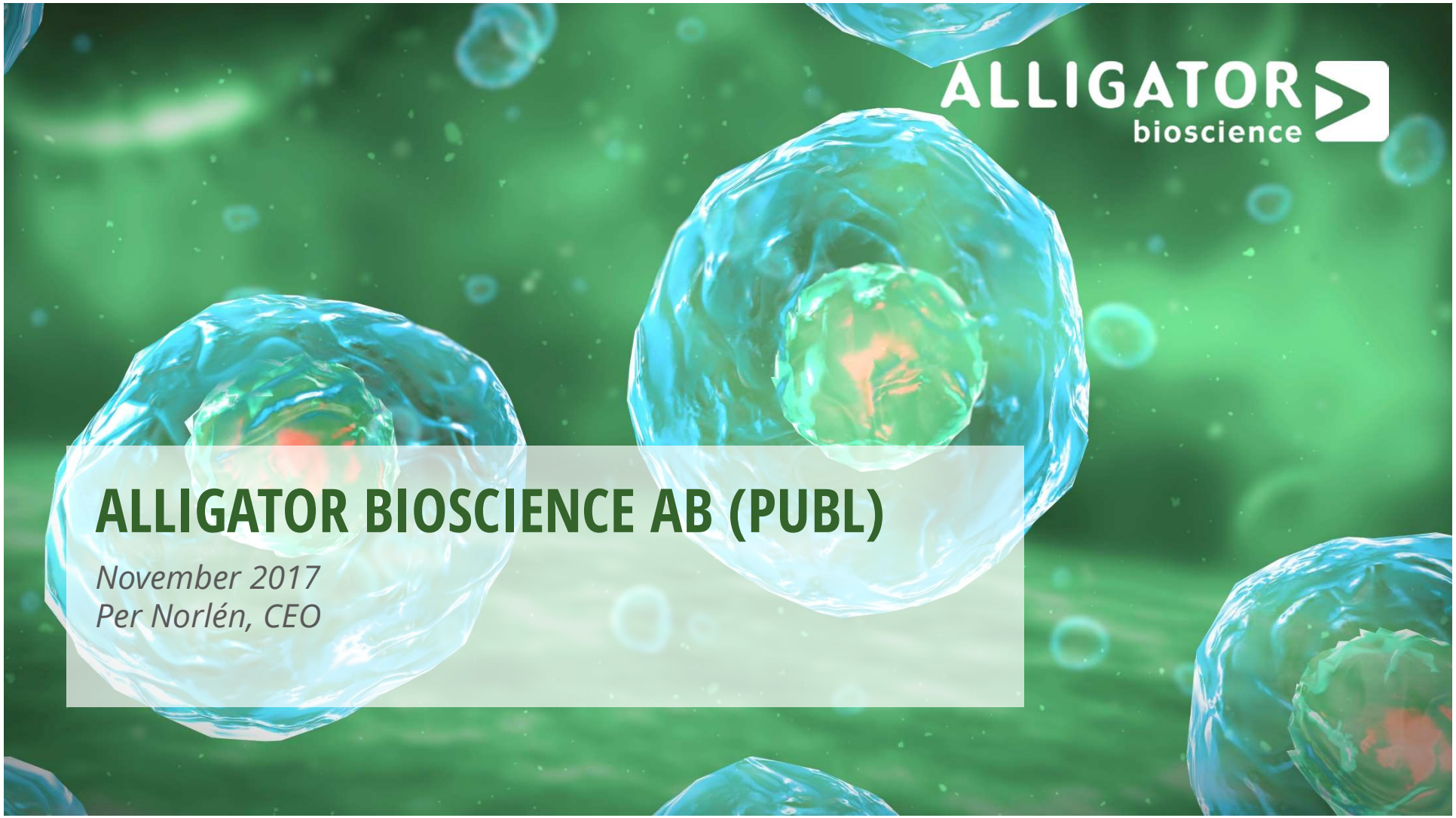

ALLIGATOR BIOSCIENCE AB (PUBL)

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Per Norlén, CEO

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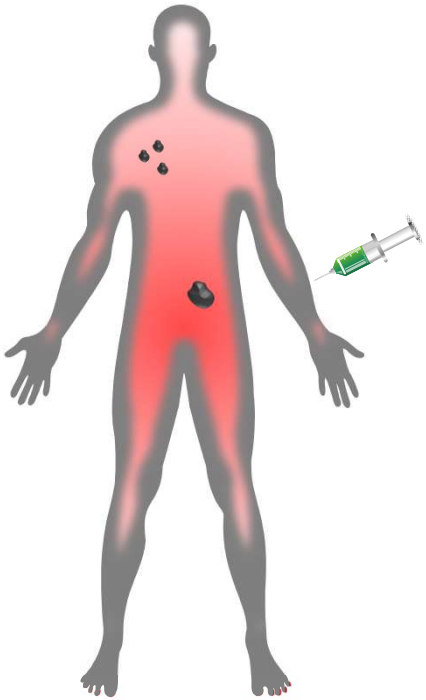
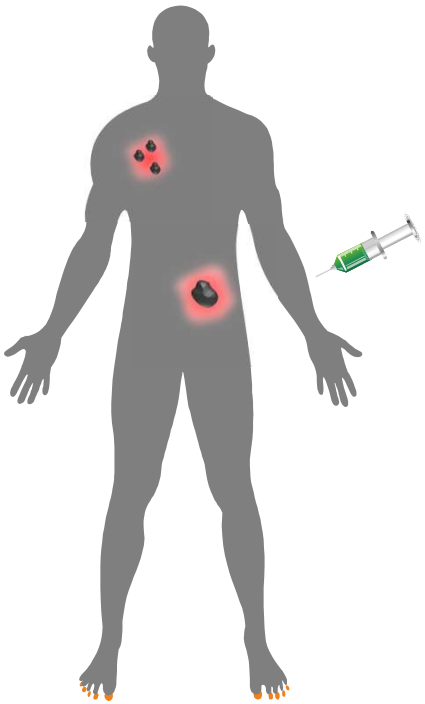
Tumor-directed immuno-oncology



GENERAL IMMUNE-ACTIVATION

General immune activation is associated with risk of severe adverse effects



TUMOR-DIRECTED IMMUNE-ACTIVATION

Selective activation of tumor-specific immune cells results in systemic immunity with limited toxicity

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Drug development pipeline

Research	Pre-clinical development	Phase I	Phase II
ADC-1013 (CD40)	*Partnered with Janssen Biotech Inc., developed as JNJ-7107*		
ATOR-1015 (OX40-CTLA4)			
ATOR-1017 (4-1BB)			
ALG.APV-527 (4-1BB-TAA)	*co-developed with Aptevo Therapeutics Inc.*		
(TNFRSF-ND)			

TNFRSF: Tumor Necrosis Factor Receptor Superfamily
TAA: Tumor-Associated Antigen
ND: Not Disclosed

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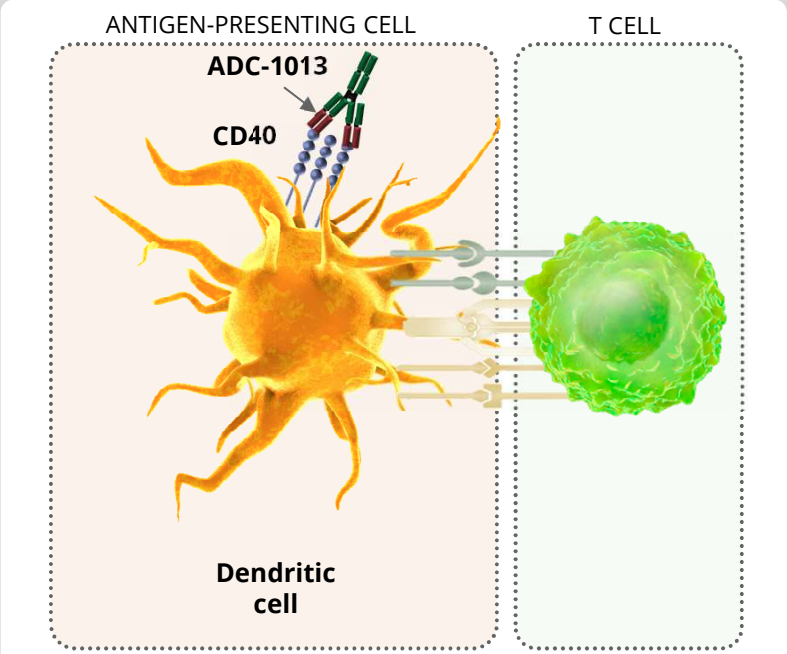
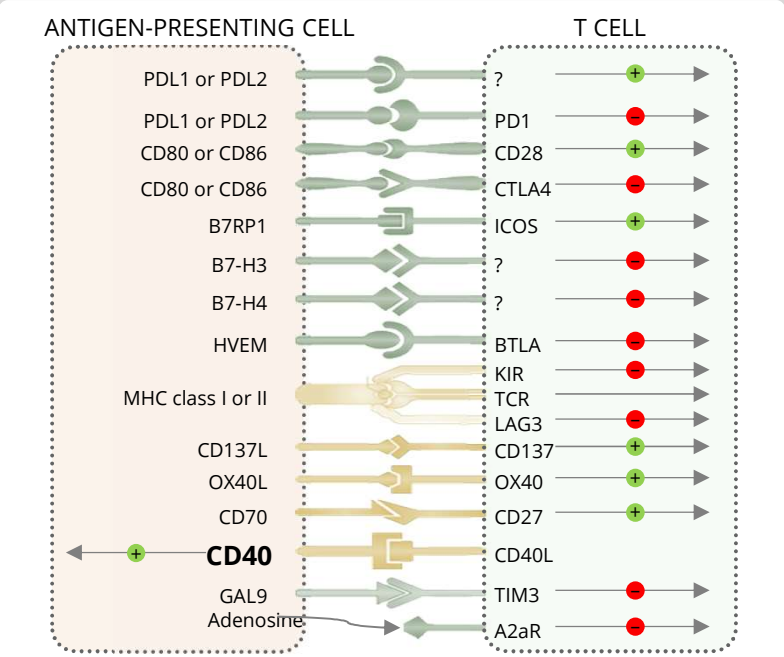
ADC-1013 targeting CD40

ADC-1013 Mode of Action



Immuno-modulating receptors



CD40 is the only defined receptor that selectively activates the antigen-presenting cell and is a highly promising target for combination with T-cell activating antibodies such as PD-1 and CTLA-4

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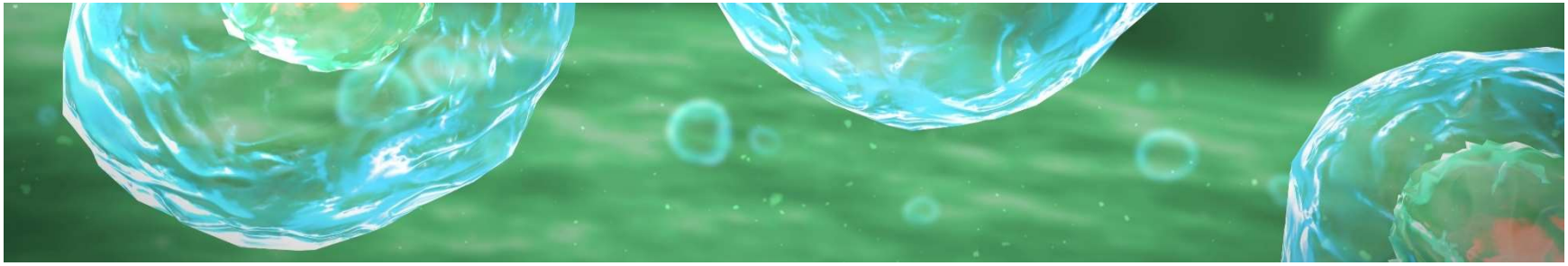
First-in-human clinical phase I

ADC-1013 intratumoral dose escalation every 14 days to evaluate safety and tolerability in patients with advanced solid tumors

Status:

- 1st patient dosed April, 2015
- Five clinical centers in Sweden, Denmark and UK
- Study completed March 2017, 24 patients enrolled



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Demographics

Administration route	Intratumoral				IV
Dose level (µg/kg)	**22.5**	**75**	**200**	**400**	**75**
Number of patients dosed	**3**	**4**	**3**	**8**	**5**
Age median (years)	**67.0**	**62.5**	**74.0**	**59.0**	**60.0**
Sex: Male/Female	**3/0**	**2/2**	**2/1**	**3/5**	**4/1**
Tumor type					
Colon/Rectal cancer		1	3	3	2
Melanoma	1			1	
Kidney	2			2	
Bile duct				1	1
Breast				1	
Ovarian		1			
Lung Cancer		2			
Peritoneal Cancer					1
Oesophageal Cancer					1

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Results ADC-1013 clinical phase I

ADC-1013 is well tolerated by cancer patients at clinically relevant doses

- Adverse events mainly low grade and transient
- ADC-1013 induces CD40-mediated pharmacodynamics effects
- Best overall response: stable disease in one patient for at least 12 months

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- A second clinical phase I study is ongoing, performed by Janssen Biotech, Inc.,
- Approx. 50 patients enrolled to date
- Intravenous dose escalation, with 3 expansion cohorts
- Combination studies are planned
- All further clinical development is run by Janssen

janssen

Immuno-oncology market and pipeline

Compound	Company	Indication	Phase	Target
Yervoy® (ipilimumab)	Bristol-Myers Squibb	Melanoma	M	CTLA-4
Keytruda® (pembrolizumab)	Merck	Melanoma, lung cancer, H&N cancer	M	PD-1
Opdivo® (nivolumab)	Bristol-Myers Squibb	Melanoma, lung, renal, H&N, bladder	M	PD-1
Tecentriq® (atezolizumab)	Roche	Bladder cancer, lung cancer	M	PD-L1
Bavencio® (avelumab)	Pfizer & Merck KGaA	Merkel cell cancer	M	PD-L1
Imfinzi® (durvalumab)	AstraZeneca	Bladder cancer	M	PD-L1
tremelimumab	AstraZeneca	Lung, bladder and H&N cancer	III	CTLA-4
PDR-001	Novartis	Melanoma	III	PD-1
RG7888	Roche	Solid tumors	II	OX40
urelumab	Bristol-Myers Squibb	Solid tumors and lymphoma	II	CD137
varlilumab	Celldex	Solid tumors	II	CD27
IMP-321	Prima Biomed	Solid tumors	II	LAG3
BMS-986016	Bristol-Myers Squibb	Solid tumors	II	LAG3
APX005M	Apexigen	Solid tumors	I/II	CD40
ADC-1013	**Alligator & JnJ**	**Solid tumors, hematological cancer**	**I**	**CD40**
RG7876	Roche	Solid tumors	I	CD40
SEA-CD40	Seattle Genetics	Solid tumors, hematological cancer	I	CD40
ABBV-428	Abbvie	Solid tumors	I	CD40-TAA
BMS-986178	Bristol-Myers Squibb	Solid tumors	I	OX40
MEDI0562	AstraZeneca	Solid tumors	I	OX40
GSK-3174998	GlaxoSmithKline	Solid tumors	I	OX40
PF-04518600	Pfizer	Solid tumors	I	OX40
INCAGN1949	Agenus and Incyte	Solid tumors	I	OX40
utomilumab	Pfizer	Solid tumors	I	CD137
BMS-986156	Bristol-Myers Squibb	Solid tumors	I	GITR
MK-4166	Merck	Solid tumors	I	GITR
MK-1248	Merck	Solid tumors	I	GITR
MEDI1873	AstraZeneca	Solid tumors	I	GITR
GWN-323	Novartis	Solid tumors and lymphoma	I	GITR
INCAGN1876	Agenus and Incyte	Solid tumors	I	GITR
JTX-2011	Jounce Therapeutics	Solid tumors	I	ICOS
MBG-403	Novartis	Solid tumors	I	TIM-3

- Approx. 70 immuno-oncology antibodies in clinical development
- Five CD40-targeting antibodies in clinical development
- Best and first in class potential

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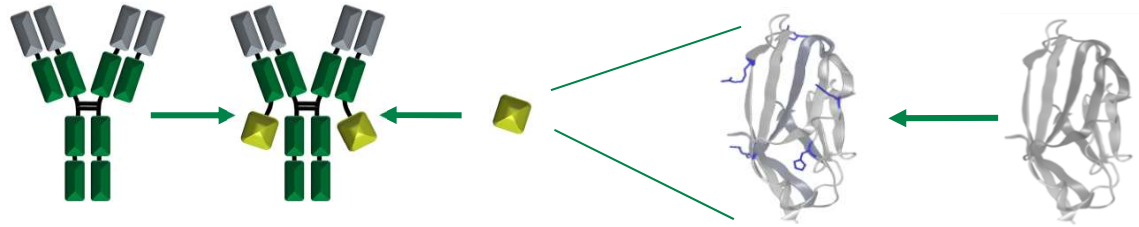
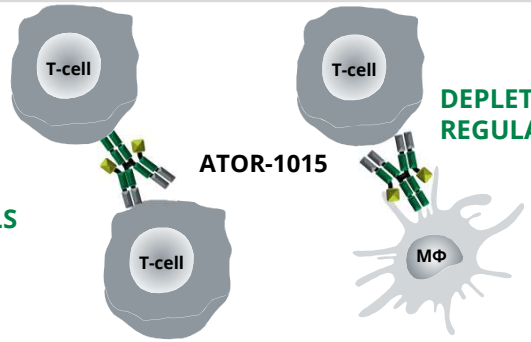
ATOR-1015: Dual binding to OX40 and CTLA-4



5 mutations were introduced
→ Affinity increased 100-fold

ACTIVATION OF EFFECTOR T-CELLS

SUPPRESSION OF REGULATORY T-CELLS



DEPLETION OF REGULATORY T-CELLS

Source: Company information

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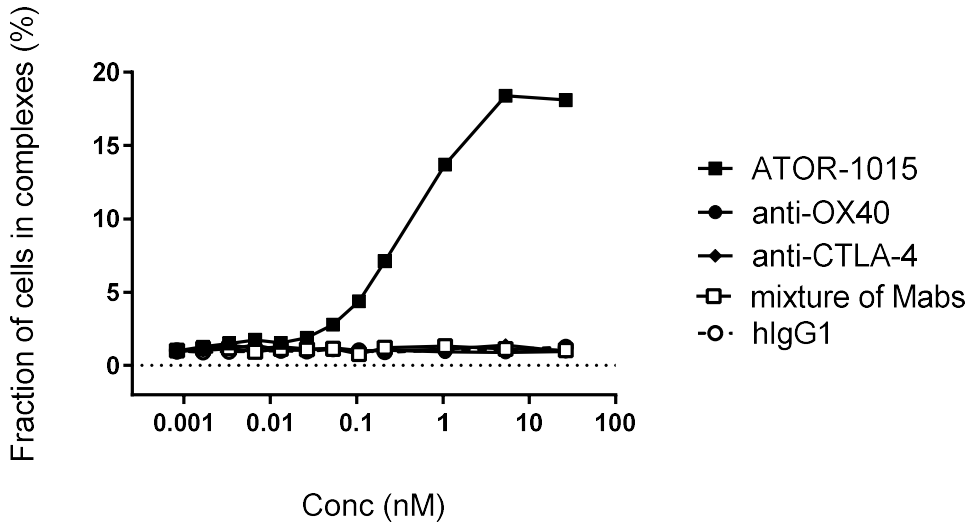
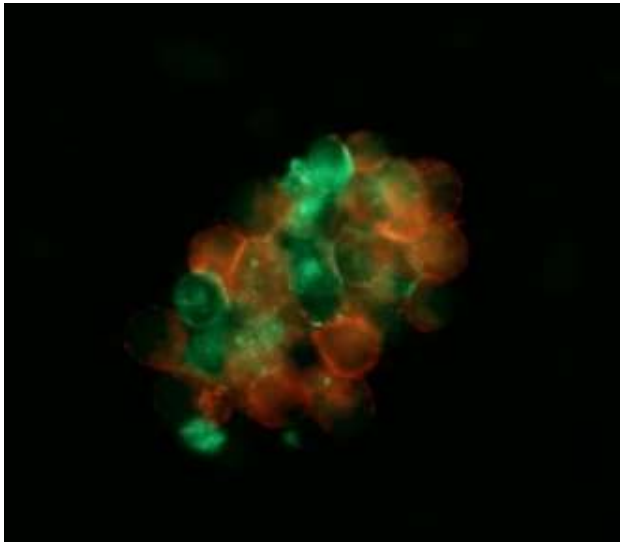
ATOR-1015 promotes cell-to-cell interactions





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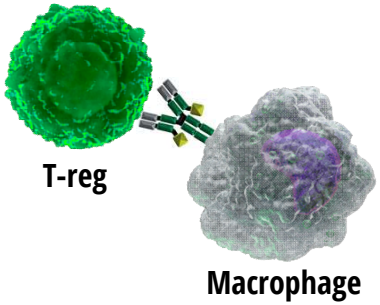
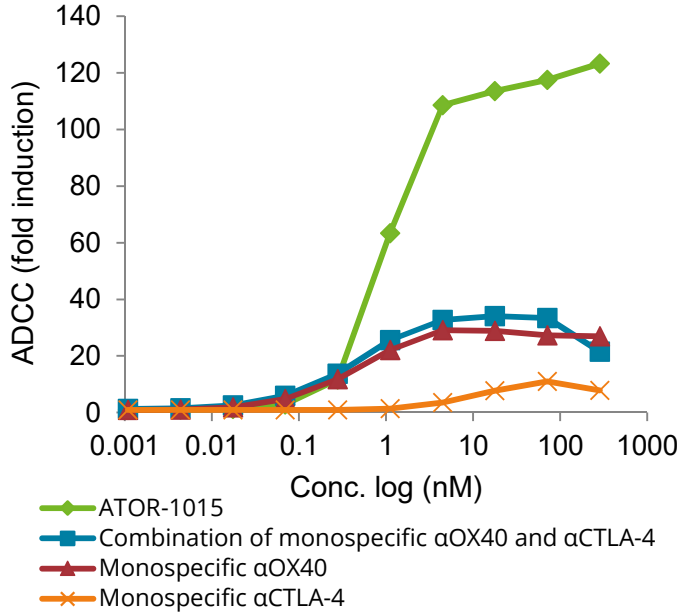
ATOR-1015: In vitro synergy

ATOR-1015 induces ADCC on CTLA-4/OX40 expressing T-reg



- ATOR-1015 kills regulatory T-cells (ADCC)
- ATOR-1015 is superior to the combination of monospecific αOX40 and αCTLA-4 binders

Synergistic T-reg depletion



ATOR-1015 is superior to the combination of the two monospecific antibodies

Source: Patent application: 1605450.4. map ATOR-1015

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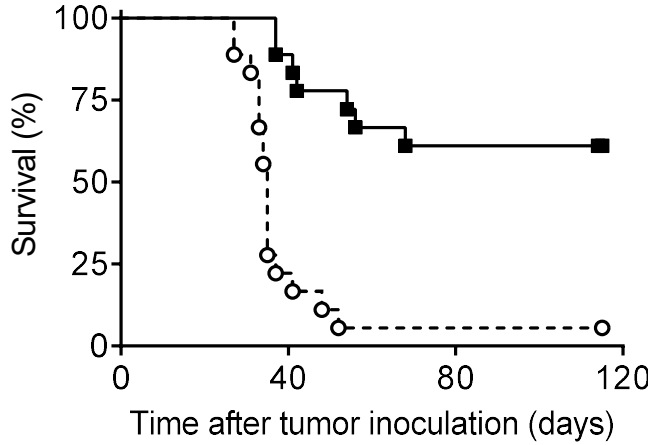
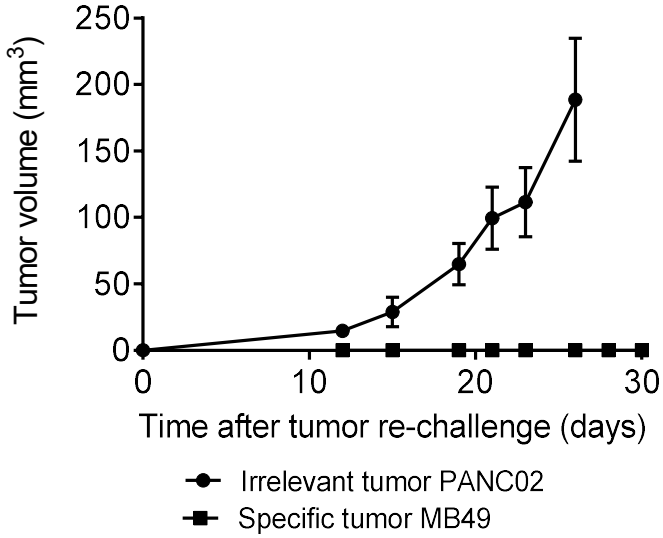
ATOR-1015 anti-tumor efficacy

Survival bladder cancer (MB49)



Tumor-specific long-term immunity



ATOR-1015 demonstrates anti-tumor efficacy in multiple tumor models: bladder, colorectal, melanoma and pancreas

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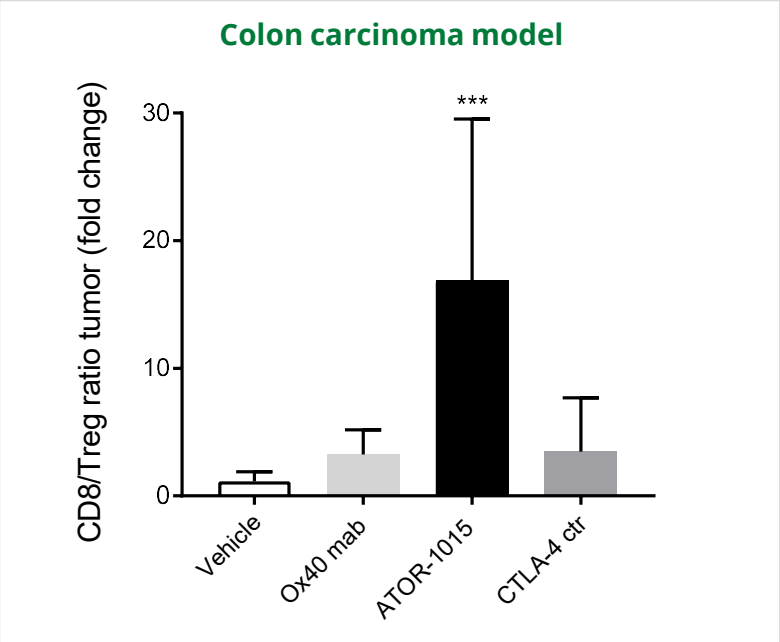
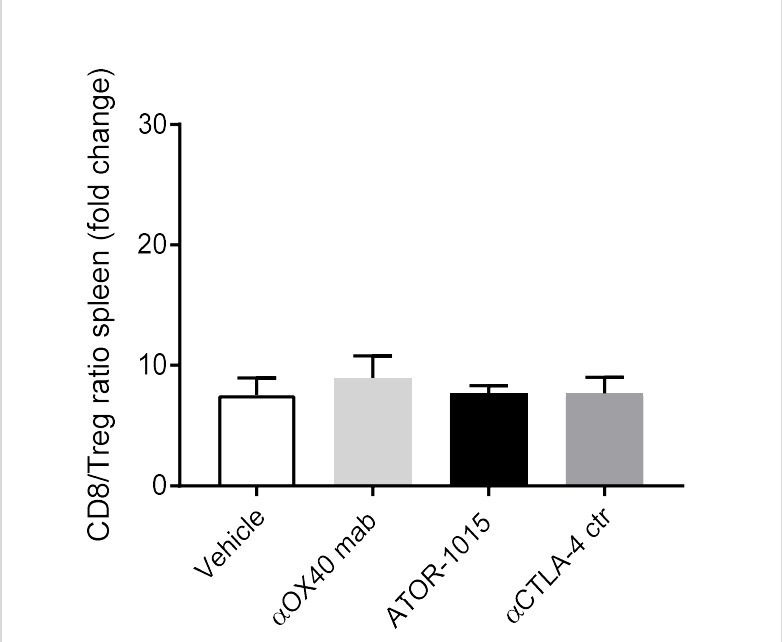
Tumor-directed suppression of regulatory T cells

ATOR-1015 increases Teff/Treg ratio in tumor



ATOR-1015 does not affect systemic T-cells



ATOR-1015 activates the immune system in tumors, but not elsewhere in the body

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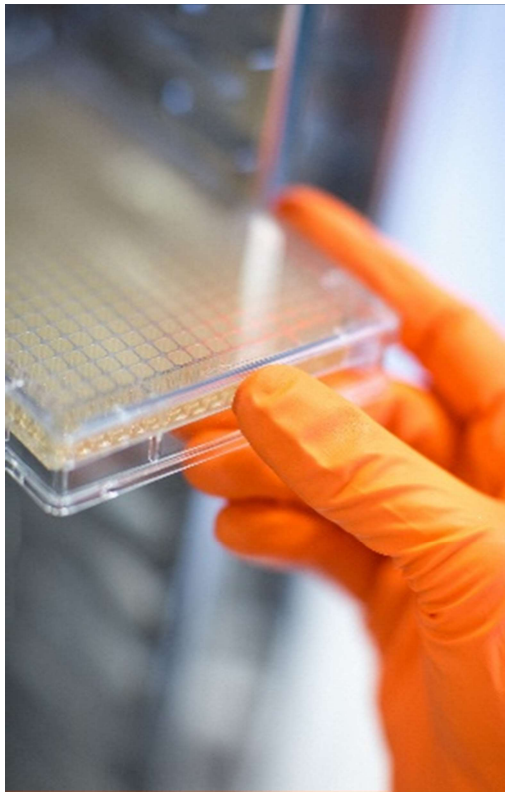
ATOR-1015 positioning

- Next generation CTLA4 antibody with augmented T-reg depletion
- First in class dual immune activator
- Expected synergy with PD-1
- Excellent bispecific format
- Clinical trial in cancer patients starts 2018



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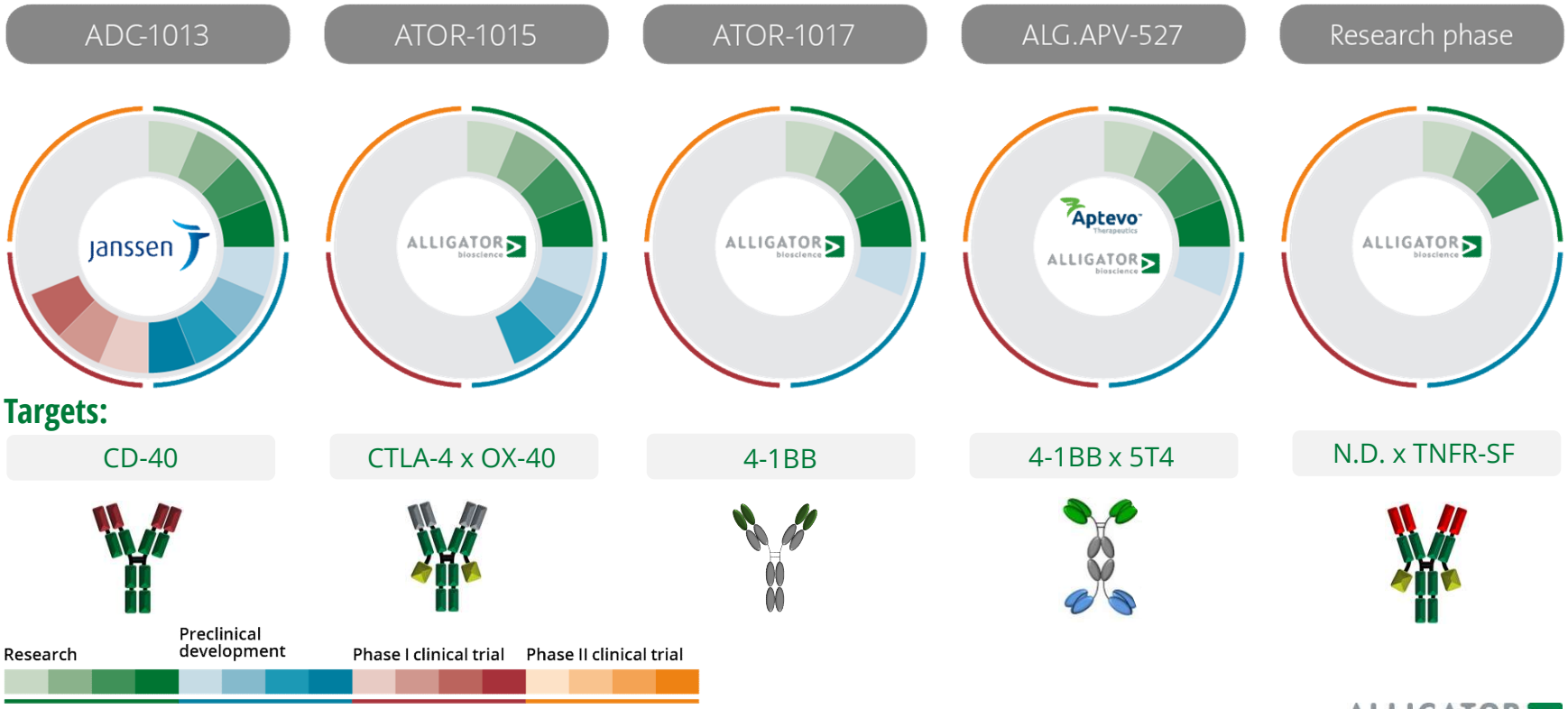
Strong immuno-oncology pipeline

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