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

Abivax, a late-stage clinical biotech company

September 2021

abivax

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Future clinical development including phase 3 design and initiation is subject to assessment of the overall preclinical, CMC, toxicology, clinical efficacy and safety data of ABX464 by EMA, FDA and other regulatory authorities. These top-line results have not yet been reviewed by regulatory authorities.

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

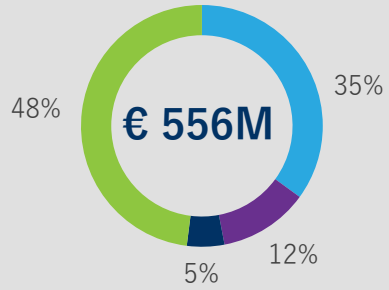
Head Office
Paris

Cooperative Lab with CNRS
Montpellier

abivax

BREAKING NEWS
August 2021
Abivax receives approval for ABX464 phase 1 study in Japanese subjects for subsequent inclusion of Japan into the global phase 3 program in UC

Shareholder structure[1] and market cap[2]



Operations

28
Employees

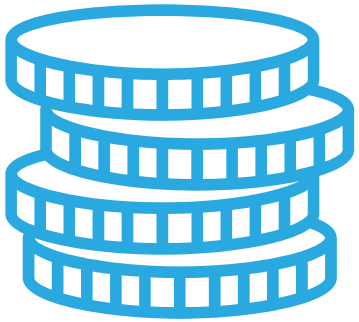
Cash runway until Q2 2022

Key R&D and manufacturing partners

IQVIA™ evotec SEQENS DELPHARM

1) Undiluted – as of 27/07/2021
2) As of 07/09/2021 EOB

ABX464: A promising candidate addressing large unmet medical needs

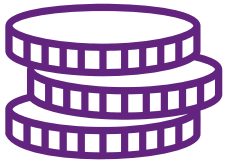


Total market size[1] in inflammatory diseases

greater than **USD 90B**

Market size[1,2]
UC: USD 6B
CD: USD 11.9B
RA: USD 20.4B

ABX464 addresses a market of **USD 40B**

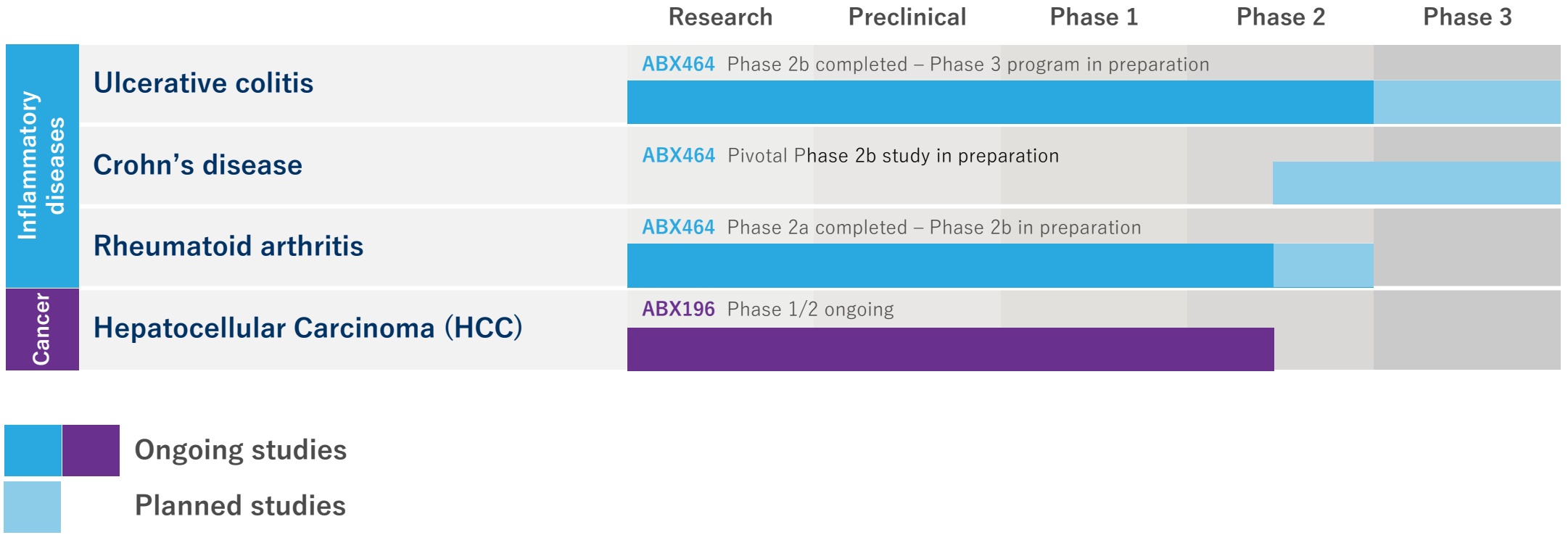


1) 2020 data for Europe G5, U.S. and Japan
2) 2nd and 3rd line

Source: Global Data & Informa

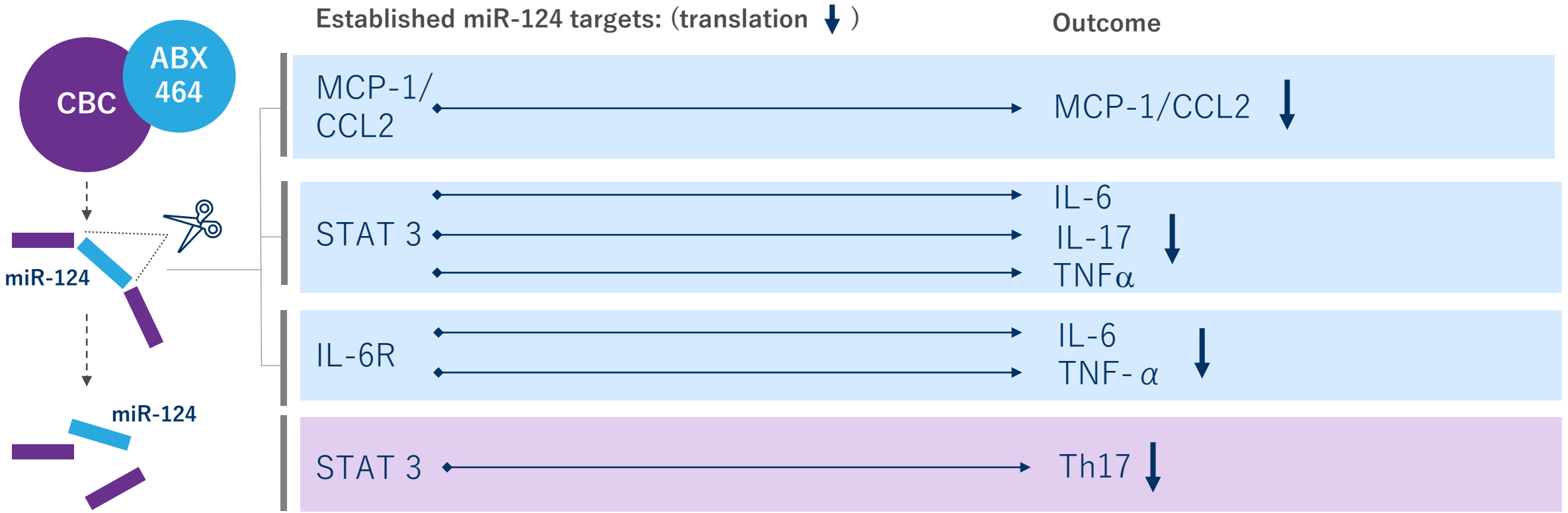
- Coming from the **proprietary Abivax library of compounds**, designed to **modulate RNA biogenesis** (>2,200 molecules); Collaboration with EVOTEC
- **Small molecule**, administered as an **oral capsule** (once a day) ABX464 tablet form under development
- **First-in-Class, novel mechanism of action:** Selective upregulation of anti-inflammatory microRNA, miR-124
- **Good safety profile** after administration to **>850 patients and volunteers**
- **Strong short- and long-term anti-inflammatory effect** confirmed in phase 2a and 2b studies in ulcerative colitis and in a **phase 2a induction study in RA**
- **Start of phase 3 in UC and phase 2b in Crohn's disease planned for end of 2021** and **a phase 2b induction study in RA beginning of 2022**
- **High unmet medical need and commercial opportunities** for novel safe and efficacious drugs for inflammatory diseases

