



Identification of CTIM-76, a CLDN6 x CD3 bispecific antibody

December 1, 2022



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Overview

Martin Lehr – Chief Executive Officer



Claudin 6 Target Biology

Eric Butz, PhD – Scientific Lead



Discovery of CTIM-76

Joseph Rucker, PhD – Research Lead



Concluding Remarks

Martin Lehr – Chief Executive Officer

Q&A Session



Overview

Martin Lehr – Chief Executive Officer

Context Therapeutics Overview

Focus on Women's Oncology	<ul style="list-style-type: none"> • Unmet clinical need in breast, ovarian, and endometrial cancers
ONA-XR <i>oral PR antagonist</i>	<ul style="list-style-type: none"> • ONA-XR is a novel, potentially first-in-class progesterone receptor (PR) antagonist • Endometrial cancer Phase 2 trial initial data reports 4-month PFS rate of 77%¹ • Breast cancer SMILE trial initial data to be presented Dec. 7 at San Antonio Breast Cancer Symposium • Breast cancer ELONA trial Phase 1b data expected Q4 2023
CTIM-76 <i>CLDN6 x CD3 bispecific antibody</i>	<ul style="list-style-type: none"> • Claudin 6 (CLDN6) is uniquely expressed in certain adult and pediatric cancers • CTIM-76 is Context's CLDN6 x CD3 bispecific antibody Development Candidate • IND submission on track for Q1 2024
Cash Guidance	<ul style="list-style-type: none"> • Expected cash runway into Q1 2024

Pipeline

Cancer	Clinical Indication	Preclinical	Phase 1 Clinical	Phase 2 Clinical	Milestones	
ONA-XR (PR antagonist) ¹						
Breast Cancer	2L/3L ER+,PR+,HER2- Combination w/ elacestrant	Phase 1b/2 ELONA Trial			Initiated Q4 2022 Phase 1b data Q4 2023	<input checked="" type="checkbox"/>
	2L/3L ER+,PR+,HER2- Combination w/ fulvestrant	*Phase 2 SMILE Trial			Initial data Dec 2022	
Endometrial Cancer	Recurrent PR+ Endometrioid Combination w/ anastrozole	*Phase 2 Trial			Initial data Q4 2022 Data update mid-2023	<input checked="" type="checkbox"/>
Ovarian Cancer	Recurrent PR+ Granulosa Cell Tumor Combination w/ anastrozole	*Phase 2 Trial			Initial data Q4 2022 Data update mid-2023	<input checked="" type="checkbox"/>
CTIM-76 (CLDN6xCD3 bispecific antibody)						
	CLDN6-positive cancers				Candidate selection Q4 2022 IND submission Q1 2024	<input checked="" type="checkbox"/>



Claudin 6 Target Biology

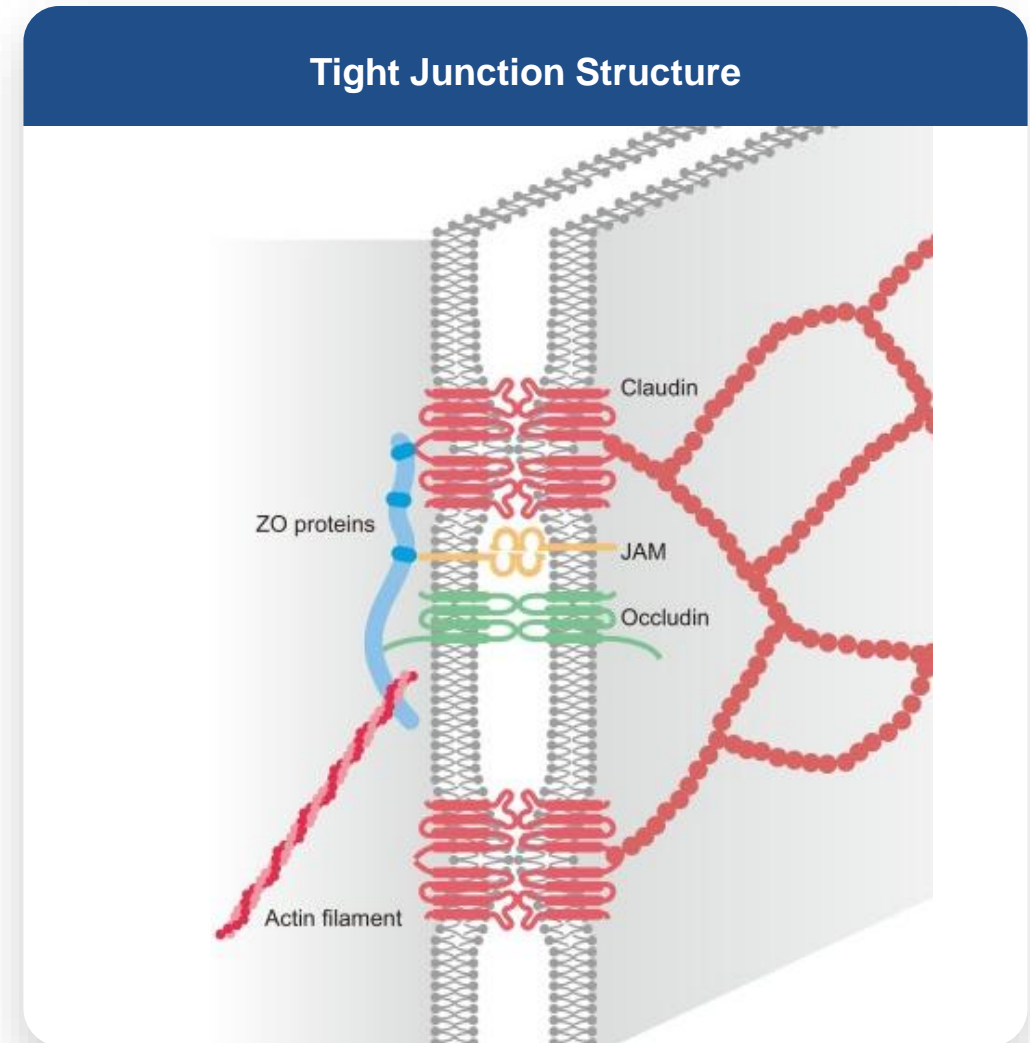
Eric Butz, PhD – Scientific Lead

Claudin 6 (CLDN6) is an Emerging Oncology Target

Opportunity	<ul style="list-style-type: none"> CLDN6 is a tumor-specific protein that is present at high surface density across certain adult and pediatric cancers¹ CLDN6 is expressed at very low levels or absent in normal adult tissue
Challenge	<ul style="list-style-type: none"> CLDN6 antigen is conformationally dependent, which limits access to antibody-antigen binding Antigen binding region is highly conserved with CLDN3, CLDN4, and CLDN9 CLDN6 selectivity is required to avoid off-target liabilities identified in murine knockout studies with CLDN3 (pancreas), CLDN4 (kidney, pancreas), and CLDN9 (ear, gut)
Target Validation	<ul style="list-style-type: none"> BNT211 CAR-T establishes Proof of Concept²: <ul style="list-style-type: none"> Novel CAR-T + mRNA vaccine evaluated in Phase 1 dose-escalation study in CLDN6+ solid tumors 50% response rate (ORR) in second dosing cohort
Unmet Need	<ul style="list-style-type: none"> Selectivity: preferentially target CLDN6 over other CLDN proteins Potency: specific lysis of CLDN6+ cancer cells over normal cells Safety: activation of cytotoxic T cells without concomitant activation of free cytokines Manufacturability: scalable process and on-demand therapy

Claudin (CLDN) Protein Family

- Tight junctions (TJ) regulate cell barrier and permeability
- CLDN proteins constitute a structural core of TJ, along with junction adhesion molecule (JAM) and occludin
- 27 CLDN proteins have been characterized to date
- Dysregulation of CLDN protein expression and function occurs in multiple diseases, including cancer

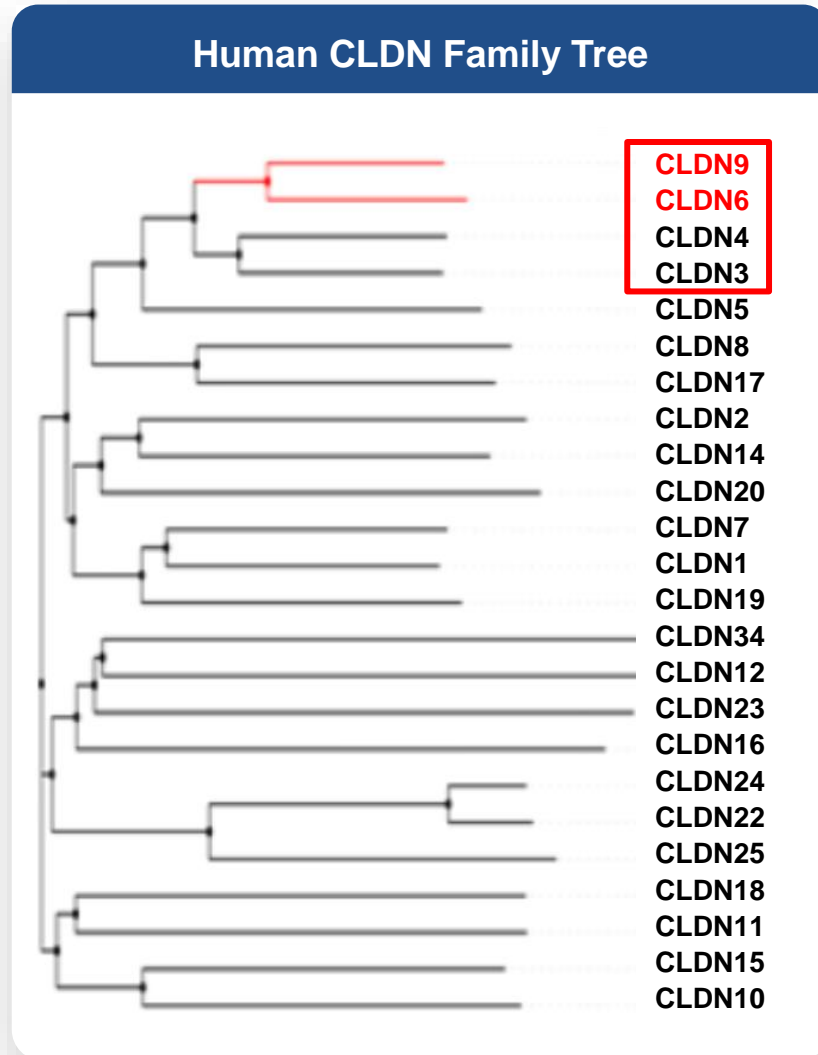


Many CLDN Proteins are Associated with Disease

CLDN	Disease
CLDN 1	Colitis, skin permeability
CLDN 2	Colorectal cancer, IBD
CLDN 3	Psoriasis, ovarian cancer
CLDN 4	Diabetes, ovarian cancer
CLDN 5	Cerebral edema, depression
CLDN 6	Multiple cancers
CLDN 7	Colon cancer
CLDN 9	Hearing loss

