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

Abivax, a late-stage clinical biotech company

March, 2021

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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

Location

Head Office
Paris

Cooperative Lab with CNRS
Montpellier

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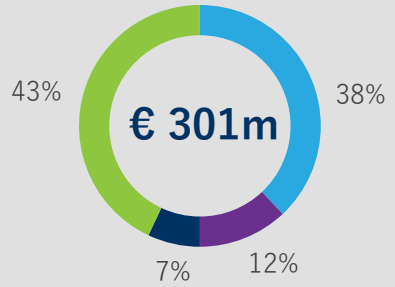
BREAKING NEWS

March 2021: ABX464 Covid-19 indication stopped

Shareholder structure[1] and market cap[2]



Operations

27
Employees

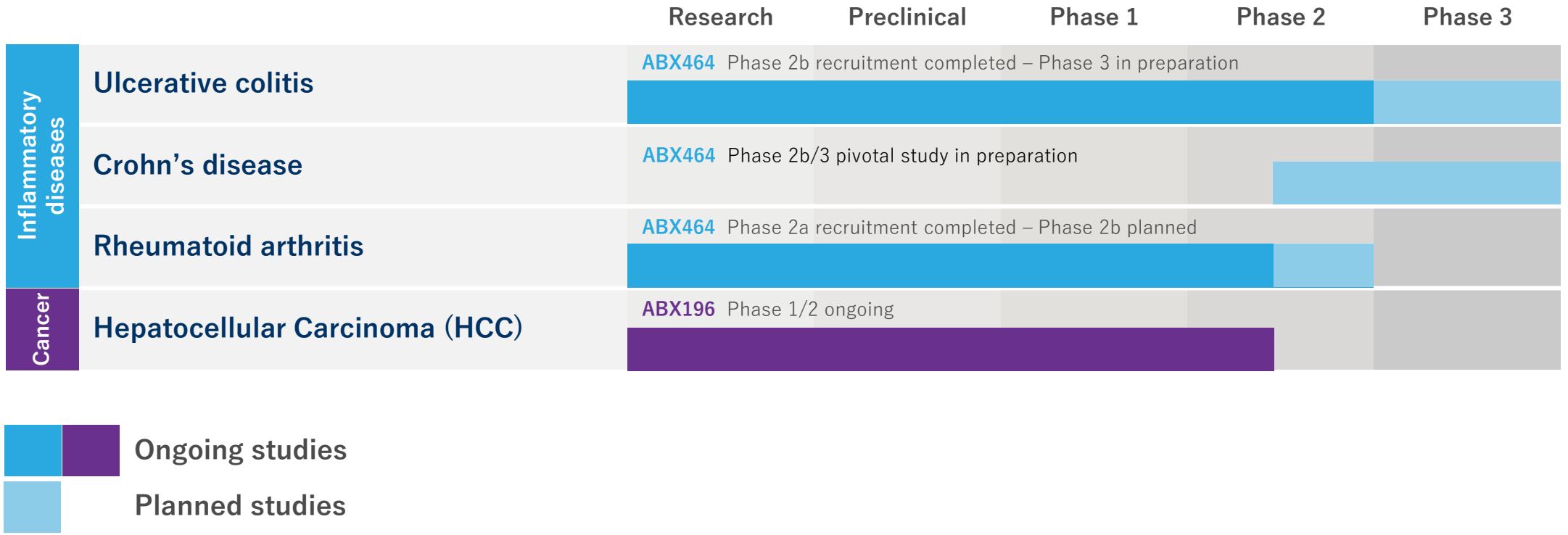
Cash[3]
€ 29.3m
Cash runway until Q4 2021

Key R&D and manufacturing partners

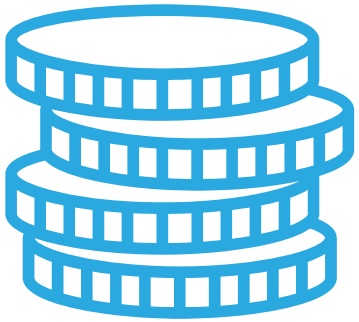
IQVIA™ evotec SEQENS DELPHARM

1) Undiluted – as of 31/01/2021
2) As of 08/03/2021 EOB
3) December 2020 estimate

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

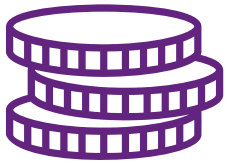


ABX464: A promising candidate addressing large unmet medical needs



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 >**800 patients and volunteers**
- **Strong anti-inflammatory effect** confirmed in phase 2a studies in ulcerative colitis
- **INN (International Nonproprietary Names) submitted** for ABX464 and final decision of WHO expected in Q2 2021
- **High unmet medical need and commercial opportunities** for novel safe and efficacious drugs for inflammatory diseases