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



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.**

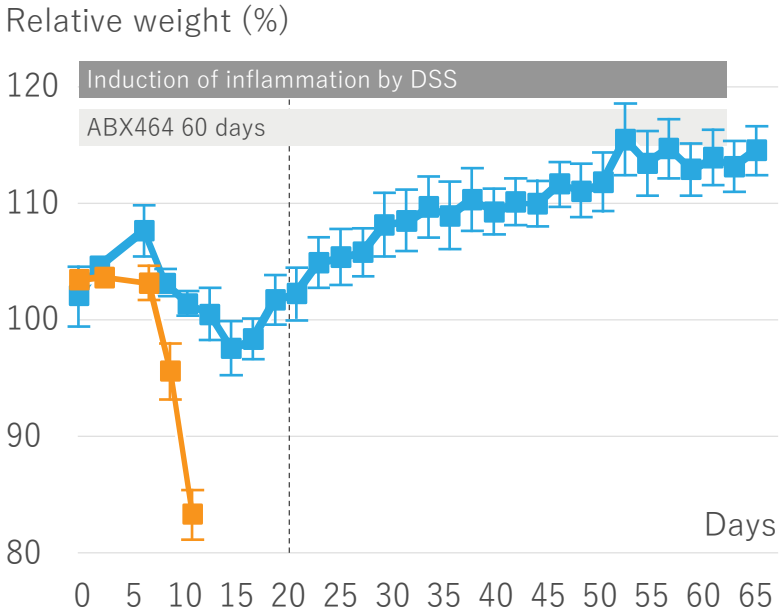


Tazi et al. *Drug Discov. Today* (2021); Poholek et al. *J Exp Med* (2020) 217 (10): e20191761; *Lin S, et al. Frontier in Onc (2020)*

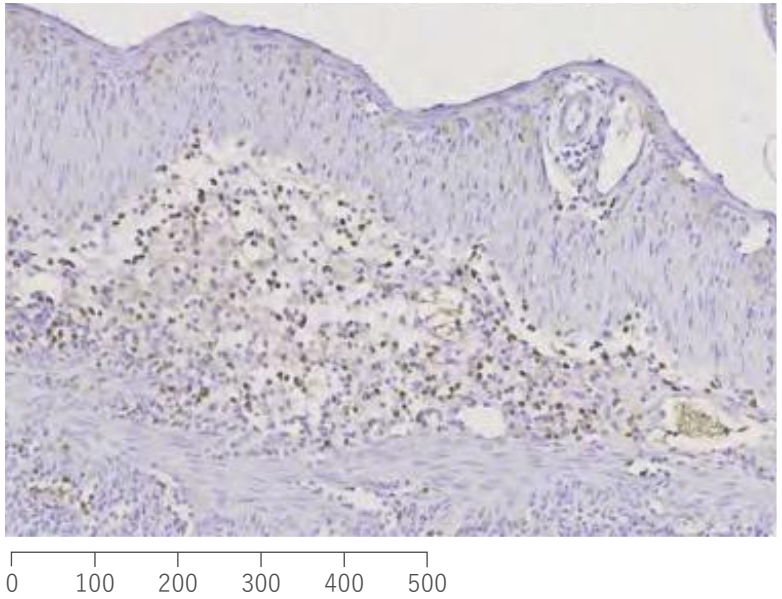
ABX464: Clinical Development in IBD

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

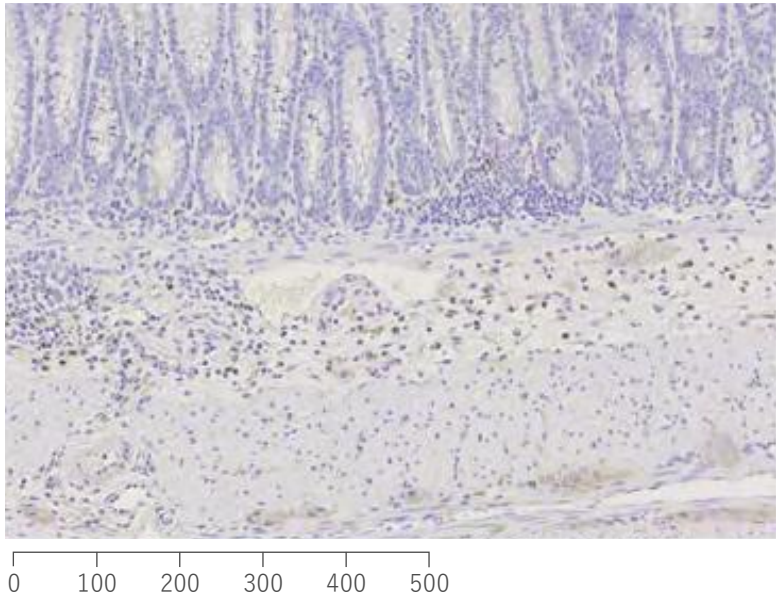
ABX464 protects mice from death in the DSS mouse model



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 phase 2a POC induction study in ulcerative colitis: Impressive efficacy achieved for all endpoints (induction and maintenance)

Study Design:

PI: Prof. Severine Vermeire, Leuven, BE

32 patients with moderate to severe UC: randomized (2:1) 50mg ABX464 vs placebo, 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
miR-124 expression in rectal biopsies (fold increase)	7.69	1.46	0.004

29/32	4/6	22/23	16/19
Patients completed the induction study	Countries granted regulatory approval for maintenance study	Eligible patients enrolled in the maintenance study, 19 out of 22 patients completed first year	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%)

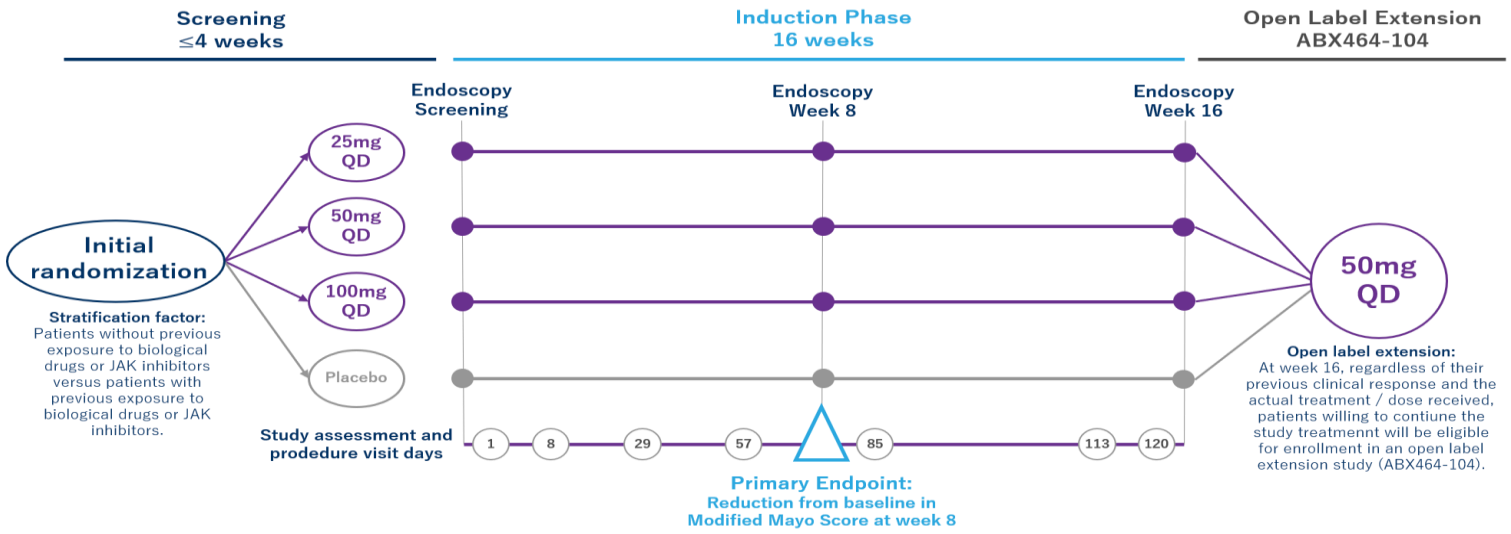
* 16 out of 19 patients had endoscopy

ABX464 phase 2b clinical study in ulcerative colitis

Ulcerative colitis phase 2b:

- 254 patients in 15 European countries, US and Canada in 130 study sites
- 4 study arms (placebo, 25, 50, 100mg QD) / Central blinded reading of endoscopies

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



Baseline characteristics well-balanced among the treatment groups, indicating a moderate to severe UC population, very similar with recent published data

