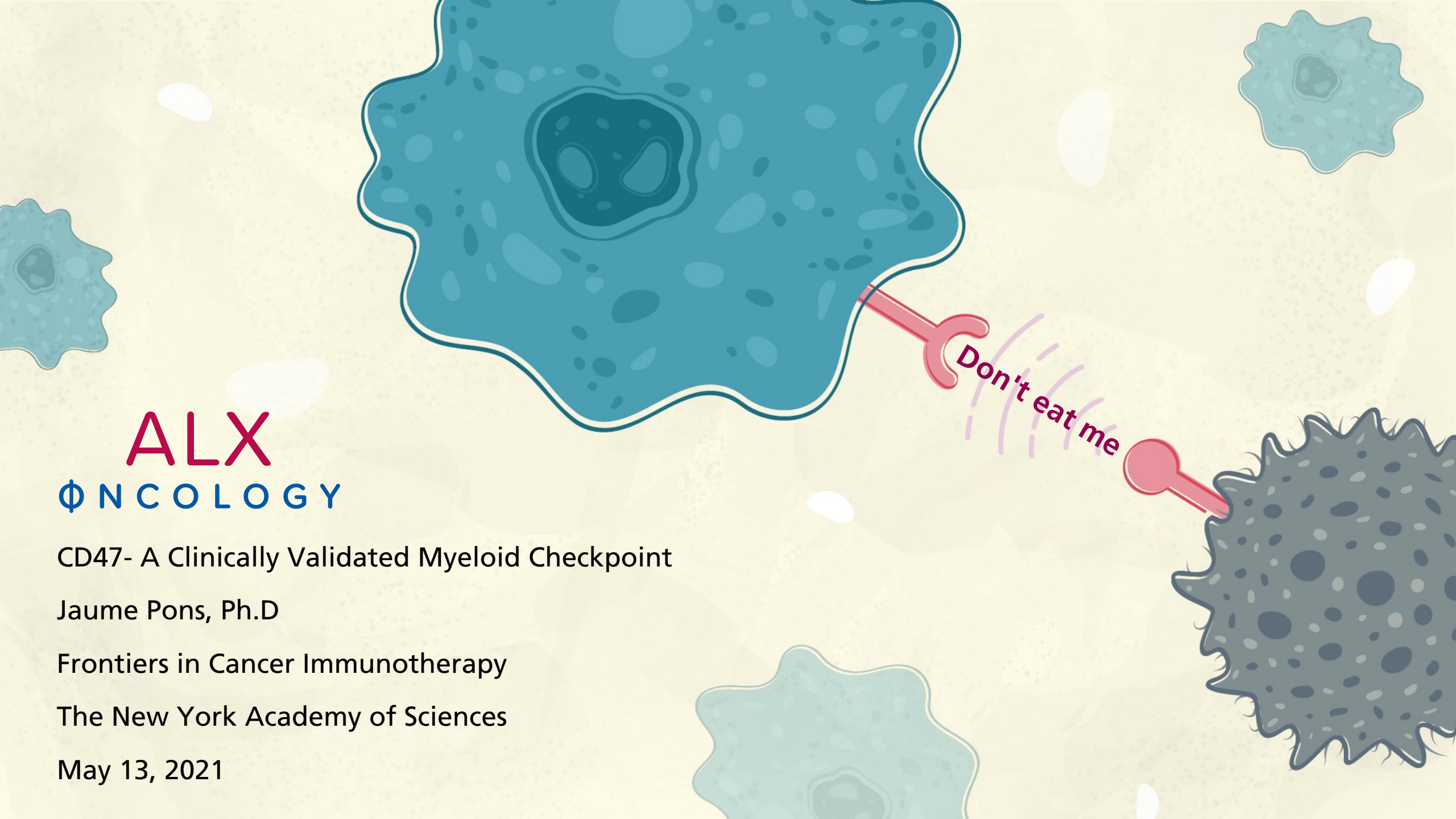

ALX ONCOLOGY

CD47- A Clinically Validated Myeloid Checkpoint

Jaume Pons, Ph.D

Frontiers in Cancer Immunotherapy

The New York Academy of Sciences

May 13, 2021

DISCLAIMER

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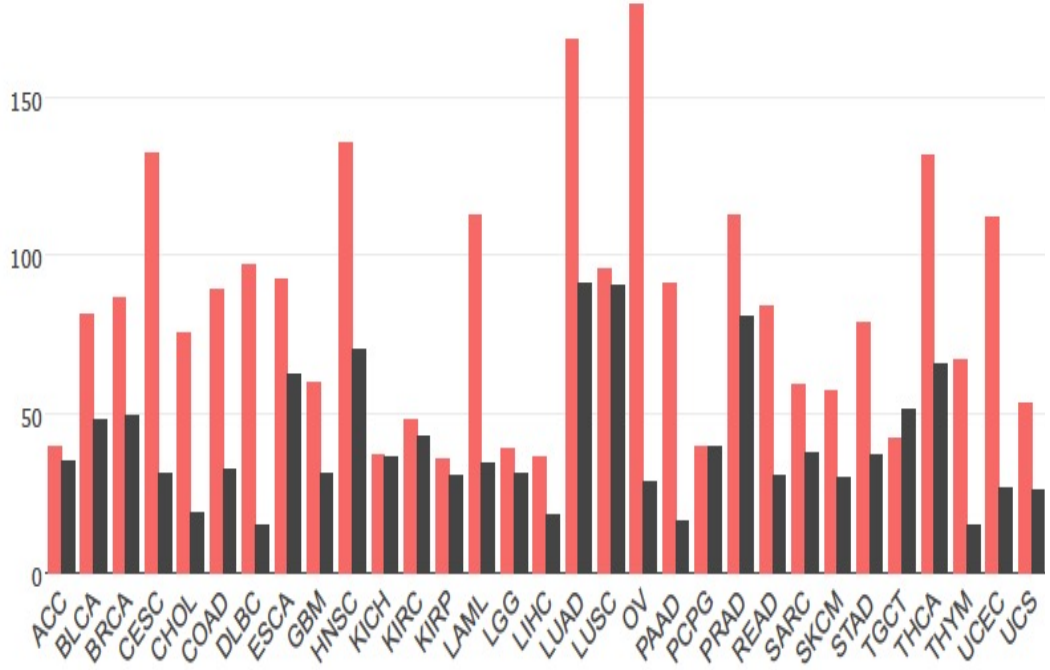
ALX ONCOLOGY

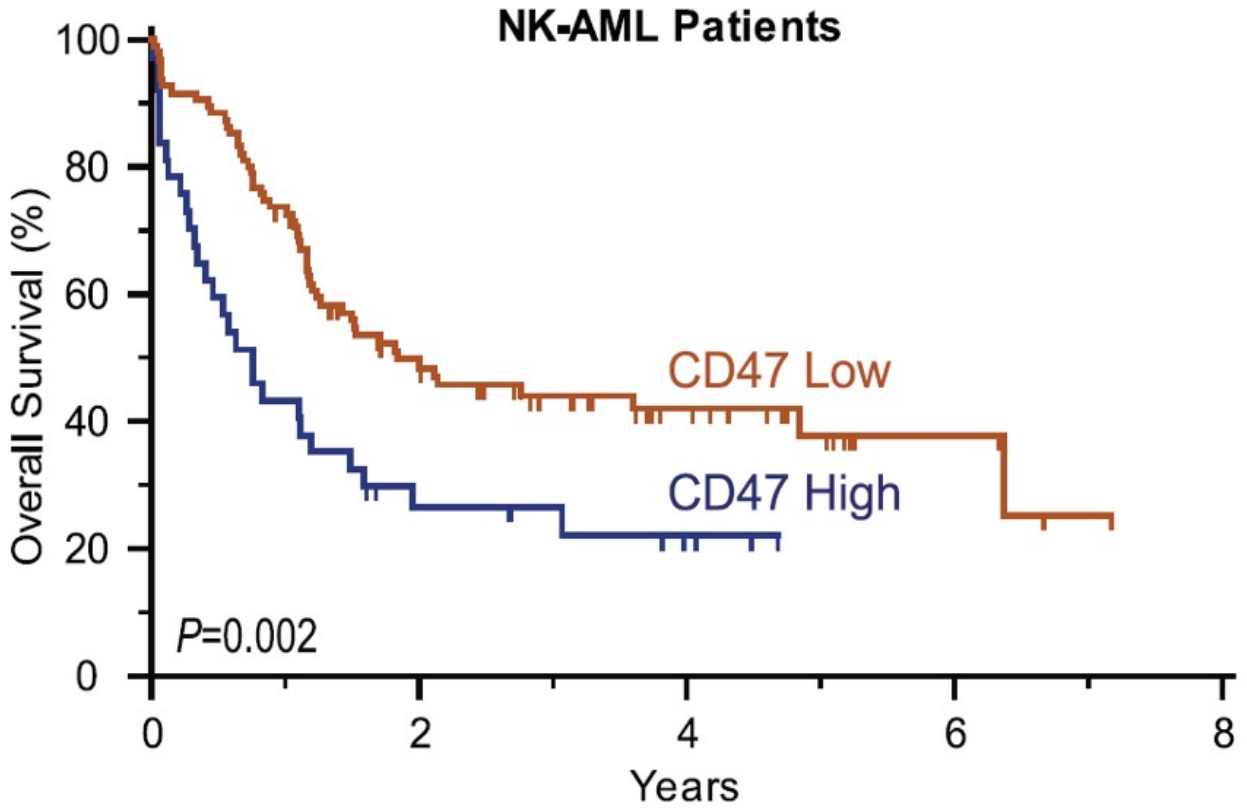
CD47: OVEREXPRESSED IN CANCER AND MARKER OF WORSE PROGNOSIS

CD47-Expression levels in cancer and normal tissue



The Cancer Genome Atlas (**TCGA**)