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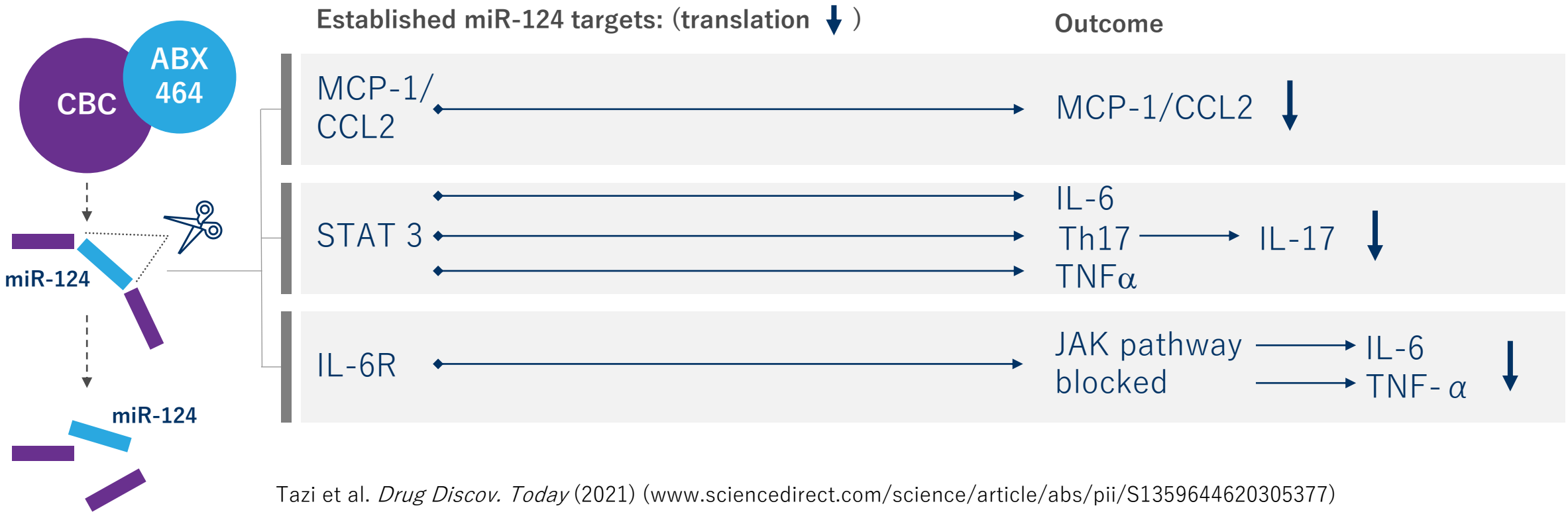
ABX464 novel mechanism of action: Potent and specific upregulation of miR-124, activating a “physiological brake” of inflammation

- **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)

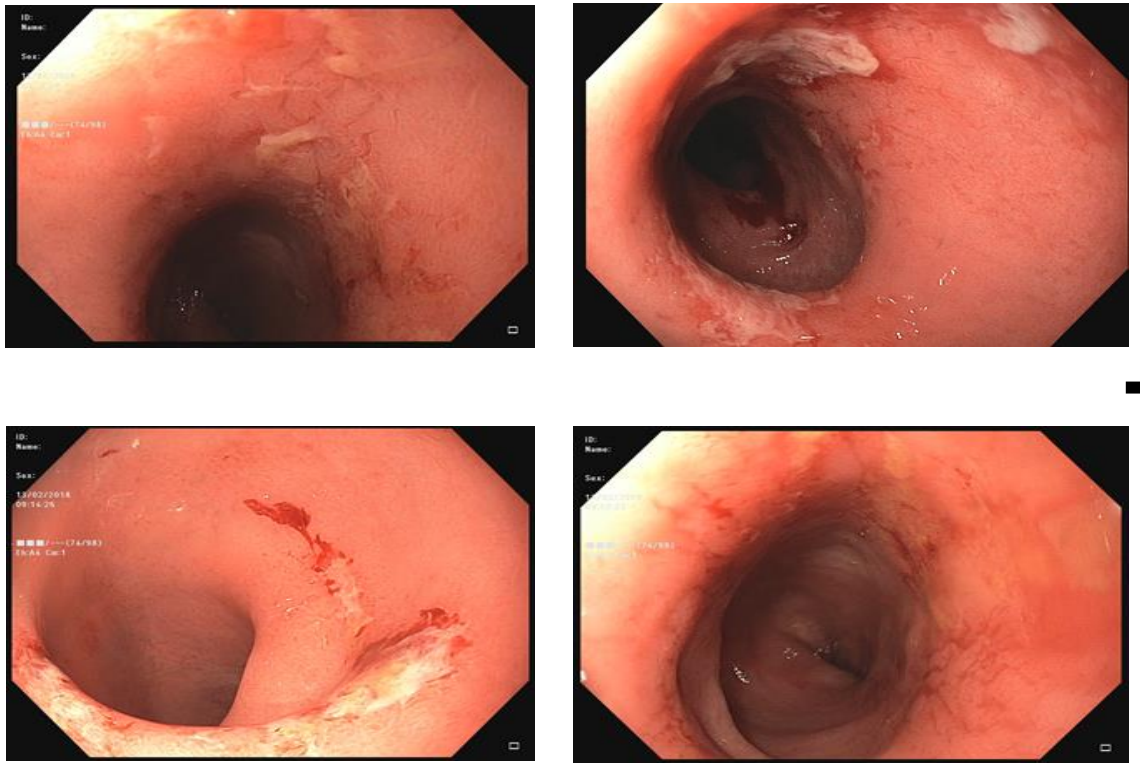
Followed by open-label maintenance study (now in 4th year)