	Statistic	100mg (N=64)	50mg (N=63)	25 mg (N=61)	Placebo (N=64)
Age (years)	Mean (SD)	42.2 (12.34)	40.2 (13.94)	41.5 (14.16)	41.1 (14.43)
Male	n (%)	41 (64.1)	27 (42.9)	40 (65.6)	40 (62.5)
Baseline Modified Mayo Score (MMS)	Mean (SD)	7,0 (1,07)	7,1 (0,96)	7,1 (1,09)	7,0 (1,20)
4	n (%)	0	0	0	1 (1.6)
5 to 6	n (%)	17 (26.6)	16 (25.4)	17 (27.9)	21 (32.8)
7 to 9	n (%)	47 (73.4)	47 (74.6)	44 (72.1)	42 (65.6)
Previous exposure to biological/JAK inhibitors*	n (%)	32 (50.0)	30 (47.6)	30 (49.2)	31 (48.4)
Previous exposure to:					
TNF-a	n (%)	31 (48.4)	25 (39.7)	25 (41.0)	27 (42.2)
TNF-a only	n (%)	1 (1.6)	0	3 (4.9)	1 (1.6)
Vedolizumab	n (%)	20 (31.3)	20 (31.7)	19 (31.1)	22 (34.4)
Vedolizumab only	n (%)	0	1 (1.6)	0	1 (1.6)
JAK	n (%)	13 (20.3)	12 (19.0)	10 (16.4)	12 (18.8)
JAK only	n (%)	0	0	0	1 (1.6)
Concomitant UC Medication					
Corticosteroids [b]	n (%)	37 (57.8)	33 (52.4)	32 (52.5)	29 (45.3)
5-ASA [b]	n (%)	47 (73.4)	48 (76.2)	46 (75.4)	52 (81.3)
Immunosuppressants [b]	n (%)	6 (9.4)	9 (14.3)	10 (16.4)	10 (15.6)
Body Mass Index at baseline	Mean (SD)	25.09 (3.864)	24.70 (5.100)	25.15 (5.464)	24.46 (4.788)
Tobacco use occurrence (current)	n (%)	3 (4.7)	2 (3.2)	3 (4.9)	4 (6.3)
Duration of disease since diagnosis (years)	Mean (SD)	7.77 (7.291)	8.22 (7.785)	7.35 (6.848)	8.82 (6.783)
Disease Extent					
Proctitis	n (%)	0	8 (12.7)	7 (11.5)	6 (9.4)
Left-sided	n (%)	35 (54.7)	33 (52.4)	30 (49.2)	26 (40.6)
Extensive	n (%)	29 (45.3)	22 (34.9)	24 (39.3)	32 (50.0)

Top-Line week 8 Efficacy Results (ITT): Primary Endpoint met - Efficacy confirmed

Week 8 top-line Results (ITT[1] population / n=252)		Placebo	25mg	50mg	100mg
Primary Endpoint					
Modified Mayo Score Mean change from baseline	All patients	-1.9	-3.1 **	-3.2 **	-2.9 *
	Bio exposed	-1.0	-2.8 **	-2.9 **	-2.8 **

*p-values of <0.01 versus placebo (ANCOVA)
**p-values of <0.001 versus placebo (ANCOVA)

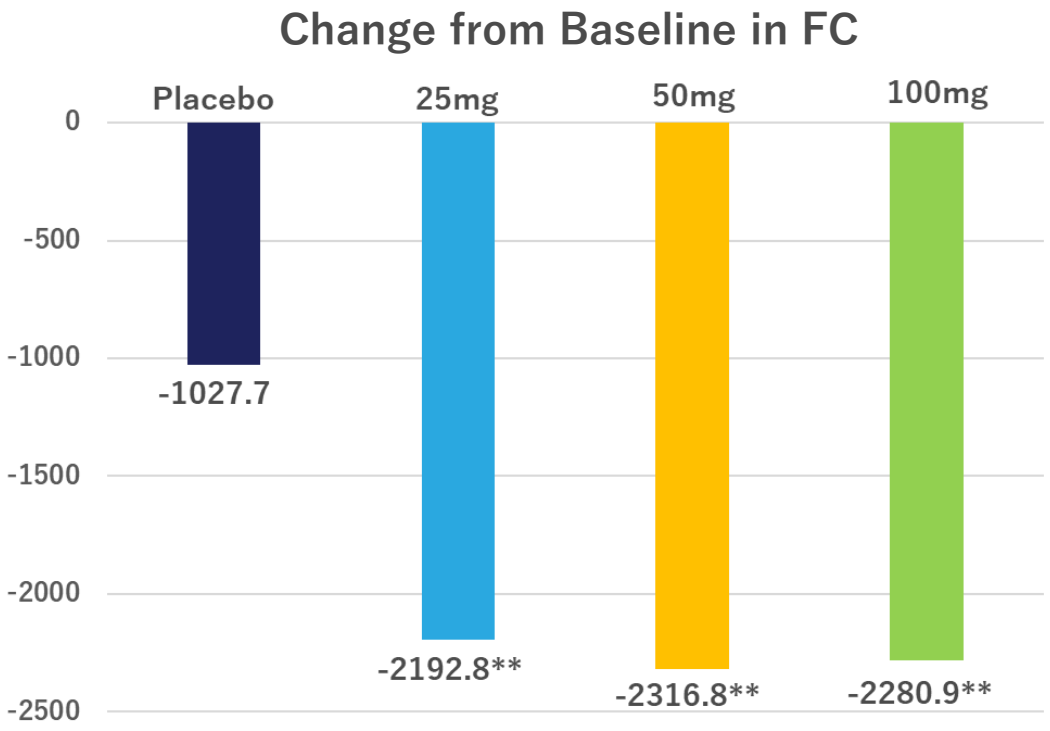
1) Intent-to-treat patient population. Drop-out patients were considered as failure for all endpoints. Nearest neighbor imputation, as defined in the SAP. Patient characteristics well balanced between all groups (Modified Mayo Score, ConMeds, Gender, etc.).

Top-Line week 8 Efficacy Results (ITT): Secondary endpoints - Efficacy confirmed

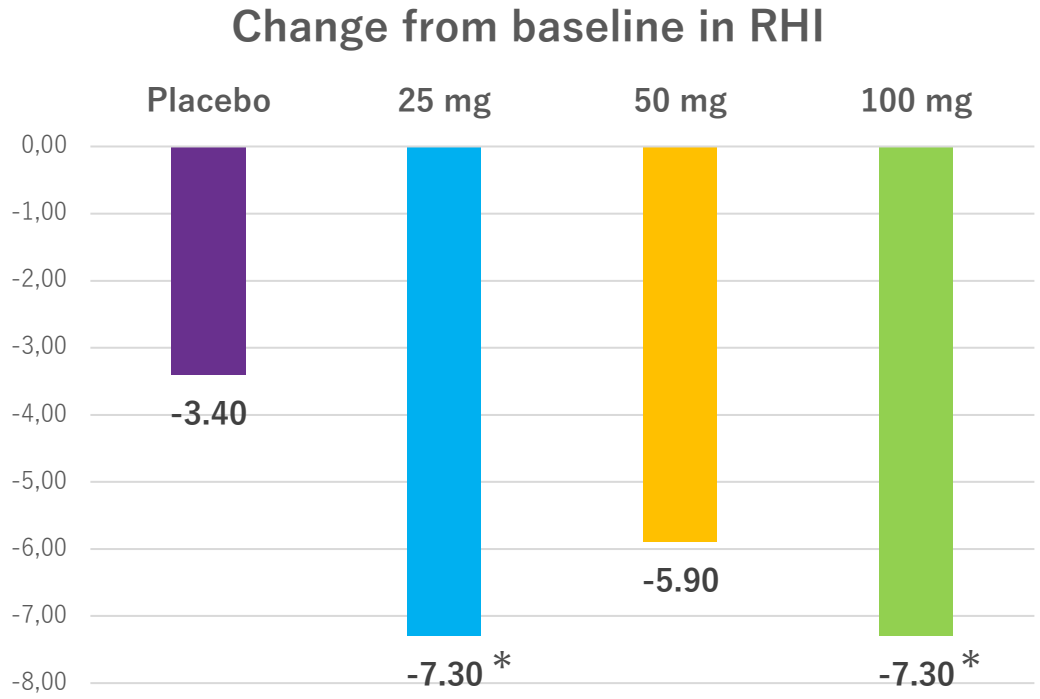
Week 8 top-line Results (ITT population / n=252)		Placebo	25mg	50mg	100mg
Key Secondary Endpoints (not powered for statistical significance)					
Endoscopic Improvement [a] †	All patients	8 (13.6%)	20 (34.5%) *	21 (39.6%) *	24 (44.4%) *
	Bio exposed	1 (3.7%)	8 (28.6%) *	7 (30.4%) *	8 (26.6%) *
*p-values of <0.05 versus placebo using a likelihood ratio chi-square test					
Clinical Remission [b] †	All patients	8 (12.5%)	17 (27.9%) *	11 (17.5%)	16 (25.0%)
	Bio exposed	1 (3.2%)	6 (20.0%) *	2 (6.7%)	6 (18.8%) *
*p-values of <0.05 versus placebo using a likelihood ratio chi-square test but not according to the predefined Mantel-Haenszel Chi Square test (p=0.06 to 0.08)					
Clinical Response [c] †	All patients	23 (35.9%)	40 (65.6%) *	38 (60.3%) *	35 (54.7%) *
	Bio exposed	5 (16.1%)	17 (56.6%) *	13 (43.3%) *	15 (46.8%) *
*p-values of <0.05 versus placebo using a likelihood ratio chi-square test					
Fecal Calprotectin (µg/g) Mean change from baseline	All patients	-1027.7	-2192.8 **	-2316.8 **	-2280.9 **
**p-values of <0.01 versus placebo (MMRM)					

