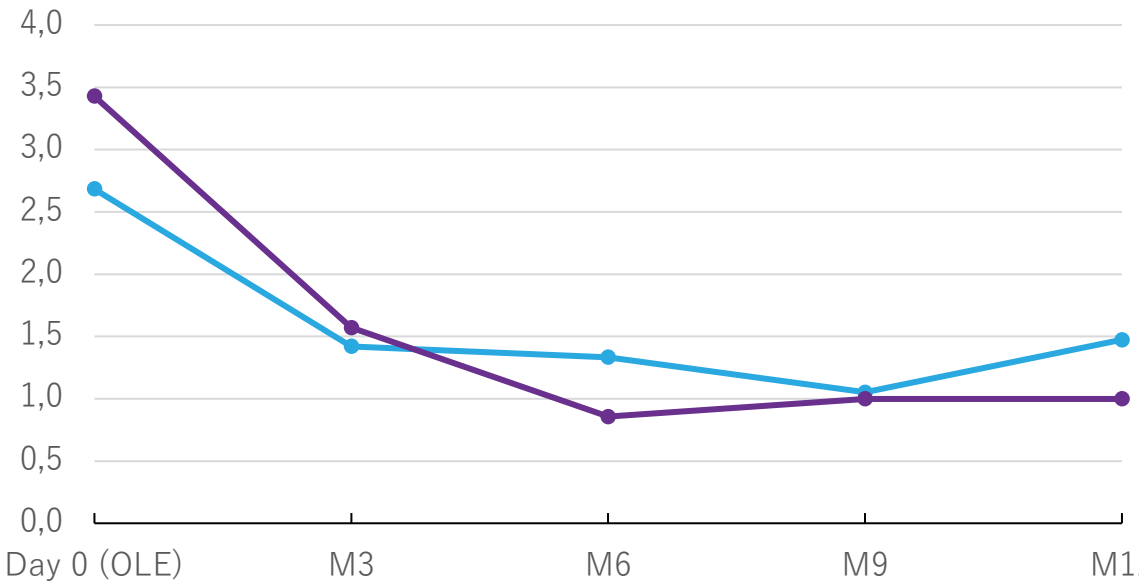
	Vedoluzimab* Phase 3			Tofacitinib** Phase 3			ABX464 Phase 2a		
Post Induction	**Active**	**Placebo**	**Delta**	**Active**	**Placebo**	**Delta**	**Active**	**Placebo**	**Delta**
Clinical Remission (%)	16.9	5.4	11.5	16.8-18.5	3.6-8.2	13.2-10.3	35	11	24
Endoscopic improvement (%)	40.9	24.8	16.1	28.4-31.3	11.6-15.6	16.8-15.7	50	11	39
Post 1st Year Maintenance									
Clinical Remission (%)	41.8	15.9	25.9	34.3-40.6	11.1	23.2-29.5	75		
Endoscopic improvement (%)	51.6	19.8	31.8	37.4-45.7	13.1	24.3-32.6	100		

ABX464 phase 2a maintenance study allowed all patients irrespective of treatment assignment or response during induction to be included.