Vermeire at al. Induction and long-term follow-up with ABX464 for moderate-to-severe ulcerative colitis: Results of phase 2a trial. Gastroenterology, 2021.02.054	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

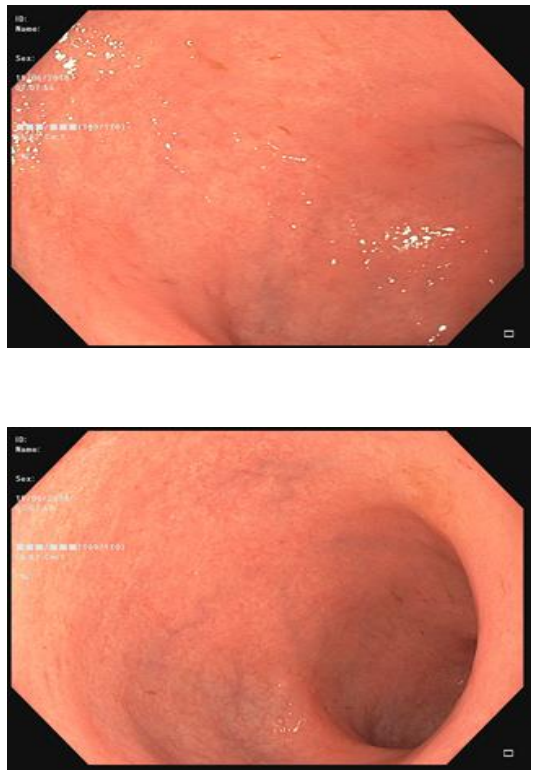
* Clinical remission according to previous FDA definition. With application of most recent FDA definition (excluding physician assessment), clinical remission rate was 40% in ABX464 group and remained at 11% with placebo
** PP: Per protocol / ITT: Intent to treat
*** Study was not powered to show statistical significance