CLDN	Disease
CLDN 11	Myelin dysfunction
CLDN 14	Kidney stones, hearing loss
CLDN 15	Celiac
CLDN 16	Hypercalcinuria
CLDN 17	Renal dysfunction
CLDN 18.2	Gastric cancer
CLDN 19	Renal dysfunction, vision loss

The Challenge: developing a highly selective CLDN6 antibody

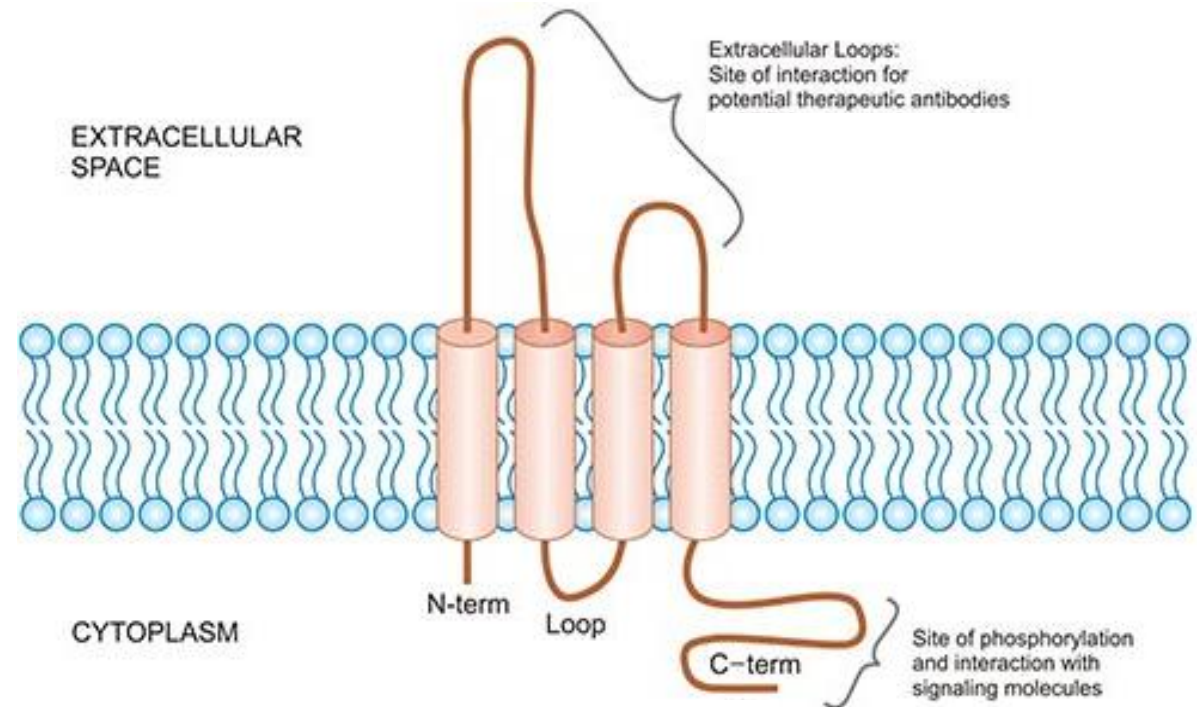


- CLDN6 antigen is **conformationally-dependent**, which limits access to antibody-antigen binding
- Antigen binding region is **highly conserved** with CLDN3, CLDN4, and CLDN9, making target selectivity a challenge¹
- CLDN6 **selectivity is required** to avoid off-target liabilities identified in murine knockout studies with CLDN3 (pancreas)², CLDN4 (kidney, pancreas)³, and CLDN9 (ear)⁴

CLDN6 is an Oncofetal Protein, Considered Favorable Candidates for Immunotherapy

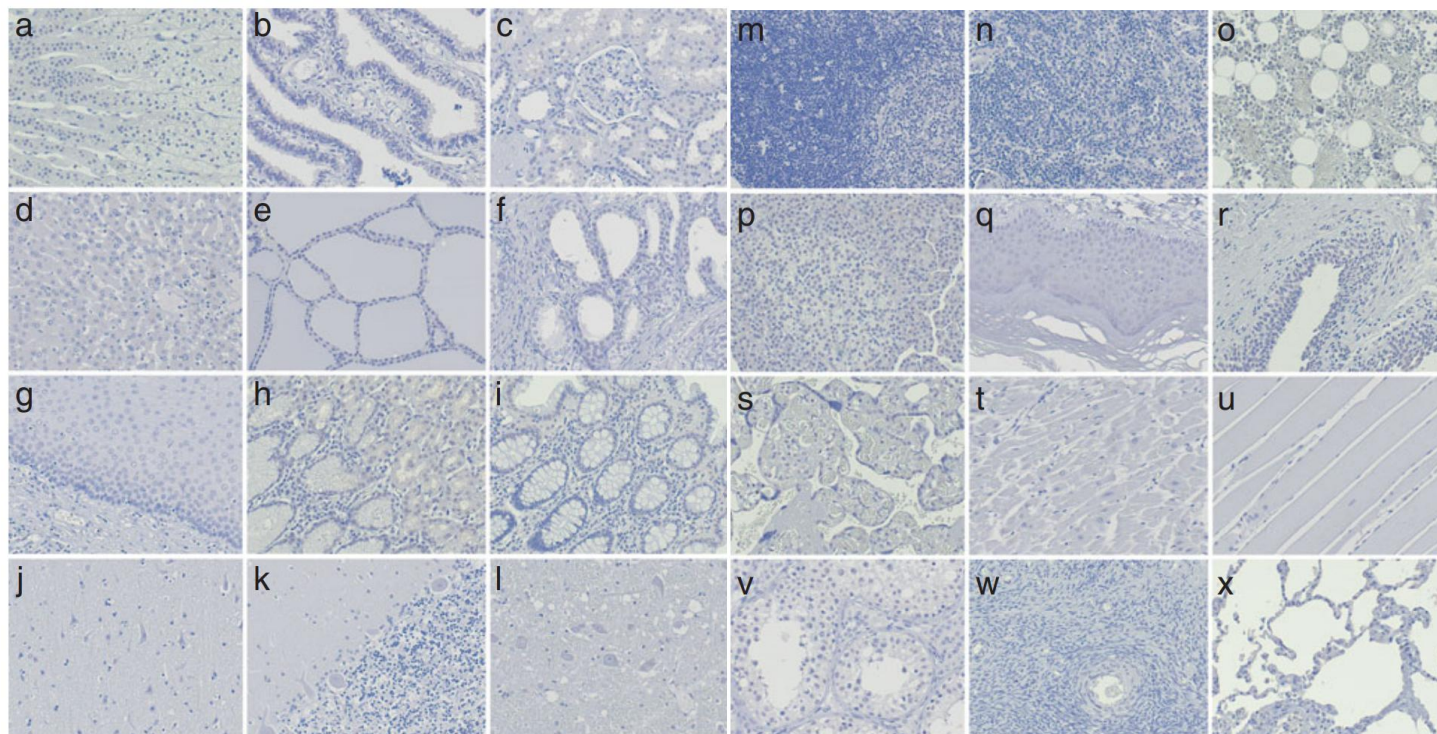
CLDN6 Biology

- Normally present at higher levels during embryonic development
- Turned off or have low levels of expression in adult tissues
- Increased expression of these antigens can occur in some tumor cells, and are referred to as “tumor-associated antigens” or TAA



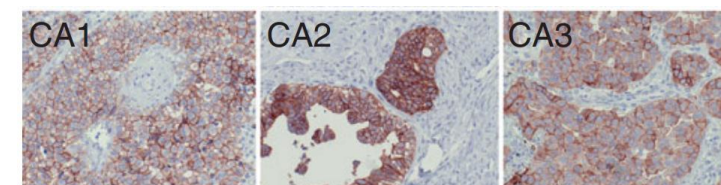
CLDN6 is Selectively Expressed on Cancer Cells

Normal Tissue



(a) adrenal gland, (b) fallopian tube, (c) kidney, (d) liver, (e) thyroid, (f) prostate, (g) esophagus, (h) stomach, (i) colon, (j) cerebrum, (k) cerebellum, (l) spinal cord. (m) thymus, (n) spleen, (o) bone marrow, (p) pancreas, (q) skin, (r) bladder, (s) placenta, (t) heart muscle, (u) striated muscle, (v) testis, (w) ovary, (x) lung