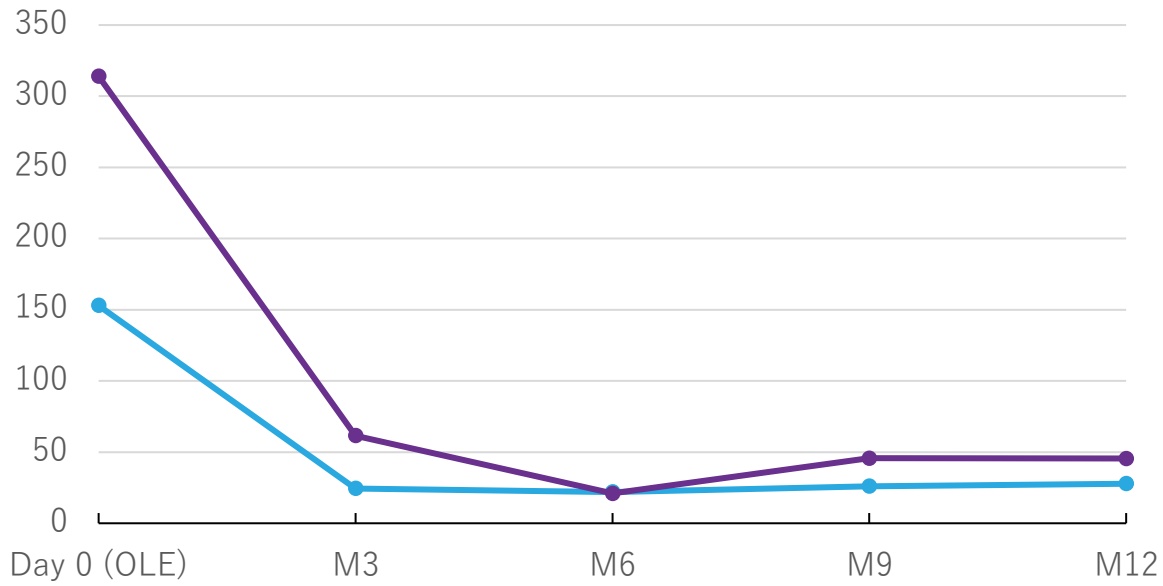
* Feagan et al. Vedolizumab as induction and maintenance therapy for ulcerative colitis. N Engl J Med 2013;369:699-710
** Sandborn et al. Tofacitinib as Induction and Maintenance Therapy for Ulcerative Colitis. N Engl J Med 2017;376:1723-36

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).

Completed studies: Favorable ABX464 Safety Profile

Common (> 5%) adverse events (cut-off date Nov. 30, 2020)

System Organ Class	Adverse effect	ABX464 (50mg QD) (N=115 subjects)		ABX464 (All doses) (N=203 subjects)		Placebo (N=33 subjects)	
		Number of reports	n (%) of pts with TEAE (Incidence)	Number of reports	n (%) of pts with TEAE (Incidence)	Number of reports	n (%) of pts with TEAE (Incidence)
Nervous system disorders	Headache	49	35 (30.4)	115	83 (40.9)	6	4 (12.1)
Gastrointestinal Disorders	Abdominal pain	6	6 (5.2)	15	13 (6.4)	1	1 (3.0)
	Abdominal pain (upper)	9	7 (6.1)	34	16 (7.9)	0	0
	Diarrhea	5	4 (3.5)	15	10 (4.9)	4	3 (9.1)
	Nausea	13	9 (7.8)	47	35 (17.2)	3	2 (6.1)
	Vomiting	11	7 (6.1)	37	26 (12.8)	0	0
Musculoskeletal and Connective Tissue Disorders	Arthralgia	4	4 (3.5)	12	10 (4.9)	1	1 (3.0)
	Back Pain	4	4 (3.5)	24	19 (9.4)	1	1 (3.0)

Most frequently reported adverse events are transient and mild (headache, nausea, gastrointestinal pain)

Similar AE profile in non completed studies (> 500 patients) across various indications

No new type of AE in long term maintenance studies with chronic ABX464 treatment up to 37 months

No clinically meaningful changes in laboratory parameters (LFTs, Hb, lymphocytes, neutrophils, etc.)