a Endoscopic improvement is defined as endoscopic subscore ≤1.
b Clinical remission (per Modified Mayo Score) is defined as stool frequency subscore (SFS) ≤1, rectal bleeding subscore (RBS) of 0 and endoscopic subscore ≤1.
c Clinical response (per Adapted Mayo Score) is defined as a decrease from baseline in the Modified Mayo Score ≥2 points and ≥30 percent from baseline, plus a decrease in RBS ≥1 or an absolute RBS ≤1.
† Evidence of friability during endoscopy confers an endoscopic subscore of 2 or 3

Top-Line week 8 Efficacy Results (ITT): Fecal calprotectin (µg/g) and Robarts Histopathology Index

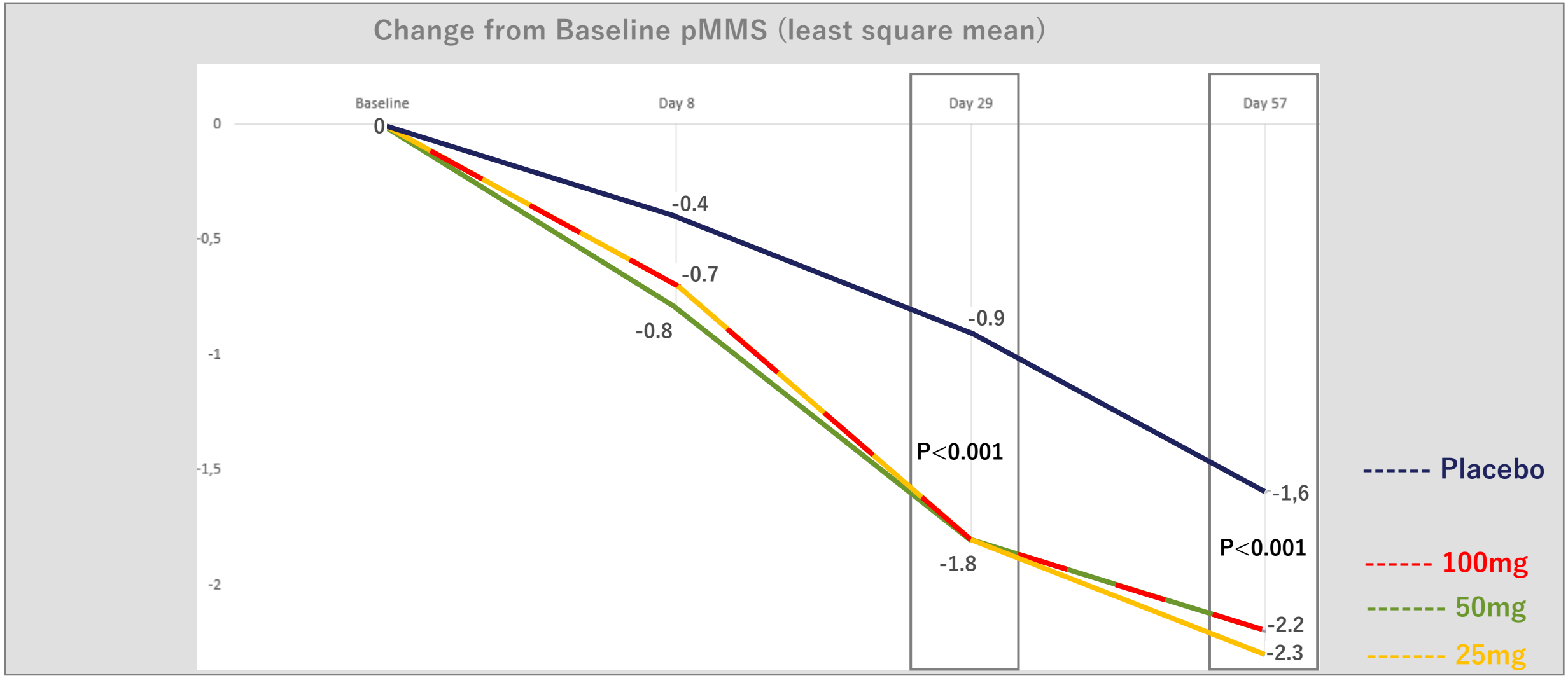


**p-values of <0.01 versus placebo (MMRM)



*p-values of <0.05 versus placebo (MMRM)

Top-Line Efficacy Results (ITT): Fast onset of action



Preliminary data from the maintenance study (ABX464-104): Further increased and durable efficacy at one year (Cut-off date: May 11, 2021)

Preliminary data from the first 51 patients* enrolled and treated with once-daily 50mg ABX464 in the open-label maintenance study showed increased and durable clinical remission and endoscopic improvement after 48 weeks

Patients at W48:	All patients (PP n=44 / ITT n=51)	Patients with at least a clinical response after induction (PP n=26 / ITT n=28)	Patients without at least a clinical response after induction (PP n=18 / ITT n=23)
Clinical Remission	61% / 53%	69% / 64%	50% / 39%
Endoscopic Improvement	68% / 59%	77% / 71%	55% / 43%

*Irrespective of patient outcome at the end of the induction phase

ABX464 well positioned in the competitive landscape for both induction and maintenance

Clinical Remission Rates

Drug	Study	Active	Placebo	Delta
Results of Induction studies (ITT)*				
Adalimumab	ULTRA I (Ph 3)	18.5%	9.2%	9.3%
	ULTRA II (Ph 3)	16.5%	9.3%	7.2%
Vedolizumab	GEMINI I (Ph 3)	16.9%	5.4%	11.5%
Tofacitinib	OCTAVE I (Ph 3)	18.5%	8.2%	10.3%
	OCTAVE II (Ph 3)	16.6%	3.6%	13.0%
Ustekinumab	Phase 3	15.5%	5.3%	10.2%
Ozanimod	Truenorth (Ph 3)	18.4%	6.0%	12.4%
Upadacitinib	U-Achieve (Ph 3)	26.0%	5.0%	21.0%
	U-Accomplish (Ph 3)	33.0%	4.0%	29.0%
	Phase 2	19.6%	0.0%	19.6%
ABX464	Phase 2a (50mg)	30.4%	11.1%	19.3%
	Phase 2b (25mg)	27.9%	12.5%	15.4%

Drug	Active	Placebo	Delta
Results of Maintenance studies (ITT)* (Patients with Clinical response at the end of the induction)			
Infliximab	34.7%	16.5%	18.2%
Adalimumab	17.3%	8.5%	8.8%
Golimumab	27.8%	15.4%	12.4%
Vedolizumab	44.8%	15.9%	28.9%
Tofacitinib	40.6%	11%	29.6%
Ustekinumab	43.8%	24%	19.8%
Ozanimod	37%	18.5%	18.5%
Upadacitinib (30mg)	52.0%	12%	40.0%
Upadacitinib (15mg)	42.0%	12.0%	30.0%
ABX464 Phase 2a (PP)	77.0%		
ABX464 Phase 2b	64.0%		

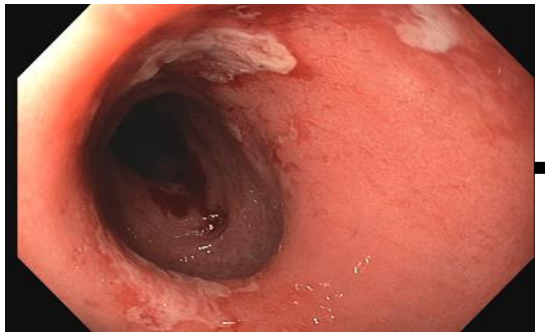
Marketed drugs in IBD

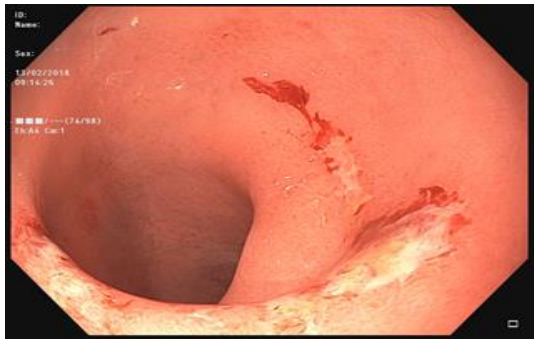
Drug candidates in late-stage development in IBD