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

Endoscopy before ABX464



Endoscopy after ABX464

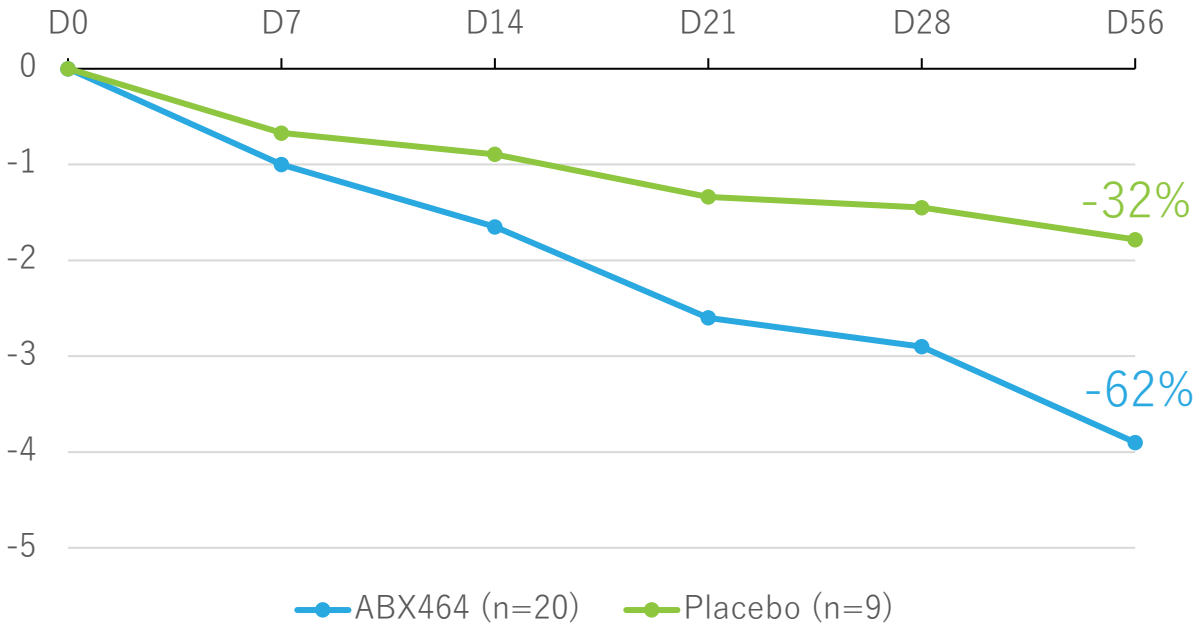


Courtesy of Prof. Severine Vermeire, Leuven, Belgium

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

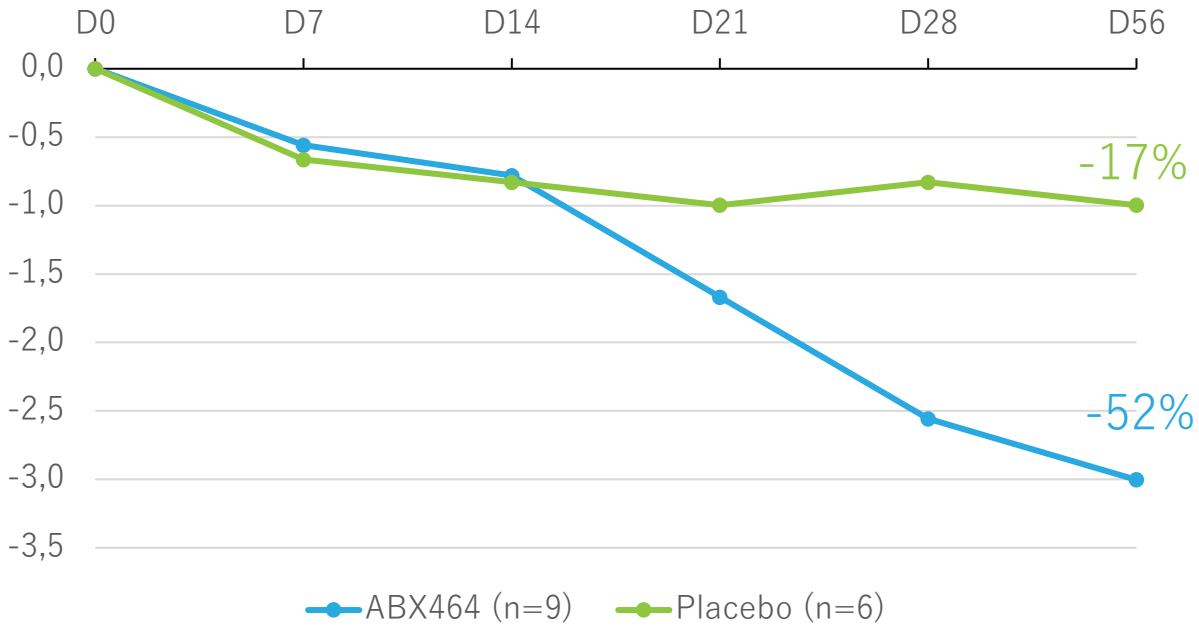
Overall Patient Population

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

Vermeire at al. Induction and long-term follow-up with ABX464 for moderate-to-severe ulcerative colitis: Results of phase 2a trial. J Gastro 2021.02.054

As of March 9, 2021, all ongoing phase 2a maintenance patients (N=15) have completed at least 31 months of continuous daily treatment with ABX464, with the longest treated patient being on ABX464 for over 39 months.

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

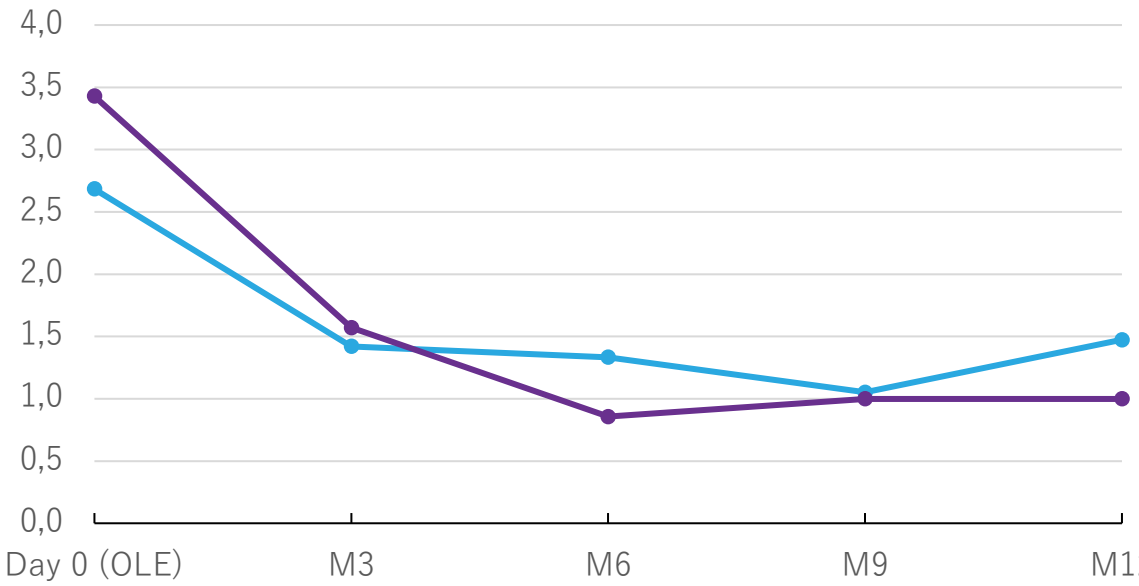
	Vedoluzimab* Phase 3			Tofacitinib** Phase 3			ABX464 Phase 2a***		
Post Induction	**Active**	**Placebo**	**Delta**	**Active**	**Placebo**	**Delta**	**Active**	**Placebo**	**Delta**
Clinical Remission (%)	16.9	5.4	11.5	16.8-18.5	3.6-8.2	13.2-10.3	35	11	24
Endoscopic improvement (%)	40.9	24.8	16.1	28.4-31.3	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.