No increased incidence of infections

How to bring ABX464 to the finish line

Ulcerative colitis Phase 2b ongoing:

- Enrollment completed with 254 patients in 15 European countries, US and Canada in 130+ study sites
- 4 study arms (placebo, 25, 50, 100 mg QD)
- Central blinded reading of endoscopies
- Conducted with IQVIA as CRO
- Top-line data for induction phase and initial maintenance data in **Q2 2021**
- 1st year maintenance data expected in **Q1 2022**

Ulcerative colitis Phase 3 in preparation:

- End of Phase 2b meeting planned for **Q3 2021**
- FPI planned for **Q4 2021**

Crohn's disease Phase 2b/3 pivotal study in preparation:

- 900 patients
- FPI expected for **Q3 2021**

Rheumatoid arthritis Phase 2a study ongoing:

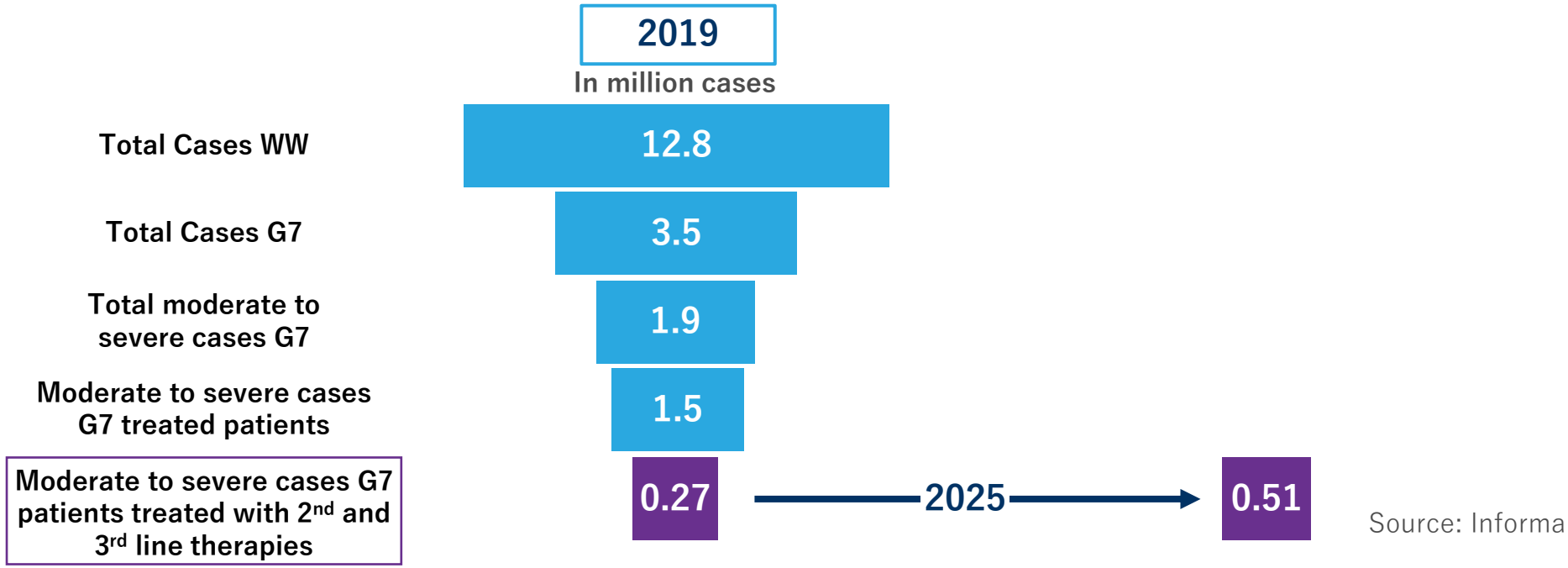
- Enrollment completed (60 patients in 5 European countries)
- Top-line data for induction phase in **Q2 2021**
- Phase 2b study planned for **Q4 2021**

Covid-19 Phase 2b/3 study ongoing:

- 1,034 patients
- Recruitment to be completed in **Q1 2021**, dependent on the dynamics of the pandemic
- Top-line data in **Q2 2021**

ABX464: A future blockbuster in IBD
Size of targeted market doubling in UC and increasing by 34% in CD (2019 - 2025)