*** non-comparative studies conducted versus placebo**

Complete resolution of UC lesions in an ABX464 treated patient (vedolizumab, infliximab and adalimumab resistant) after 1, 2 and 3 years of treatment

Endoscopy before ABX464

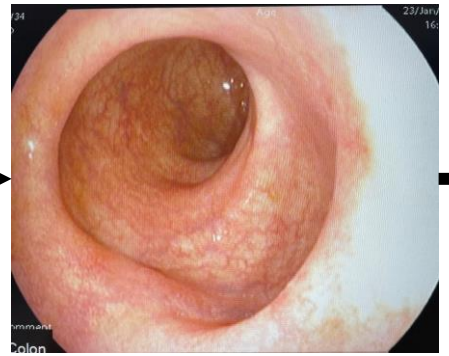




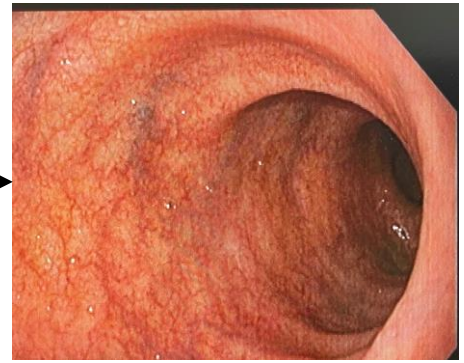
Courtesy of Prof. Severine Vermeire, Leuven, Belgium

Endoscopy after 1st year of ABX464

Endoscopy after 2nd year of ABX464



Endoscopy after 3rd year of ABX464



- 52-year-old patient with severe UC
- Patient had failed on vedolizumab, infliximab and adalimumab
- Fall 2017: Patient was counseled for colectomy
- Nov. 2017: Patient was enrolled in phase 2a induction study with ABX464
- Jan. 2018: Patient was enrolled in open-label maintenance study with ABX464

Favorable safety results

- ✓ **No new safety signal**
- ✓ **Low overall drop-out rate (8.7%) at week 8 despite Covid-19**
- ✓ **Serious adverse events (SAEs)** (related and non-related)
  - **6.2% (placebo), 1.6% (25mg), 6.3% (50mg), 6.2% (100mg)**
- ✓ **Severe** (grade 3 or 4) **treatment emergent adverse events (TEAEs)** (related and non-related) :
  - **4.7% (placebo), 4.8% (25mg), 7.9% (50mg), 10.9% (100mg)**
- ✓ **No death and no malignancy**
- ✓ **Similar low infection rates between ABX464 (8.4% all doses) and placebo (9.4%)**
- ✓ **Labs:**
  - **No clinically significant changes in laboratory parameters (Liver function tests, Hb, lymphocytes, neutrophils, etc.)**

Favorable ABX464 safety profile

Most common (> 5%) Adverse Events (AE): Drug-related or non-drug-related

System Organ Class	Adverse effect	Placebo (N=64)		ABX464 25mg (N=63)		ABX464 50mg (N=63)		ABX464 100mg (N=64)	
		Number of reports	n (%) of pts with AE (Incidence)	Number of reports	n (%) of pts with AE (Incidence)	Number of reports	n (%) of pts with AE (Incidence)	Number of reports	n (%) of pts with AE (Incidence)
Nervous System Disorders	Headache	5	5 (7.8)	14	13 (20.6)	21	19 (30.2)	29	27 (42.2)
Gastrointestinal Disorders	Nausea	4	4 (6.3)	5	5 (7.9)	5	4 (6.3)	9	9 (14.1)
	Vomiting	1	1 (1.6)	1	1 (1.6)	2	2 (3.2)	5	5 (7.8)
	Upper abdominal pain	0	0 (0)	4	3 (4.8)	4	3 (4.8)	4	4 (6.3)
Musculo-skeletal Disorders	Arthralgia	3	3 (4.7)	1	1 (1.6)	1	1 (1.6)	6	5 (7.8)
	Myalgia	0	0 (0)	0	0 (0)	0	0 (0)	6	5 (7.8)

Most frequently reported adverse events are transient (few days) and mild (headache, nausea, gastrointestinal pain) and manageable with or without OTC medications

25mg clearly stands out with a similar safety profile observed in the placebo group (except transient headaches)

Phase 2b safety confirms profile observe in the phase 2a study

Following Phase 2b results, ABX464 is moving to phase 3 by end of year

- Primary endpoint (statistically significant reduction of Modified Mayo Score) was met with once-daily ABX464 (25mg, 50mg, 100mg) at week 8 in these 254 patients randomized, double-blind and placebo-controlled clinical trial ($p<0.01$, intent-to-treat population [ITT])
- Key secondary endpoints, including endoscopic improvement, clinical remission, clinical response and the reduction of fecal calprotectin showed significant difference in patients dosed with ABX464 compared to placebo
- ABX464 also showed rapid efficacy in all patients, including those who were previously exposed to biologics and/or JAK inhibitors treatment
- ABX464 was safe and well tolerated
- Preliminary data from 51 patients treated with 50mg ABX464 in the open-label maintenance study showed further increased and durable clinical remission and endoscopic improvement after 48 weeks

ABX464 clinical differentiation factors and positioning

First-in-class small molecule with unique mechanism of action

Easy, oral once-daily administration

Fast onset of action

Durable and maintained efficacy

Good safety and tolerability profile

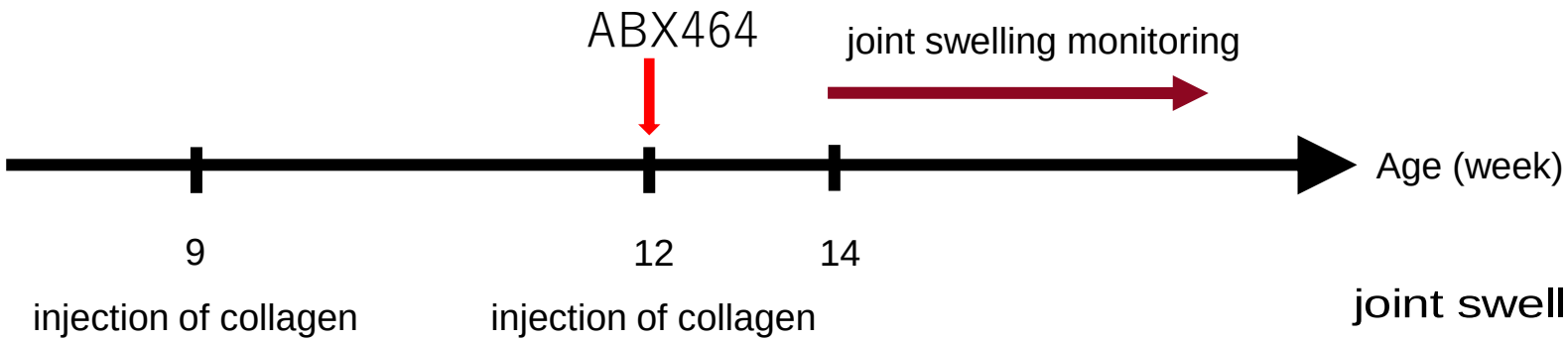
ABX464 has all necessary clinical differentiation factors to be positioned as