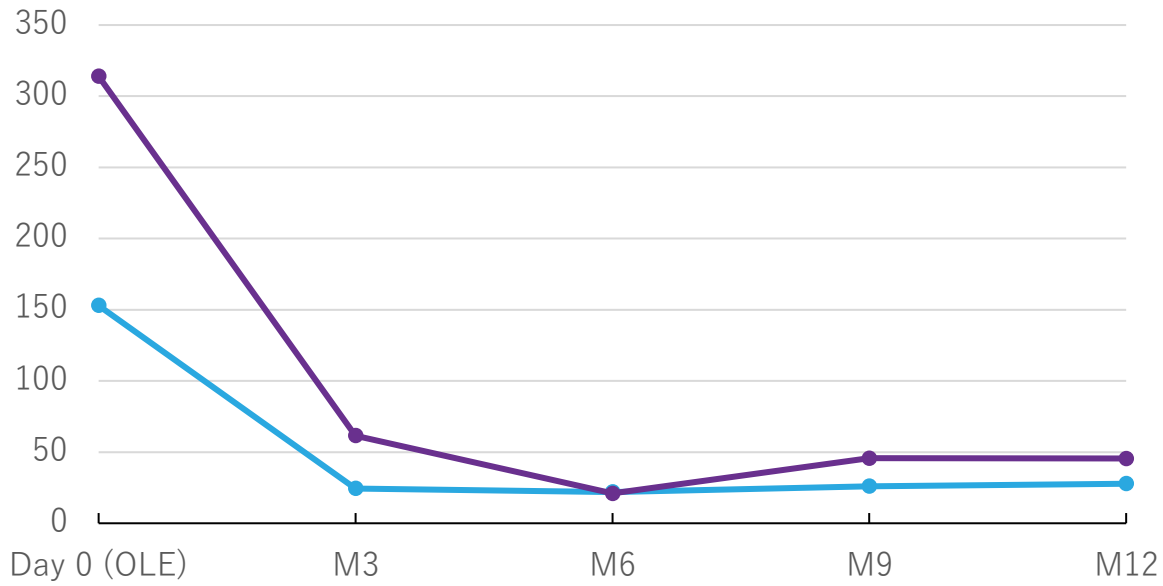
* Feagan et al. Vedolizumab as induction and maintenance therapy for ulcerative colitis. N Engl J Med 2013;369:699-710
** Sandborn et al. Tofacitinib as Induction and Maintenance Therapy for Ulcerative Colitis. N Engl J Med 2017;376:1723-36
*** Vermeire at al. Induction and long-term follow-up with ABX464 for moderate-to-severe ulcerative colitis: Results of phase 2a trial. J Gastro 2021.02.054

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 39 months

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

No increased incidence of infections

ABX464 phase 2b clinical study in ulcerative colitis

Ulcerative colitis Phase 2b ongoing:

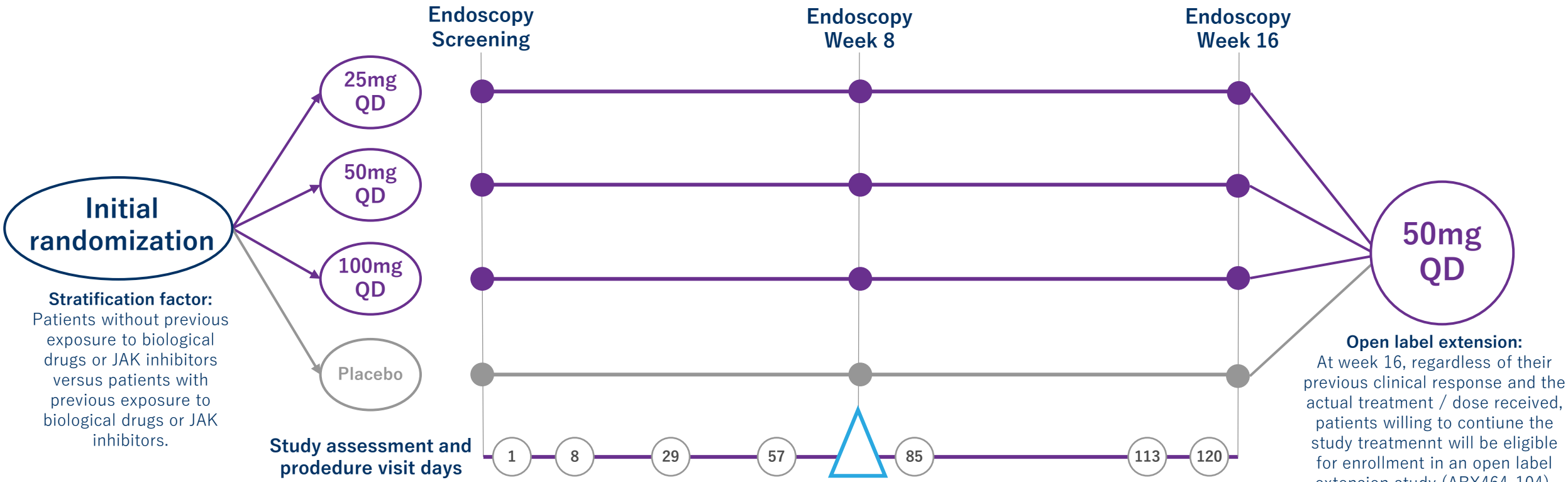
- Enrollment completed with 254 patients in 15 European countries, US and Canada in 130+ study sites
- 4 study arms (placebo, 25, 50, 100 mg QD)
- Central blinded reading of endoscopies
- Conducted with IQVIA as CRO
- Top-line data for induction phase and initial maintenance data in **Q2 2021**
- 1st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

Study design: ABX464 phase 2b clinical study in ulcerative colitis

Screening
≤4 weeks

Induction Phase
16 weeks

Open Label Extension
ABX464-196



Stratification factor:
Patients without previous exposure to biological drugs or JAK inhibitors versus patients with previous exposure to biological drugs or JAK inhibitors.

Open label extension:
At week 16, regardless of their previous clinical response and the actual treatment / dose received, patients willing to contiune the study treatmennt will be eligible for enrollment in an open label extension study (ABX464-104).

Primary Endpoint:
Reduction from baseline in Modified Mayo Score at week 8

How to bring ABX464 to the finish line

Phase 1 TQT study:
- 66/120 subjects enrolled
- Results expected in June 2021

Phase 1 DDI study:
- 24/42 subjects enrolled
- Results expected in August 2021

Phase 1 ADME study:
- 12 subjects to be enrolled, starting June 2021
- Results expected in late Q4 2021

Phase 1 study in Japanese subjects
- PMDA interactions ongoing
- 54 subjects to be enrolled in Japan, starting July 2021

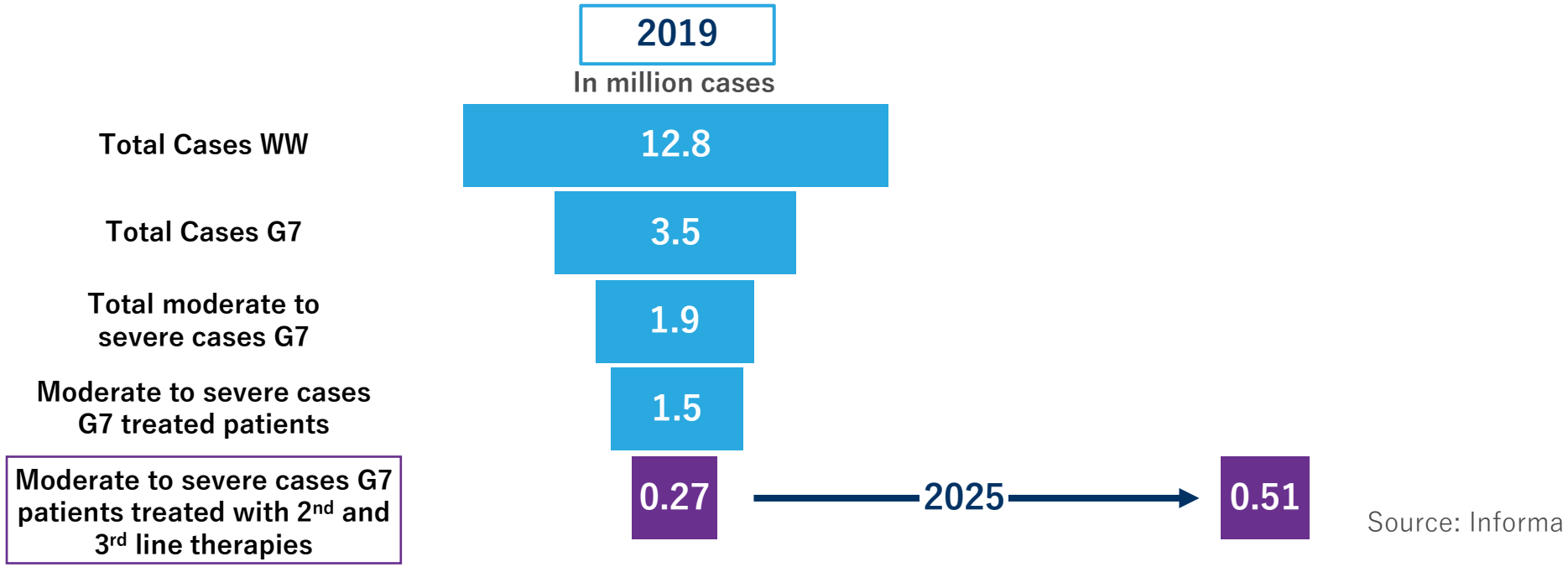
Ulcerative colitis Phase 3 in preparation:
- End of Phase 2b meeting planned for **Q3 2021**
- **IQVIA** involved in study preparation
- **App. 2x600 patients** planned
- FPI planned for **Q4 2021**

