UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 31, 2023

Context Therapeutics Inc.
(Exact name of registrant as specified in its charter)

Delaware	001-40654	86-3738787
(State of other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

2001 Market Street, Suite 3915, Unit#15
Philadelphia, Pennsylvania 19103
(Address of principal executive offices including zip code)

(267) 225-7416
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Title of each class	Trading Symbol	Name of exchange on which registered
Common Stock $0.001 par value per share	**CNTX**	**The Nasdaq Stock Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

On October 31, 2023, Context Therapeutics Inc. (the "Company") issued a press release to announce preclinical data regarding the Company's preclinical asset, CTIM-76. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

On October 31, 2023, the Company also updated its corporate presentation for use in meetings with investors, analysts and others. A copy of the corporate presentation is filed as Exhibit 99.2 to this Current Report on Form 8-K and incorporated herein by reference.

The information in this Item 7.01, and Exhibits 99.1 and 99.2 attached hereto, are being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, regardless of any general incorporation language in such filing.

Item 8.01. Other Events

On October 31, 2023, the Company announced its anticipated filing of an Investigational New Drug Application for CTIM-76 late in the first quarter of 2024.

Item 9.01. Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Press Release issued by Context Therapeutics Inc., dated October 31, 2023
99.2	Context Therapeutics Inc. Corporate Presentation - November 2023
104	Cover Page Interactive Data File (embedded within the inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: October 31, 2023

Context Therapeutics Inc.

By: /s/ Martin A. Lehr
Name: Martin A. Lehr
Title: Chief Executive Officer

Context Therapeutics Announces Preclinical Data Demonstrating Differentiated and Active Profile of its Claudin 6-Targeted Bispecific Antibody CTIM-76

CTIM-76 exhibits dose-proportional tumor responses and safety in preclinical models

Benchmarking studies comparing CTIM-76 with clinical-stage CLDN6 therapies support CTIM-76's differentiated product profile

CTIM-76 IND filing on track for late Q1 2024

Data to be presented at SITC 38th Annual Meeting on November 3rd

PHILADELPHIA, PA— October 31, 2023—Context Therapeutics Inc. ("Context" or the "Company") (Nasdaq: CNTX), a biopharmaceutical company advancing medicines for solid tumors, today announced encouraging preclinical data regarding the Company's preclinical asset, CTIM-76, a Claudin 6 (CLDN6) x CD3 T-cell engaging bispecific antibody.

Findings from Context's research team, in conjunction with development partner Integral Molecular, illustrate the potential of CTIM-76 to treat CLDN6-positive tumors. Notably:

- CTIM-76 was shown to have high potency and target selectivity in both binding and cytotoxicity assays.
- In *in vivo* xenograft experiments, CTIM-76 induced dose-proportional tumor regressions and was well tolerated.
- In IND-enabling toxicology studies, CTIM-76 was well tolerated, and a potential first-in-human dose was identified.
- Clones of clinical-stage molecules TORL-1-23 and AMG-794 were generated for benchmarking purposes. In comparison studies, TORL-1-23 activity appeared dependent upon high CLDN6 expression whereas CTIM-76 activity was retained across a range of cell lines expressing with low through high CLDN6. Additionally, CTIM-76 demonstrated ten-fold higher potency than AMG-794 in *in vitro* cytotoxicity and cytokine activation.

"It is estimated that there are 70,000 patients with CLDN6-positive metastatic solid tumors in the United States, and no approved targeted treatment options exist," said Martin Lehr, CEO of Context. "We're encouraged by the promise CTIM-76 has shown with these first *in vivo* data, which reinforce the selectivity and potency seen in earlier *in vitro* data and demonstrate CTIM-76's ability to induce complete tumor regressions across multiple dose levels. