ABX464 – A future game changer for the treatment of chronic inflammatory diseases

Abivax, a late-stage clinical biotech company

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abivax

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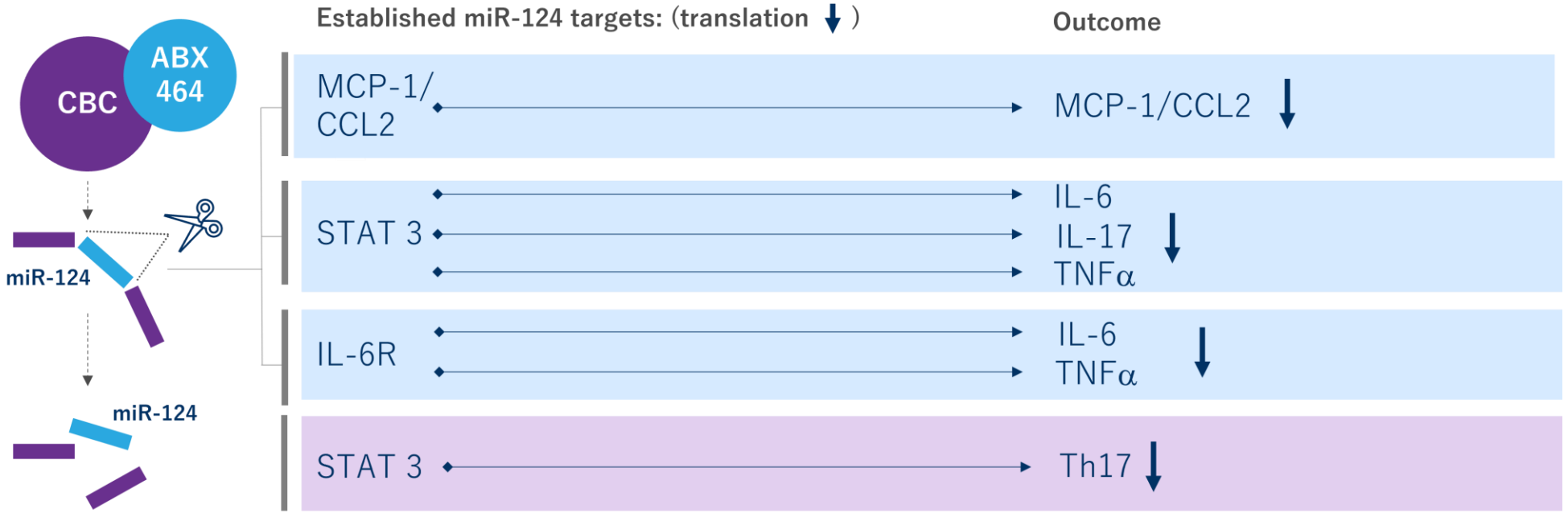
Future clinical development including phase 3 design and initiation is subject to assessment of the overall preclinical, CMC, toxicology, clinical efficacy and safety data of ABX464 by EMA, FDA and other regulatory authorities. These top-line results have not yet been reviewed by regulatory authorities.

Abivax and ABX464 for chronic inflammatory diseases: Main take-home messages

1. ABX464 is a potent anti-inflammatory oral drug candidate with a novel first-in-class mechanism of action: Upregulation of the physiological anti-inflammatory microRNA, miR-124
2. Safety and efficacy demonstrated in phase 2a and 2b induction and maintenance studies in moderate to severe ulcerative colitis (UC): ABX464 clinically differentiated from competitors, especially through impressive clinical remission rates during maintenance
3. FDA EoP2 feedback and EMA scientific advice feedback allow the finalization of the design of the ABX464 UC phase 3 global pivotal study program; FPI planned for Q2 2022
4. Abivax plans to go straight into a phase 2b in Crohn's disease (CD) - based on similar mechanisms of disease propagation - and in rheumatoid arthritis (RA) - based on encouraging phase 2a proof-of-concept data: ABX464 has the potential to treat a variety of chronic inflammatory diseases
5. Manufacturing ready for phase 3
6. 2021 total pharmaceutical sales in UC, CD and RA were USD 42B – ABX464 has the potential to take a significant market share and become a potential mega-blockbuster in IBD and RA

