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

February, 2020

Breaking News 26/02/2020:
Abivax includes First Patient in U.S. Phase 1/2 clinical trial of ABX196 to treat hepatocellular carcinoma

abivax

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Key company facts

Milestones

Founded in 2013
by Truffle Capital

Focus on inflammatory diseases with ABX464 in Sept. 2018

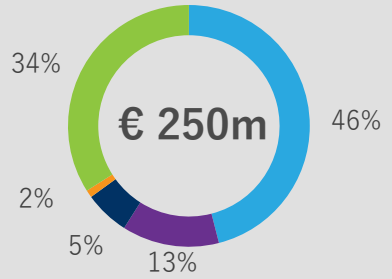
Abivax went public in June 2015, raising € 57.7m

Location

Head Office
Paris

Cooperative Lab with CNRS
Montpellier

Shareholder structure[1] and market cap[2]



Operations

26
Employees

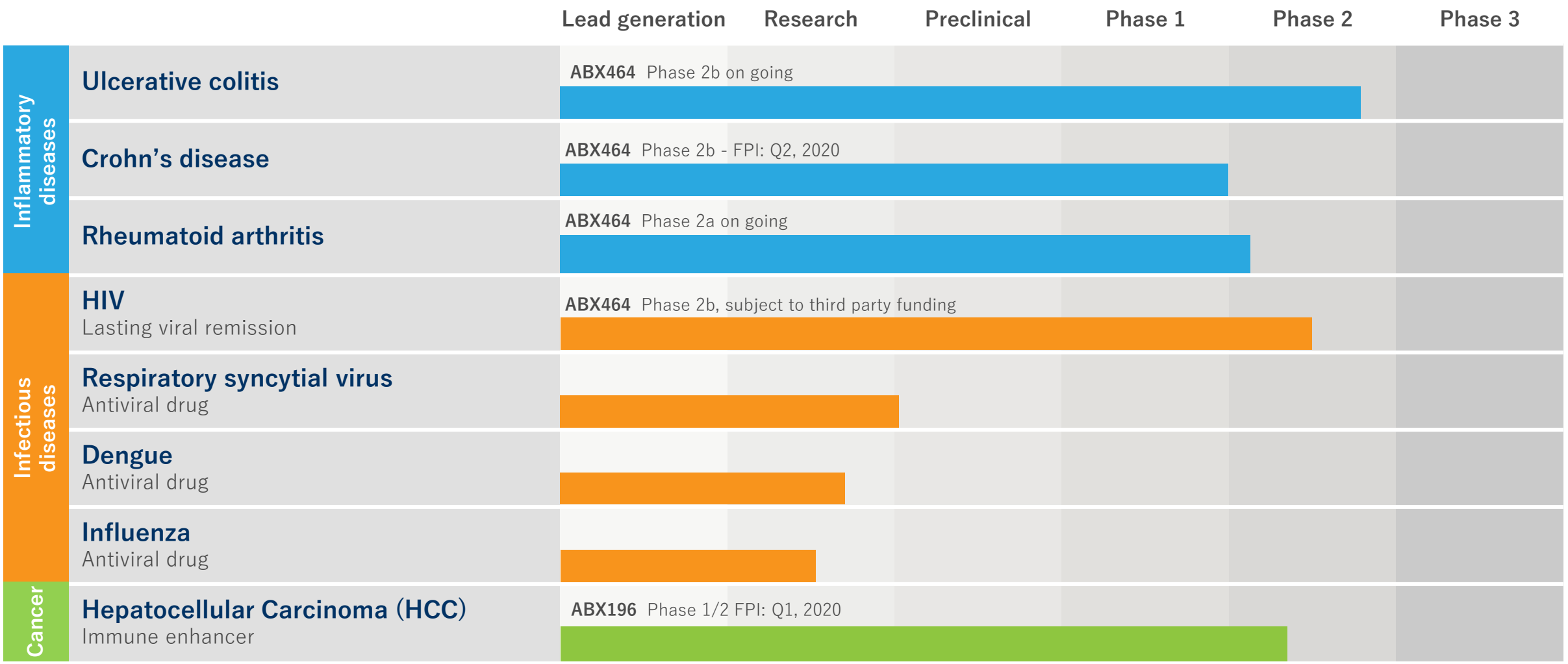
Cash proforma[3]
€ 23.6m

20
in R&D

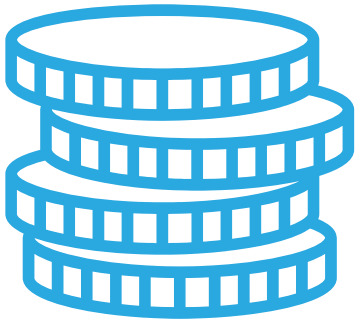
6
in Support

1) Undiluted – as of 31.07.2019
2) As of 10.01.2020 EOB
3) Actual June 2019 + Sofinnova capital raise in July 2019

Abivax: A strong and diversified pipeline

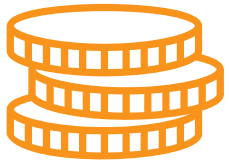


ABX464: A promising candidate addressing attractive markets



Total market size
in inflammatory diseases

greater than
USD 70 B



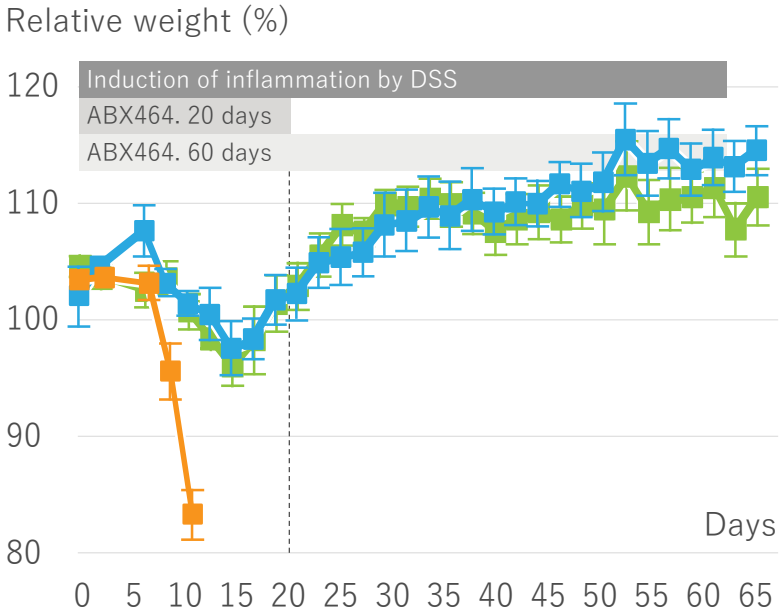
Market size
in first indication (ulcerative colitis)

around
USD 5.7 B

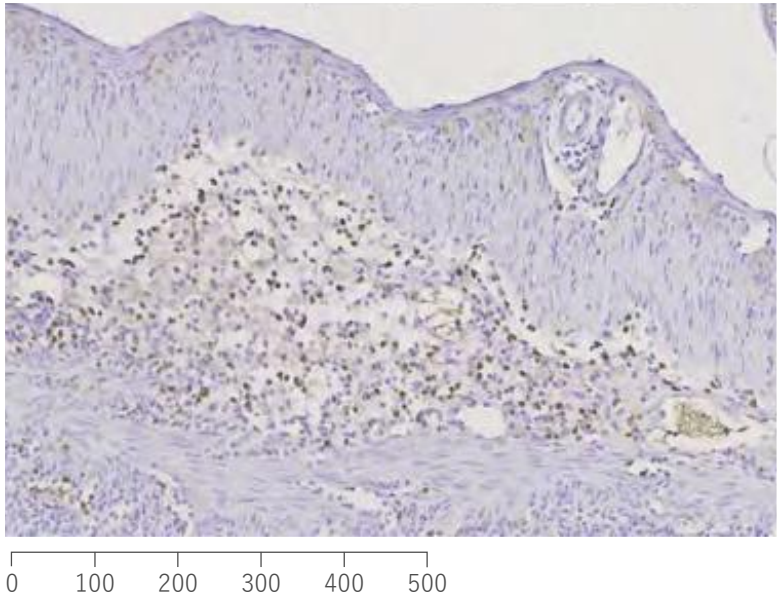
- Coming from the **proprietary** Abivax library of compounds, biased to **modulate RNA biogenesis** (>2200 molecules); Close collaboration with EVOTEC
- **Small molecule** (quinoline), administered as an **oral capsule** (once a day)
- **First-in-Class, novel mechanism of action:** Selective upregulation of anti-inflammatory microRNA miR-124
- Good safety profile after administration to >**210 subjects**
- **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 phase 2a in rheumatoid arthritis in 60 patients
- **High medical need** for novel safe and efficacious drugs in inflammatory diseases

ABX464 showed efficacy in DSS mouse model*

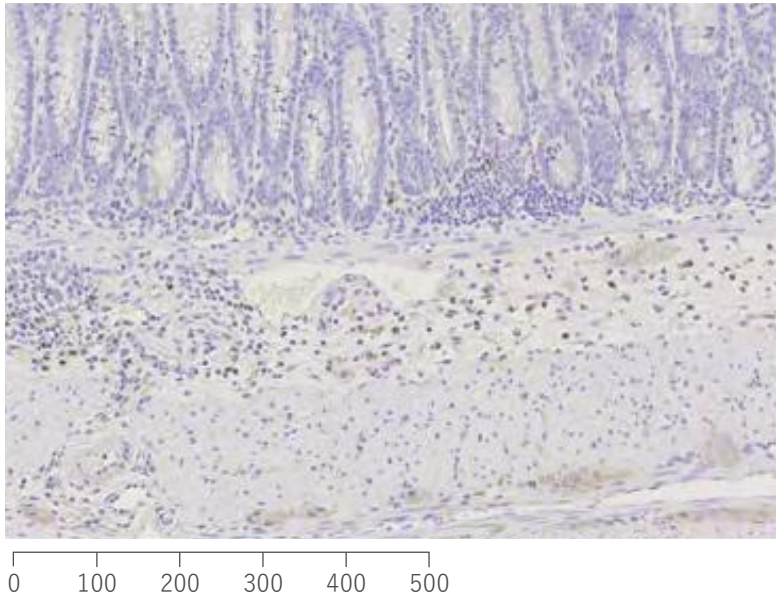
ABX464 protects mice from death in the DSS mouse model



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)
First year completed, second year completing by end of January 2020 and going into 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 (Induction)

Patient demographics and baseline disease characteristics
Groups generally well-balanced

		ABX-464 N = 23	Placebo N = 9	Total N = 32
Age (years)	Mean (Min-Max)	42.96 (20.0 – 73.0)	44.11 (20.0 – 64.0)	43.28 (20.0 -73.0)
Sex	Male	12 (52.2%)	8 (88.9%)	20 (62.5%)
BMI (kg/m^2) at Screening	Mean	25.63 (17.6 - 38.6)	25.96 (20.3 - 32.9)	25.72 (17.6 – 38.6)
CRP (mg/L)	Mean / Median	7.4 / 2.5	4.5 / 1.8	6.6 / 2.3
	Min-Max	0.4- 66.8	0.4-19.2	0.4- 66.8
Fecal Calprotectin (µg/g)	Geometric Mean (N)	958.9 (23)	786,01 (8)	910,9 (31)
	Min-Max	78.7 – 19109.0	39.2 – 5150.3	39.2 – 5150.3
Disease Duration (years)	Mean / Median	7.72 / 5.80	6.53 / 5.20	7.38 / 5.50
	Min-Max	0.3- 26.3	2.9- 13.0	0.3- 26.3
Previous Biologics Exposure		10/23 (43.5%)	6/9 (66.7%)	16/32 (50%)
Refractory to anti-TNF & Vedo		5/10 (50%)	4/6 (67%)	9/16 (56%)
Refractory to anti-TNF		5/10 (50%)	2/6 (33%)	7/16 (44%)
Total Mayo Score	Mean (Min-Max)	8.65 (6 – 11)	7.89 (4 – 11)	8.44 (4 – 11)
Partial Mayo Score	Mean (Min-Max)	6.17 (4 – 8)	5.56 (2 – 8)	6,0 (2 – 8)

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

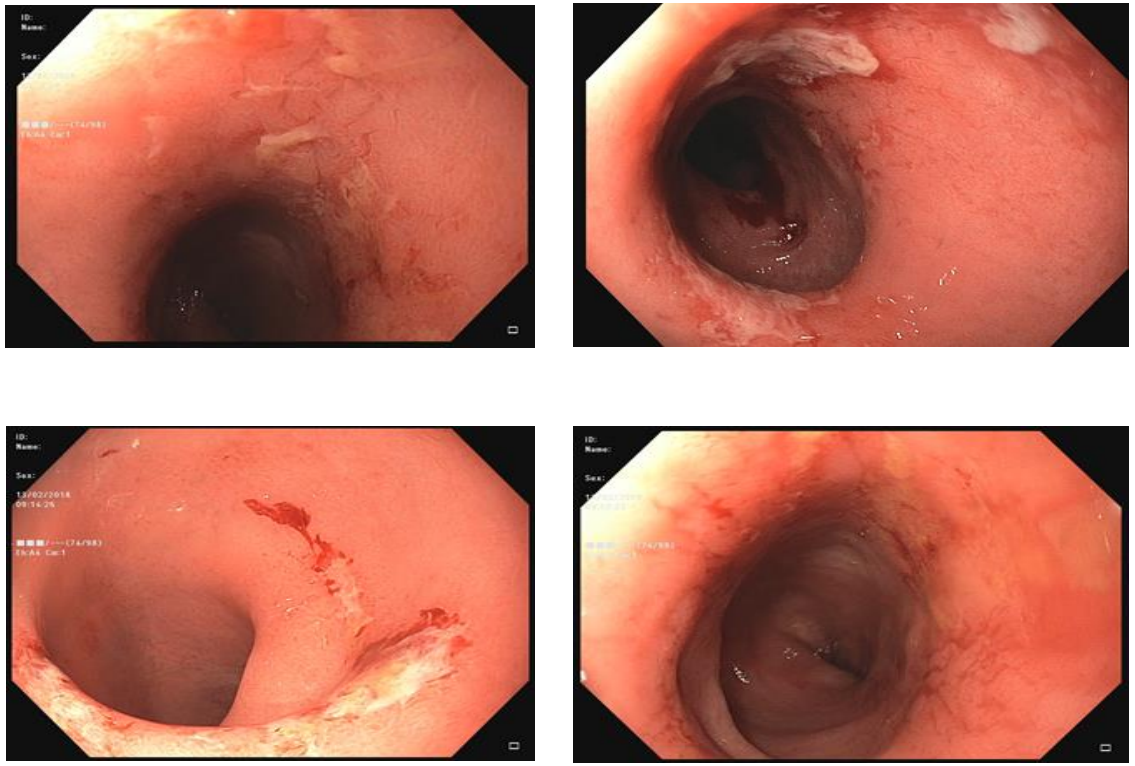
Clinical response:
TMS decrease of min 3 points and 30% from baseline + decrease of bleeding sub-score of min 1 point or absolute baseline of 0 or 1