Crohn's disease Phase 2b/3 pivotal study in preparation:
- 900 patients in Europe and the US
- 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**

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	

ABX196: An iNKT agonist for the treatment of checkpoint inhibitor refractory liver cancer patients

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

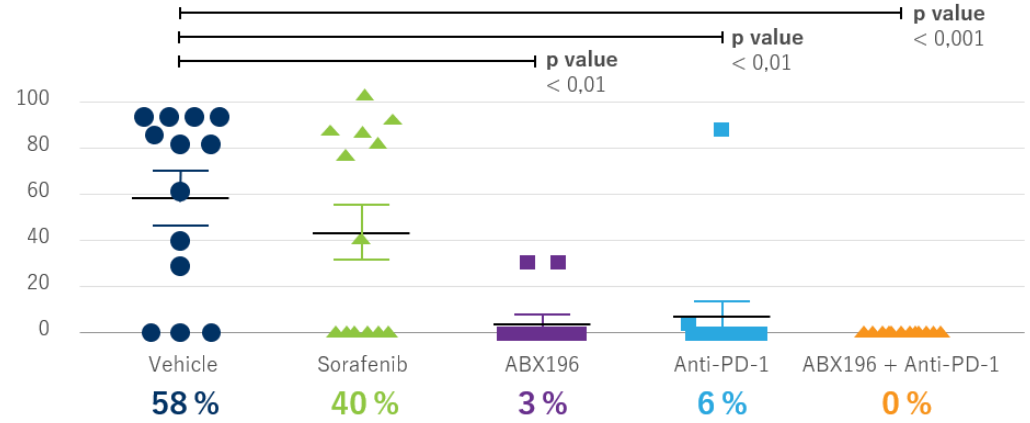
Synthetic glycolipid agonist of iNKT (invariant Natural Killer T) cells in liposomal formulation

Strong preclinical data in liver cancer and melanoma

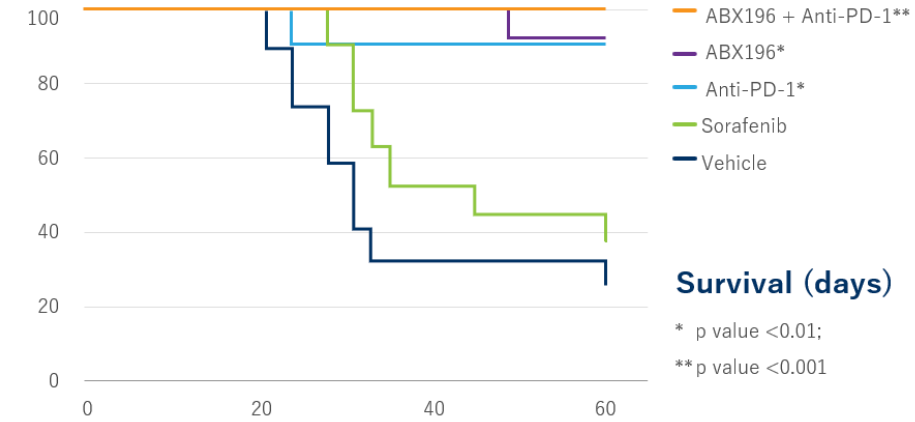
Phase 1 completed in volunteers: ABX196 was safe and well tolerated, and triggered both humoral and iNKT responses

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)