UC Epidemiology



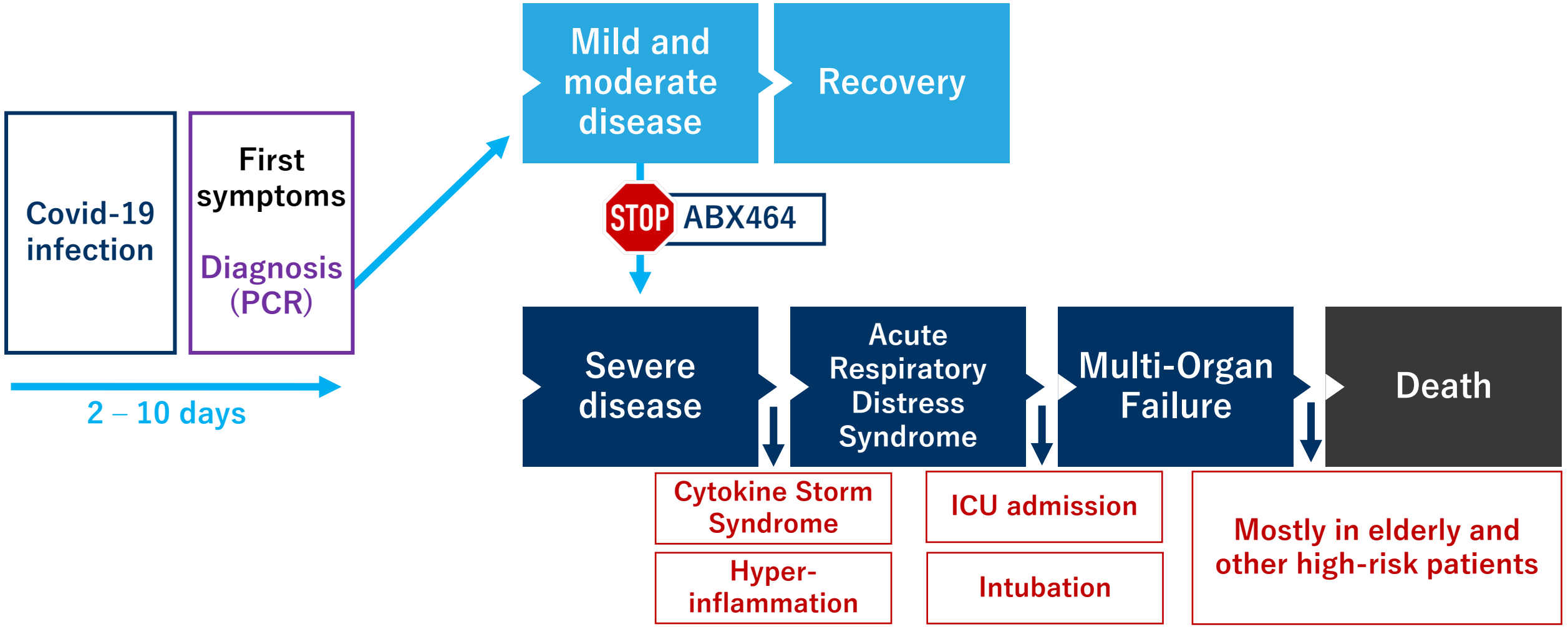
Source: Informa

UC & CD Market Potential

	Ulcerative Colitis	Crohn's Disease
ABX464 TPP	Patients with moderate to severe UC and CD who failed on first line therapy Therefore, positioned as 2nd and 3rd line treatment	
ABX464 First Launch	2025 for UC	2026 for CD
G7 Market Size (2nd & 3rd line)	2019: USD 5.1 B for UC 2025: USD 11.2 B for UC	2019: USD 10.7 B for CD 2025: USD 14.3 B for CD
ABX464 Market Share Assumptions	10-20% market share at peak sales for both indications	

Covid-19 infection and pathology

ABX464 to be administered to prevent severe disease and death in high-risk patients