ABX464 novel mechanism of action: Potent and specific upregulation of miR-124, activating a “physiological brake” by reducing the expression of inflammatory cytokines and cells to normal levels

- **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.**
- **Out of 1,105 microRNAs, miR-124 was the only microRNA upregulated by ABX464.**
- **ABX464 has no impact on the splicing of cellular mRNA besides lncRNA00599-205.**

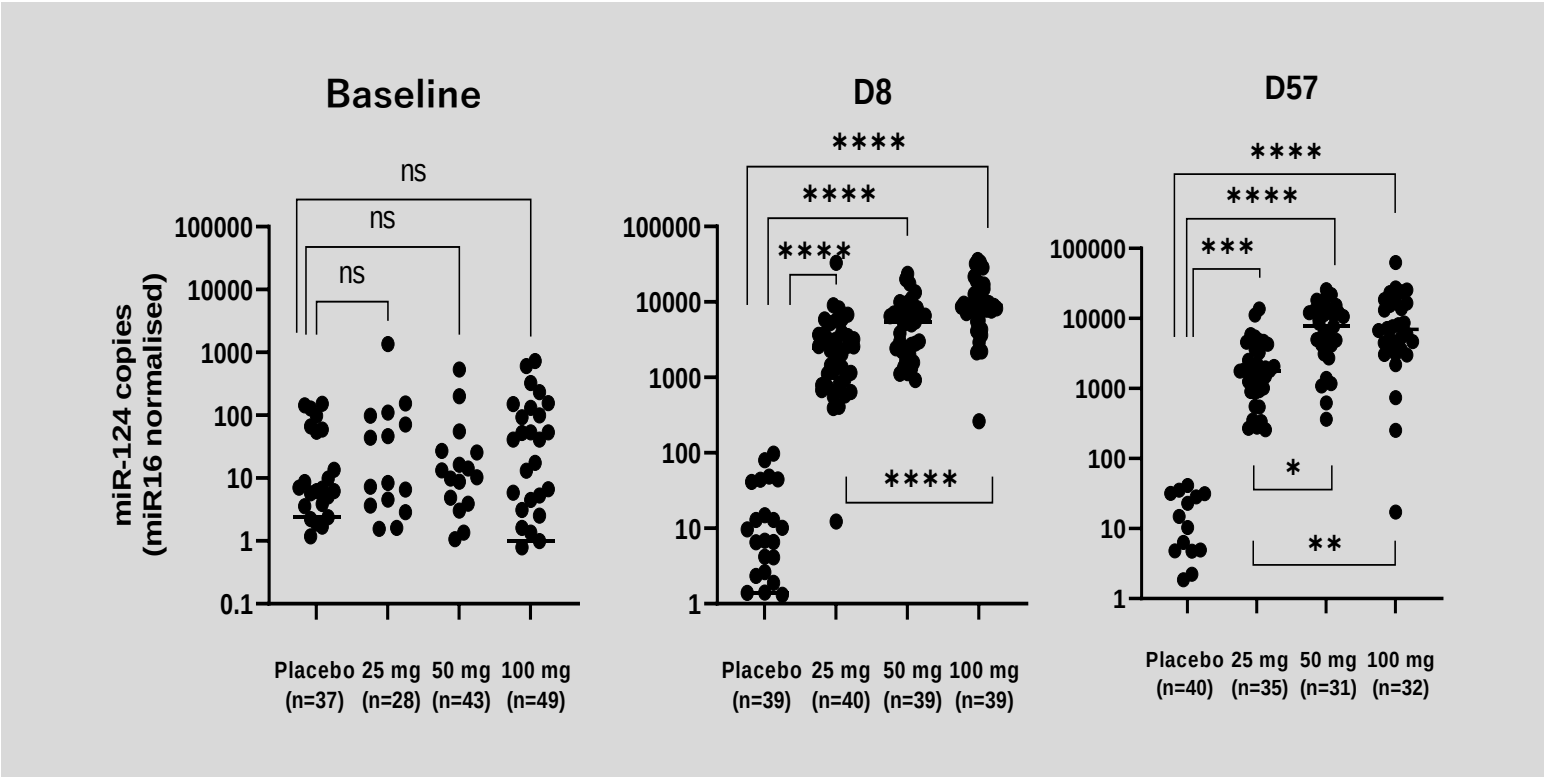


Tazi et al. *Drug Discov. Today* (2021); Poholek et al. *J Exp Med* (2020) 217 (10): e20191761; *Lin S, et al. Frontier in Onc (2020)*

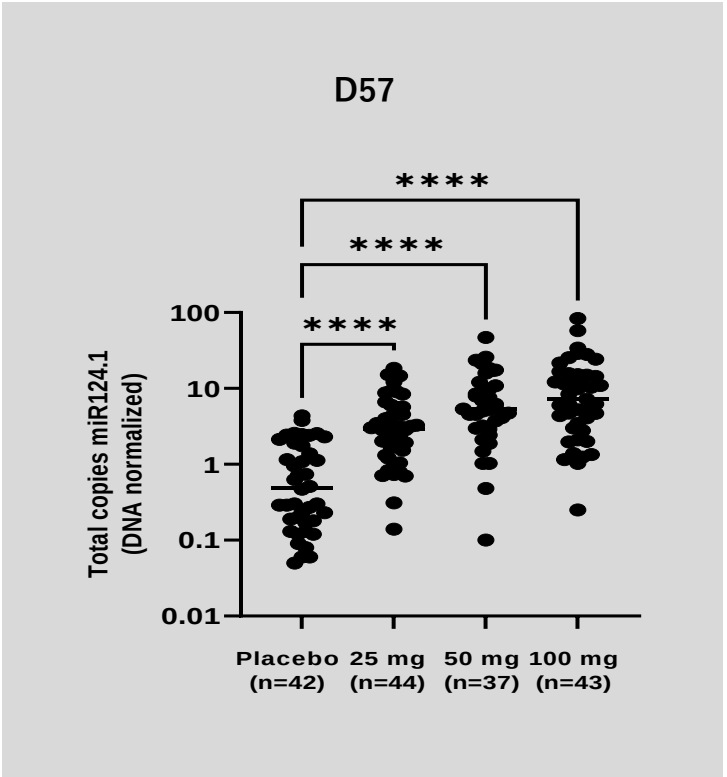
Significant miR-124 upregulation detected in rectal biopsies and blood (phase 2b UC study)