	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

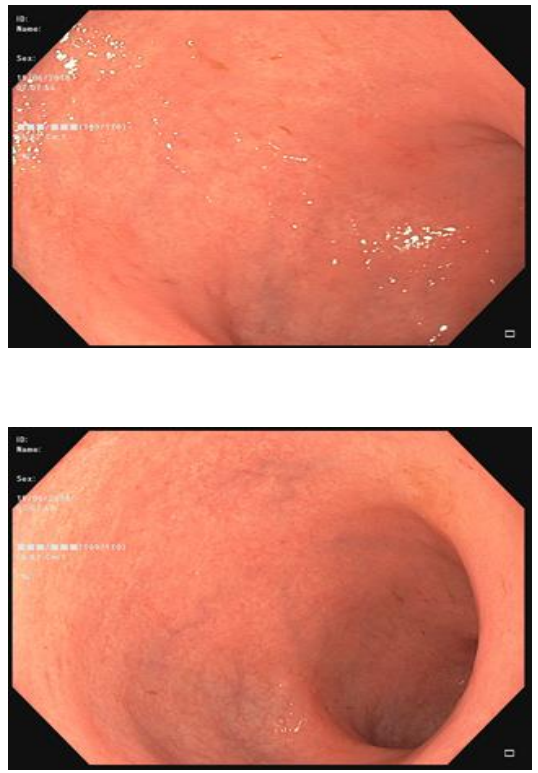
*Clinical remission according to previous FDA definition. With application of most recent FDA definition(excluding physician assessment), clinical remission rate was 40% in ABX464 group and remained at 11% with placebo

Mucosal healing in an ABX464 treated patient
Courtesy of Prof. Severine Vermeire

Before ABX464



After ABX464

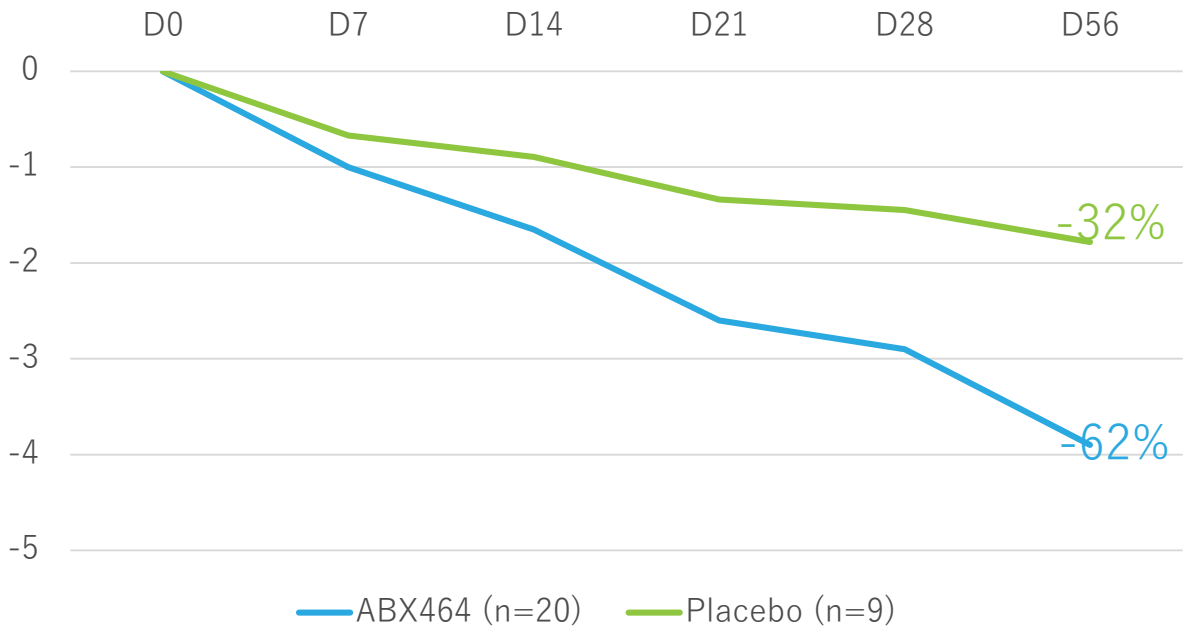


ABX464-101 Partial Mayo Score Results

Fast onset of action and clear responses in patients previously treated with biologics

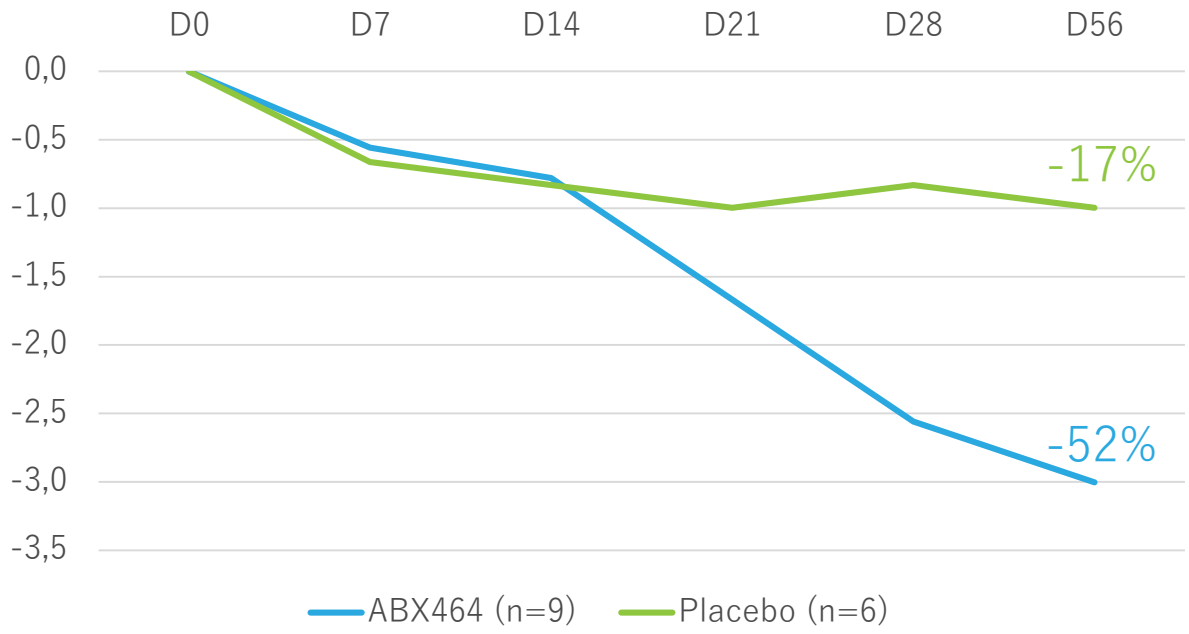
Overall Patient Population

Change from Baseline Partial Mayo Score



Patients previously treated with biologics

Change from Baseline Partial Mayo Score



ABX464-102 Maintenance study: Patient disposition

ABX464 -101 Induction study

ABX464 Evaluable patients at Week 8
N = 20

Placebo Evaluable patients at Week 8
N = 9

Full regulatory clearance in 4/6 countries:
22/23 eligible patients enrolled into the maintenance study

ABX464-102 Maintenance study
All patients receive
ABX464 50mg QD Oral Caps

ABX464 50mg QD N=15

1 lack of efficacy at M1
1 loss to Follow-Up

ABX464 Evaluable
Patients at week 52
N=13

3 drop outs:

ABX464 50mg QD N=7

1 grade 2 headache at M4

ABX464 Evaluable
Patients at week 52
N=6

As of Oct 21, 2019: Mean cumulative exposure to ABX464 in maintenance study is 19.5 months (Min 16.4, Max 23.5)

Clinical Remission after induction (8 weeks) and Maintenance (52 weeks)

Double Blind ABX464 50mg versus Placebo (centrally randomised)