ABX464 miR-AGE phase 2b/3 clinical trial: Fully powered and placebo controlled to establish safety and efficacy in preventing severe Covid-19 disease

Main objective	Early treatment of high-risk Covid-19 patients to prevent excessive inflammation and acute respiratory failure / death
Inclusion criteria	Patients aged ≥65 and aged ≥18 with at least one additional risk factor who are infected with SARS-CoV-2
Primary endpoint	Absence of high-flow oxygen (>3 l/min), assisted ventilation (positive pressure or intubation) and/or death after 28 days
Key design features	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

Preparation for marketing authorization in 2021 (regulatory, manufacturing, commercial) ongoing, should study results be positive.

miR-AGE: Quo vadis

- Top line data expected for Q2 2021
- Submission to be supported on primary endpoint or subject to data and regulatory discussions on secondary endpoints
- If ABX464 proves to be efficacious against the original SARS-CoV-2 virus, it is likely to be efficacious against emerging mutant viruses
- Subsequent submission of EUA or MAA in target geographies
- Ongoing dialog with French regulatory authority ANSM
- Initial discussions with the French government
- First sales expected in 2021

ABX196: An iNKT agonist for the treatment of liver cancer

Licensed from Scripps Research, University of Chicago, Brigham-Young University

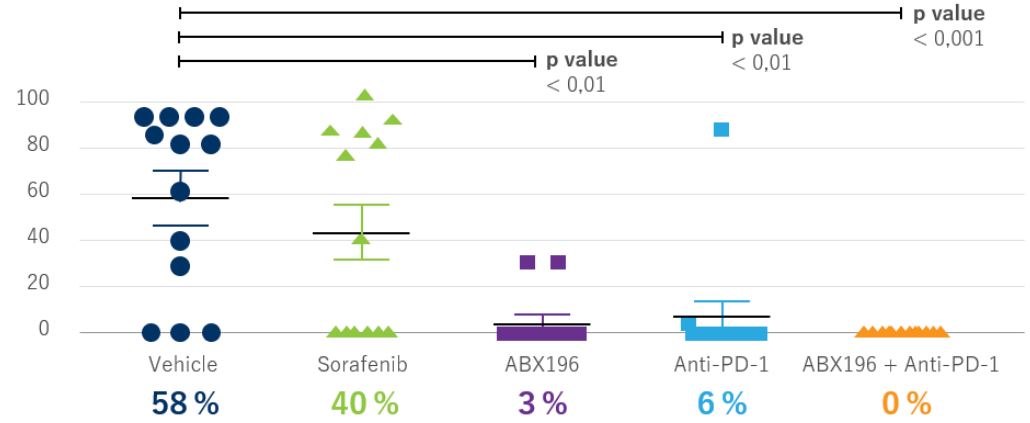
Synthetic glycolipid agonist of iNKT (invariant Natural Killer T) cells in liposomal formulation

Strong preclinical data in liver cancer and melanoma

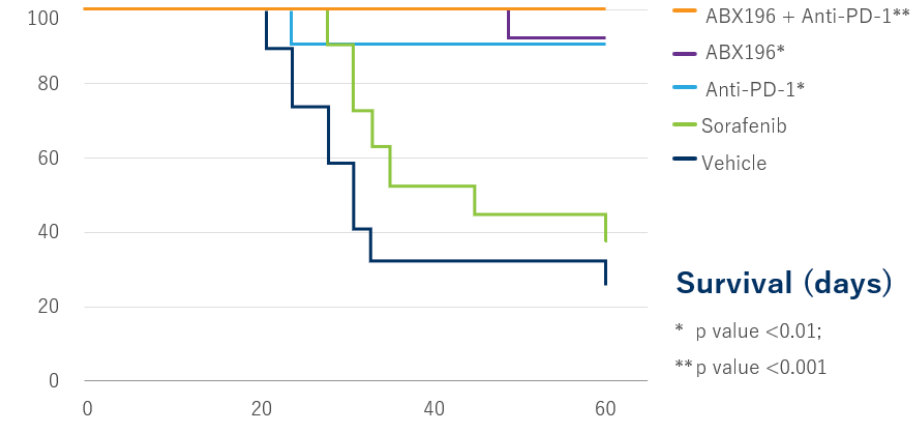
Phase 1 completed in volunteers: ABX196 was safe and well tolerated, and triggered both humoral and iNKT responses