Cancer Tissue

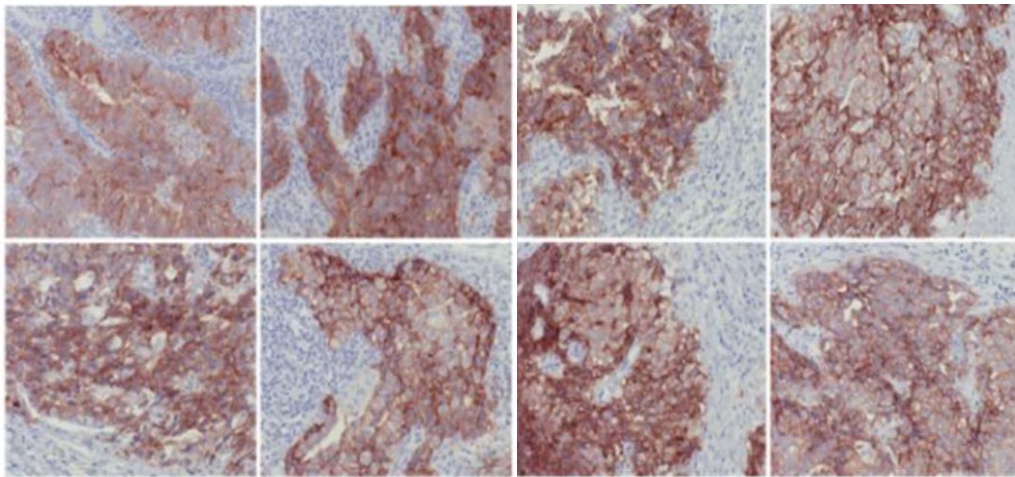


(CA1) testicular cancer, (CA2) ovarian cancer, and (CA3) lung cancer

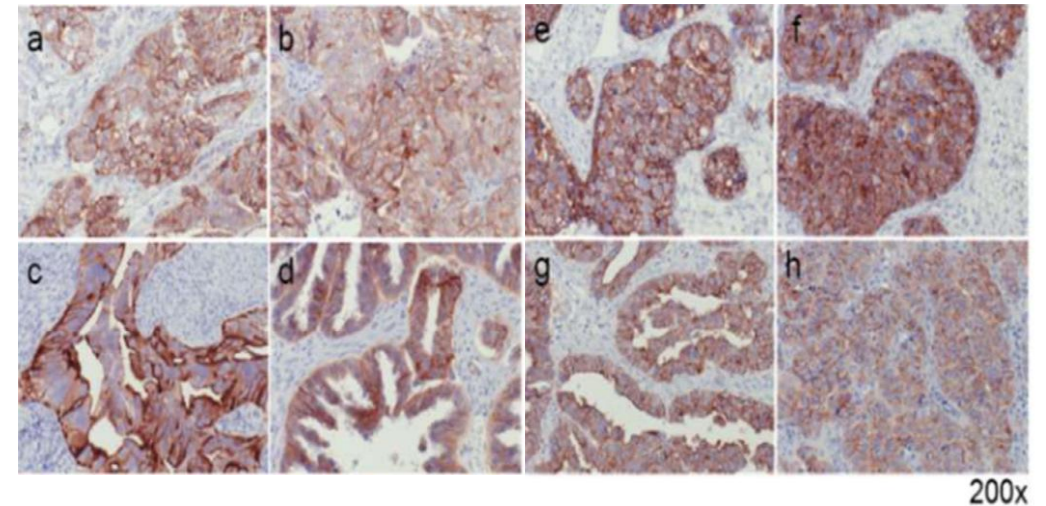
CLDN6 Exhibits High, Homogeneous Expression on Cancer Cells

Consistent expression makes CLDN6 a promising tumor associated antigen (TAA) for immunotherapy

Testicular Cancer



Ovarian Cancer



- CLDN6 protein expression in testicular and ovarian tumors each from eight different patients analyzed by IHC
- Testicular: all embryonal carcinoma
- Ovarian: (a) adenocarcinoma, (b,c,e-h) serous cystadenocarcinoma, (d) papillary serous cystadenocarcinoma

CLDN6 Has the Potential to Reach a Large Patient Population

~62,500 patients per year in the US only in Relapse/Refractory Setting

Initial indications of interest based on:

- CLDN6 prevalence
- Patient population size
- Observed clinical responses
- Eligibility for Orphan or Rare Pediatric Designation

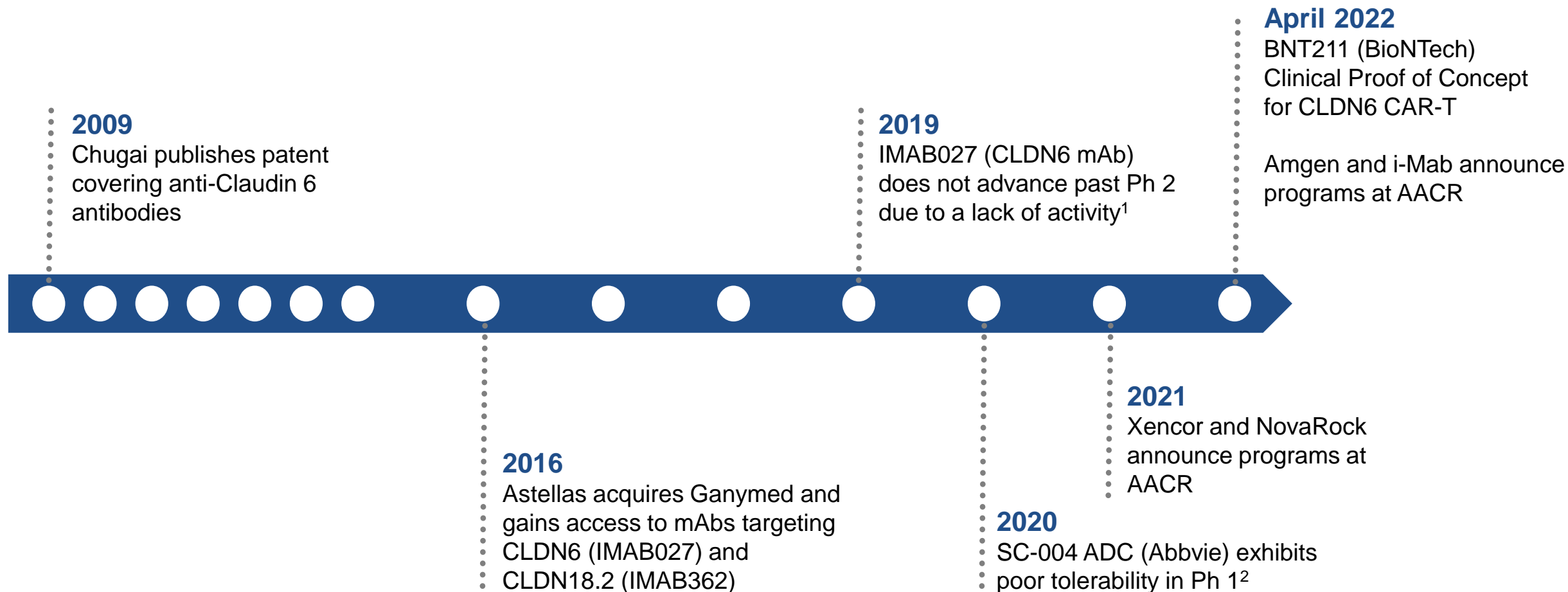
Selected Cancer indications	Incidence	R/R Incidence	CLDN6 Positive	Patient Population Based on R/R Incidence
Testicular	9,910	400	95% ¹	380
Ovarian	19,900	12,800	54-55% ^{1,2}	6,982
NSCLC	201,229	110,653	6-50% ^{3,4,5}	35,221
Malignant Rhabdoid	50	500	29-44% ^{1,2,6,7}	183
Gastric	26,380	11,090	13-55% ^{8,9}	3,771
Breast	290,600	43,800	2-41% ^{1,10,11}	9,417
Endometrial	65,900	12,500	20-31% ^{1,12,13}	3,188
Glioma	19,000	10,000	21% ⁸	2,100
Bladder	81,180	17,100	2-8% ^{1,13}	855
SCLC	35,511	19,527	2% ¹	391

1 Reinhard, Science, 2020; 2 Wang, Diagn Pathol., 2013; 3 Gao, Oncol Lett., 2013; 4 Kohmoto, Gastric Cancer, 2020; 5 Lin, Diagn Pathol., 2013; 6 Micke, Intl J Cancer, 2014; 7 Soini, Pol J Path, 2022; 8 Antonelli, Brain Pathol., 2011; 9 Sullivan, Am J Surg Pathol., 2012; 10 Jia, Intl J Clin Exp Pathol., 2019; 11 Yafang, J Breast Cancer, 2011; 12 Kojima, Cancers, 2020; 13 Ushiku, Histopath., 2012

Incidences based on public estimates; Relapsed/refractory (R/R) or last-line patient population approximated by annual mortality; CLDN6 target prevalence is based on IHC or RNAseq from published reports. Patient population derived from midpoint of CLDN6 positive population multiplied by R/R incident population.

Key Developments in CLDN6 R&D Timeline

R&D activity has recently accelerated



CLDN6 – Drug Development Strategy Comparison

CLDN6 is a tumor-associated antigen (TAA) for tumor-targeting therapeutics such as CAR-T and T cell engaging bispecific antibodies

Drug Development Strategy	CLDN6 Dependence / Rationale	Supporting Evidence
Monoclonal Antibody (mAb)	Receptor-mediated signaling	Poor Weak signaling dependence ¹
Bispecific Antibody (bsAb)	Cell surface antigen for T-cell targeting	High <i>In vivo</i> PoC + BNT211 clinical PoC ^{2,3}
Antibody-Drug Conjugate (ADC)	Receptor internalization	Poor Weak internalization ⁴
CAR-T	Cell surface antigen for T-cell targeting	High BNT211 clinical PoC ³



CLDN6 is Not Ideally Suited for Conventional mAb or ADC Therapy

CLDN6 has weak signaling activity and poor internalization

CLDN6 mAb Exhibits Weak Monotherapy Activity¹

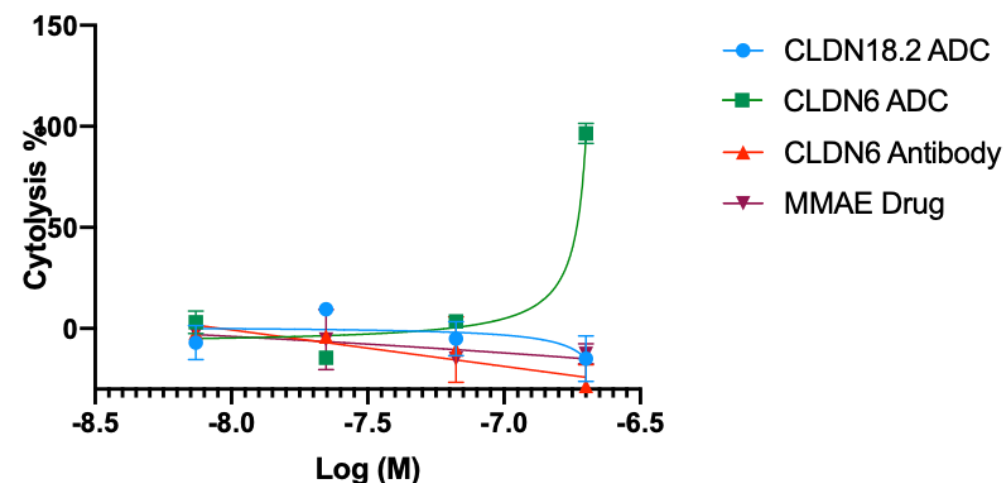
IMAB027 Phase 1 Dose Escalation Trial

IMAB027 Treatment	Stage 1/2 1-1000 mg/m ²	Stage 2 100 mg/m ²	Stage 2 300 mg/m ²	Stage 2 600 mg/m ²	Stage 2 1000 mg/m ²
Patients (n)	2	10	10	10	9
CR (n)	0	0	0	0	0
PR (n)	0	0	1	0	0
SD (n)	0	1	3	3	7