Evaluable Patients /N=19

Induction

8 weeks

N=13 — *Clinical Remission*

N=6 — *No Clinical Remission*

N=5

N=8

52 weeks ABX464 open label oral 50mg qd

Maintenance

52 weeks

N=5

No endoscopy N=1

CR N=4

N=8

No endoscopy N=1

CR N=5

No CR N=2

CR : Clinical Remission = Total Mayo Score (TMS) equal or lower than 2 + no sub-score >1

No CR: No Clinical Remission

AFTER 8 WKS ABX464 : 5/13 CLINICAL REMISSION

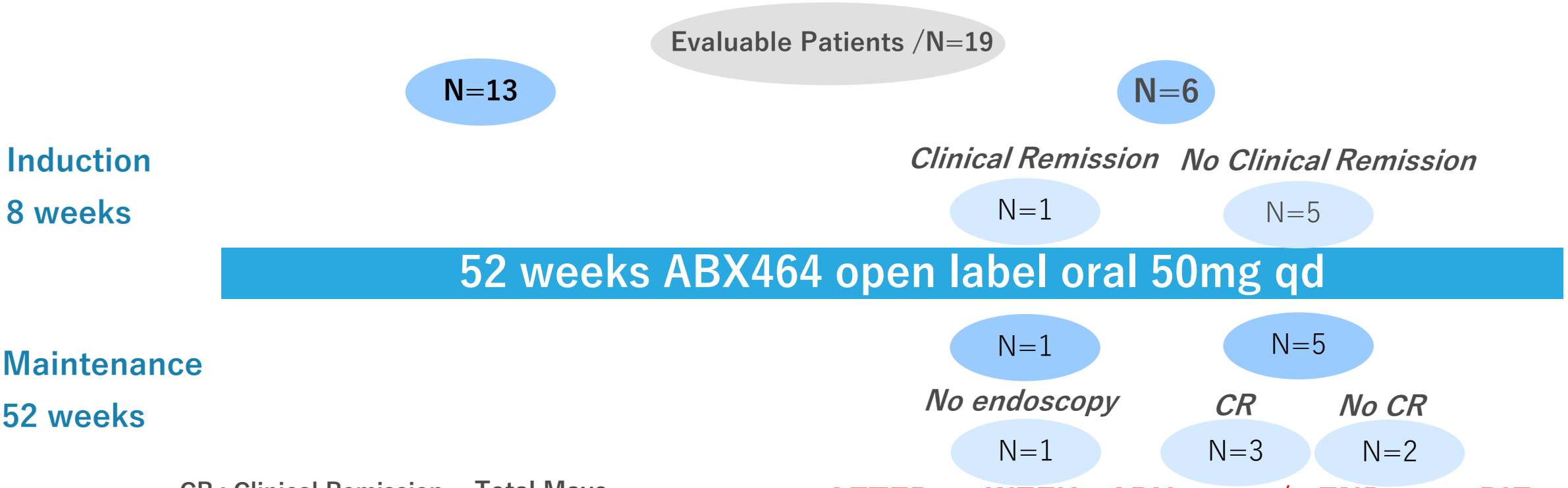
AFTER ANOTHER 52 WEEKS ABX464 : 11/13 ENDOSCOPIES

11/11 ENDOSCOPIC SUBSCORE 0 OR 1

9/13 NOW IN CLINICAL REMISSION

Clinical Remission after induction (8 weeks) and Maintenance (52 weeks)

Double Blind ABX464 50mg versus Placebo (centrally randomised)



CR : Clinical Remission = Total Mayo Score (TMS) equal or lower than 2 + no sub-score >1

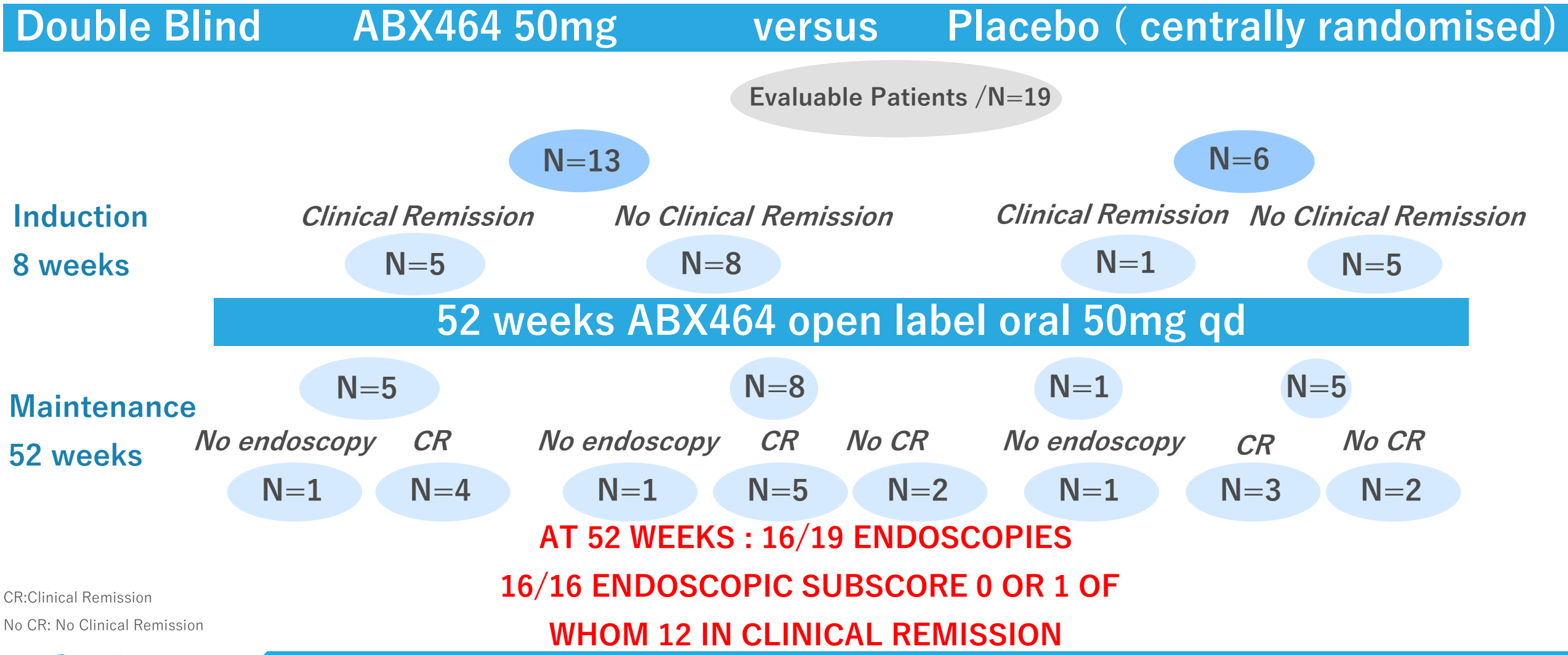
No CR: No Clinical Remission

AFTER 52 WEEKS ABX464 : 5/6 ENDOSCOPIES

5/5 ENDOSCOPIC SUBSCORE 0 OR 1

3/6 NOW IN CLINICAL REMISSION

Clinical Remission after induction (8 weeks) and Maintenance (52 weeks)