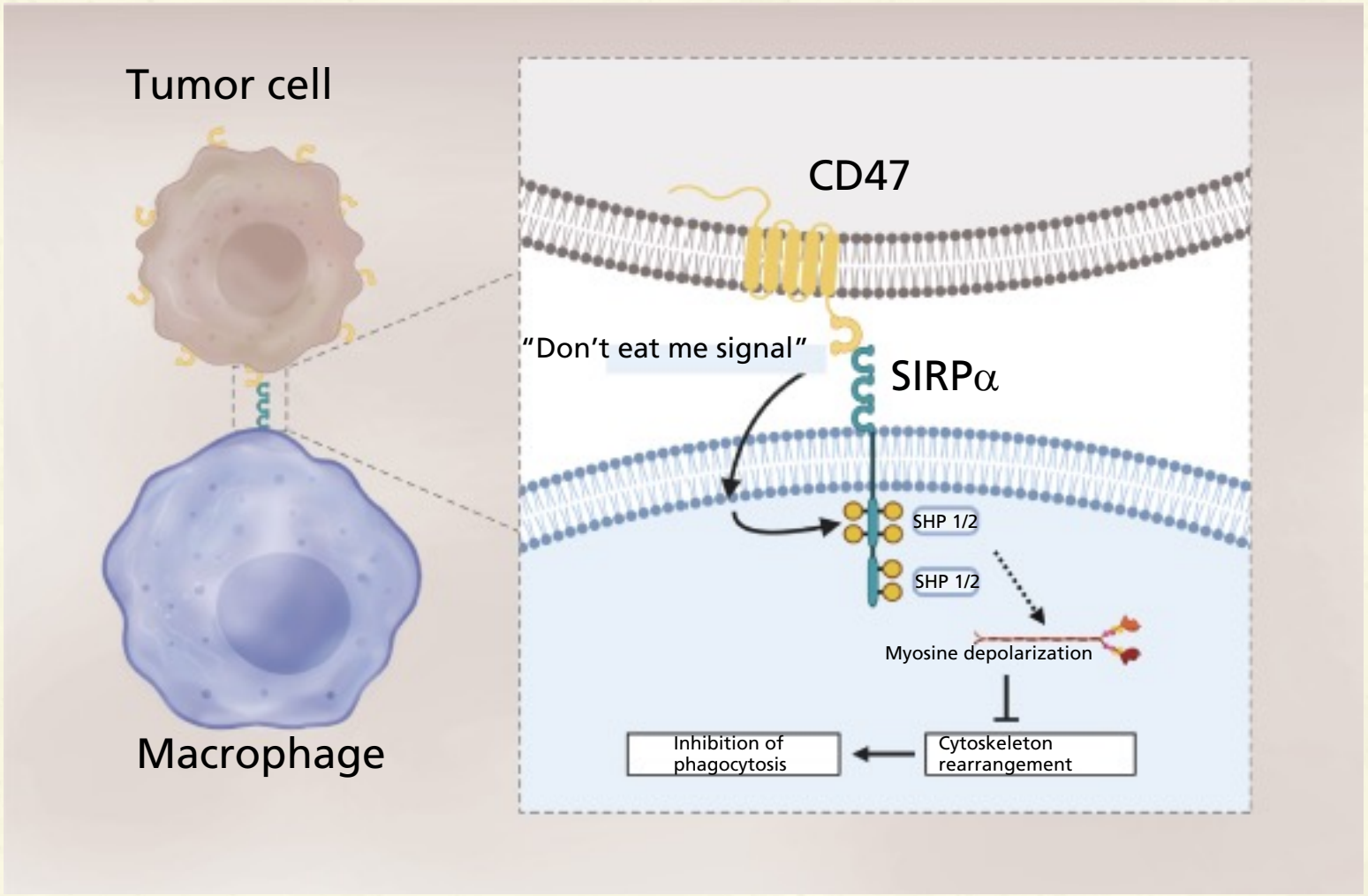
Survival by CD47 expression-AML



Majeti et al, Cell 2009

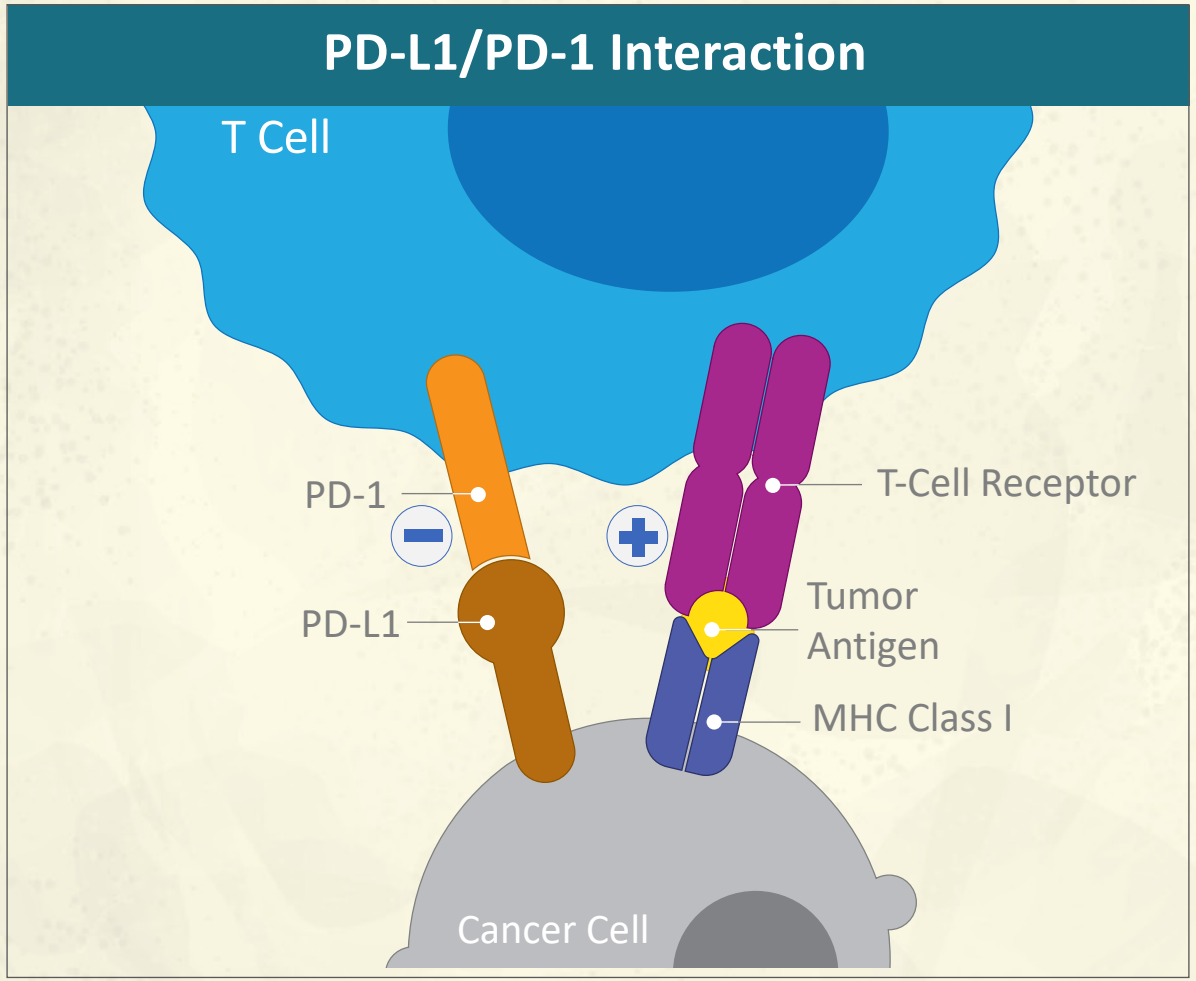
ALX ONCOLOGY

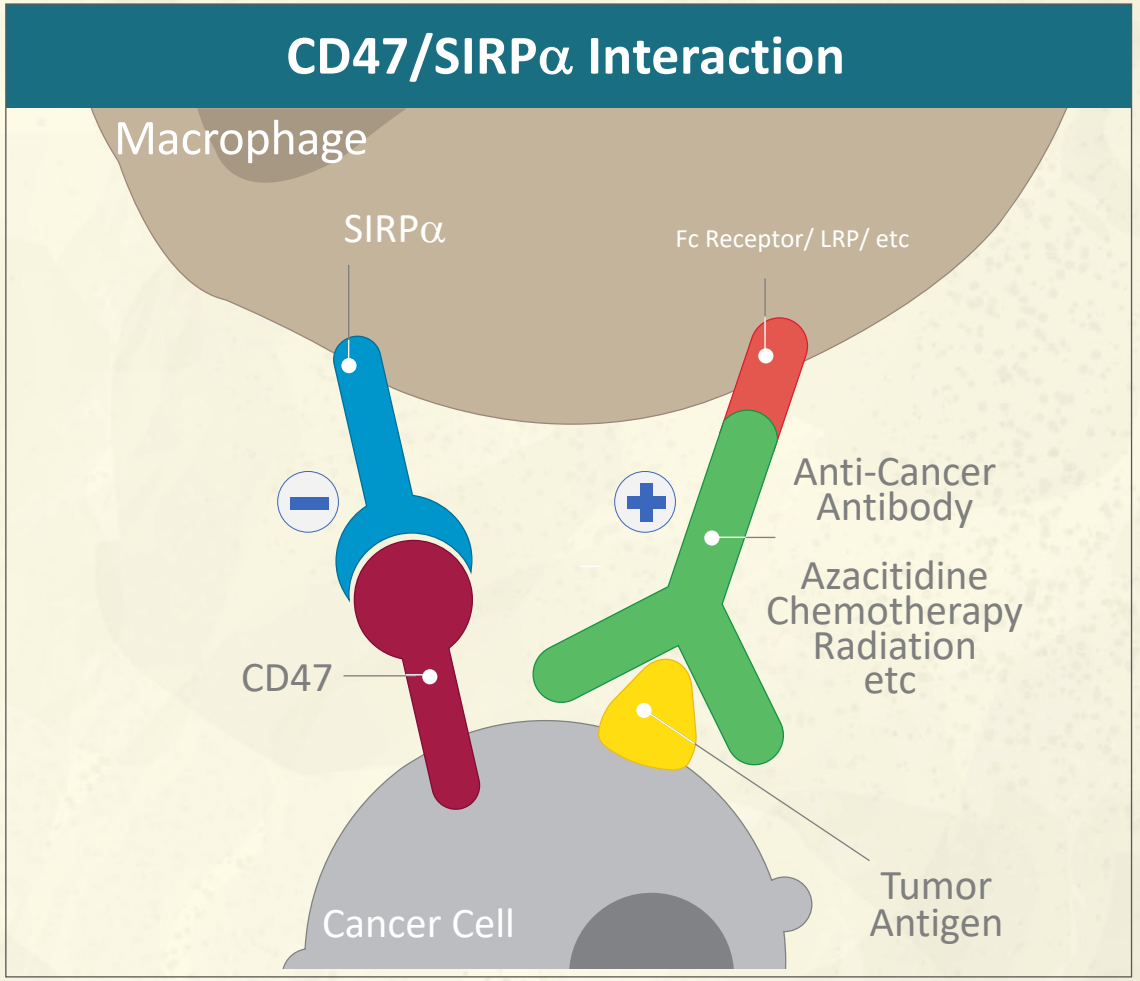
CD47/SIRPα IS A MYELOID CHECKPOINT – "DO NOT EAT ME SIGNAL"



Journal of Immunology Research, vol. 2020, Article ID 9435030, 8 pages, 2020. https://doi.org/10.1155/2020/9435030

CD47/SIRPα IS A MYELOID CHECKPOINT-THERAPEUTIC IMPLICATION





CD47/SIRPα "Don't Eat Me" signal counters the phagocytic "Eat Me" signal similar to PD-L1/PD-1 inhibiting T-cell activation triggered by TCR antigen recognition

ALX ONCOLOGY

AFFINITY TO CD47 AND FCγ RECEPTORS

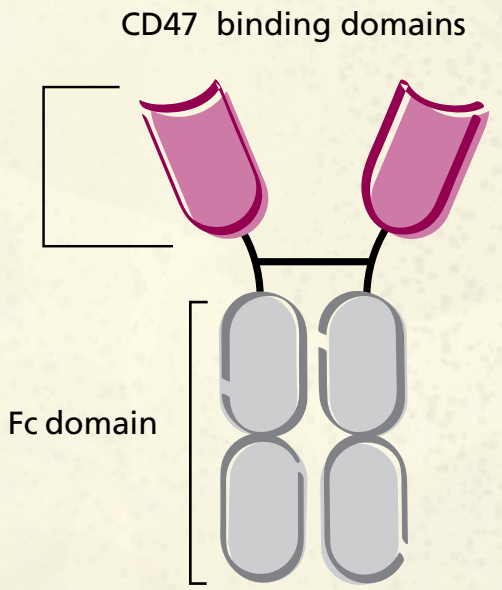
Name	Fc Domain (Human)	Human CD47 (KD nM)	Mouse CD47 (KD nM)	Effector function
ALX148	IgG1 DEAD	0.14	9	-
ALX216	IgG4 S228P	0.14	9	++
ALX377	IgG1 wt	0.14	9	++++
5F9 (magrolimab)*	IgG4 S228P	7	NB	++
TTI-621*	IgG1 wt	500	NB	++++
TTI-622*	IgG4 S228P	500	NB	++