- 41 patients with recurrent ovarian cancer were treated with IMAB027 in a Phase 1 dose escalation trial
- 1 PR and 14 SD noted
- IMAB027 was well tolerated

CLDN6 Does Not Rapidly Internalize²

OVCAR3 Cell Killing Assay

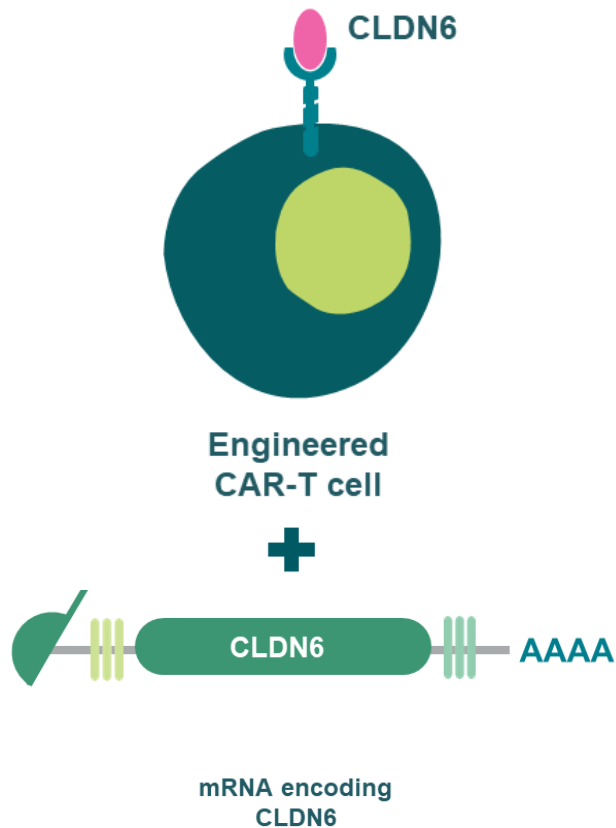


- CLDN6 and CLDN18.2 antibodies from Integral Molecular were converted to ADC utilizing MMAE payload
- ADC constructs evaluated in OVCAR3 cell killing assay
- CLDN6 ADC cell killing achieved only at supratherapeutic doses

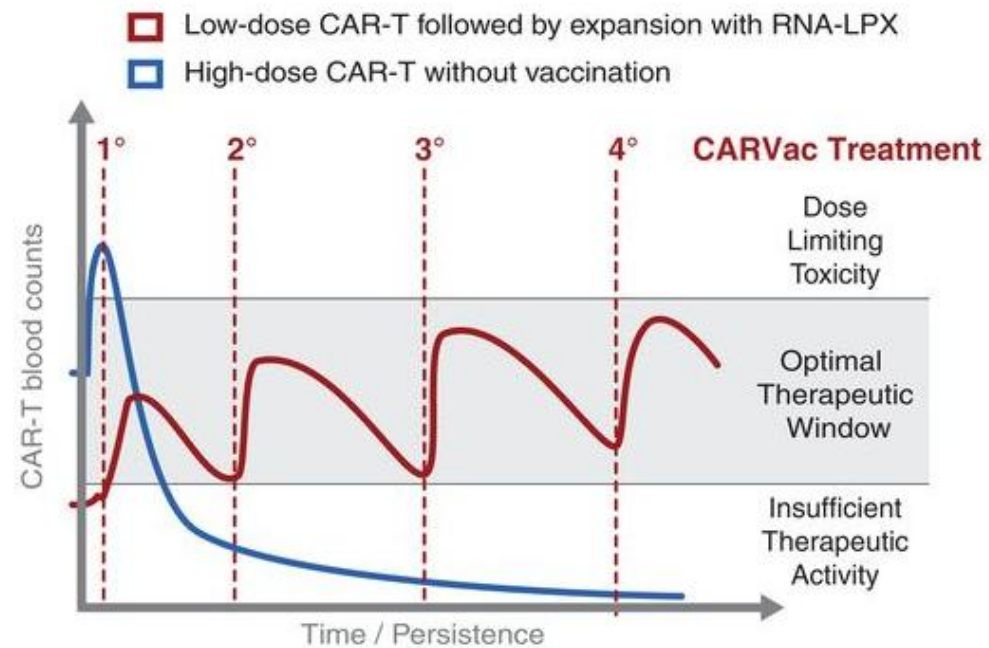
CLDN6 is an Ideal Tumor Associated Antigen for T-cell Targeting

BNT211 (BioNTech) demonstrates preliminary clinical proof of concept

BNT211 CAR-T + CLDN6 CARVac



CARVac mRNA Vaccine Strategy

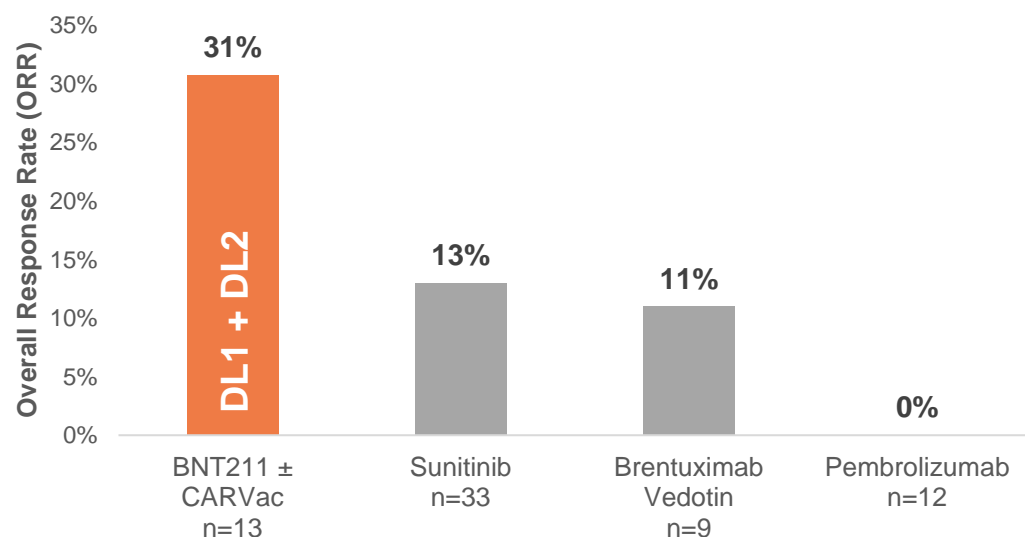


- CARVac intended to drive in vivo expansion, persistence, and efficacy of CAR-T
- Strategy intended to minimize number of CAR-T cells infused and offset cytokine storm risk

BNT211 ± CARVac Exhibited Activity Across CLDN6+ Advanced Cancers

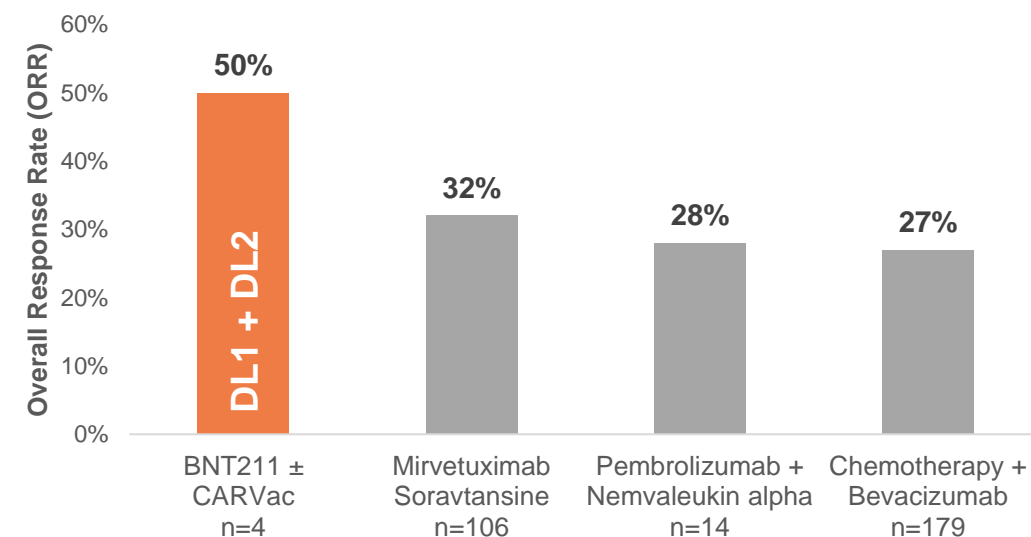
Initial clinical efficacy benchmarked to standard of care or emerging treatments

Testicular Cancer



- **DL1 + DL2:** 13 testicular cancer patients received BNT211 ± CARVac across DL1 (1×10^7 cells) and DL2 (1×10^8 cells) for a **response rate of 31%**
- **DL2 only:** Seven (7) testicular cancer patients received the second BNT211 dose level (DL2) after lymphodepletion with four (4) patients responding, including one complete response (CR), for a **response rate of 57%**

Ovarian Cancer



- **DL1 + DL2:** 4 ovarian cancer patients received BNT211 ± CARVac for a **response rate of 50%**
- **DL2 only:** Two (2) ovarian cancer patients received the second BNT211 dose level (DL2) after lymphodepletion with both patients responding for a **response rate of 100%**

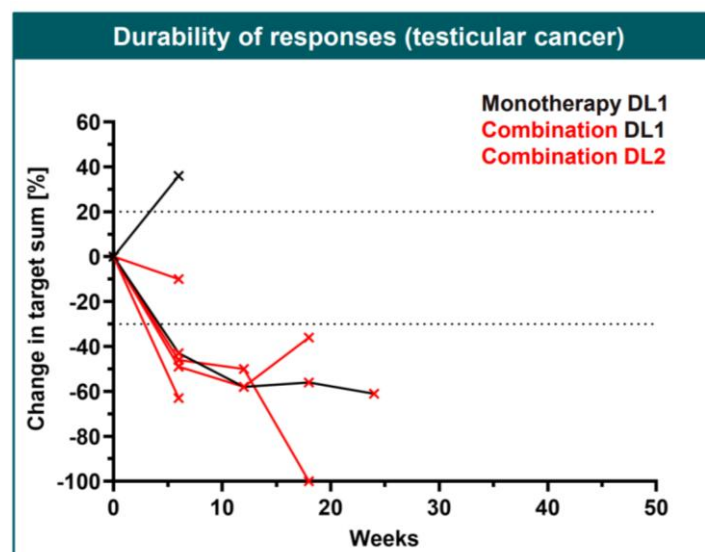
Limitations of CLDN6 CAR-T + CARVac Approach

Limited Dose Sparing^{1,2}

Target	Asset	Ph 1 Dose Range	RP2D
CLDN6	BNT211	1×10^7 to 1×10^9 cells	TBD
CLDN18.2	CT041	2.5×10^8 to 5×10^8 cells	2.5×10^8 cells

- BNT211 + CARVac T-cell infusion is consistent with similar CAR-T products
- Without CAR-T dose sparing, patients may be exposed to high dose CAR-T side effects, including neurologic and hepatic

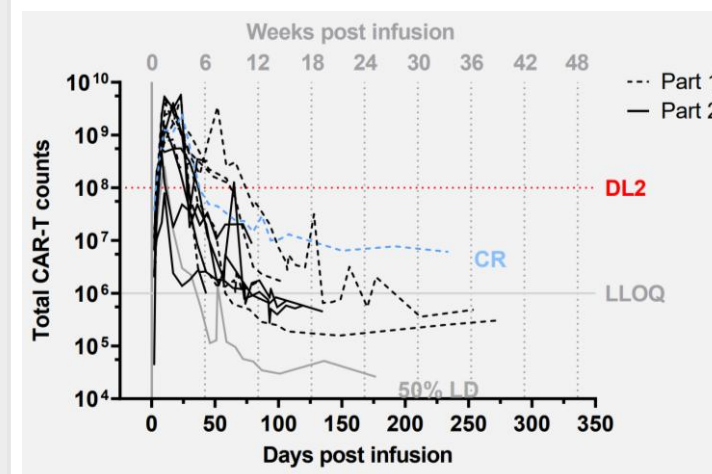
Limited Durability¹



- CAR-T activity in solid tumors is often limited by a weak durability of response
- BNT211 + CARVac exhibits a limited durability of response in advanced solid tumors

Limited T Cell Persistence¹

DL2 (1×10^8 CLDN6 CAR-T)



- CARVac is intended to enhance T-cell persistence
- Preliminary findings indicate that CARVac provides limited enhancement of T-cell persistence

CTIM-76 Differentiation¹

BNT211 + CARVac

CTIM-76

Administration

Complex + In-Patient

Hospital administered autologous cell therapy in combination with repeat mRNA vaccination utilizing lipid nanoparticle carrier

Easy + Out-Patient

Outpatient infusion every 2-4 weeks based on IgG backbone

Lymphodepletion

Required

None

Treatment Durability

Weak T cell persistence

Fully stimulated T cell

Selectivity and Safety

Elevated transaminase and lipase

Selective for CLDN6



Discovery of CTIM-76

Joseph Rucker, PhD – Research Lead

Bispecific Antibody Considerations

Candidates evaluated based on a range of scaffolds, CLDN6, and T-cell engagers

CLDN6 Targeting Arm

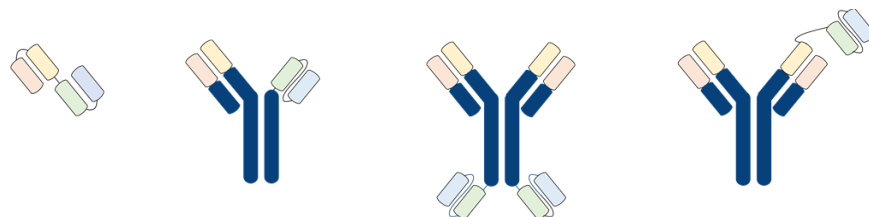
- High affinity anti-CLDN6 binding
- High specificity for CLDN6 vs other CLDN
 - Especially CLDN3, CLDN4, CLDN9

CD3 Targeting Arm

- Clinically validated
- Freedom to operate
- Explore a range of potencies

Bispecific Scaffolds

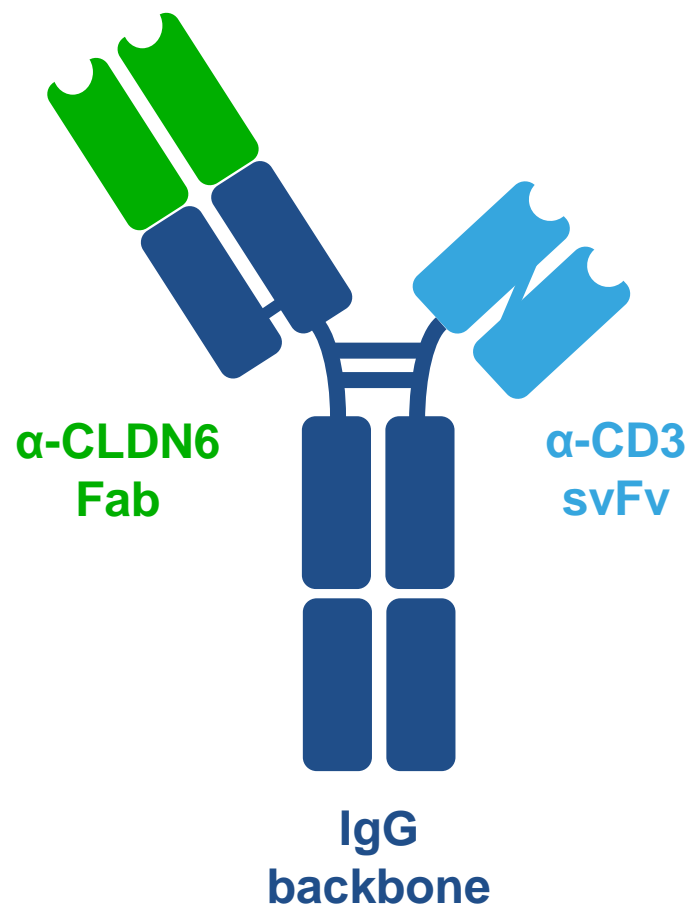
- Multiple formats evaluated



Other Factors

- Cross reactivity to NHP desirable for both arms
- FcRn binding for half-life extension
- Silencing variants to eliminate FcR binding

CTIM-76 Nominated as Development Candidate



Wide therapeutic window

- Highly selective CLDN6 binding Fab arm
- CD3 binding single-chain Fv domain is designed to be functionally monovalent to avoid aberrant T-cell activation, potentially enhancing safety profile
- Silenced Fc domain to avoid T-cell activation by Fc-gamma receptor positive cells

Convenient dosing with low immunogenicity risk

- T-cell dependent cellular cytotoxicity with no or minimal activation of circulating cytokines
- Humanized CLDN6 and CD3 binding domains

Ease of manufacturing

- IgG backbone is highly stable and enables high yield

Identification of CLDN6-targeting Arm

The Problem

- The extracellular binding region of **CLDN6 is highly conserved** with CLDN3 (78% homology), CLDN4 (81%), and CLDN9 (96%)
- Antigen is **conformationally dependent**, which limits conventional antibody discovery methods
- Human CLDNs share approximately 95% extracellular sequence homology with their mouse counterparts, necessitating the use of **divergent species for immunization**

Our Solution

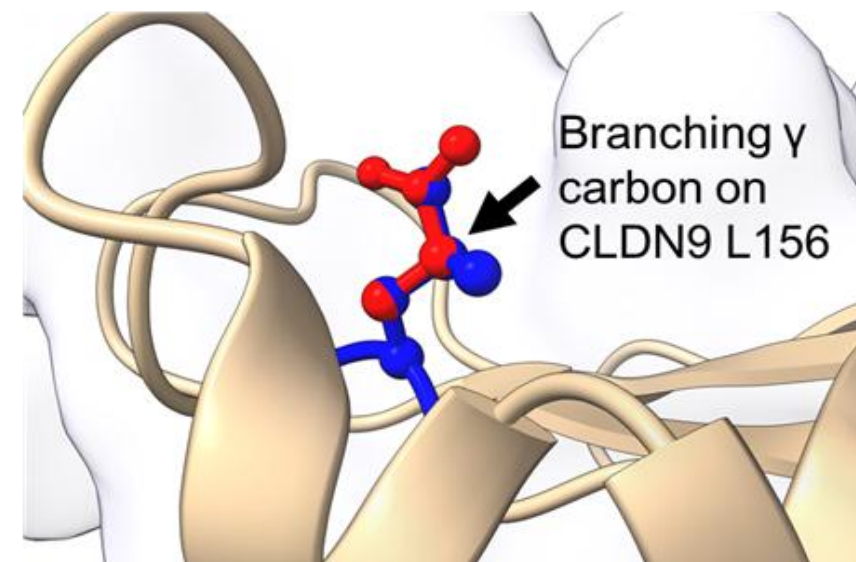
- Using discovery strategies tailored to complex membrane proteins at our partner, Integral Molecular, we isolated and characterized rare antibodies with **picomolar affinity and specificity for CLDN6**
- Epitope mapping at single-atom resolution identified **steric hindrance** near the γ -carbon of residue 156 as critical for discriminating CLDN6 versus CLDN9 binding¹

CLDN6 Monospecificity Challenge¹

Residue 156 CLDN6 vs CLDN9

■ CLDN9 L156

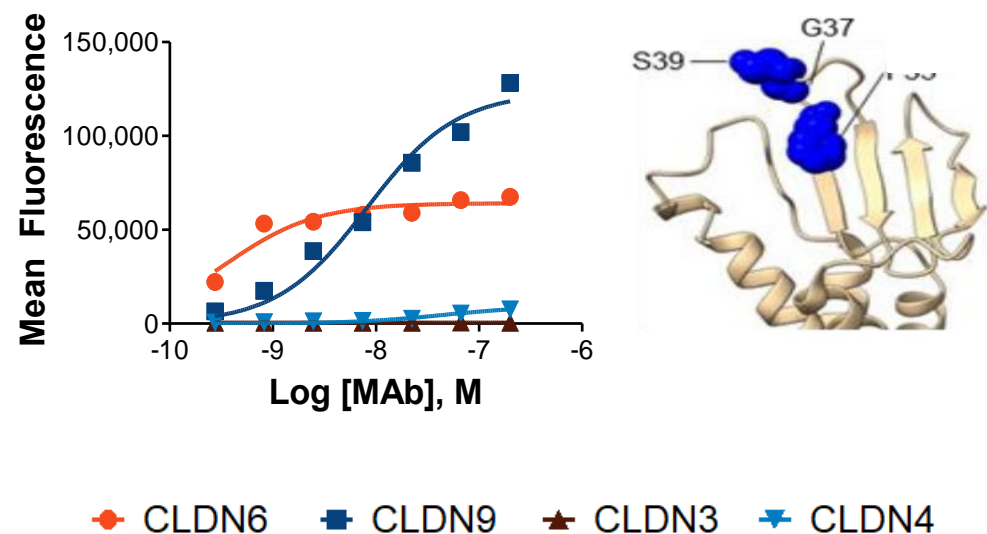
■ CLDN6 Q156



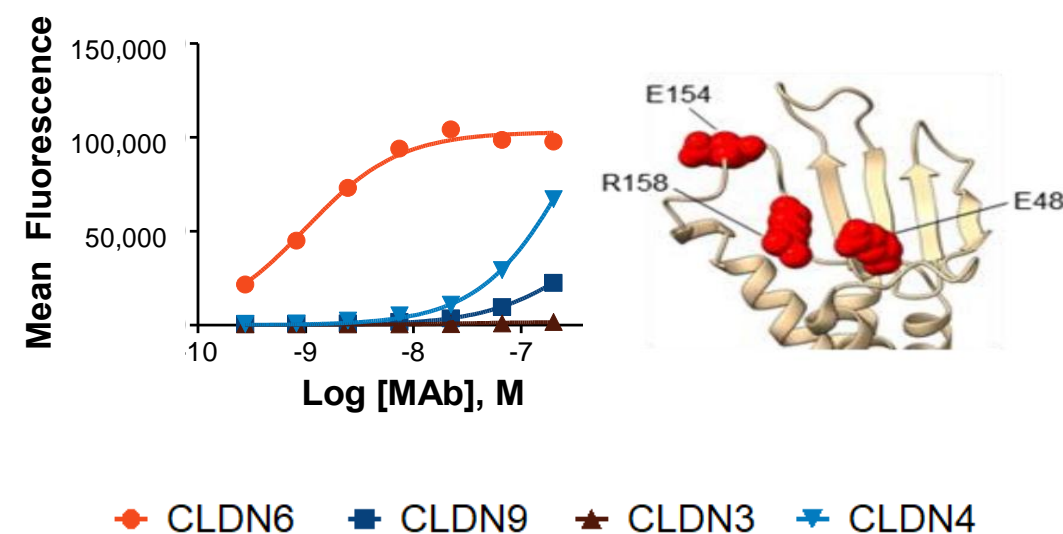
Identification of Selective CLDN6 MAbs

- IM301 (CLDN6 arm of CTIM-76) exhibits high CLDN6 selectivity¹
- Epitope mapping of IM301 identifies unique binding location relative to benchmark IMAB027/ASP150 (Ganymed/Astellas)

IMAB027/ASP1650

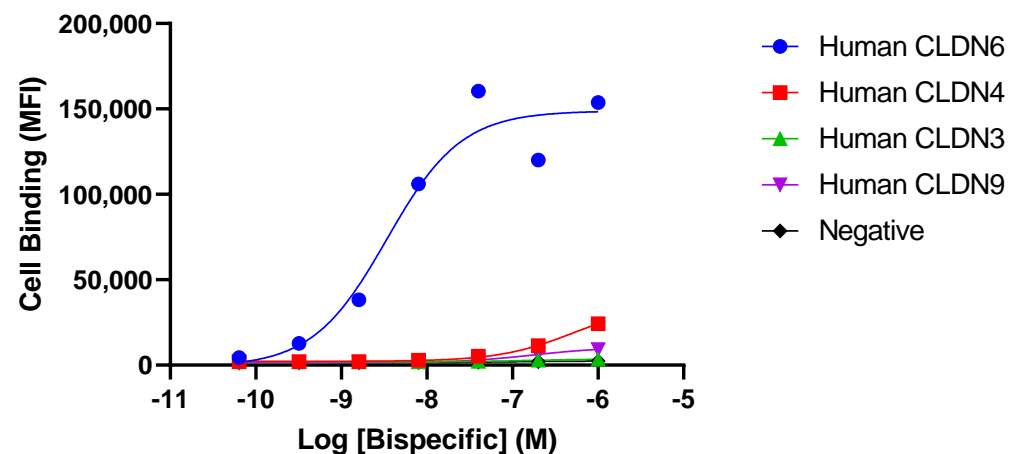


IM301



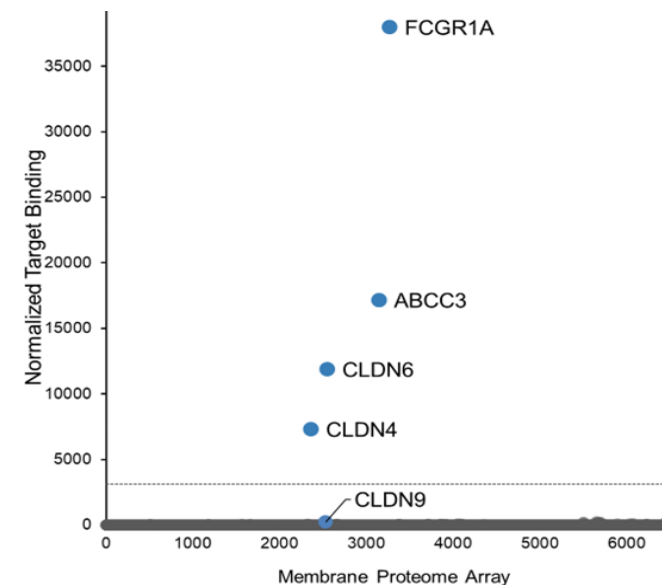
CTIM-76 Exhibits Excellent Selectivity and Specificity

CLDN6 Selectivity



- CTIM-76 **CLDN6 EC50 of 3.41 nM**
- CTIM-76 **preferentially binds** to CLDN6 over CLDN3/4/9
- CLDN3/4/6/9 were transiently transfected in HEK-293F cells (4:1 Target:GFP)

CLDN6 Specificity

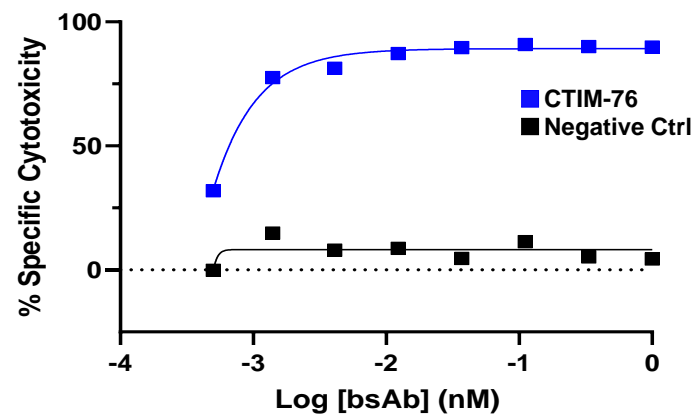


- IM301 Mab screened for specificity using Integral Molecular Membrane Proteome Array, consisting of **~6,000 human membrane proteins** in their native state in unfixed cells
- IM301 Mab was cross-reactive for internal control FCGR1A (Fc gamma) and intracellular epitope of ABCC3

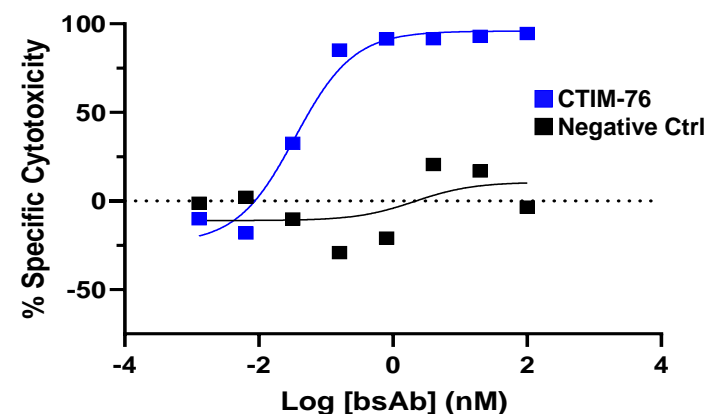
Specific Lysis

T-cell mediated cell killing is dependent on CLDN6 expression

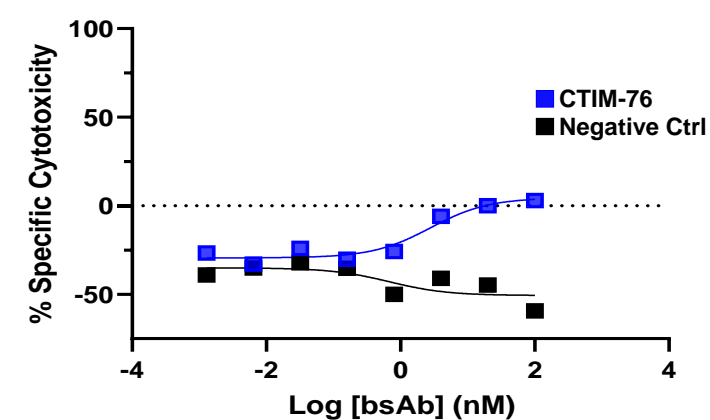
K562-CLDN6 Cell Line



OV90 Cell Line



HEK Cell Line



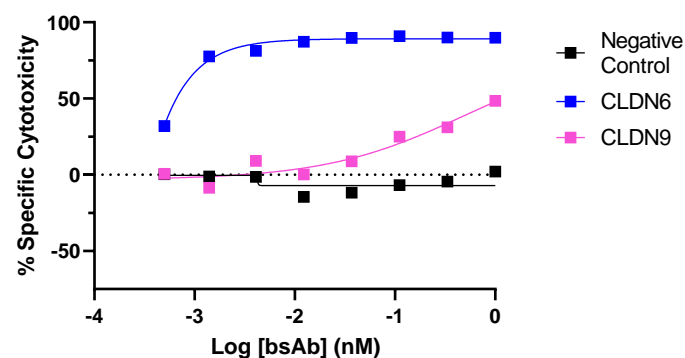
	K562-CLDN6	OV90	HEK
CLDN6 Expression	High	Medium	Low
CTIM-76 (EC50)	0.0004 nM	0.049 nM	2.79 nM