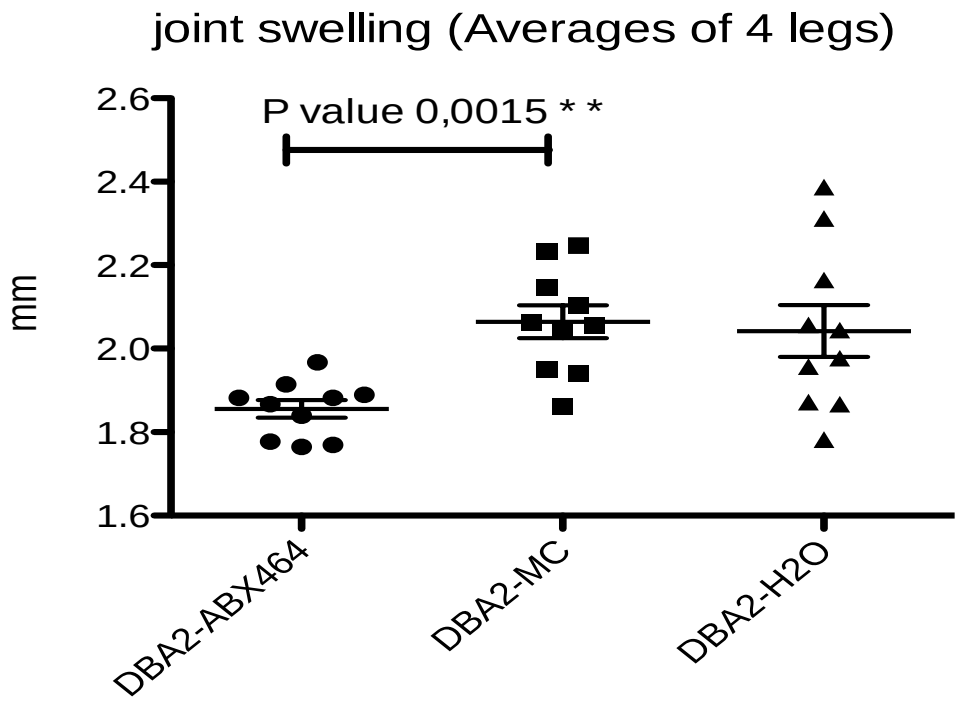
2nd and 3rd line therapy in moderate to severe ulcerative colitis and Crohn's disease patients

1st line: Corticosteroids, immunosuppressant drugs and 5-ASA
2nd line: Biologics and JAKs
3rd line: Any failure or intolerance to 2nd line treatments

ABX464: Clinical Development in rheumatoid arthritis

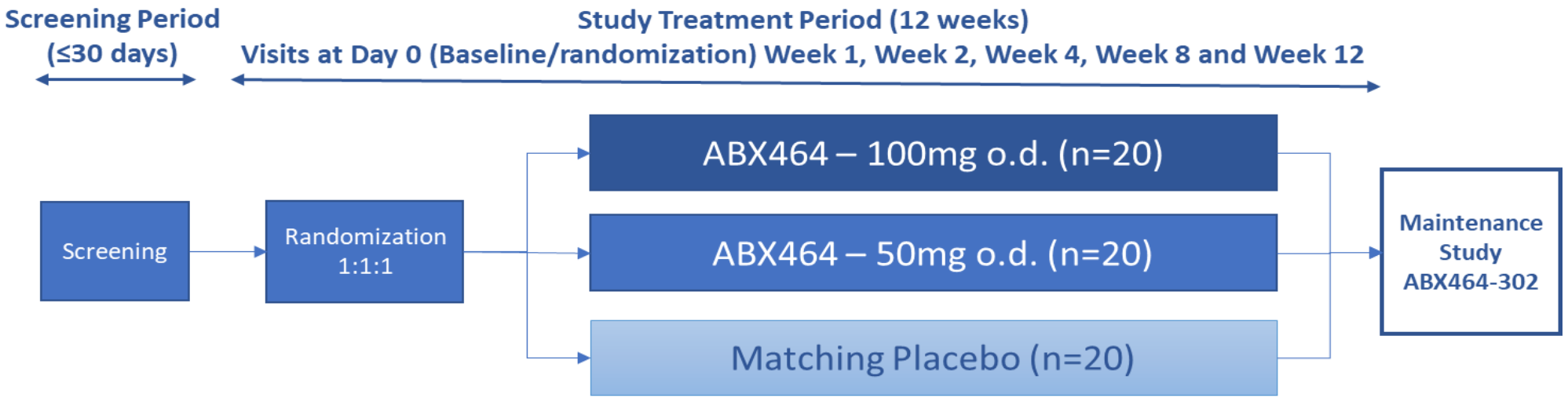
ABX464 prevents joint swelling in the Collagen Induced Arthritis model





ABX464 study design for phase 2a in RA following positive results in Collagen Induced Arthritis model

Phase 2a Randomized, double-blind, placebo controlled



Primary objective

Evaluate the safety profile of ABX464 given at two different doses (100mg and 50mg) vs placebo **in combination with methotrexate (MTX)** in patients with moderate to severe active rheumatoid arthritis with inadequate response to MTX and/or TNFa inhibitors.

Phase 2a clinical study in RA – Study results (ACR)

Strong efficacy signal observed with 50mg o.d.

- Patients' characteristics well-balanced among the treatment arms
- 70% (n=42) had inadequate response to methotrexate
- 30% (n=18) had inadequate response/intolerance to TNF α inhibitors
- Statistically significant difference on ACR20 and ACR50 at 50mg compared to placebo (PP)

	Placebo		50mg		100mg	
	PP # (n=19)	ITT (n=20)	PP # (n=16)	ITT (n=21)	PP # (n=7)	ITT (n=19)
Early discontinuations	1		3		12	
Mean DAS28-CRP at Baseline	5.3		5.5		5.5	
ACR20	4 (21%)	4 (20%)	9 (56%)*	9 (43%)	3 (43%)	3 (16%)
ACR50	1 (5%)	1 (5%)	5 (31%)*	5 (24%)	2 (29%)	2 (11%)
ACR70	1 (5%)	1 (5%)	4 (25%)	4 (19%)	1 (14%)	1 (5%)

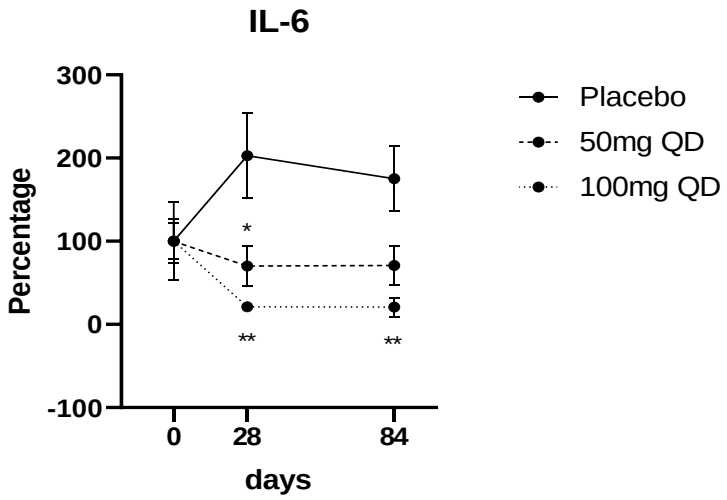
#Per Protocol set for ACR endpoint
*$p<0.05$

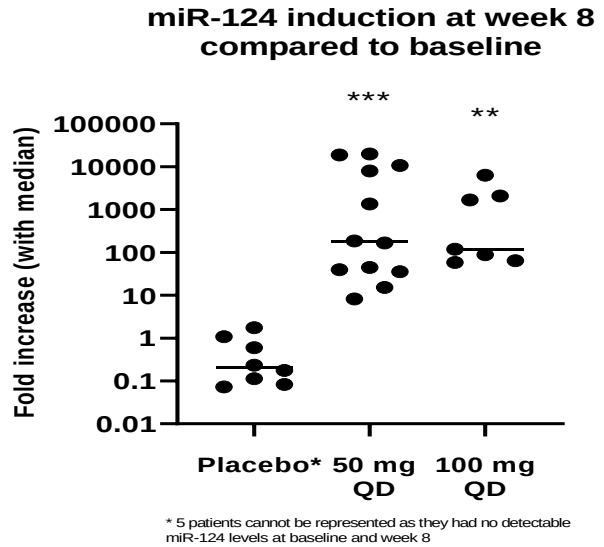
Phase 2a clinical study in RA – Study results

Other efficacy endpoints and biomarkers

	Placebo		50 mg		100 mg	
	*p<0.05					
	PP (n=19)	ITT (n=20)	PP (n=16)	ITT (n=21)	PP (n=7)	ITT (n=19)
DAS28-CRP change from baseline	-0.63	-0.60	-1,79*	-1,41*	-1,94*	-0,72
Low Disease Activity (DAS28-CRP ≤ 3.2)	2 (11%)	2 (10%)	4 (25%)	4 (19%)	3 (43%)	3 (16%)
CDAI ≤ 10	2 (11%)	2 (10%)	5 (31%)	5 (24%)	3 (43%)	3 (16%)

- ACR results confirmed by DAS28-CRP and CDAI
- Decreased levels of IL-6 observed in 50mg and 100mg ABX464 groups
- Statistically significant upregulation of miR-124 in 50mg and 100mg active groups compared to placebo (blood)