Fc Domain	CD16a (KD nM)	CD32a (KD nM)	CD32b/c (KD nM)	CD64 (KD nM)
IgG1	370	400	2000	0.004
IgG4 S228P	3000	810	850	1
IgG1 DEAD	NB	NB	NB	NB

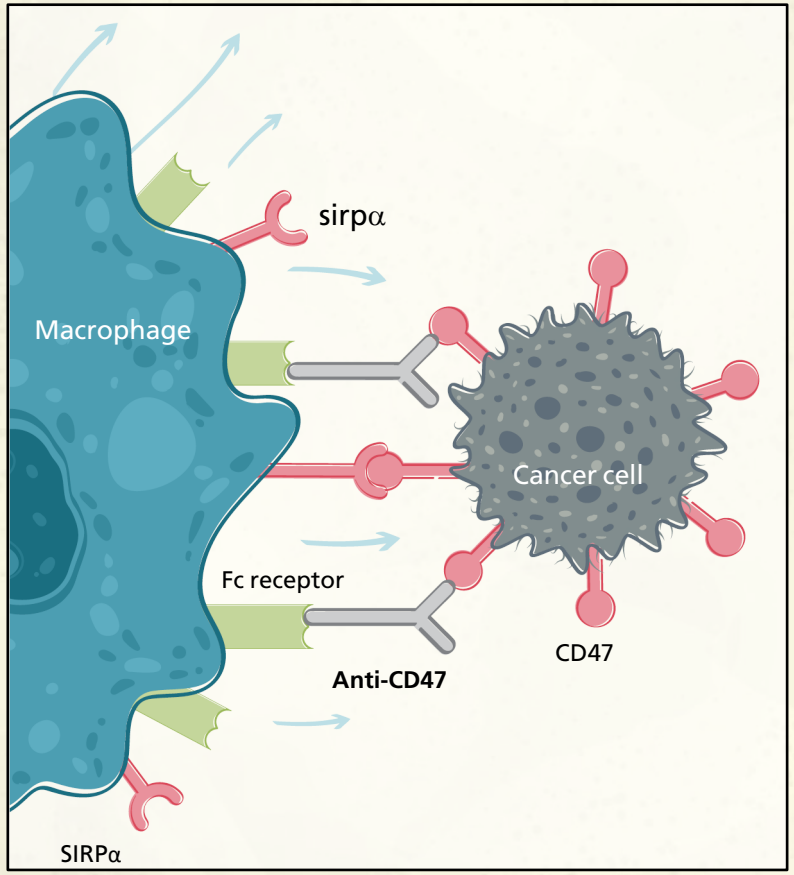
ALX ONCOLOGY

* Produced at ALX Oncology based on public information, KD measured by SPR at ALX Oncology

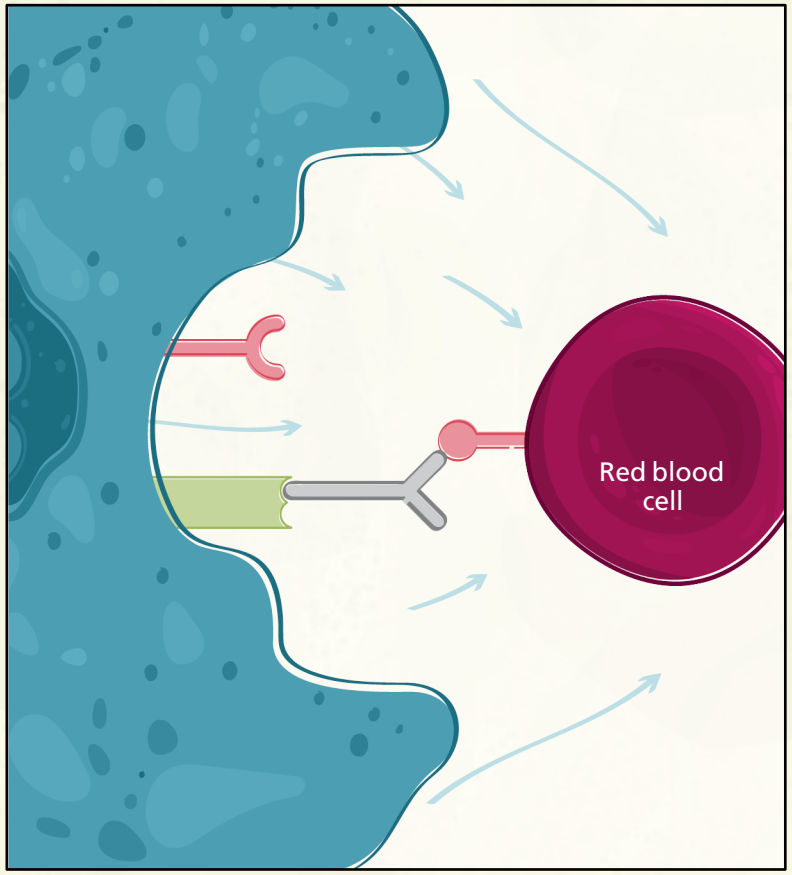
CD47 blocker components



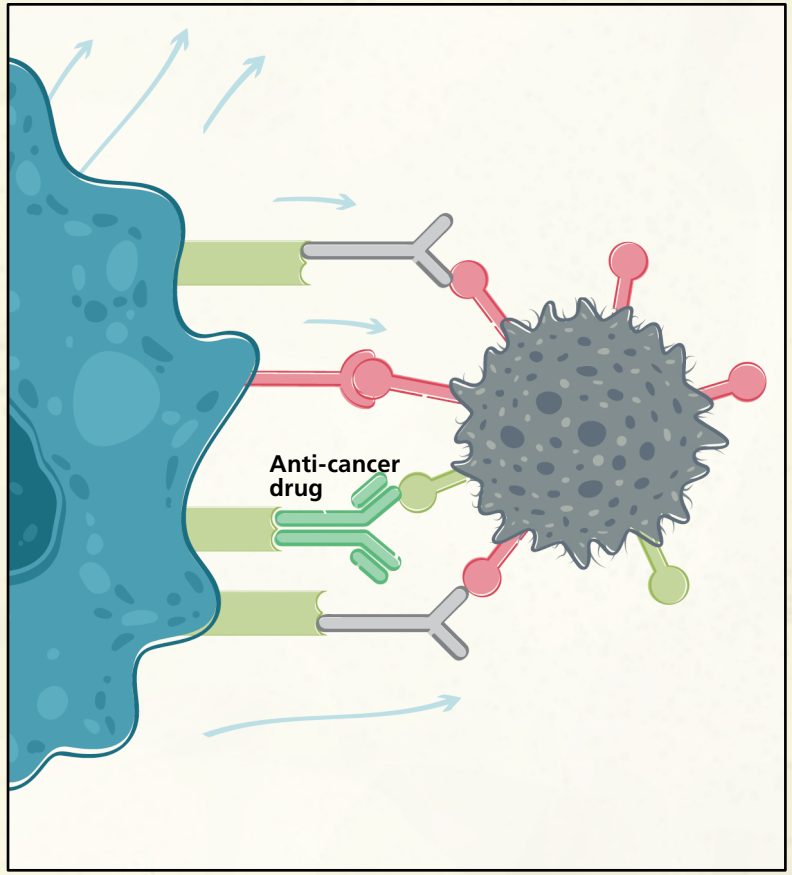
SINGLE AGENT ACTIVITY: TARGETING CD47 AS TUMOR ASSOCIATED ANTIGEN



Anti CD47 with active Fc directly targets cancer cells



But also targets normal cells



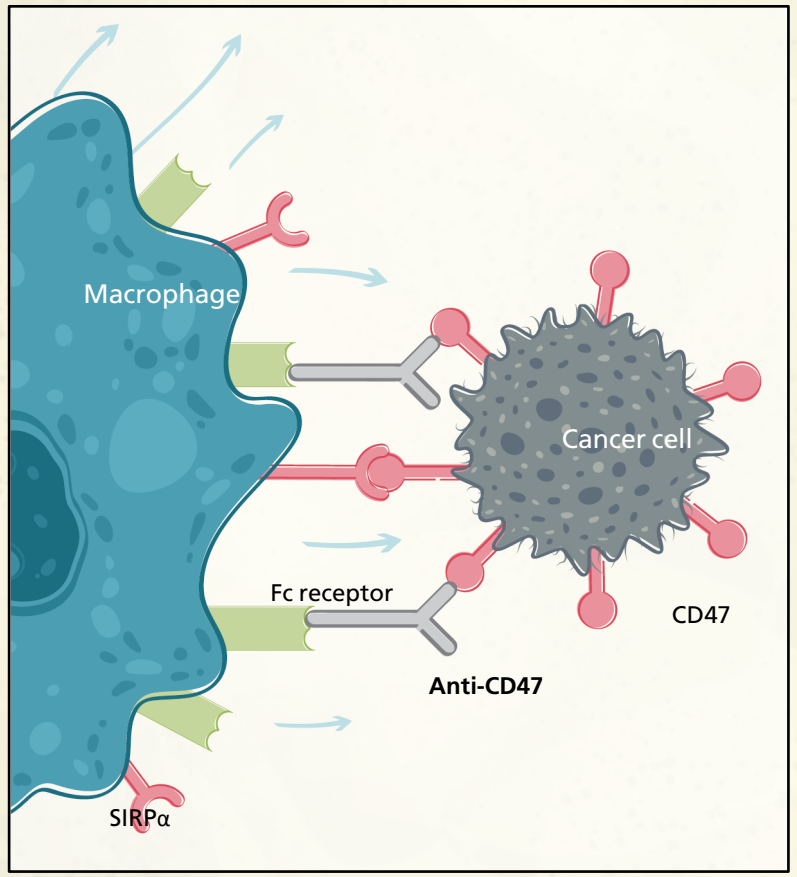
Is it possible to separate anti cancer activity from anti normal cell activity?

Will dose limitations prevent full blockade of CD47?