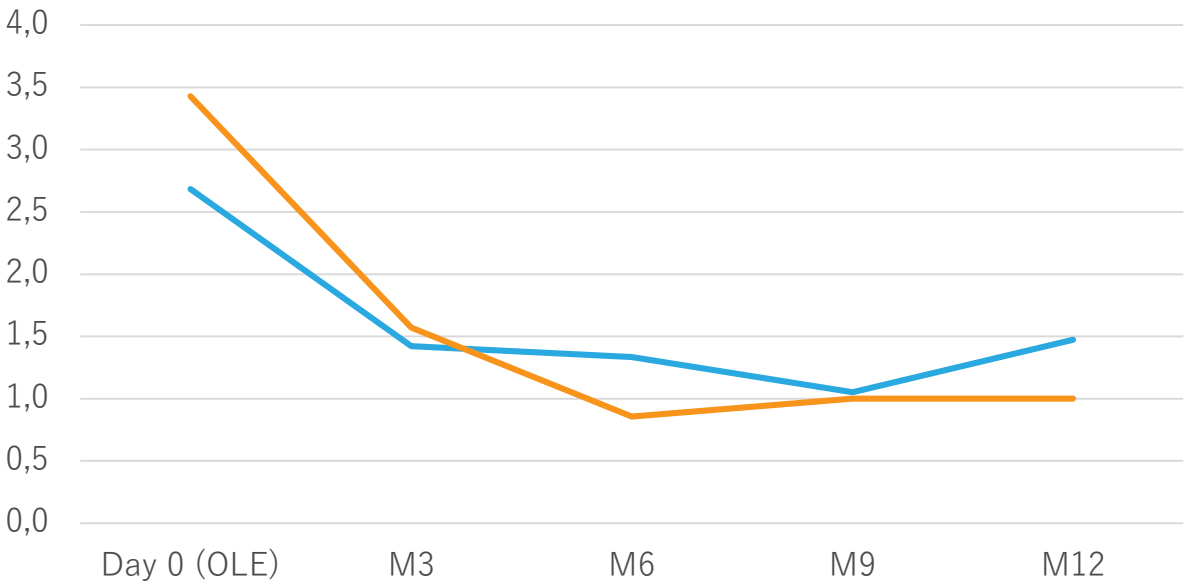


CR:Clinical Remission

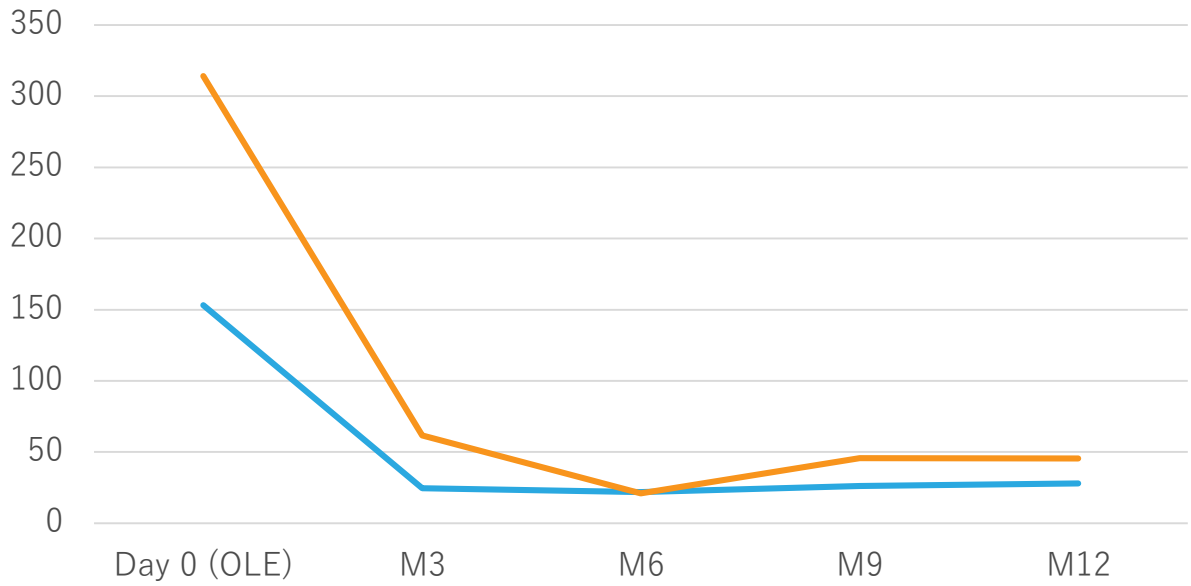
No CR: No Clinical Remission

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)**

ABX464-102: Efficacy data at 52 weeks open label extension

	ABX464 50 mg, PP	ABX464 50 mg, ITT
Clinical remission*	75% (N=16)	55% (12/22)
Endoscopic improvement*	100% (N=16)	72% (16/22)
Total Mayo Score reduction from maintenance baseline	- 57% (N=16)	- 52% (N=22)
Partial Mayo score reduction from maintenance baseline	- 45% (N=19)	- 41% (N=22)
Fecal calprotectin reduction from maintenance baseline	- 85% (N=19)	- 81% (N=22)
miR-124 expression in total blood (fold increase at M12)	215.0 (N=19)	–

***Clinical remission:**
TMS equal or lower than 2 and no sub-score >1

***Endoscopic improvement:**
Endoscopy sub-score 0 or 1

ABX464 showed a good safety profile during induction and 12 months open label maintenance phase

Safety profile consistent with previous and ongoing clinical studies

(>210 healthy volunteers and patients exposed to ABX464)

Overall: No deaths, no malignancies, no severe infections, no significant changes in the laboratory parameters including blood cell counts

No Serious Adverse Reactions, most AEs were of mild to moderate intensity

Most frequently reported AEs: Headache and epigastric pain; occurring mainly during the first days of treatment

Two patients prematurely withdrew due to an AE

Induction study:

Out of 20 patients dosed with ABX464, one patient prematurely withdrew due to AE (Transaminase elevation = 3xULN; no changes in other LFTs)

Maintenance study:

Out of 22 patients who rolled over into the maintenance, one patient withdrew due to AE (Grade 2 Headache at M4)

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 further supported by safety analysis in healthy volunteers and HIV infected patients (no serious adverse reactions, no severe infections, no lymphopenia, no neutropenia)

Confirmed preliminary 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 strengthened by 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

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 2 months induction phase expected for end 2020

→ Phase 2b study in 232 patients with moderate to severe ulcerative colitis is currently ongoing in Canada and Europe, and with FDA clearance of IND (19/01/20) now preparing for patient recruitment in the US

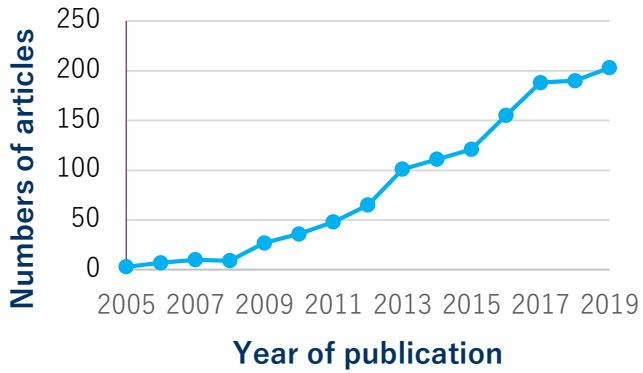
→ Phase 2a study ongoing in rheumatoid arthritis and Phase 2b planned in Crohn's disease

→ Preclinical models running in several inflammatory diseases, including Parkinson's, multiple sclerosis, NASH, psoriasis and PAH