Dose relationship observed in rectal tissue and whole blood

miR-124 blood levels



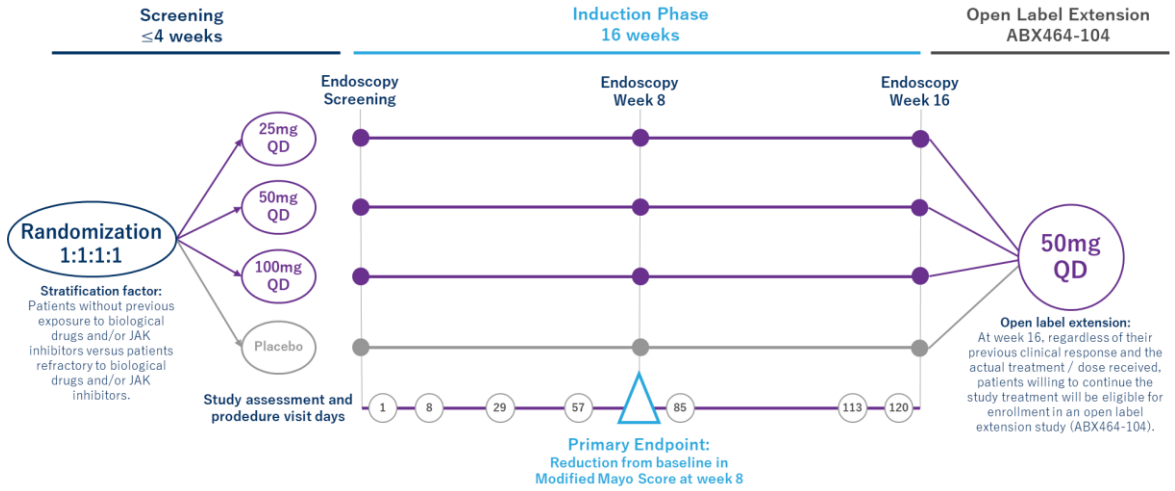
miR-124 in rectal tissue



Positive phase 2a study led to the conduct of a large-scale phase 2b study of ABX464 in patients with moderate-to-severe Ulcerative Colitis

- 254 patients in 15 countries in Europe, US and Canada (130 study sites)
- Moderate-to-severe active UC (Modified Mayo Score 5-9)
- Central, independent and blinded reading of endoscopies
- Baseline characteristics well-balanced among the treatment groups, incl. modified mayo sub-score, endoscopic sub-score, fecal calprotectin, majority of patients refractory to several biologics and JAK inhibitor treatments

		100mg	50mg	25mg	Placebo
		(N=64)	(N=63)	(N=61)	(N=64)
Modified Mayo Score (MMS)	Mean (SD)	7.0 (1.07)	7.1 (0.96)	7.1 (1.09)	7.0 (1.20)
Endoscopic sub-score = 3	%	66%	75%	67%	75%
Fecal Calprotectin (µg/g)	Mean	3778	3441	3022	2452
Previous exposure to biologics/Tofacitinib	n (%)	32 (50.0)	30 (47.6)	30 (49.2)	31 (48.4)
anti-TNF α	n (%)	31 (48.4)	25 (39.7)	25 (41.0)	27 (42.2)
anti-TNF α 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)
Tofacitinib	n (%)	13 (20.3)	12 (19.0)	10 (16.4)	12 (18.8)



Week 8 Efficacy Results (ITT): Primary Endpoint met - Efficacy confirmed for all patients and also for subset of bio-refractory patients

Week 8 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-refractory	-1.0	-2.8 **	-2.9 **	-2.8 **

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

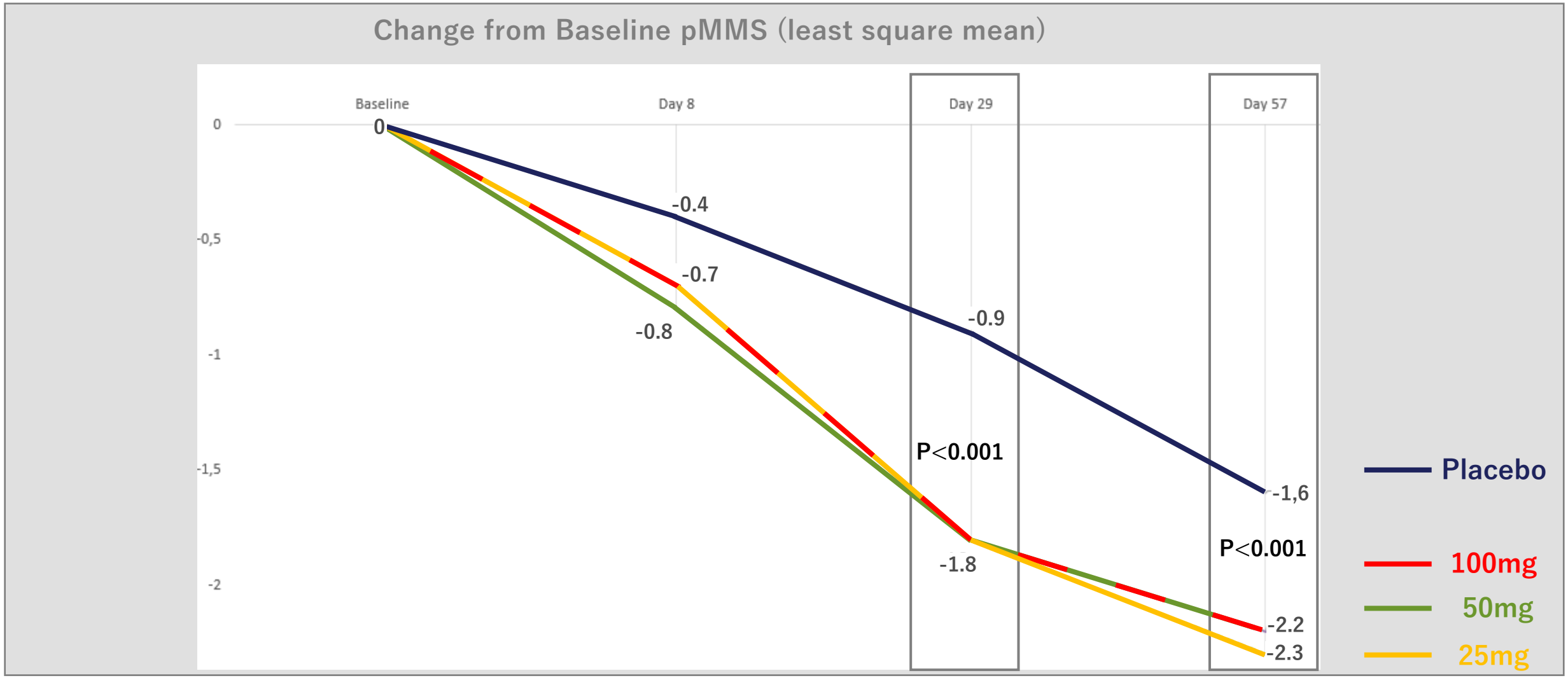
1) ITT: Intent-to-treat patient population. Drop-out patients were considered as failure for all endpoints. Nearest neighbor imputation, as defined in the SAP. Patient characteristics well balanced between all groups (Modified Mayo Score, ConMeds, Gender, etc.).

Week 8 Efficacy Results (ITT): Secondary endpoints - Efficacy confirmed for all patients and also for subset of bio-refractory patients

Week 8 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-refractory	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-refractory	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-refractory	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 vs 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

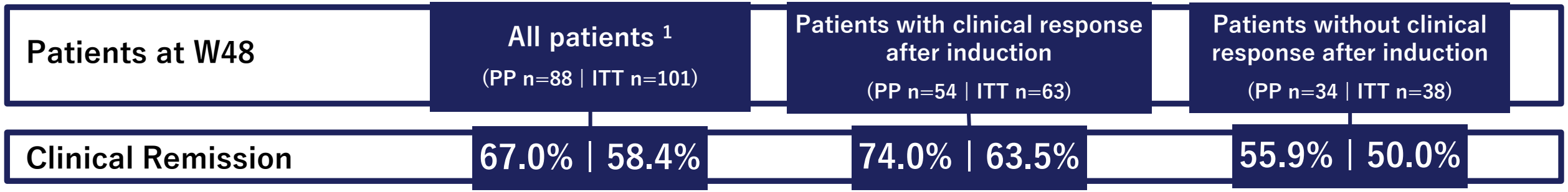
Week 4 and Week 8 Efficacy Results (ITT): Fast onset of action



ABX464 phase 2b maintenance study – impressive one-year efficacy confirmed

Phase 2b study: 217/222 eligible patients enrolled into maintenance

The first 101 patients of the 217 were to complete 1st year of maintenance by Sept. 15, 2021:
(12 patients were drop-outs, and no data available for 1 patient at W48, these 13 patients were considered treatment failures in ITT)



[1] Irrespective of patient outcome at the end of the induction phase

ABX464 phase 2a maintenance study – impressive long-term efficacy (3 years) confirmed

Phase 2a study [2]

	1st year	2nd year	3rd year
Clinical remission (ITT)	12/22 (54.5%)	11/22 (50.0%)	11/22 (50.0%)

[2] 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	Active	Placebo	Delta
		Results of Induction studies (ITT)*			Results of Maintenance studies (ITT)* (Patients with clinical response at the end of the induction, except for "all comers" in the Etrasimod study)		
Adalimumab	ULTRA I (Ph 3)	18.5%	9.2%	9.3%	17.3%	8.5%	8.8%
	ULTRA II (Ph 3)	16.5%	9.3%	7.2%			
Ustekinumab	Phase 3	15.5%	5.3%	10.3%	43.8%	24%	19.8%
Vedolizumab	GEMINI I (Ph 3)	16.9%	5.4%	11.5%	44.8%	15.9%	28.9%
Tofacitinib	OCTAVE I (Ph 3)	18.5%	8.2%	10.3%	40.6%	11%	29.6%
	OCTAVE II (Ph 3)	16.6%	3.6%	13.0%			
Ozanimod	Truenorth (Ph 3)	18.4%	6.0%	12.4%	37%	18.5%	18.5%
Etrasimod	Phase 2** (12 weeks)	33%	8.1%	24.9%	33%		
Upadacitinib	U-Achieve (Ph 3)	26.0%	5.0%	21.0%	52.0% (30mg) 42.0% (15mg)	12.0% (30mg) 12.0% (15mg)	40.0% (30mg) 30.0% (15mg)
	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%	66.7% (50mg)	-	-
	Phase 2b (25mg)	27.9%	12.5%	15.4%	63.5% (50mg)	-	-

Marketed drugs in IBD

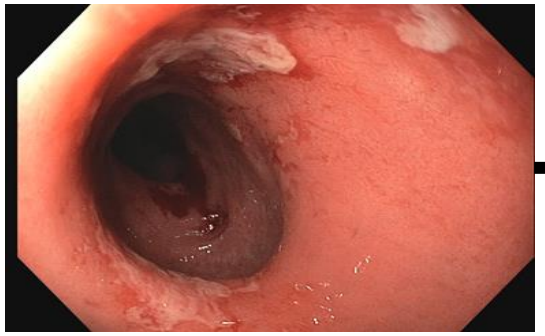
Drug candidates in late-stage development in IBD

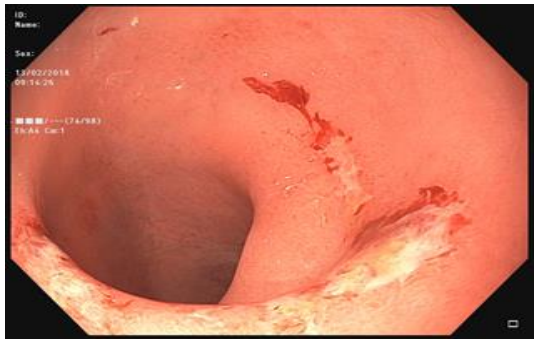
*non-comparative studies conducted versus placebo

**Sandborn et al, 2020: 12W Induction results

Complete resolution of UC lesions in an ABX464 treated patient (vedolizumab, infliximab and adalimumab resistant) during 3 years of open-label maintenance treatment