ALX ONCOLOGY

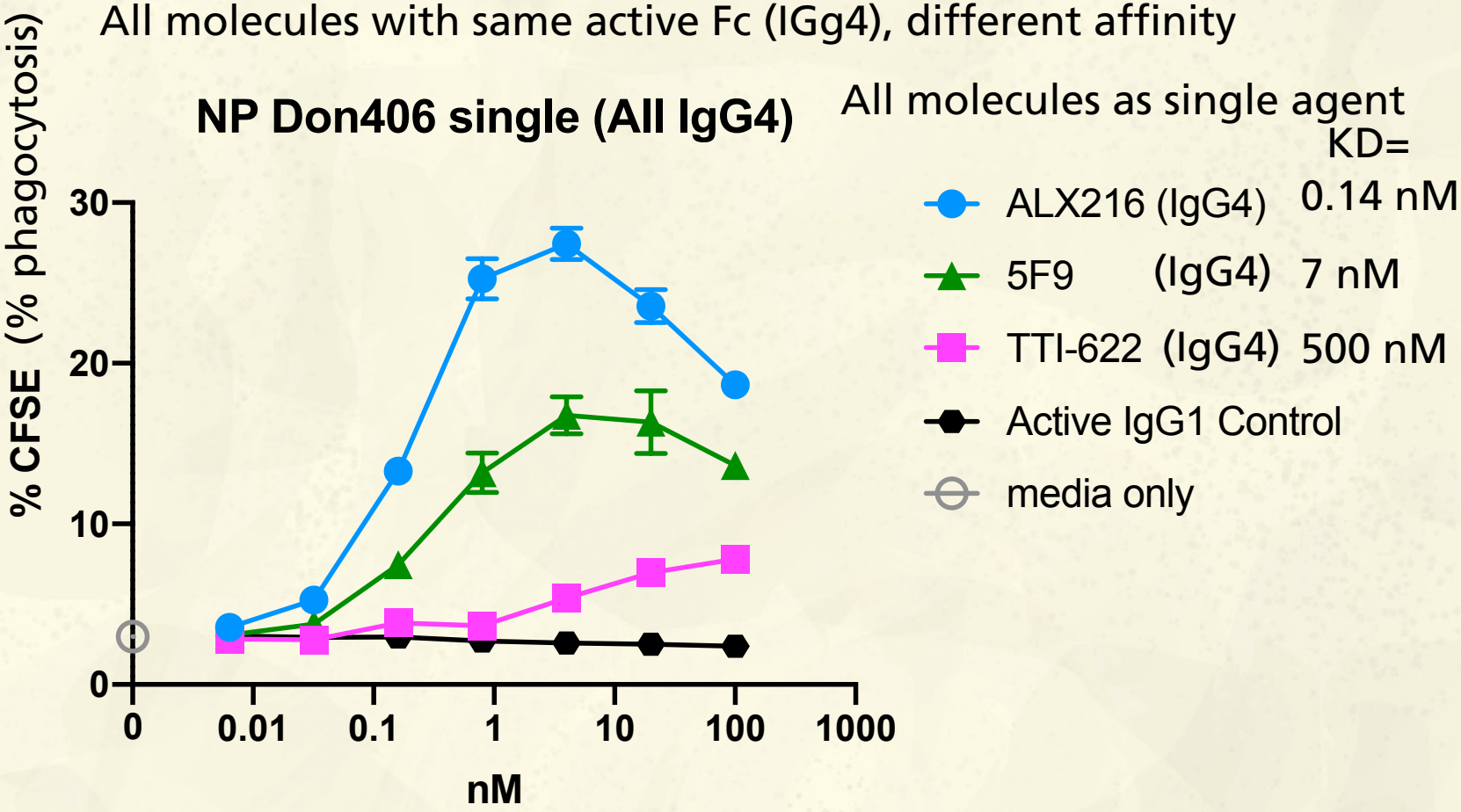
AMONG CD47 BLOCKERS WITH ACTIVE FC- AFFINITY CORRELATES WITH ACTIVITY

Phagocytosis assay



Anti CD47 with active Fc directly targets cancer cells

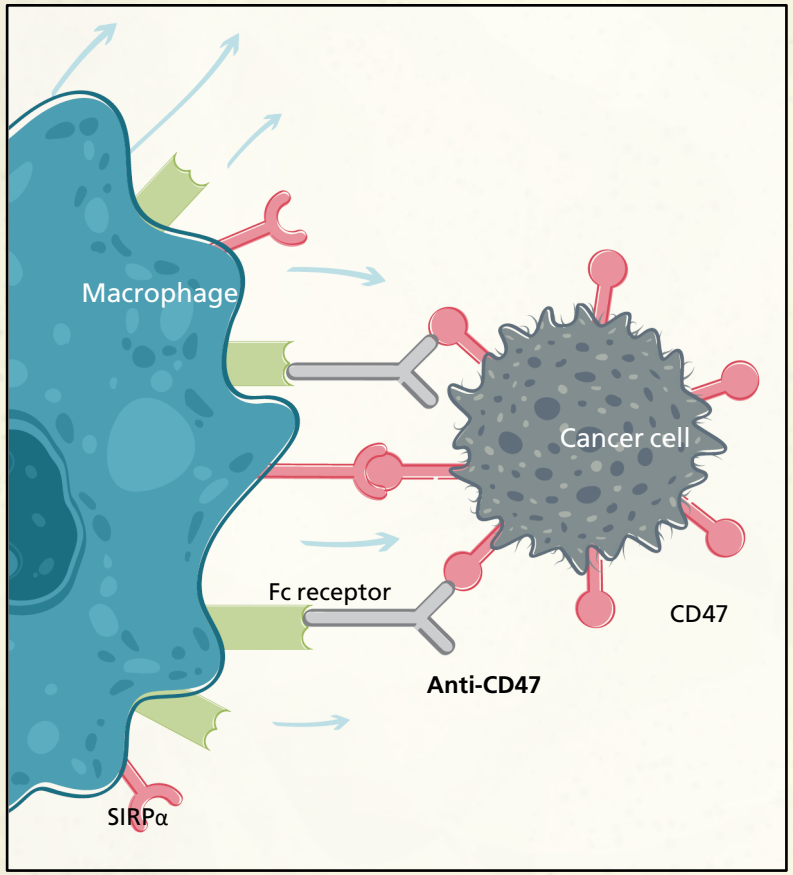
All molecules with same active Fc (IGg4), different affinity



DLD1 cells co-cultured with human monocyte derived macrophages

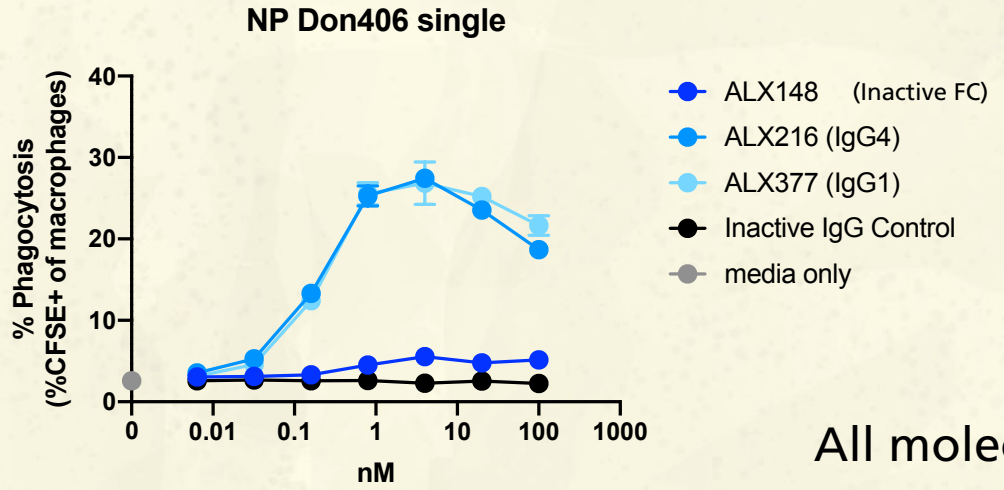
ALX ONCOLOGY

SINGLE AGENT: EFFECTOR FUNCTION AND AFFINITY CORRELATE WITH ACTIVITY



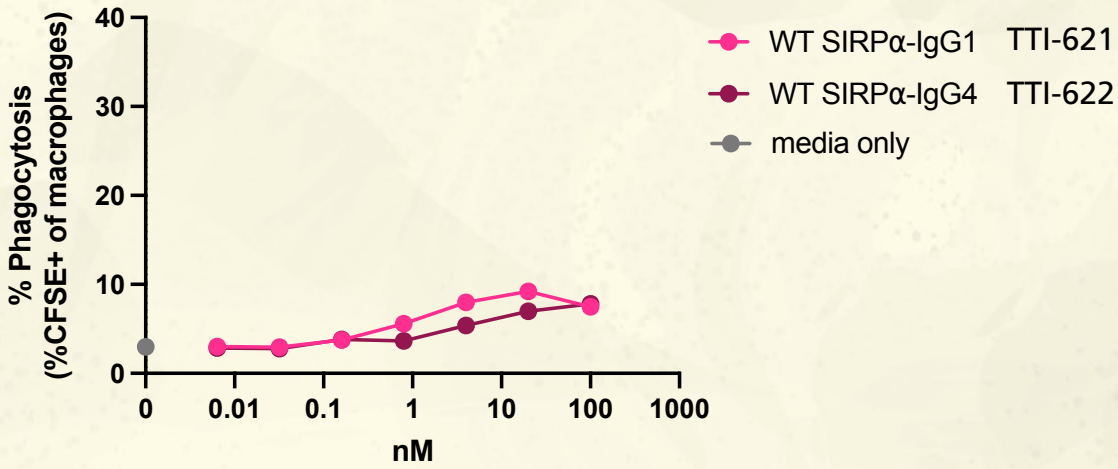
Anti CD47 with active Fc directly targets cancer cells

Molecules with same HIGH affinity CD47 binding domain (0.14 nM), Different effector function (Fc)



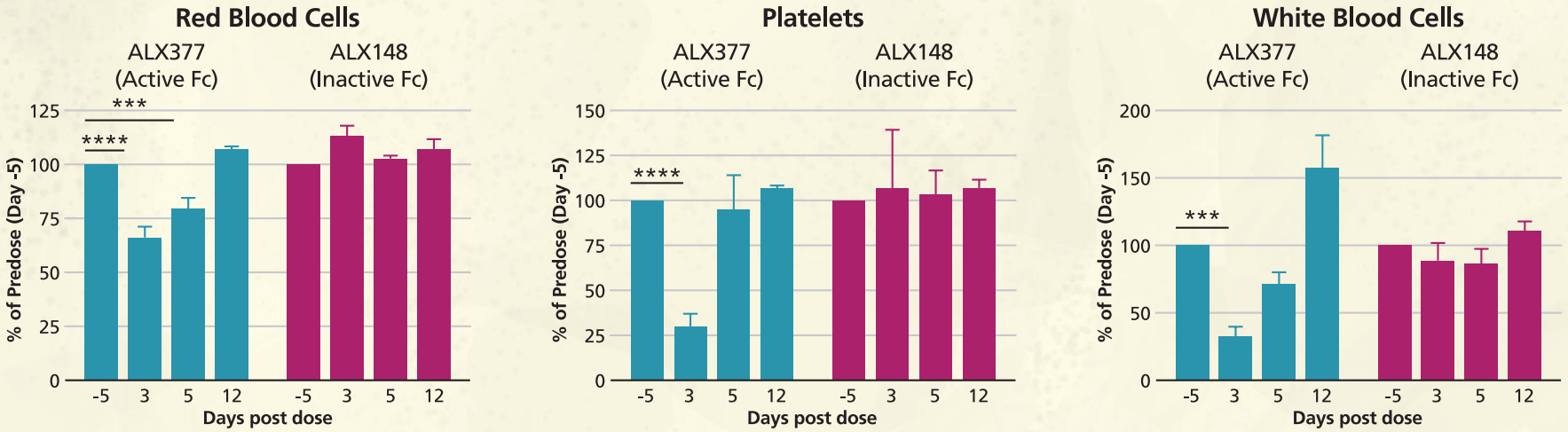
All molecules as single agent

Molecules with same LOW affinity CD47 binding domain (500 nM), Different effector function (Fc)



ALX ONCOLOGY

FC ACTIVITY CORRELATES WITH CYTOPENIA IN MICE



CD-1 mice received 30 mg/kg IV single dose

****p<0.0001, ***p<0.001

Mouse cross-reactivity allows for safety and efficacy testing in mouse models

Inactive Fc is the core determinant of safety profile

ALX ONCOLOGY

TTI-621 (IgG1) VS TTI-622 (IgG4) SINGLE AGENT AND SIDE EFFECTS CORRELATE WITH EFFECTOR FUNCTION

TTI-621 (IgG1)0.05-0.5 mg/kg 0.5-2mg/kg

Related Adverse Events n (%)	Parts 1-3 n=218		Part 4 n=24	
Grade	1-2	3-4	1-2	3-4
IRR	87 (40)	6 (3)	9 (38)	3 (13)
Thrombocytopenia	17 (8)	48 (22)	2 (8)	6 (25)
Chills	48 (22)		2 (8)	
Fatigue	34 (16)	2 (1)	2 (8)	
Anemia	10 (5)	20 (9)		
Pyrexia	26 (12)		1 (4)	
Nausea	23 (11)		2 (8)	
Diarrhea	19 (9)	1 (0.5)	2 (8)	
Neutropenia	4 (2)	15 (7)	3 (13)	
Headache	16 (7)		3 (13)	
Vomiting	14 (6)	1 (0.5)	1 (4)	
Hypotension	10 (5)	2 (0.9)		

TTI-622 (IgG4) 0.8-18mg/kg

Adverse Events n (%)	Total n=43		All AEs		Related AEs	
	All	Related	Gr 1-2	Gr 3-4	Gr 1-2	Gr 3-4
Thrombocytopenia	13 (30)	9 (21)	8 (19)	5 (12)	7 (16)	2 (5)
Constipation	8 (19)	1 (2)	8 (19)		1 (2)	
Nausea	8 (19)	3 (7)	8 (19)		3 (7)	
Pyrexia	7 (16)	2 (5)	6 (14)	1 (2)	2 (5)	
Fatigue	6 (14)	4 (9)	6 (14)		4 (9)	
Neutropenia	6 (14)	5 (12)	1 (2)	5 (12)	1 (2)	4 (9)
Diarrhea	5 (12)	1 (2)	4 (9)	1 (2)	1 (2)	
Abdominal pain	4 (9)	2 (5)	4 (9)		2 (5)	
Anemia	4 (9)	4 (9)	3 (7)	1 (2)	3 (7)	1 (2)
Hypotension	4 (9)		4 (9)	1 (2)		
Insomnia	4 (9)	1 (2)	4 (9)		1 (2)	
Pain	4 (9)		3 (7)	1 (2)		

Indication	Response evaluable n	CR	PR	OR
CTCL	62	2 (3%)	10 (16%)	12 (19%)
PTCL	22	2 (9%)	2 (9%)	4 (18%)
DLBCL	7	1 (14%)	1 (14%)	2 (29%)

Indication	Response evaluable N	CR	PR	OR
DLBCL	11	1 (9%)	2 (18%)	3 (27%)
PTCL	6	0 (0%)	2 (33%)	2 (33%)
CTCL	4	1 (25%)	2 (50%)	3 (75%)
FL	3	0 (0%)	1 (33%)	1 (33%)
HL	3	0 (0%)	0 (0%)	0 (0%)
TOTAL	**27**	**2 (7%)**	**7 (26%)**	**9 (33%)**

ALX ONCOLOGY

MAGROLIMAB (7 nM AFFINITY-IgG4) FIH PH1 SINGLE AGENT DATA

Medium effector function IgG4 has very modest single agent and still significant side effects

Safety

TABLE 3. Adverse Event Summary for Patients Treated With Maintenances Doses of 20 mg/kg or Higher

	Patients Treated, No. (%)								
	Part B, Biopsy Cohort, and Part C Prime + 20 mg/kg Maintenance Dose (n = 29)			Part C: Prime + 30 mg/kg Load and Maintenance Dose (n = 9)			Part C: Prime + 45 mg/kg Load and Maintenance Dose (n = 6)		
Adverse Event*	All Grades	Grade 3	Grade 4	All Grades	Grade 3	Grade 4	All Grades	Grade 3	Grade 4
Anemia	19 (66)	5 (17)	0	3 (33)	0	0	3 (50)	1 (17)	0
Hemagglutination	12 (41)	1 (3)	0	2 (22)	0	0	2 (33)	0	0
Hyperbilirubinemia	11 (38)	3 (10)	0	0	0	0	1 (17)	0	0
Thrombocytopenia	5 (17)	0	0	0	0	0	0	0	0
Lymphocyte count decreased	4 (14)	4 (14)	0	3 (33)	2 (22)	1 (11)	1 (17)	1 (17)	0
Arthralgia/myalgia	5 (17)	0	0	2 (22)	0	0	1 (17)	0	0
Headache	11 (38)	0	0	6 (67)	1 (11)	0	4 (67)	0	0
Nausea	3 (10)	0	0	2 (22)	0	0	3 (50)	0	0
Fatigue	18 (62)	0	0	6 (67)	0	0	4 (67)	0	0
Fever	14 (48)	0	0	4 (44)	0	0	2 (33)	0	0
Chills	12 (41)	0	0	5 (56)	0	0	3 (50)	0	0
Infusion-related reaction	7 (24)	2 (7)	0	2 (22)	1 (11)	0	2 (33)	1 (17)	0

*Adverse events occurred in > 15% of patients across all three cohorts listed (n = 44) and selected adverse events of interest.

<u>Efficacy (20 mg/kg):</u>

2PR in ovarian or fallopian tube carcinomas

1 Mixed response in DLBCL

Sikic et al, JCO 2018

ALX ONCOLOGY

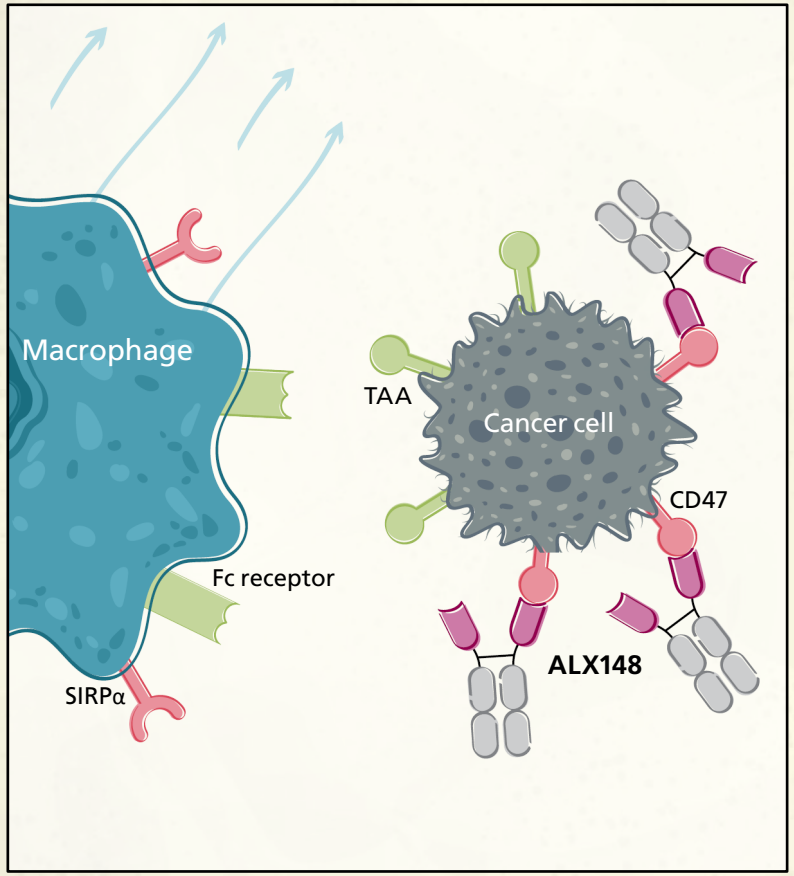
SUMMARY 1- CD47 BLOCKERS WITH ACTIVE FC AS SINGLE AGENT

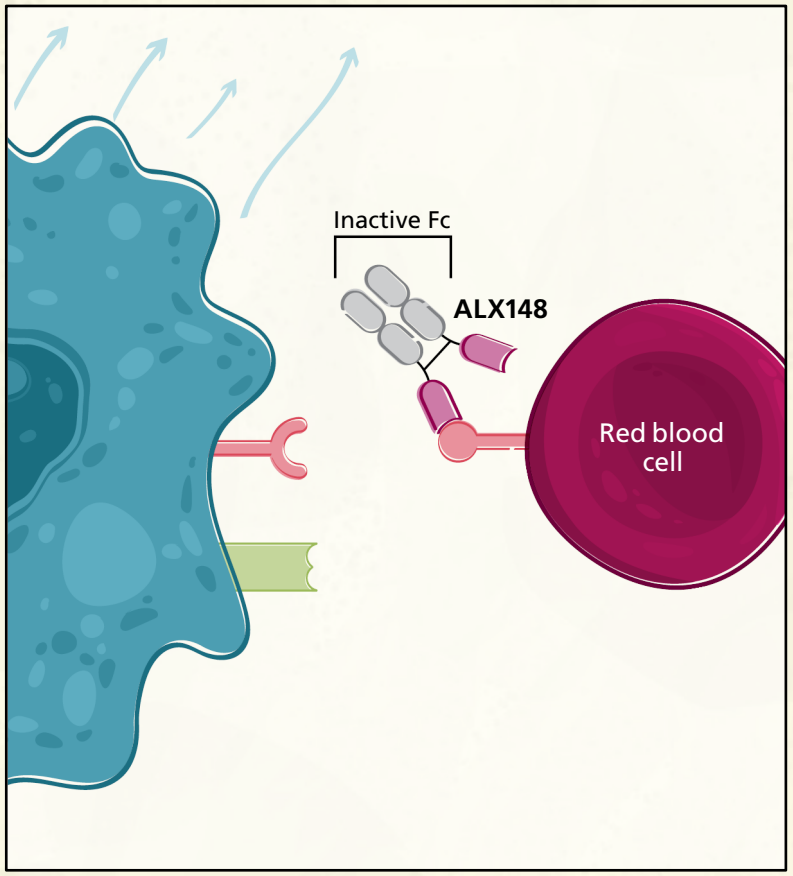
- **Higher affinity allows for effective blockade of the CD47-Sirpa interaction, and enhancement of Fc mediated phagocytosis**
- **Stronger Fc effector function correlates with higher phagocytosis of cancer and normal cells**
- **Single agent activity with active Fc is modest**
- **It is hard to separate efficacy from side effects using CD47 as tumor associated antigen**

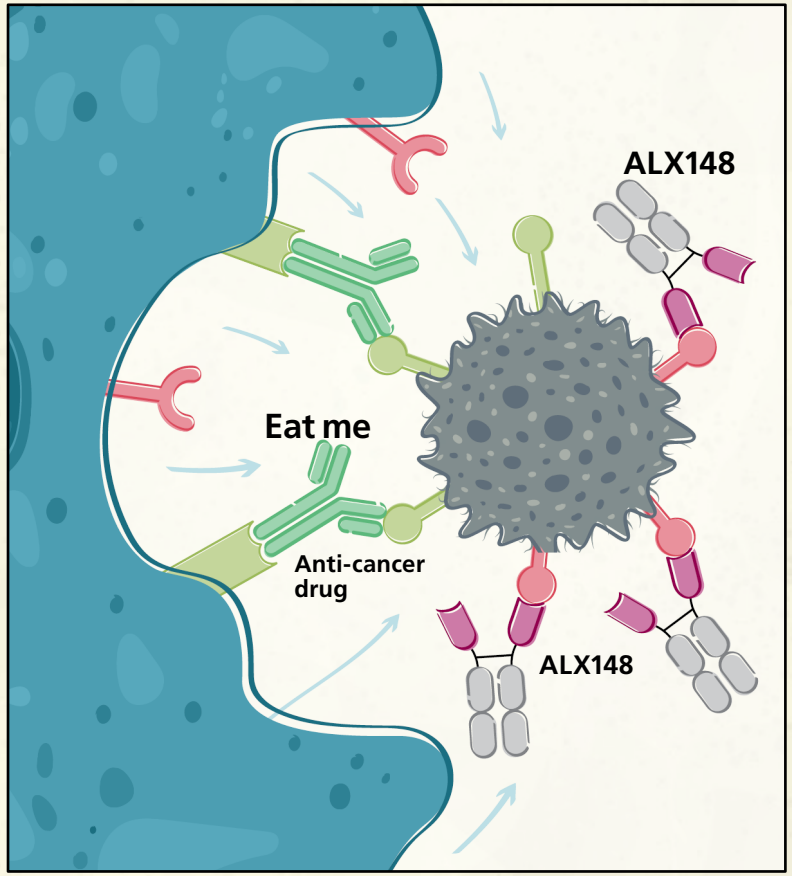
ALX ONCOLOGY

COMBO THERAPY: CD47 BLOCKERS AS MYELOID CHECKPOINT MODULATOR

It spares normal cells





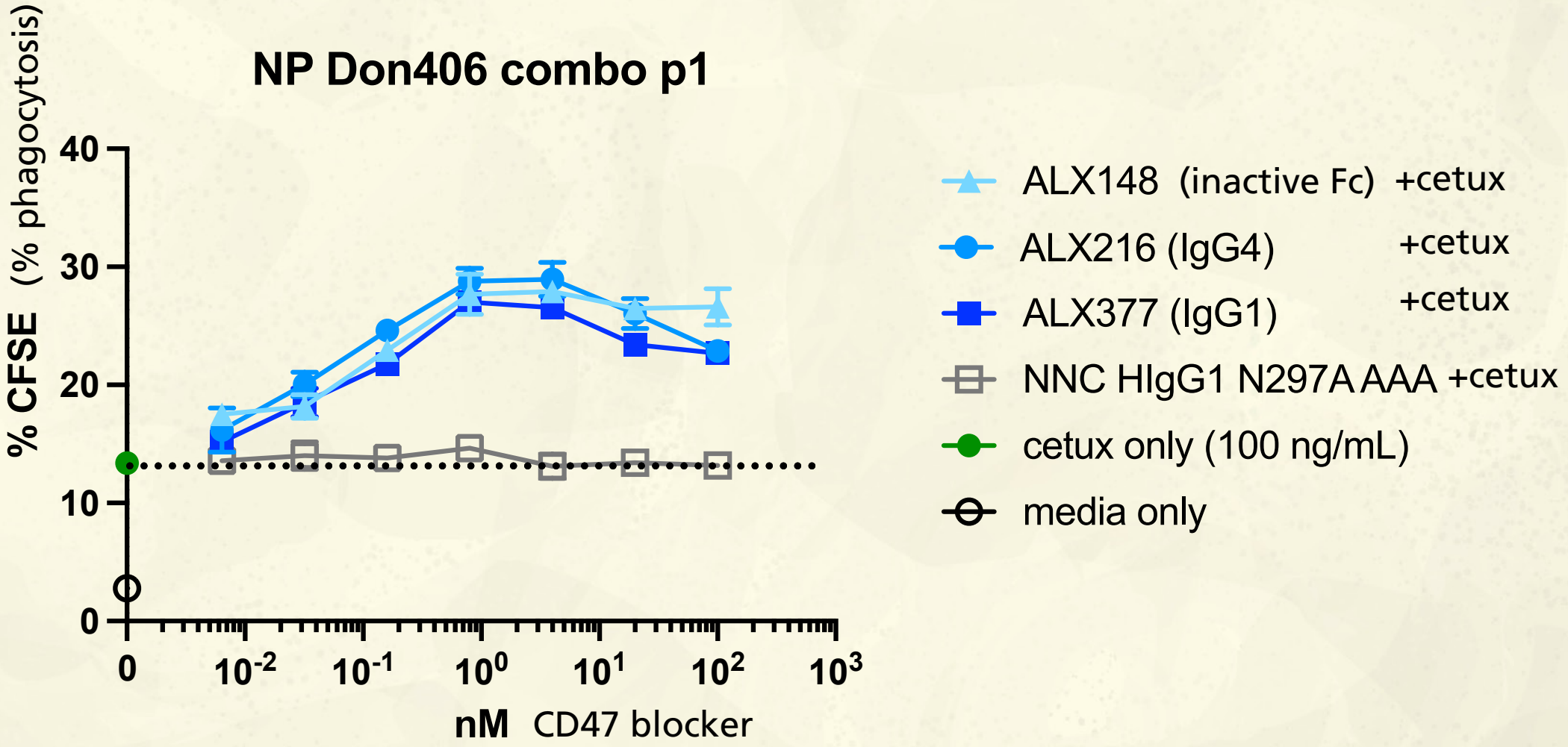


Anti CD47 with inactive Fc binds and block CD47-SIRPα interaction

Can we get maximum activity with inactive Fc in the combination setting?

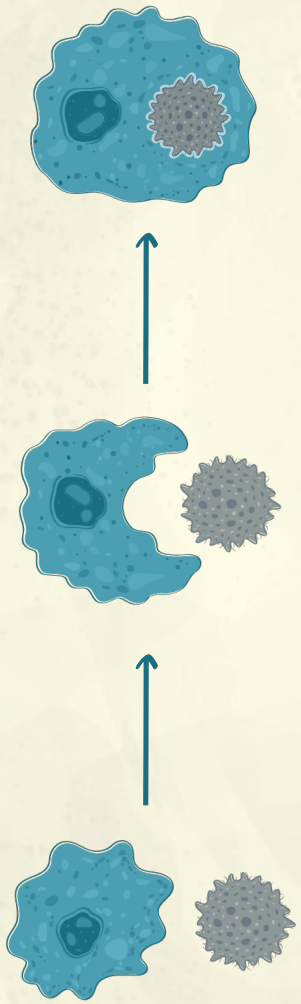
ALX ONCOLOGY

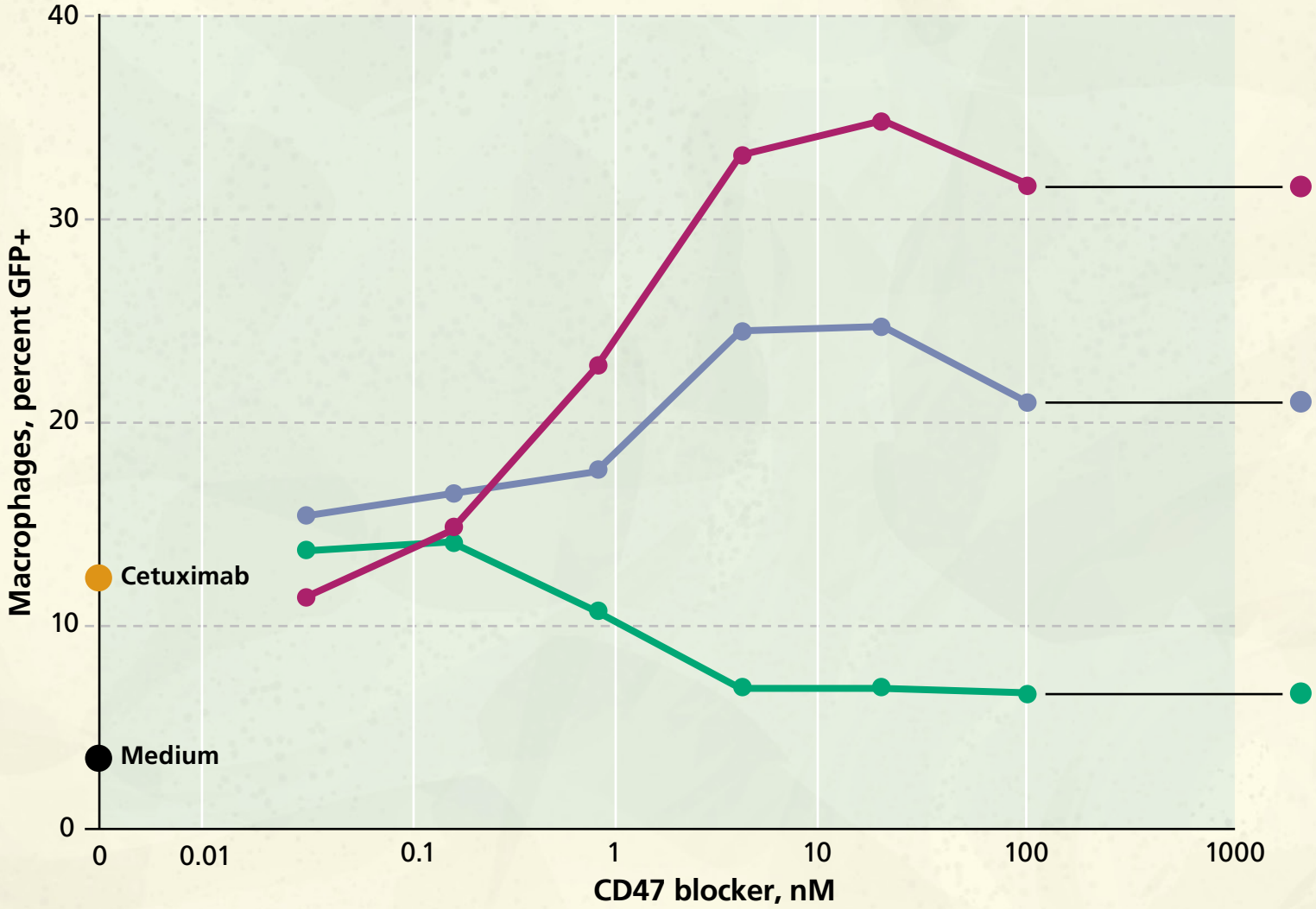
COMBO ACTIVITY IS INDEPENDENT OF CD47 BLOCKER EFFECTOR FUNCTION



DLD1 cells (EGFR+) co-cultured with human monocyte derived macrophages and cetuximab

COMBO ACTIVITY CORRELATES WITH CD47 BLOCKER AFFINITY





ALX148 inactive Fc + Cetuximab KD= 0.14 nM

ADCP by cetuximab is enhanced by inactive Fc and high affinity

5F9 (Magrolimab) IgG4 + Cetuximab KD= 7 nM

Enhances ADCP with cetuximab but at lower levels

TTI-621 IgG1 + Cetuximab KD= 500 nM

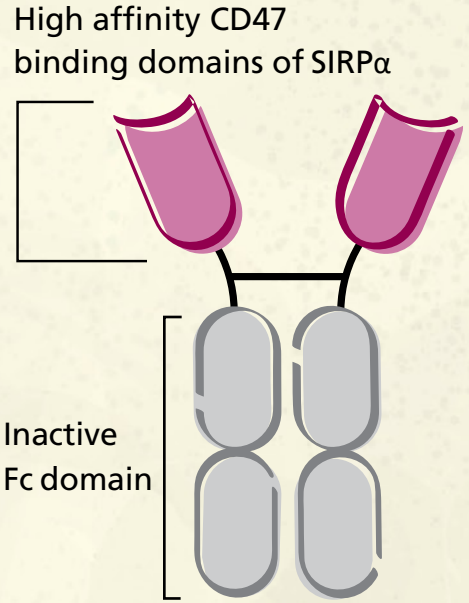
Does not enhance ADCP in combination with cetuximab

ALX ONCOLOGY

ALX148: A PURE CD47 BLOCKER WITHOUT EFFECTOR FUNCTION

High affinity CD47 binding domain of SIRPα	→	**Potently blocks CD47 signal on cancer cells**
Inactive Fc domain eliminates binding activity	→	**No dose dependent cytopenia**
Presence of Fc domain ensures slow clearance and long half-life	→	**Less frequent dosing**

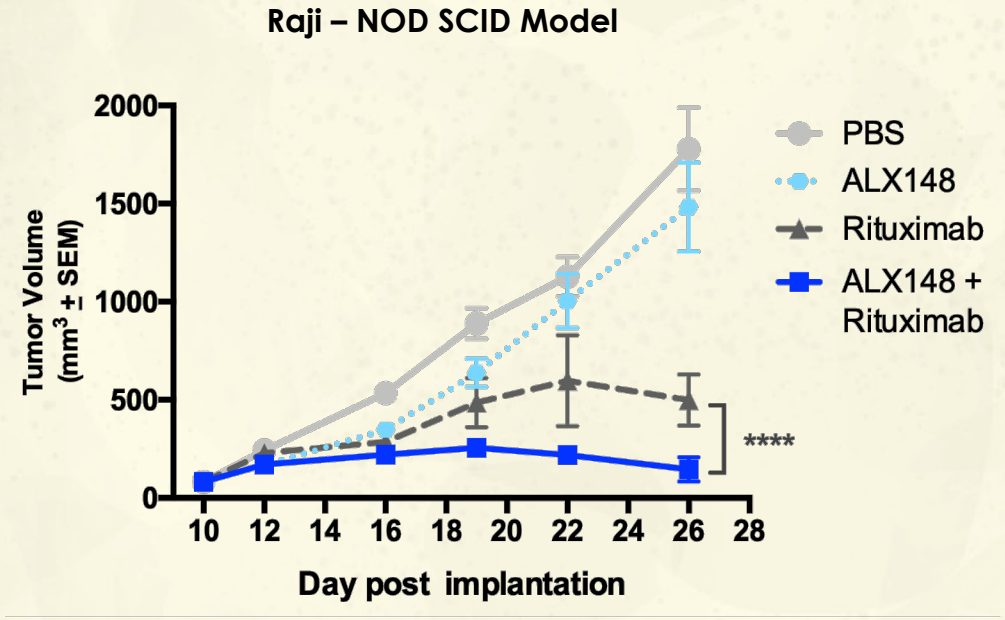
Designed for safety and efficacy

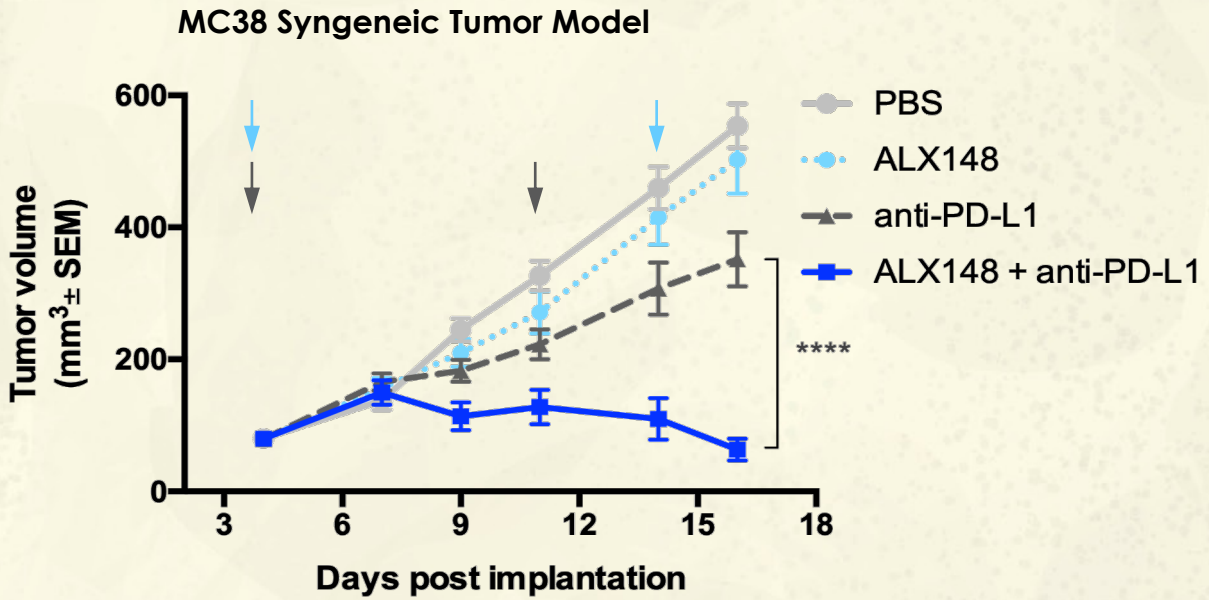


- ~Half the molecular weight of an antibody
- Increases solid tumor penetration
- Cross-reactive to human, monkey, mouse
- Standard antibody manufacturing process

ALX ONCOLOGY

COMBINATION EFFICACY WITH TAA (RITUXIMAB) ANTIBODIES AND CHECKPOINT INHIBITOR (ATEZOLIZUMAB)





Mouse cross-reactivity allows for better clinical translation of preclinical models: presence of CD47 sink and mouse models with intact immune system

ALX ONCOLOGY

ALX148 DEMONSTRATES FAVORABLE TOLERABILITY PROFILE

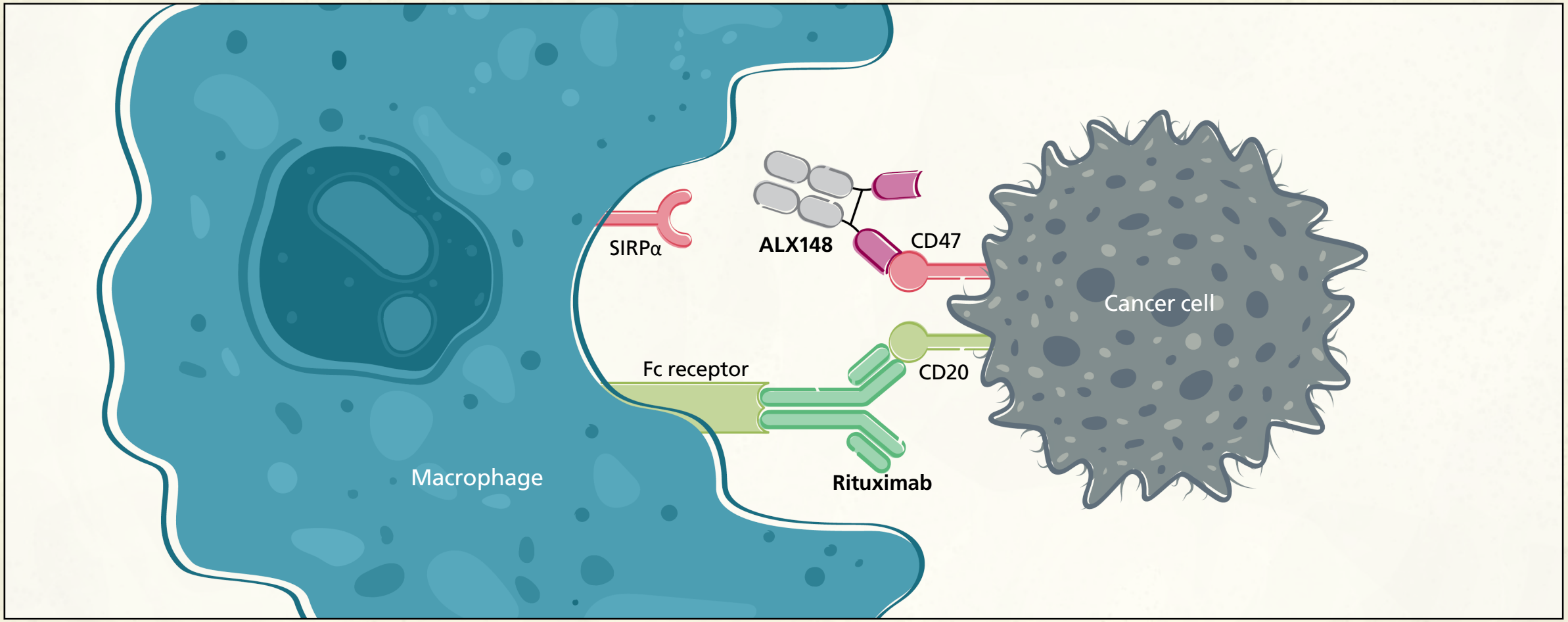
	Preclinical	Single agent	Combinations
Highest administered dose	**100 mg/kg**[1] with no observable adverse events	**30 mg/kg Q2W**[2] No evidence of dose-dependent cytopenias	**15 mg/kg QW** currently dosed **60 mg/kg Q4W** planned

[1]100 mg/kg of ALX148 ≅ 200 mg/kg of a typical antibody
[2]Single agent safety, ALX presentation, ASCO 2018 poster

ALX148 has not yet reached a maximum tolerated dose

ALX ONCOLOGY

NHL TRIAL: ALX148 + RITUXIMAB MECHANISM OF ACTION



ALX148 increases antibody dependent cellular phagocytosis in combination with Rituximab

ALX ONCOLOGY

NHL TOLERABILITY

	CD47 KD: 0.14 nM Inactive Fc		1 nM Active Fc (IgG4)		7 nM Active Fc (IgG4)	
Selected hematologic, treatment related adverse events	**ALX148 + Rituxan** (N=33)[1]		**CC-90002 + Rituxan** (n=26)[2]		**5F9 (magrolimab) + Rituxan** (n=115)[3]	
	Total % (n)	≥Grade 3	Total % (n)	≥Grade 3	Total %	≥Grade 3
Neutropenia	**6% (2)**	**6% (2)**	**50% (13)**	**39% (10)**	**~13%**	**~7%**
Thrombocytopenia/ Decreased Platelets	**-**	**-**	**35% (9)**	**23% (6)**	**~20%**	**~13%**
Anemia	**6% (2)**	**3% (1)**	**12% (3)**	**4% (1)**	**~30%**	**~15%**

terminated

[1]ASH 2020 Abstract 3016
[2]ASH 2019 Abstract 4089
[3]EHA 2019 Abstract S867

CD47 blockers : Inactive Fc tolerability profile compares favorably to active Fc

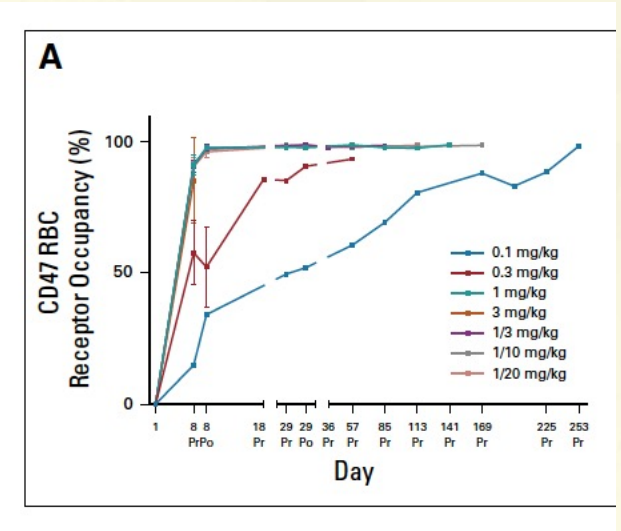
ALX ONCOLOGY

MAGROLIMAB + RITUX NHL RESPONSE RATES AND DOSING

DLBCL w/ Rituxan	Ph1	Ph2
N	21	38
Dosing (mg/kg)	up to 30 **Weekly**	30 and 45 **Every Other Week**
ORR	48%	29%
CR	33%	5%
PR	14%	24%

ORR = overall response rate.
CR = complete response rate.
PR = partial response rate.