Phase 1/2 dose escalation study ongoing: Combination therapy with checkpoint inhibitors at Scripps MD Anderson Cancer Center (San Diego, CA) and MD Anderson Cancer Center (Houston, TX)

Macroscopic liver tumor invasion on day 61 or at death in retrograde mouse hepatocellular carcinoma model (tumor invasion as % of liver)



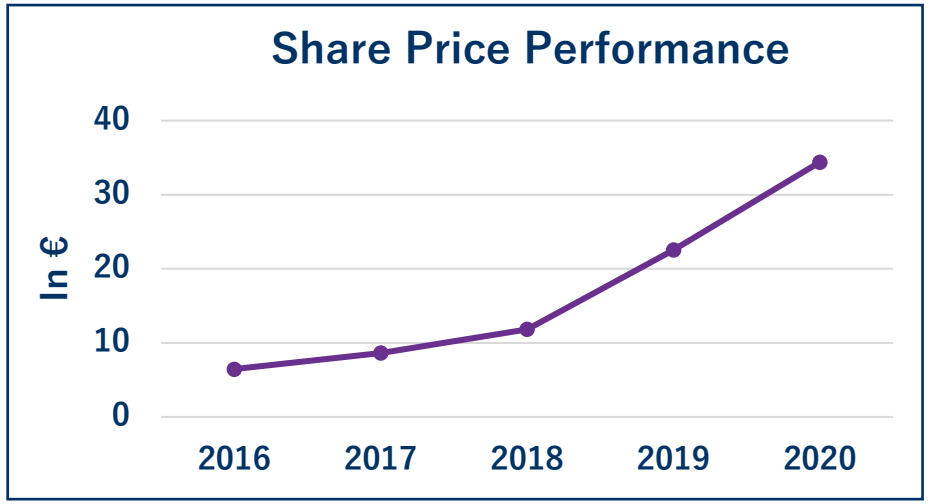
Percent survival

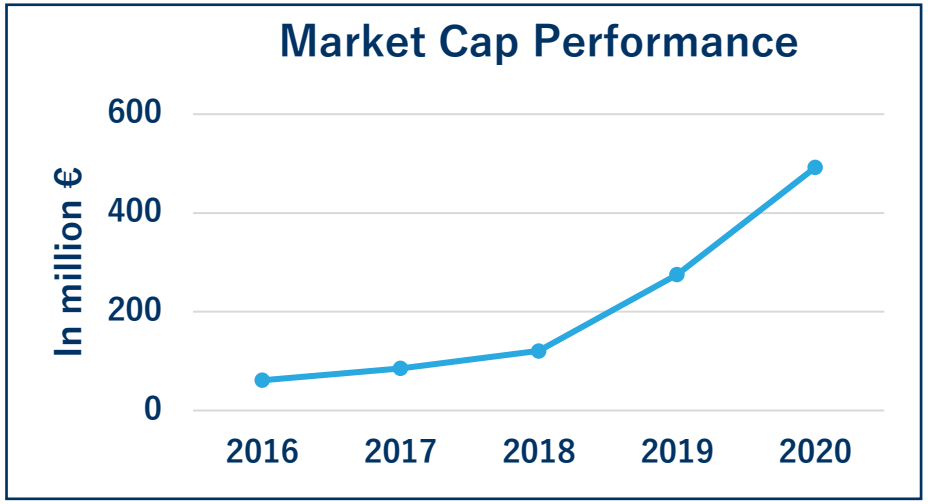


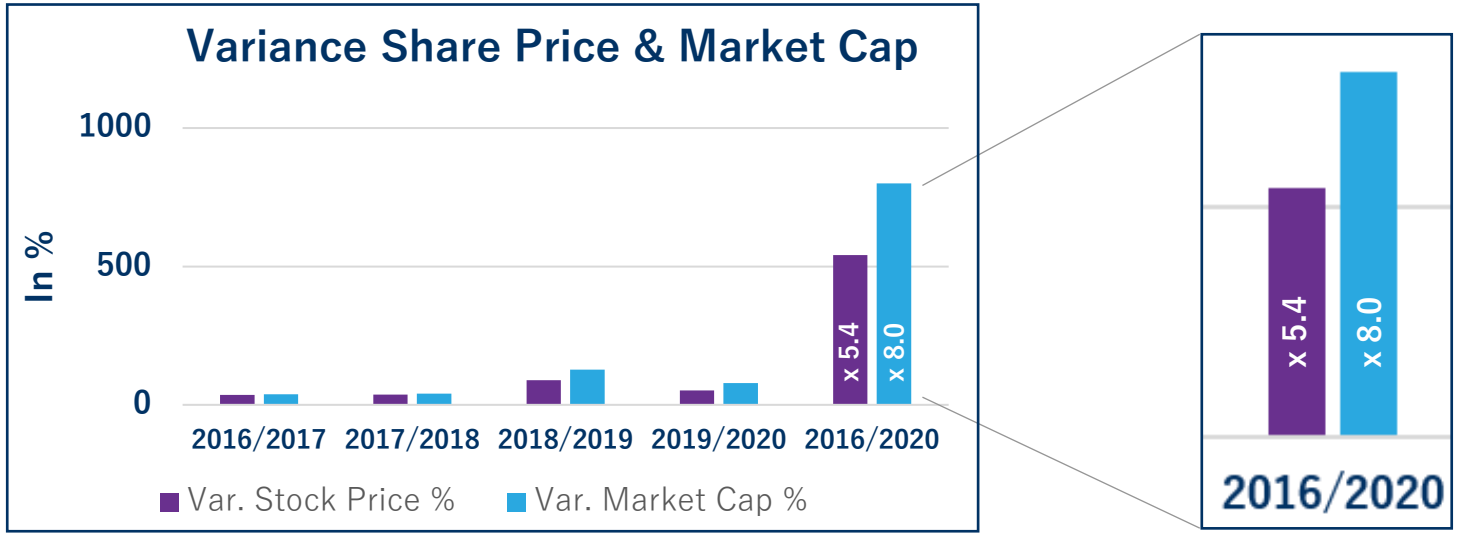
Newsflow through end of 2021

	Q4 2020	Q1 2021	Q2 2021	Q3 2021	Q4 2021
UC - Phase 2b (ABX464)	Enrollment completed		Top-line results (Induction and initial maintenance data)		FPI Phase 3
CD - Phase 2b/3 pivotal (ABX464)				FPI	
RA - Phase 2a (ABX464)		Enrollment completed	Top-line results (Induction and initial maintenance data)		
Covid-19 - Phase 2b/3 (ABX464)		Enrollment completed	Top-line results	Potential MAA submission	
HCC - Phase 1/2 (ABX196)		Enrollment completed (Dose escalation)	Top-line results (Dose escalation)		

2016-2020: Positive and durable increase in shareholder value







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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

Pierre Courteille Pharmacist, MBA

Chief Commercial Officer & VP, BD

sanofi pasteur · Guerbet Contrast for Life

Jean-Marc Steens, M.D.

Chief Medical Officer

ViiV Healthcare · gsk GlaxoSmithKline

Paul Gineste Pharm.D.

VP, Clinical Operations

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