CTIM-76 Preferentially Targets CLDN6 Over Other Claudin Family Proteins

- There is high sequence homology between CLDN6 and CLDN9 in the extracellular loops
- CTIM-76 preferentially targets CLDN6, with minimal activity against CLDN9-expressing cells
- No binding is observed to other CLDN family proteins that have <85% homology in the extracellular loops

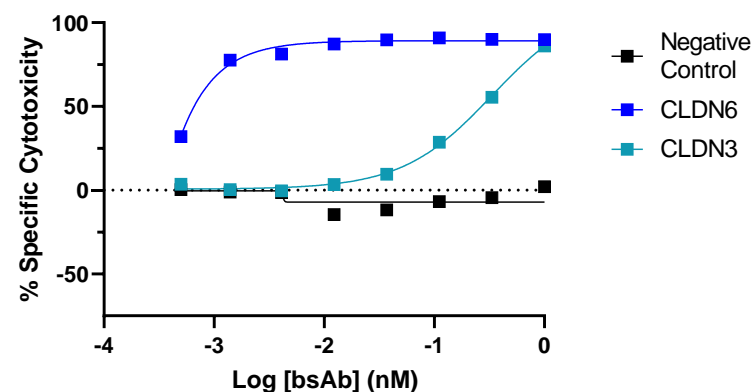
CLDN6:CLDN9

Activity Gap
~1192x



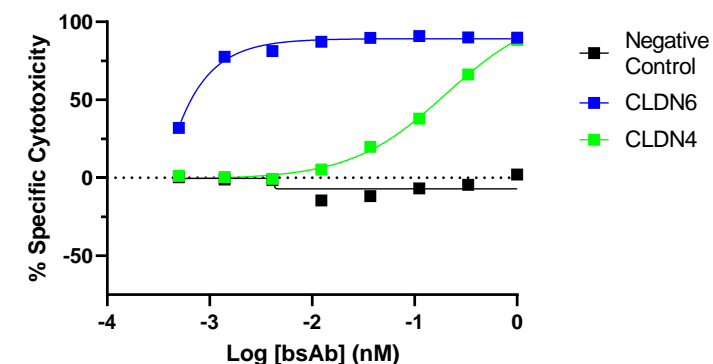
CLDN6:CLDN3

Activity Gap
~836x



CLDN6:CLDN4

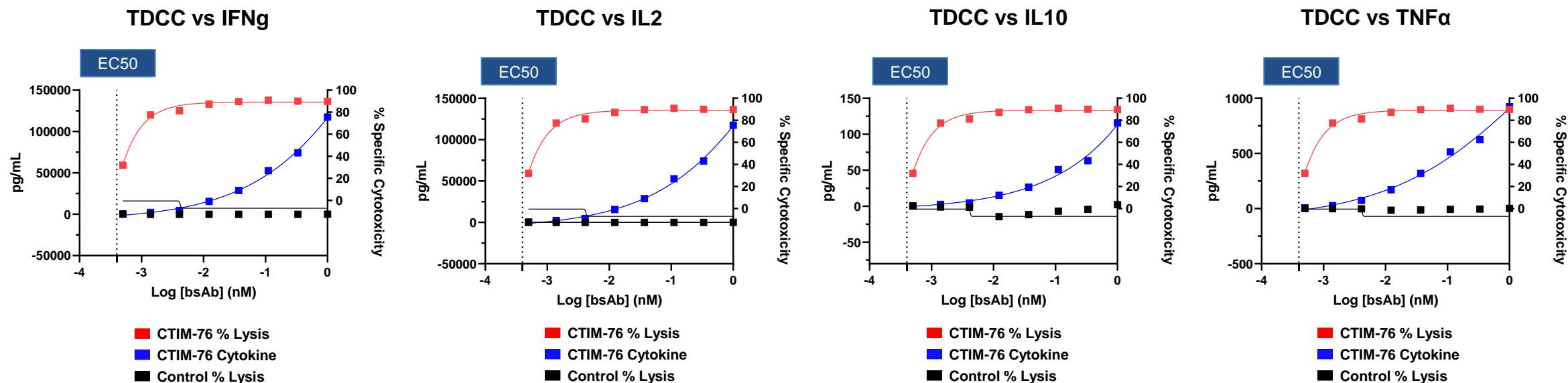
Activity Gap
~504x



CTIM-76 has the Potential for a Wide Therapeutic Window

- Cytokine production evaluated in exogenous (CLDN6-K562) cell line model
- Cytokine production happens well above the concentration of maximal killing ($EC_{50} = 0.0004$ nM) in CLDN6-K562 cells at 48 hours
- Data supports potential to dose at levels that promote cancer cell killing but have manageable levels of free cytokine production

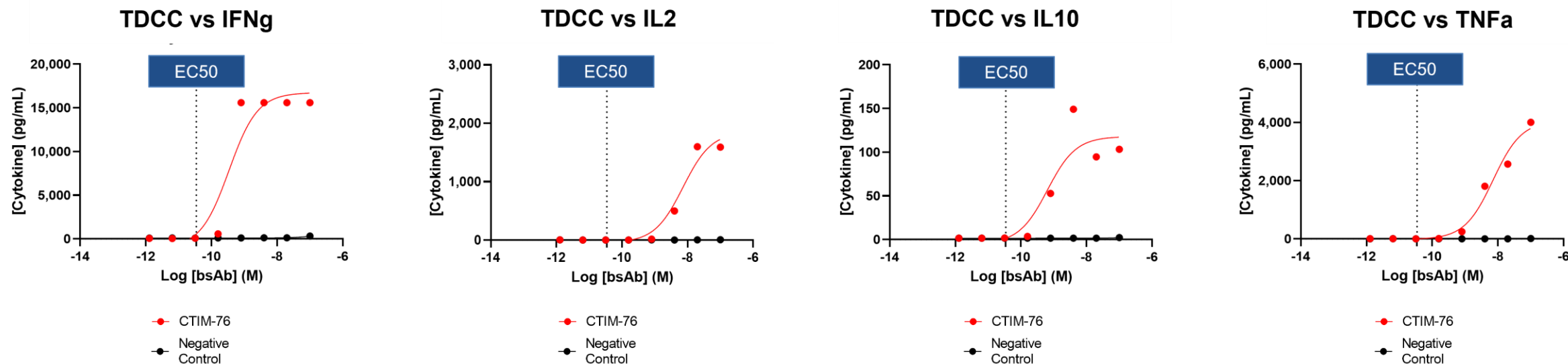
Comparison of T cell-dependent cellular cytotoxicity (TDCC) to cytokine production in CLDN6-K562 cell line



CTIM-76 Exhibits Ideal Immunomodulatory Properties

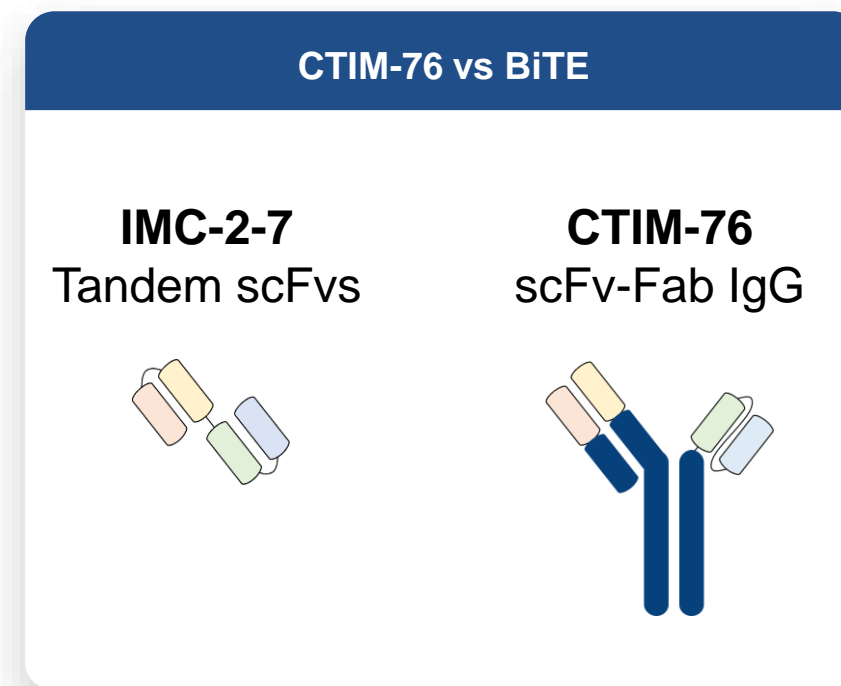
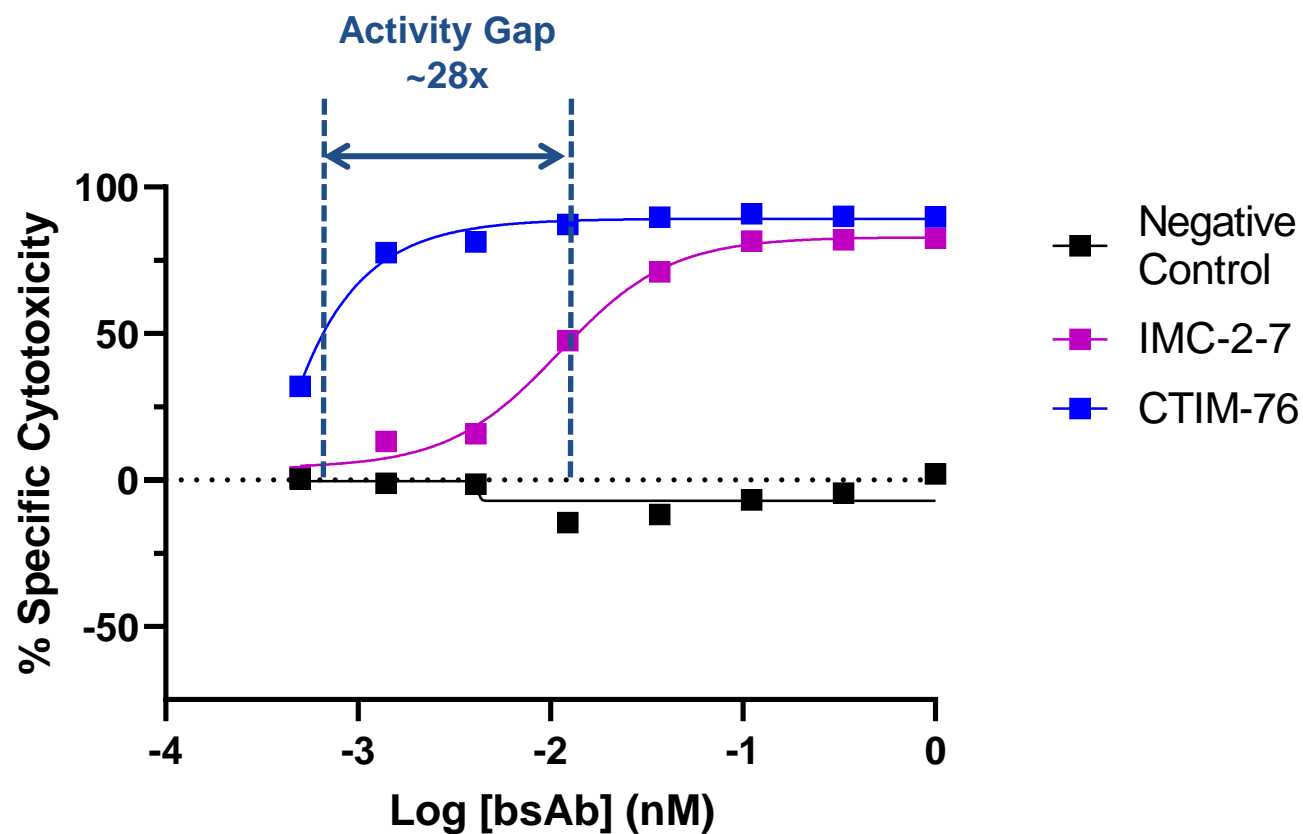
- Exogenous (CLDN6-K562) results replicated in endogenous (OV90) cell line model
- Cytokine production happens well above the concentration of maximal killing ($EC_{50} = 0.049$ nM) in OV90 cells at 48 hours