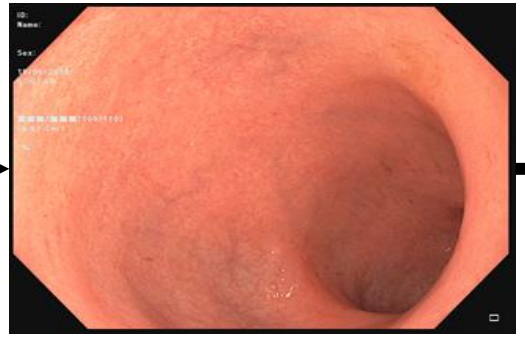
Endoscopy before ABX464



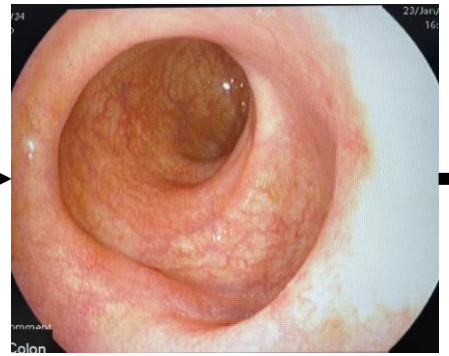


Courtesy of Prof. Severine Vermeire, Leuven, Belgium

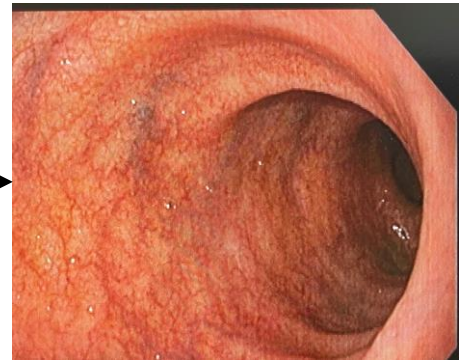
Endoscopy after 1st year of ABX464



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 ABX464 safety profile

Safety in phase 2b study in UC patients confirms profile observed in the phase 2a study

- No new safety signal, no death, no malignancy
- Most frequently reported AEs are headaches (20% for 25mg and 8% for placebo), which occur early (first 10 days of treatment) and are transient (few days), mild or moderate (grade 1 or 2) and manageable with or without OTC medications
- Other AEs ≥ 5% (related and non-related) are gastrointestinal disorders (nausea, vomiting, upper abdominal pain) and musculoskeletal (arthralgia, myalgia)
- Labs: No clinically significant changes in laboratory parameters (liver function tests, Hb, white blood cells)

% Patients with at least one AE	Placebo (N=64)	ABX464 25mg (N=62)	ABX464 50mg (N=63)	ABX464 100mg (N=64)
TEAE leading to Study Discontinuation	6.3%	1.6%	9.5%	9.4%
SAEs[1]	6.3%	1.6%	6.3%	6.3%
Severe Grade 3-4 TEAEs[1]	4.7%	4.8%	7.9%	10.9%
Infections	9.4%	4.8%	12.7%	7.8%

[1] Related and not related to study drug

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

Favorable ABX464 safety profile across all clinical studies

- **More than 1,000 subjects exposed to ABX464** (Cut-off date Nov. 30, 2021)
  - → Total subjects exposed: 1,069
  - → Subjects exposed at 25mg: 143
  - → Subjects exposed at 50mg: 750
  - → Subjects exposed at 100mg: 95

- **ABX464 also showed good safety profile in a clinical study conducted in Covid-19 patients**
  - → Phase 2b/3, randomized, double blind, 28-days study to evaluate 50mg ABX464 (n=335) compared to placebo (n=170) in SARS-CoV-2-infected high-risk patients
  - → No imbalance across the treatment groups in terms of incidence of TEAE, SAE, laboratory results; no new safety signal

How to bring ABX464 to the market in ulcerative colitis

Ulcerative colitis phase 3 preparation on track

- **FDA** end of phase 2 meeting feedback and **EMA** scientific advice with guidance and a path forward
- Abivax intends to study **25mg and 50mg** in the induction studies and possibly **one lower dose** during maintenance
- **IQVIA and US and EU KOLs** involved in finalizing study design
- **~ 2 x 700 patients** planned for induction followed by a controlled maintenance study
- FPI planned for **Q2 2022**