ABX464 and ABX464-N-Glu: Mechanism of Action

miR-124 is a well-known modulator of inflammation

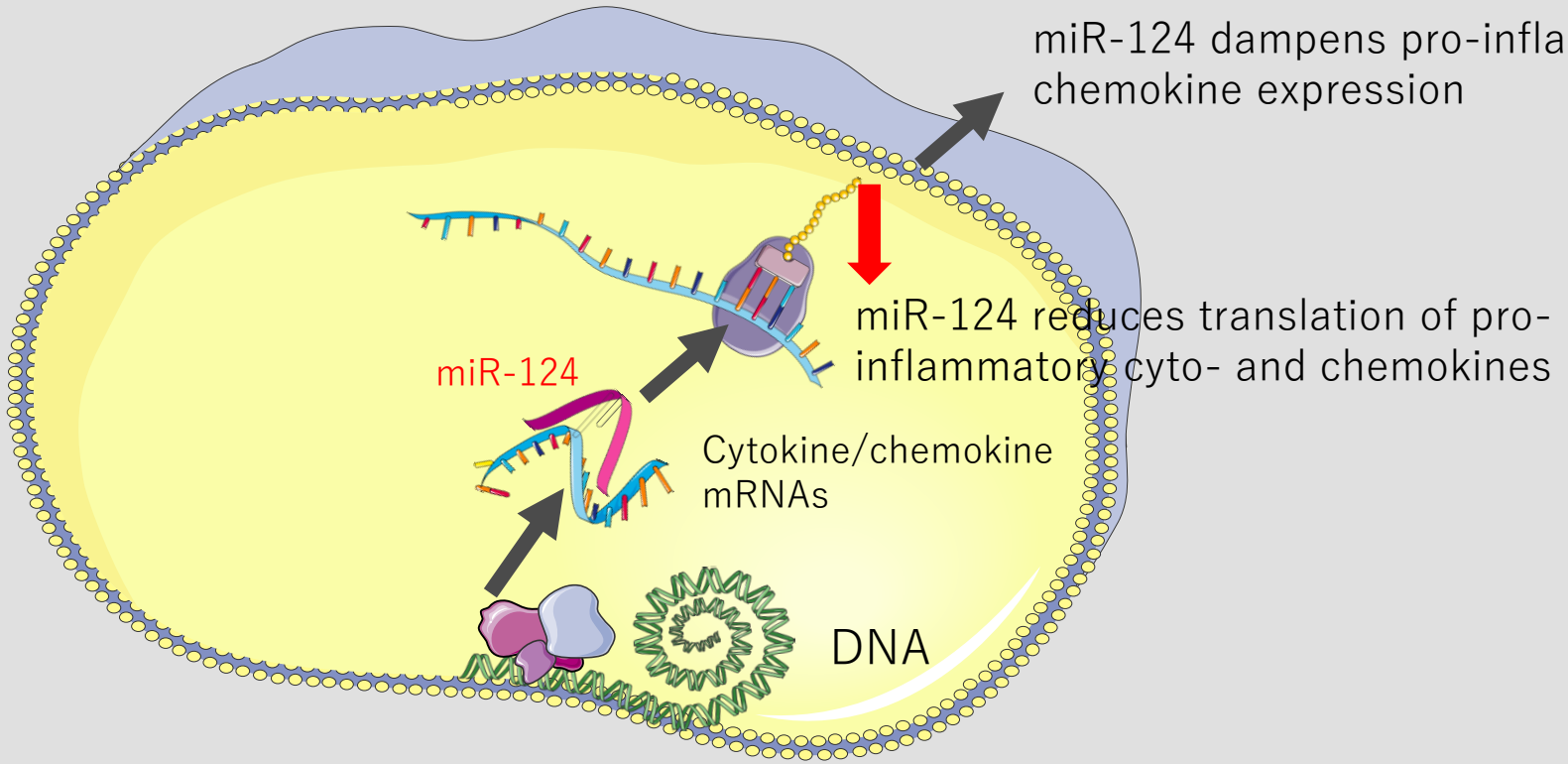
Between 2005 and 2019, more than **1100 scientific articles** have been published on miR-124 **including 133 papers** highlighting the importance of miR-124 in dampening the inflammatory process



Examples:

- miRNA-124 in immune system and immune disorders (review Qin Z, et al. Front Immunol 2016)
- miR-124/STAT3 system is a potential target for the therapeutic intervention of UC (Qin Z, et al. J Mol Med 2017)
- miR-124 regulates STAT3 expression and is down-regulated in colon tissues of pediatric patients with ulcerative colitis (Koukos G, et al. Gastroenterology 2013)
- miR-124 directly binds to the 3'UTR of MCP-1 to dampen inflammation (Li Y, et al. J Cell Mol Med 2019)
- miR-124 Mediates the cholinergic anti-Inflammatory action through inhibiting the production of pro-inflammatory cytokines (Sun Y, et al. Cell Res 2013)
- miR-124 confers brain inflammatory protection (Ponomarev ED, et al. Nat Med 2011)

miR-124 is an endogenous microRNA that regulates gene expression by preventing translation of target mRNAs (cyto- and chemokines)



miR-124 can modulate multiple pathways involved in inflammation

miR-124 can reduce the translation of targets' mRNAs and thereby protein expression:

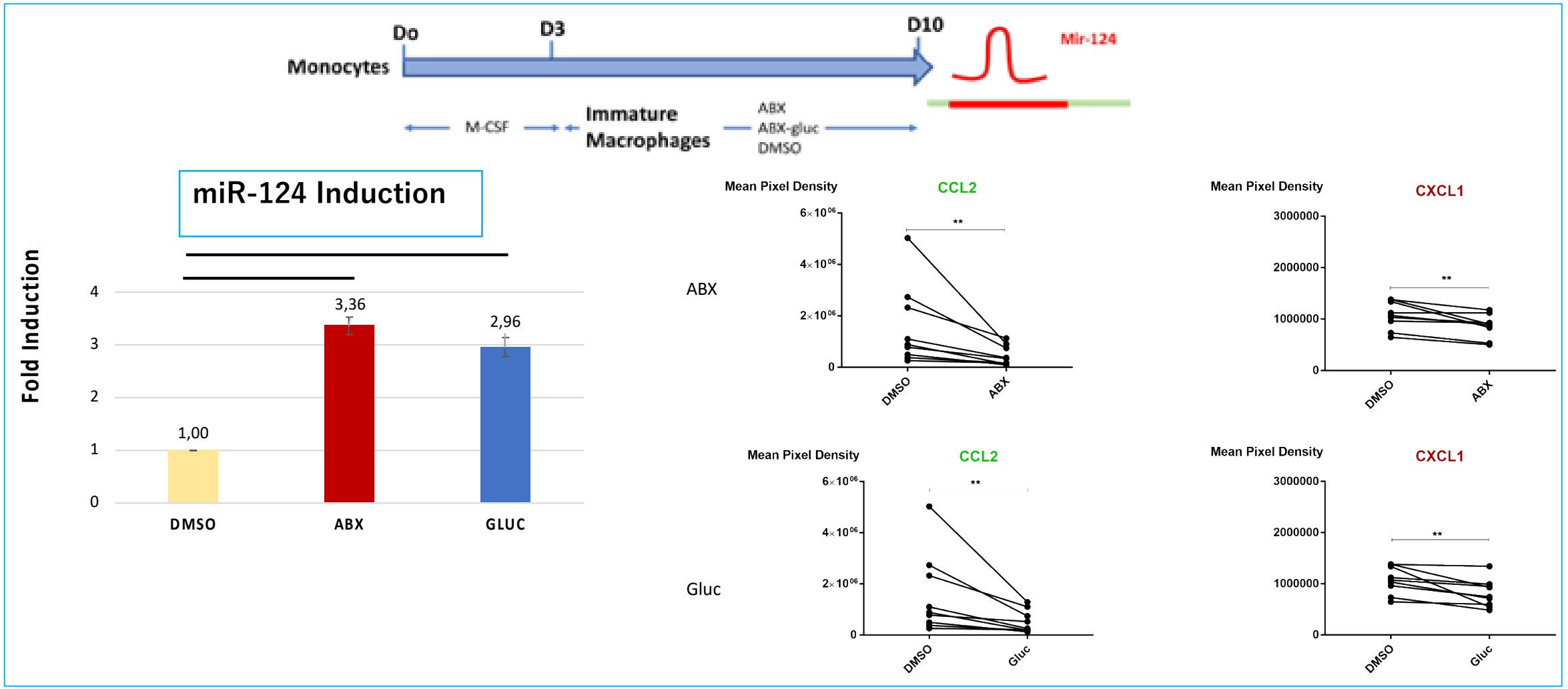
- STAT3 (A key regulator of JAK signaling, decreases IL6 and TNFa)
- IL6R (reducing IL6 action)
- MCP1 (Macrophage chemoattractant protein 1)
- PTBP1 (a splicing factor involved in remodeling the lung tissue of PAH patients)
- Elk-3 (modulates the phagocytosis of bacteria by macrophages)
- CDK2 (controls peripheral immune tolerance)
- 13 other targets that are involved in inflammation