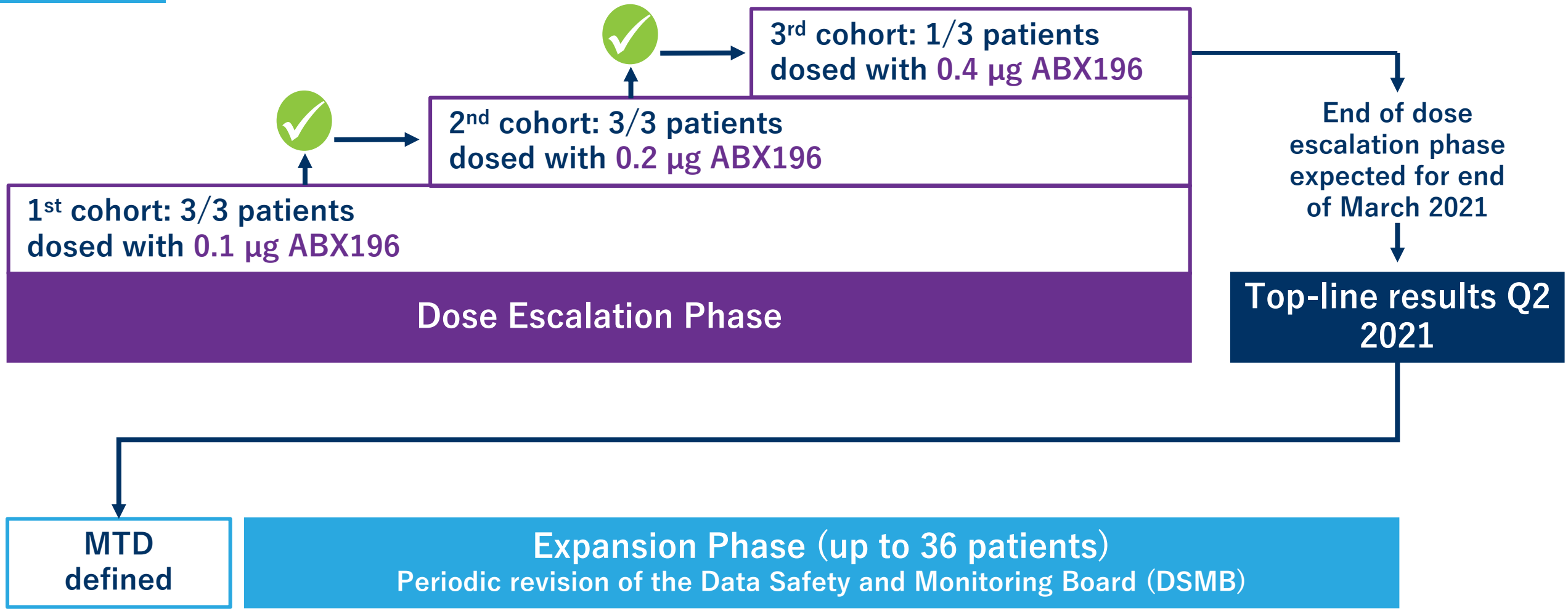
Macroscopic liver tumor invasion on day 61 or at death in retrograde mouse hepatocellular carcinoma model (tumor invasion as % of liver)



Percent survival



ABX196 study design and recruitment status



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)		
HCC - Phase 1/2 (ABX196)		Enrollment completed (Dose escalation)	Top-line results (Dose escalation)		

2020 financing completed to extend cash runway until Q4 2021

2020 Financing

- **Private Placement towards institutional investors € 28m**
- **Bpifrance funding € 36m**
  (to be tailored following ABX464 Covid-19 stop on March 5, 2021)
- **Société Générale PGE € 5m**
- **Kreos new funding € 15m**
- **TOTAL: € 84m raised in 2020**
  (€ 56m non-dilutive and € 28m dilutive)

- **In addition, available remainder of Equity Line with Kepler Cheuvreux (612 k shares, around € 12m)**

Cash Runway 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 for late 2021
  - **ABX464 in Crohn's disease (CD):** Preparation of Phase 2b/3 for late 2021
  - **ABX464 in rheumatoid arthritis (RA):** Completion of the Phase 2a induction phase and pursuance of the maintenance phase, preparation of Phase 2b for late 2021
  - **ABX464 in Covid-19:** Program stopped on March 5, 2021
  - **General corporate purposes**

Abivax analyst reports overview (after Covid-19 stop)

Analyst	Country	Last update	Target Price	Recommendation
Bryan, Garnier & Co	France	04/03/2021	€ 39.40	Buy
Degroof Petercam	Belgium	08/03/2021	€ 29.00	Buy
goetzpartners securities	UK/Germany	09/03/2021	€ 43.00	Buy
Kepler Cheuvreux	France	08/03/2021	€ 40.00	Buy
LifeSci Capital Alpha Series	US	14/05/2020	€ 41.00	Buy
Portzamparc	France	08/03/2021	€ 39.40	Buy
General recommendation: Buy		**Average target price (after Covid-19 stop): € 38.60**		

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

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Former Head of Global R&D, Baxter BioScience

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