* 5 patients cannot be represented as they had no detectable miR-124 levels at baseline and week 8

Phase 2a clinical study in RA – Topline safety results summary

No new safety signal reported with ABX464 + MTX

- **Serious Adverse Events: 1 (5%) placebo, 0 (0%) 50mg, 1 (5%) with 100mg**
- **No new safety signal reported. An increased incidence of AE was reported in the 100mg treatment group (mainly GI), leading to early study treatment interruptions in that dose group that is no longer considered as top dose following the phase 2b results in Ulcerative Colitis.**
- **The increased incidence of AEs in the 100mg group might be due to the combination with MTX and overlapping GI side effects**

ABX464 favourable safety profile

Most frequent adverse events reported in the phase 2a clinical study in RA

System Organ Class	Adverse effect	Placebo (N=20)		ABX464 50mg (N=21)		ABX464 100mg (N=19)	
		Number of reports	n (%) of pts with AE (Incidence)	Number of reports	n (%) of pts with AE (Incidence)	Number of reports	n (%) of pts with AE (Incidence)
Infections and infestations	All	4	4 (20%)	4	3 (14.3%)	6	5 (26.3%)
Gastrointestinal Disorders	All	6	4 (20%)	24	11 (52.4%)	44	16 (84.2%)
	Abdominal pain	0	0 (0%)	3	2 (9.5%)	1	1 (5.3%)
	Upper abdominal pain	1	1 (5%)	6	5 (23.8%)	10	4 (21.1%)
	Diarrhoea	2	2 (10%)	7	4 (19%)	11	7 (36.8%)
	Dyspepsia	0	0 (0%)	1	1 (4.8%)	3	3 (15.8)
	Nausea	1	1 (5%)	4	3 (14.3%)	12	9 (47.4)
	Vomiting	1	1 (5%)	2	2 (9.5%)	4	3 (15.8%)
Nervous System Disorders	All	10	5 (25%)	23	8 (38.1%)	19	10 (52.6%)
	Headache	6	4 (20%)	19	8 (38.1%)	16	10 (52.6%)

No opportunistic infection and infection, infestation rate similar between placebo and ABX464 all doses (20%)

Dose response for GIs driven by: Abdominal pain upper, diarrhea, dyspepsia, nausea and vomiting

Dose-response for Nervous system disorders driven by headaches (rates similar to a bit higher than in UC)

Phase 2a clinical study in RA – Topline results summary

- Primary endpoint met with ABX464 demonstrating good safety and tolerability profile with 50mg once daily oral administration
- A statistically significant difference ($p < 0.03$) was met on key efficacy endpoint ACR20 in the PP population with 60% of ABX464 patients dosed with 50mg reaching that endpoint versus 22% in the placebo group
- Other key efficacy endpoints (ACR50, ACR70, DAS28-CRP, CDAI) as well as biological markers (CRP, miR-124, IL-6) showed favorable differences with 50mg ABX464 over placebo
- Abivax is preparing to start a clinical phase 2b program in rheumatoid arthritis in early 2022 with doses of 50mg, 25mg and 12.5mg once daily (as in ulcerative colitis phase 3)
- Given the demonstrated safety and efficacy of ABX464 in rheumatoid arthritis and ulcerative colitis, Abivax is exploring additional programs in chronic inflammatory indications

Next steps for the clinical development of ABX464 in RA

Complete the evaluation of the clinical phase 2a induction study in Q3 2021

Obtain one year phase 2a maintenance data in Q1 2022

Initiate clinical phase 2b studies in patients with inadequate response to conventional DMARDs as well as biological DMARDs in Q1 2022

How to bring ABX464 to the finish line in chronic inflammation

Phase 1 TQT study:
- 120/120 subjects: enrollment completed
- Results expected in Q3 2021

Phase 1 DDI study:
- 60/60 subjects: enrollment completed
- Results expected in Q3 2021

Phase 1 ADME study:
- 6/12 subjects enrolled
- Results expected in late Q4 2021

Phase 1 study in Japanese subjects
- PMDA approval received
- Subjects to be enrolled in Japan, starting Q3 2021

Ulcerative colitis phase 3 in preparation:
- End of phase 2b meeting planned for **Q4 2021**
- **IQVIA** involved in study preparation
- **~ 2 x 700 patients** planned for induction followed by a controlled maintenance study
- FPI planned for **Q4 2021**

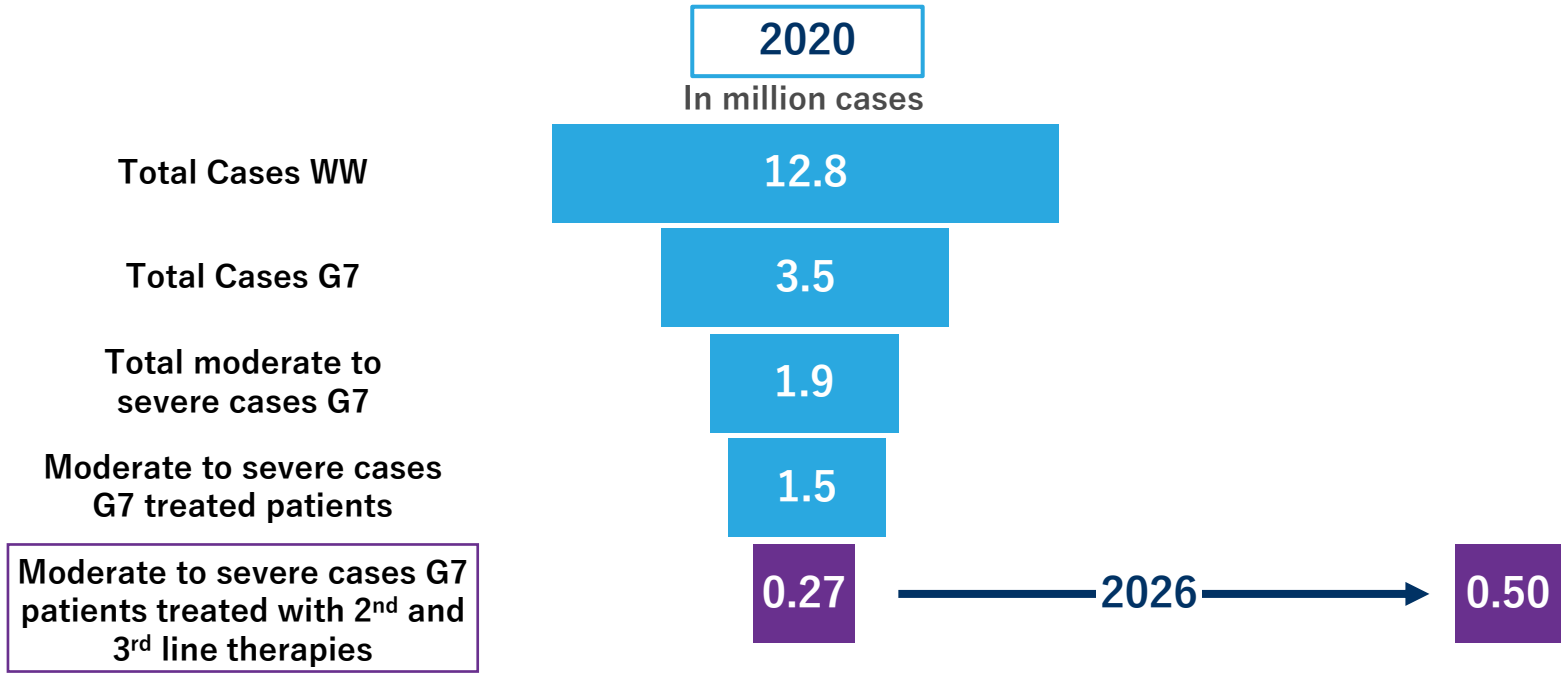
Crohn's disease phase 2b pivotal study in preparation:
- **~ 900 patients** in Europe and the US
- FPI expected for **Q4 2021**

Rheumatoid arthritis phase 2b studies planned:
- CsDMARDs and bDMARDs
- FPI expected for **Q1 2022**

ABX464: A potential blockbuster in IBD…

Size of target market doubling in UC and increasing by nearly 25% in CD (2020 - 2026)