ABX464 is the only small molecule in clinical development that can specifically induce miR-124 expression

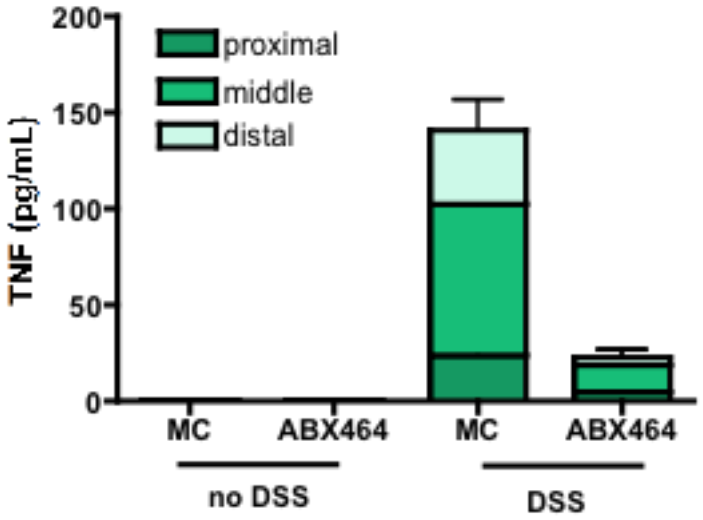
ABX464 main metabolite, ABX464-N-Glu also induces miR-124 expression

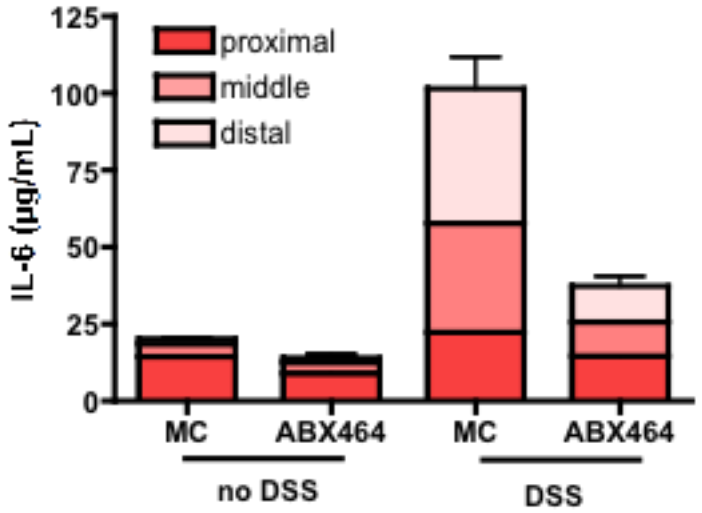
Out of 1105 microRNAs, miR-124 was the only microRNA upregulated

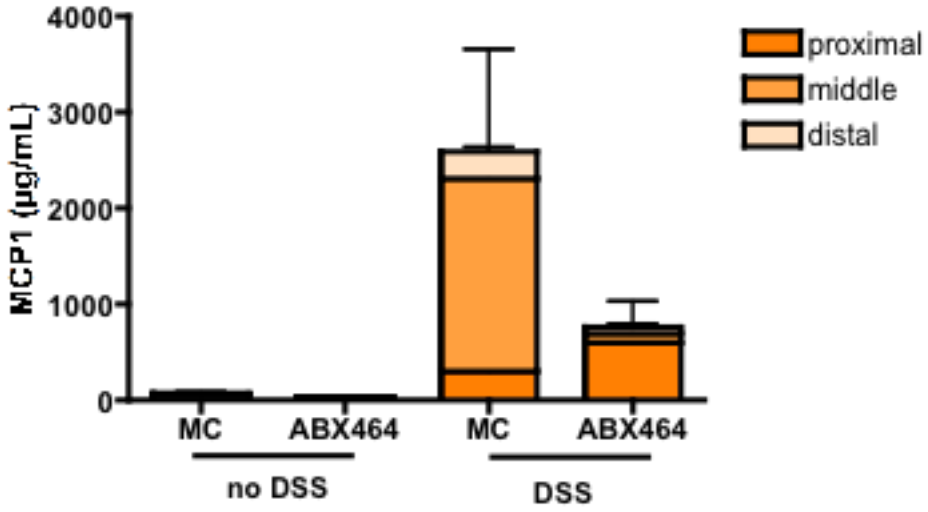
Both ABX464 and ABX464 N-Glu induce upregulation of miR-124 in purified human monocyte-derived macrophages and decrease MCP1/CCL2 expression



In ABX464 treated DSS mice, ABX464 reduces pro-inflammatory cytokines and chemokines in the colon







ABX464 induces miR-124 and reduces pro-inflammatory cytokines in PBMC and in colon tissue ABX464 treated DSS mice

Chebli & al. Scientific Reports 2017 Jul 7;7(1)

ABX464 induces miR-124 expression by specifically inducing the splicing of a single Long-Non-Coding RNA (lncRNA00599-205)

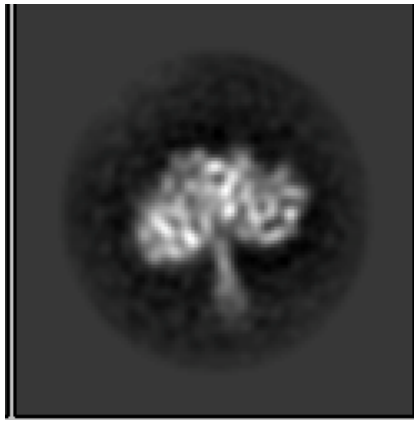
- miR-124 is transcribed from 3 genomic loci, but ABX464 induces miR-124 expression only from Locus 1
- Locus miR-124-1 contains the Long Non-Coding RNA, lncRNA00599-205, whose splicing is required for miR-124 expression
- ABX464 induces the splicing of a lncRNA00599-205 to generate miR-124
- Mutations in the splice sites of lncRNA00599-205 prevent miR-124 expression
- RNAseq data showed that ABX464 does not impact the splicing of cellular mRNA besides lncRNA00599-205

ABX464 and ABX464-N-Glu bind to the Cap Binding Complex (CBC), which is key factor for RNA processing

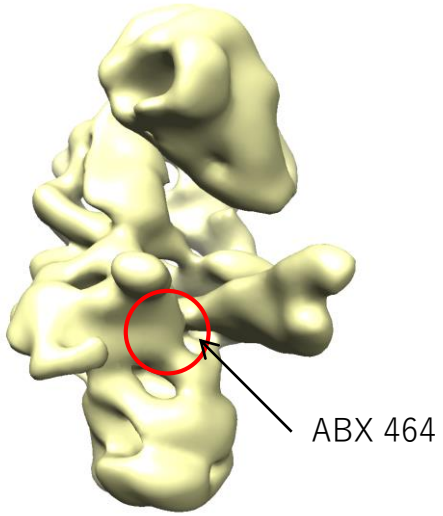
CBC binds to the 5' end of all RNAs generated in the nucleus and ensures their processing