EHA 2019 Abstract S867



Sikic et al, jco 2018

Magrolimab at 30 mg/kg QW and 30 mg/kg Q2W have near complete receptor occupancy in blood

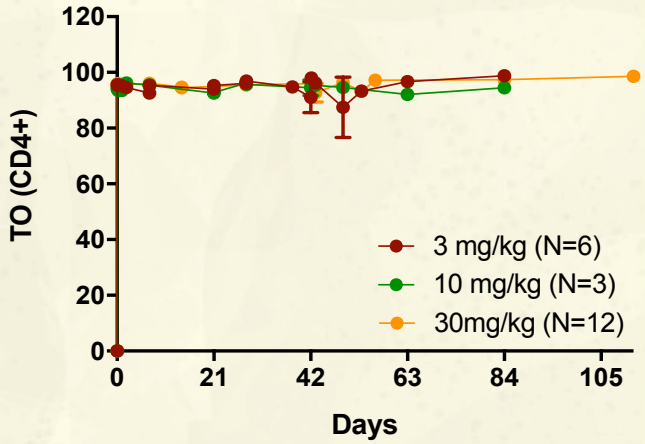
Reduced dosing led to reduced overall response rate in NHL

ALX ONCOLOGY

ALX148 + RITUXIMAB NHL PROOF-OF-PRINCIPLE TRIAL

	10 mg/kg QW		15 mg/kg QW	
Population	N	ORR	N	ORR
All	**22**	**40.9%**	**10**	**70.0%**
Aggressive	15	33.3%	6	50.0%
Indolent	7	57.1%	4	100.0%

Data Cutoff: October 1, 2020; ASH 2020 Abstract 3016
N = Response Evaluable Patients
Indolent = Follicular Lymphoma and Marginal Zone Lymphoma.
Aggressive = Diffuse Large B-cell Lymphoma and Mantle Cell Lymphoma.
ORR = Objective Response Rate.



- **ALX148 Near complete CD47 target occupancy (TO) by ALX148 is maintained at ≥ 3 mg/kg QW across dosing interval**

ALX148 demonstrated higher response rate at higher dosing

ALX ONCOLOGY

ALX148 HAS INITIAL CLINICAL ACTIVITY ACROSS TUMOR TYPES IN MULTIPLE TRIALS

Population	≥2L HER2+ GC		≥2L HER2+ GC	1L HNSCC		≥2L HNSCC (CPI-Naïve)		≥2L NHL (15mg/kg)
Combination	ALX148 + Herceptin + Cyramza + paclitaxel		ALX148 + Herceptin	ALX148 + Keytruda + 5FU + platinum		ALX148 + Keytruda		ALX148 + Rituximab
N-evaluable	14		19	4		10		10
ORR	**ALX148 64%**	Benchmark 28%	**21%**	**ALX148 75%**	Benchmark 36%	**ALX148 40%**	Benchmark 15%	**70%**
mPFS (months)	**NC**	4.4	**2.2**	**NC**	4.9	**4.6**	2.1	**NC**
mOS (months)	**NC**	9.6	**8.1**	**NC**	13.0	**22.1**	8.4	**NC**
Benchmark regimen	Cyramza + paclitaxel			Keytruda + 5FU + platinum		Single agent Keytruda		

Data as of October 1, 2020. NC = unable to be calculated, ORR = Objective Response Rate, mPFS = median progression free survival, mOS = median overall survival. CPI = checkpoint inhibitor. 2L GC benchmark, Wilke, Lancet Oncology, 2014; 2L HNSCC benchmark, Cohen, Lancet, 2018; 1L HNSCC benchmark, Burtness, Lancet, 2019.

ALX ONCOLOGY

SUMMARY 2- CD47 BLOCKERS IN COMBINATION

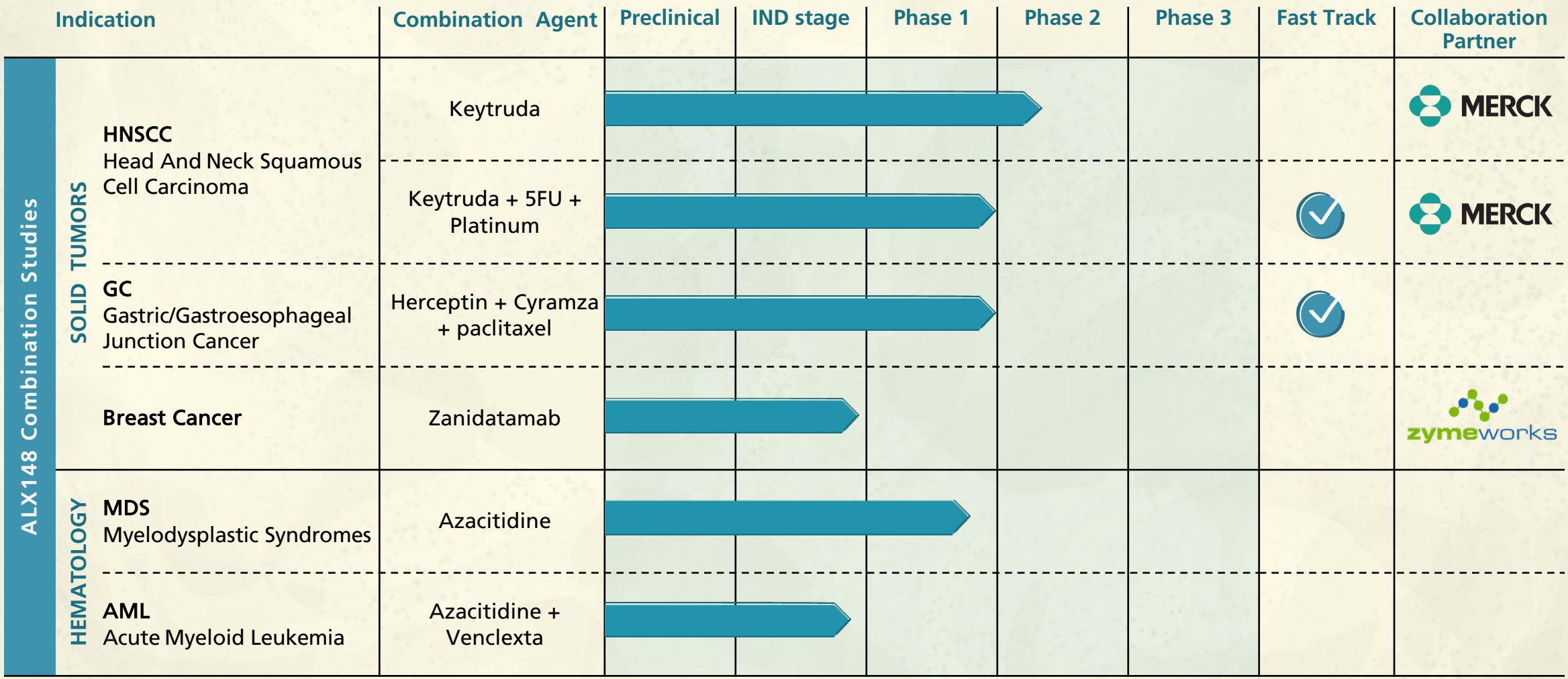
- **Higher affinity allows for effective blockade of the CD47-Sirpα interaction, and enhancement of Fc mediated phagocytosis (in this case of the combination antibody)**

- **Stronger Fc effector function (in the CD47 blocker) DOES NOT correlate with higher phagocytosis or clinical activity in combination studies**

- **CD47 blockers with INACTIVE Fc show COMBINATION anti cancer activity with good safety profile. It allows for higher dosing and maximal activity in the combination setting**

ALX ONCOLOGY

ALX148 CLINICAL DEVELOPMENT



ALX ONCOLOGY

ADDITIONAL ANTI-CD47 PROGRAMS WITH CLINICAL DATA ANNOUNCED

Company (drug)	Gilead (magrolimab)	Trillium (TTI-621)	Trillium (TTI-622)	I-Mab (TJC4)	Innovent (IBI188)
Fc	IgG4	IgG1	IgG4	IgG4	IgG4
Summary of published activity	Responses in NHL w/ rituximab, AML and MDS w/ azacitidine. Minimal activity in CRC w/ cetuximab (ORR 2/74) and ovarian w/ avelumab (ORR 0/24).	Responses in CTCL, PTCL, and DLBCL as single agent.	Reponses in DLBCL, PTCL, CTCL, and FL as single agent.	1 PR in R/R MM patient from 16 evaluable patients in single agent FIH (SITC 2020).	0 objective responses from 15 evaluable patients in single agent FIH (SITC 2020).
Summary of solid tumor trials announced^	Ph1b 2L+ solid tumor basket trial w/ pembro and RP2 HNSCC trial w/ pembro and chemo.	Ph1 leiomyosarcoma w/ doxorubicin (IND submitted).	Ph1 MM w/ carfilzomib + dexamethasone. Ph1 AML w/ aza +/- ven.	Ph1 NSCLC, urothelial, and ovarian w/ pembro (China only).	Ph1 advanced solid tumors.
Summary of heme trials announced^	Ph3 in MDS and AML w/ various aza +/- ven combos. Ph1b/2 in DLBCL w/ rituximab.	Ph2 PTCL single agent (trial design stage).	Ph1 ovarian w/ chemotherapy (trial design stage).	Ph 1 NHL w/ rituximab (China only). Ph1b/2 AML and MDS w/ azacitidine.	Ph1b/2 AML w/ aza (China only). Ph1 MDS w/ aza (China Only). Ph1 in lymphomas w/ rituximab.

^Does not include ISTs.

Additional clinical-stage programs:

IgG4 mAbs: AkesoBio (AK117)*, ImmuneOncia (IMC-002), Zai Labs (ZL-1201)

IgG2 mAbs: Arch (AO-176)*

Bispecific programs (anti-CD47 x…): Kahr (DSP107; x41BBL), Shattuck (SL-172154; xCD40L), Innovent (IBI322; xPDL1), TG Therapeutics (TG-1801; xCD19), Waterstone (HX009; xPDL1)*

Anti-SIRPα programs: Boehringer / OSE (BI 765063 / OSE-172)*, BMS (CC-95251)

*ASCO 2021 clinical data expected

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Companies with preclinical programs: Abpro (ABP-160), Aduro (ADU-1805), Alector (AL008), Apexigen (APX701), Aurigen (AUR-104, 105), Beijing Hanmi (BH-29xx), Biocad, BioThera (BAT6004), Compass (CTX-5861), Exelixis/Invenra, Genmab/BliNK, Henlius (HLX24), Hummingbird (HMB-004A), ImmuneOnco (IMM01, 0306, 2902, 0207, 2505, 2601), Kezar (KZR-261), Lightchain (NI-2401, 2601, 2801, 1801), LynkCell (LYN301), Morphiex (MBT-001), Roche, Scenic Bio, Vivoryon (PQ1565)

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- Patients and their families that trust us

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