UC Epidemiology



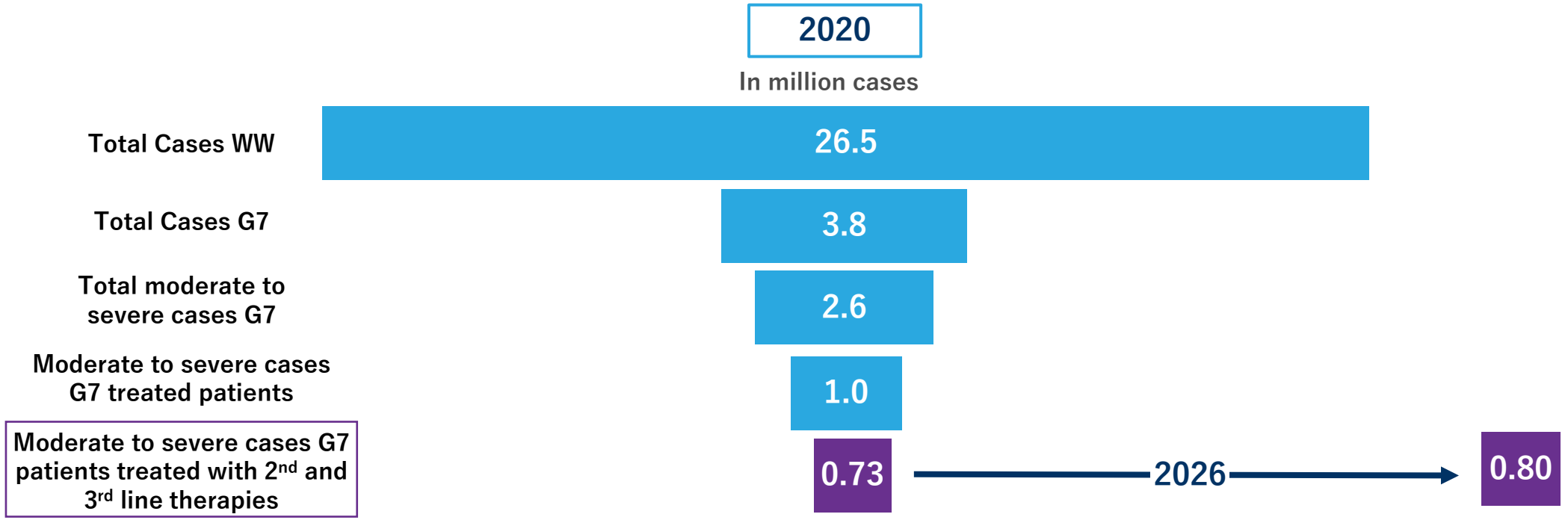
UC & CD Market Potential

	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)	2020: USD 6.0 B for UC 2026: USD 11.7 B for UC	2020: USD 11.9 B for CD 2026: USD 14.7 B for CD
ABX464 Market Share Assumptions	10-20% market share at peak sales for both indications	

Source: Informa

ABX464: As well as a potential blockbuster in RA

RA Epidemiology



RA Market Potential

ABX464 TPP	Patients with moderate to severe RA who failed on first line therapy Therefore, positioned as 2nd and 3rd line treatment
ABX464 First Launch	2027
G7 Market Size (2nd & 3rd line)	2020: USD 20.4B 2026: USD 22.4B
ABX464 Market Share Assumptions	10-20% market share at peak sales

Source: Informa

Newsflow through Q1 2022

	Q2 2021	Q3 2021	Q4 2021	Q1 2022
UC - Phase 2b (ABX464)	**Top-line results** (Induction and initial maintenance data) ✓		**FPI Phase 3**	**Top-line results** (One-year maintenance data)
CD - Phase 2b (ABX464)			**FPI Phase 2b**	
RA - Phase 2a (ABX464)	**Top-line results** (Induction data) ✓			**FPI Phase 2b** **Top-line results** (One-year maintenance data)
HCC - Phase 1/2 (ABX196)		**Enrollment completed and top-line results** (Dose escalation) **Start of expansion phase**		

EUR 85M new financing (as of July 2021)
EUR 60M capital increase of and EUR 25M convertible bonds

EUR 60M capital increase

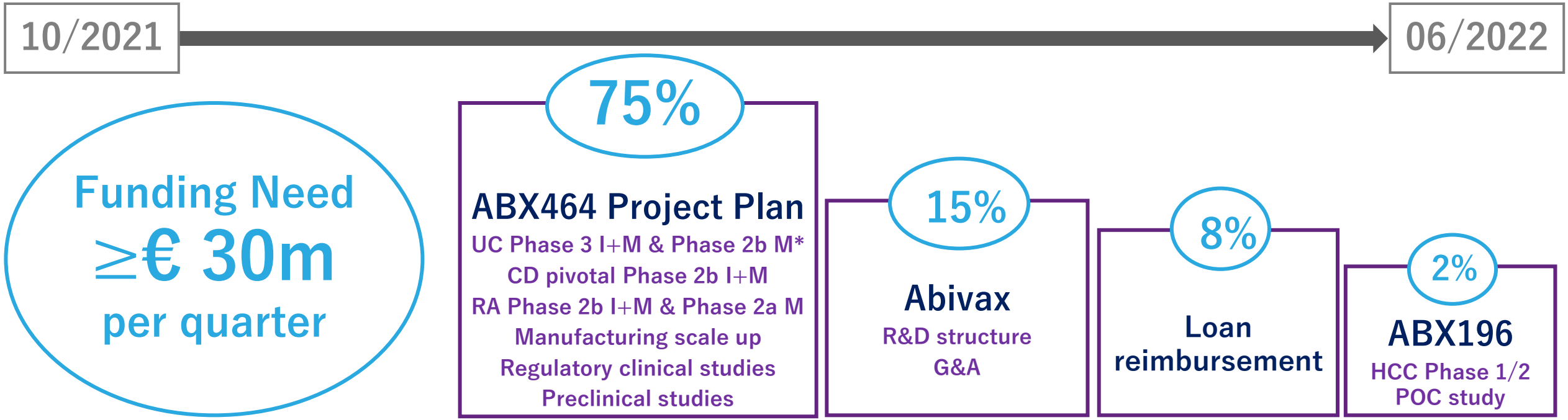
- Oversubscribed capital increase totaling EUR 60M
- Subscription price set at EUR 30.55, i.e. with a 3% discount to the last closing price (July 22, 2021)
- 1,964,031 shares with a nominal value of EUR 0.01 each, representing 13.34% of current share capital
- Existing shareholders Sofinnova Partners and Santé Holding subscribed for an amount of EUR 8M and and EUR 3M respectively
- Vivo Capital, Invus and Commodore Capital subscribed among other top-tier investors

EUR 25M convertible bonds

- Convertible bonds issued for a total of EUR 25M
- Issued at par and bear an interest of 6% per annum payable semi-annually, commencing on Jan. 30, 2022
- Nominal value of EUR 38.19 corresponds to a premium of 25% above the reference share price
- Initial conversion/exchange ratio set at one share per bond (i.e. conversion price of EUR 38.19 per ordinary share)
- Maturity Date set for July 30, 2026

Bryan, Garnier & Co and J.P. Morgan AG acted as Joint Global Coordinators and Joint Bookrunners

Abivax cash runway extended into Q2 2022



* I: Induction phase; M: Maintenance phase

Abivax financing strategy

Next strategic milestone to take place before end of 2021

Core strategic plan	Alternative strategic plan
Partnering (ranging from licensing to M&A)	**Financing round (on Euronext and/or Nasdaq)**

Highly experienced Executive Committee

Prof. Hartmut Ehrlich, M.D.

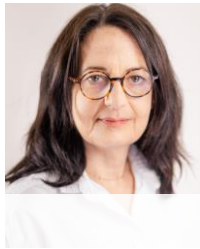
Chief Executive Officer

Baxter · SANDOZ · Lilly

Didier Blondel

Chief Financial Officer & Board Secretary

SANOFI · sanofi pasteur MSD



Sophie Biguenet, M.D.

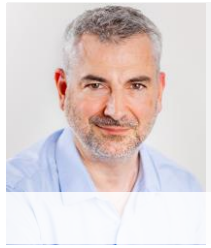
Chief Medical Officer

VESANTIS · abbvie · Bristol-Myers Squibb

Alexandra Pearce, Ph.D.

VP, Regulatory Affairs, Quality, PV

AMGEN · Pfizer



Pierre Courteille Pharmacist, MBA

Chief Commercial Officer & VP, BD

sanofi pasteur · Guerbet Contrast for Life

Paul Gineste Pharm.D.

VP, Clinical Operations

Boehringer Ingelheim · ALTANA

Jérôme Denis, Ph.D.

VP, Process Dev. & Manufacturing

imaXio · LYONBIOPOLE

Regina Jehle

Director Communications

BIONTECH

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VP, R&D

AstraZeneca

Prof. Jamal Tazi, Ph.D.

VP, Research

CNRS

Competencies from discovery to global commercialization