Comparison of T cell-dependent cellular cytotoxicity (TDCC) to cytokine production in OV90 cell line



Role of Bispecific Format in Activity

CTIM-76 format demonstrates superior potency compared to a traditional BiTE molecule

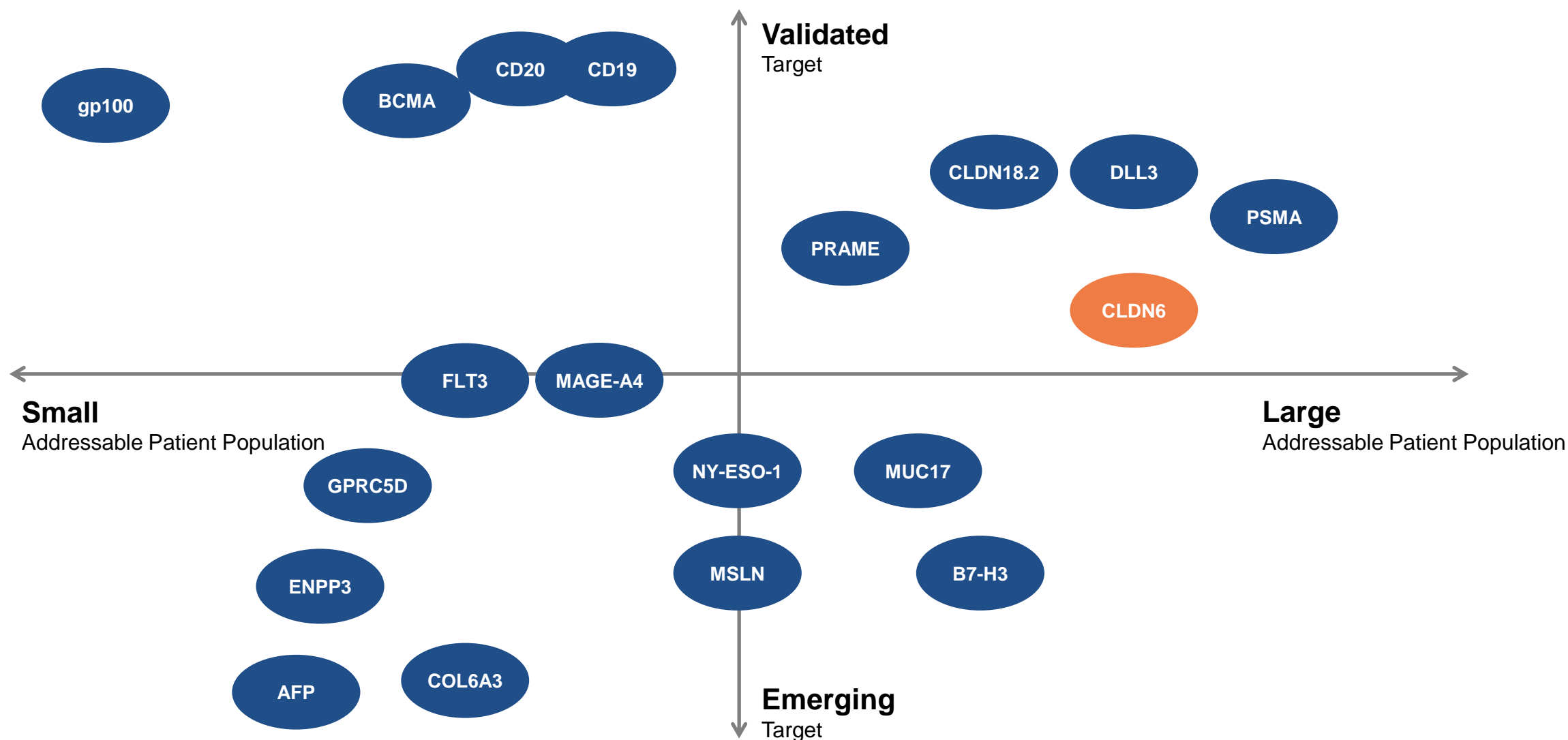




Concluding Remarks

Martin Lehr – Chief Executive Officer

CLDN6 is an Exciting Cancer Target Within the T-cell Directed Therapy Landscape¹



Competitive Landscape¹

	Candidate	IND	Phase 1
ADC	<div>  GB-7008-01 CLDN6/CLDN9 + MMAE </div> <div>  UCLA-23-ADC CLDN6 + MMAE </div>		<div>  DS-9606a CLDN6 + DXd </div>
Bispecific Antibody	<div>  NBL028 Fc Engineered CLDN6x4IBB </div> <div>  Undisclosed 2+1 bsAb CLDN6xCD3 </div> <div>  CTIM-76 bsAb CLDN6xCD3 </div> <div>  TJ-46CB 2+2 bsAb CLDN6x4IBB </div>		<div>  AMG794 BiTE CLDN6xCD3 </div> <div>  BNT142 mRNA encoded BsAb CLDN6xCD3 </div>
Cell Therapy			<div>  CAR-NK CAR-NK + IL7 secreting vector </div> <div>  BNT211 CAR-T + CARVac </div>

Clinical Experience for CLDN6 Therapies is Nascent

	Company	Program	Description / Details ³
Active Programs	BioNTech	BNT211: CLDN6CAR-T + CARVac (Phase 1)	Initial data for BNT211 was presented April 2022 (AACR), with an update in Sept 2022 (ESMO). Received PRIME Designation for testicular cancer June 2022
		BNT142: CLDN6 mRNA encoded bsAb (Phase 1)	Initiated Phase 1 development for BNT142 in mid-2022
	Amgen	AMG794: CLDN6 BiTE (Phase 1)	AMG794 candidate was presented April 2022 (AACR), trial is not yet recruiting
	Guangzhou Medical University	Undisclosed: CAR-NK + multiple gene edits (Phase 1)	Engineered to express IL7/CCL19 and/or SCFVs against PD1/CTLA4/Lag3, initiated Phase 1 development in mid-2022
	Daiichi	DS-9606a: CLDN6 + DXd (Phase 1)	Initiated Phase 1 development for DS-9606a in mid-2022
	I-Mab	TJ-46CB: CLDN6 bsAb CLDN6x4IBB (Preclinical)	Initial data was presented April 2021 (AACR), IND filing is expected in 2H 2023
	Xencor	Undisclosed: CLDN6 bsAb CLDN6xCD3 (Preclinical)	Initial data was presented April 2021 (AACR), no timeline to IND provided
Notable Deprioritized Programs	Astellas/Ganymed	IMAB027/ASP1650: CLDN6 mAb (Phase 2)	Lack of single agent activity in Phase 2 trial relapse/refractory testicular germ cell tumors ¹
	Abbvie/Stemcentryx	SC004: CLDN6/9 ADC (Phase 1)	Dose-limiting toxicity observed in Phase 1 in patients with ovarian cancer ²

Select Early-stage Bispecific Antibody Transactions in 2022¹

Licensee	Licensor	Target	Asset	Stage	Geography	Upfront (\$M)	Milestones (\$M)
TeneoTwo	AstraZeneca	CD19	TNB-486	Phase 1	WW	\$100	\$1,165
Macrogenics	Gilead	CD123	MGD024	IND	WW	\$60	\$1,700
LAVA	Seagen	EGFR	LAVA-1223	Preclinical	WW	\$50	\$650
Kelun	Merck	Claudin 18.2	SKB315	Preclinical	WW (ex-China)	\$35	\$910
CSPC	Elevation	Claudin 18.2	STSA1801	Preclinical	WW (ex-China)	\$27	\$148
LaNova	Turning Point / BMS	Claudin 18.2	LM-302	IND	WW (ex-China, Korea)	\$25	\$575
Harbour	AstraZeneca	Claudin 18.2	HBM7022	Preclinical	WW	\$25	\$350

Next Steps and Summary



Encouraging efficacy signals

- CLDN6-selective activity across binding and cytotoxicity



Well tolerated

- Preferential cytotoxicity over activation of free circulating cytokines
- PK consistent with IgG backbone
- No significant safety findings to date



On track for IND submission in Q1 2024

- Lonza selected as GMP manufacturing partner

Q&A Session



MARTIN LEHR
Chief Executive Officer



ERIC BUTZ, PhD
Scientific Lead



JOSEPH RUCKER, PhD
Research Lead



JENNIFER MINAI
Chief Financial Officer



ADVANCING MEDICINES FOR FEMALE CANCERS

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