Inclusion of Japan in the global ABX464 phase 3 study program

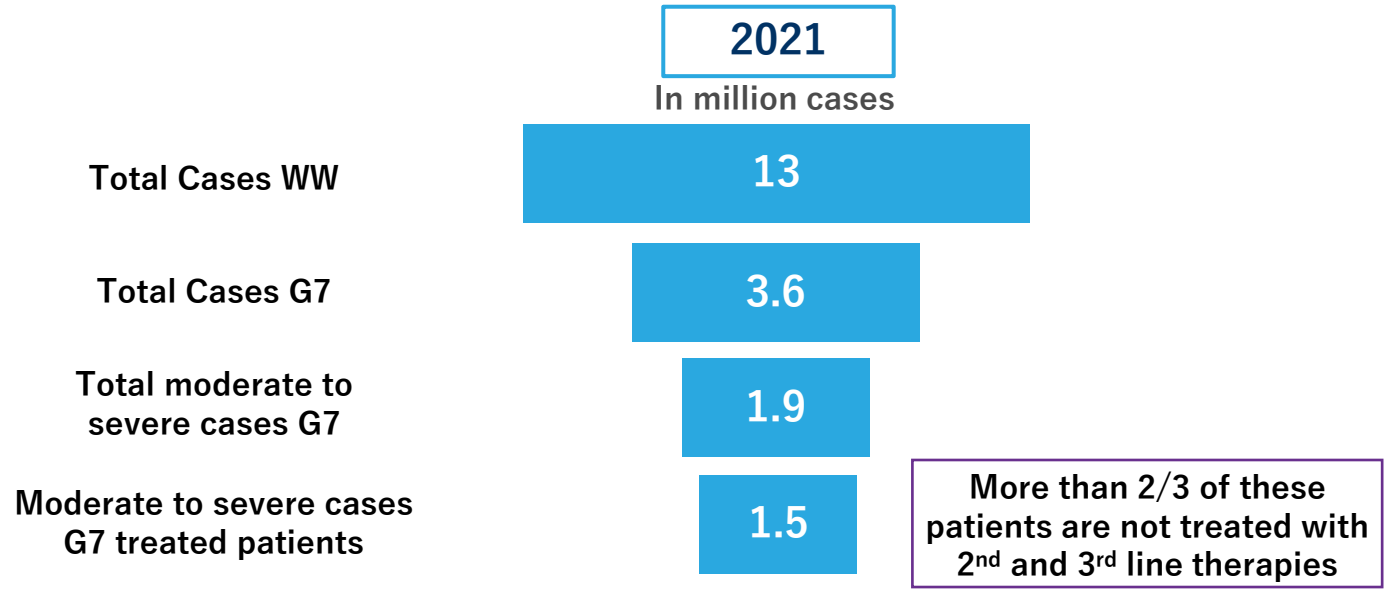
Required phase 1 study in Japanese healthy volunteers

- Enrollment completed
- Results expected in early Q2 2022

ABX464: A potential mega-blockbuster in IBD

Size of target market increasing by 70% in UC and by nearly 20% in CD (2021 - 2027)

UC Epidemiology



Total market size[1] in inflammatory diseases **> USD 90B**

Market size[1,2]
UC: USD 6.2B
CD: USD 13B
RA: USD 22.3B

ABX464 addresses a market of **USD 42B**

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 Full Launch	2027 for UC	2028 for CD
G7 Market Size (2nd & 3rd line)	2021: USD 6.2B for UC 2027: USD 10.6B for UC	2021: USD 13B for CD 2027: USD 15.4B for CD
ABX464 Market Share Assumptions	10-20% market share at peak sales for both indications	

1) 2021 data for Europe G5, U.S. and Japan
2) 2nd and 3rd line

Source: Global Data & Informa

ABX464 is a potential drug in IBD and multiple chronic inflammatory diseases
Phase 2a clinical study in RA - Top-line results allowing to move into phase 2b

- 3-months induction study in 60 patients (placebo, 50mg and 100mg ABX464): Baseline characteristics well balanced across all groups
- 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
- Phase 2a maintenance data in rheumatoid arthritis to be reported in Q1 2022
- Abivax intends to start a clinical phase 2b program in rheumatoid arthritis

ABX464 newsflow through Q2 2022

	Q4 2021	Q1 2022	Q2 2022
UC - Phase 2b (ABX464)		**Top-line results** (One-year maintenance data)	**Publication of full-length phase 2b manuscript**
UC - Phase 3 (ABX464)	**FDA feedback** ✓	**EMA feedback** ✓	**FPI phase 3 study**
RA - Phase 2a (ABX464)		**Top-line results** (One-year maintenance data)	**Publication of full-length phase 2a manuscript**

Thank you for your attention!

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