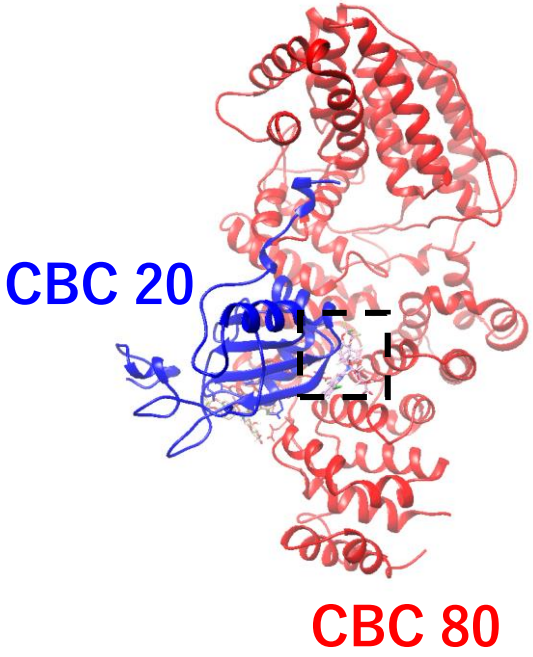
Binding of ABX464 and ABX464 N-Glu to CBC was demonstrated by:

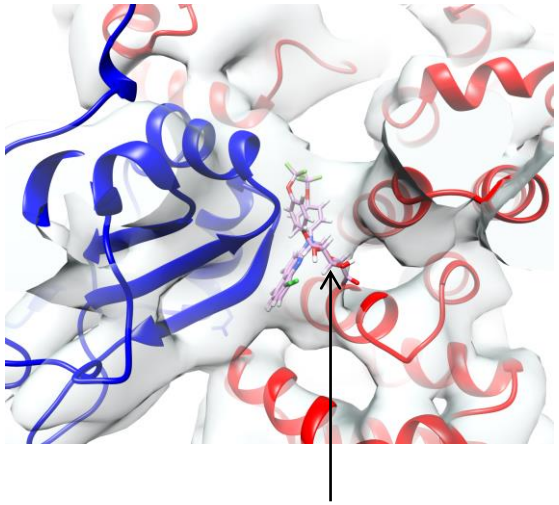
- UV crosslinking with chemically modified ABX464
- Thermoshift assay with purified complex CBC80:CBC20
- Cryo-EM and chemoinformatics



ABX464 and ABX464-N-Glu bind to the same site on CBC



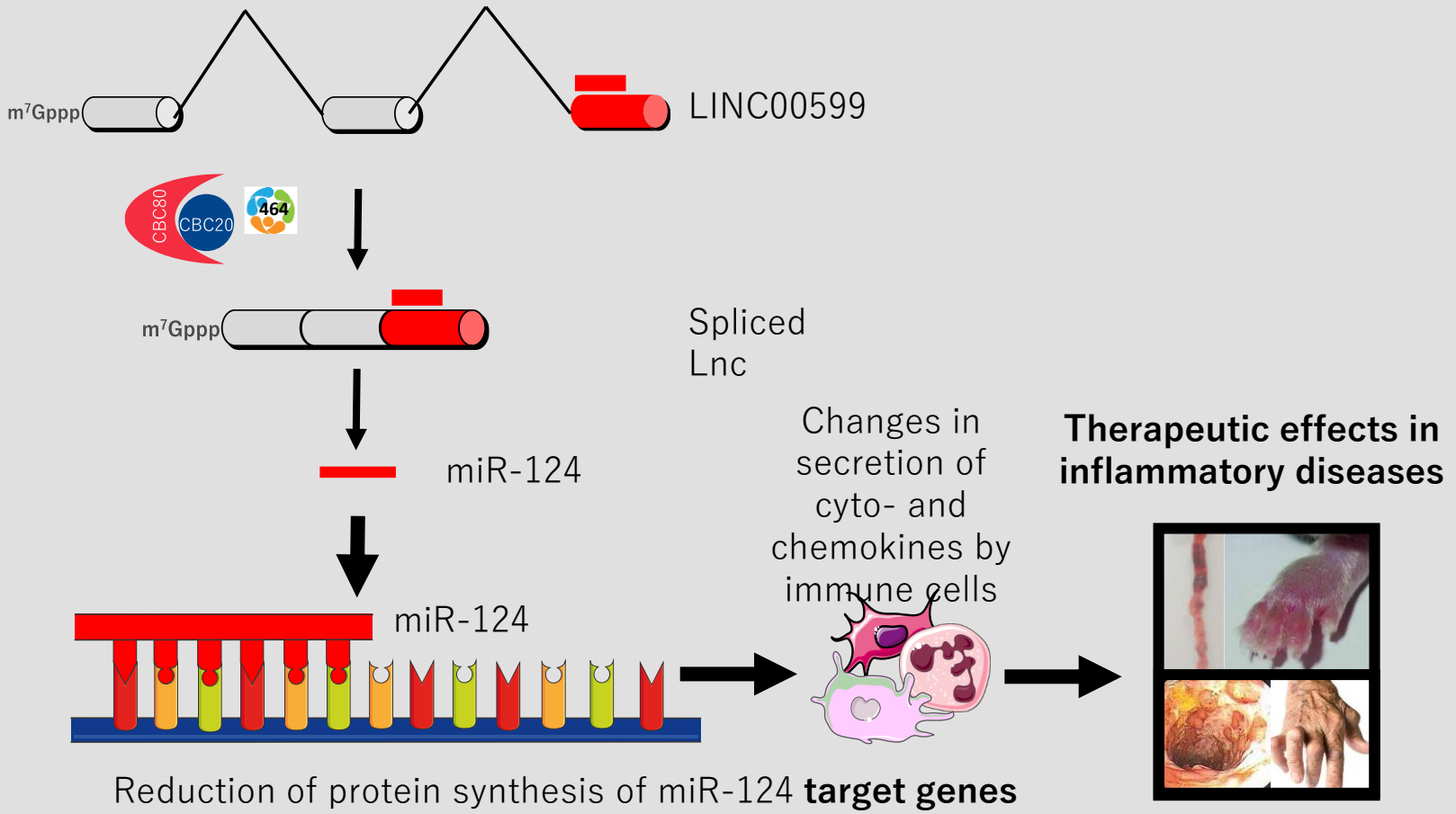




ABX464-CBC at 5.8A resolution

ABX464 N-Glu-CBC at 4.6A resolution

Inducing specifically the biogenesis of miR-124 by the drug candidate ABX464 in immune cells opens a novel way to treat Inflammatory Diseases



Summary

ABX464 mechanism of action

- miR-124 anti-inflammatory properties have been extensively described in the literature
- Abivax's oral drug candidate ABX464 is the only small molecule in clinical development that specifically induces the overexpression of a miR-124
- miR-124 expression by ABX464 is triggered by splicing of a single long non-coding RNA, LNC00599-205 after binding to CBC, without impacting expression of cellular RNAs
- Effects of ABX464 in DSS mice and immune cells are consistent with the known miR-124 anti-inflammatory effects including reduction of pro-inflammatory cytokine expression and reduced recruitment of inflammatory cells leading to an anti-inflammatory effect

Interview of Prof. Sandborn – UEG Week 2019

https://youtu.be/VB4fo0xkycY

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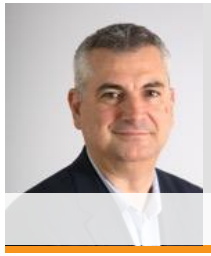

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→ Competencies from discovery to global commercialization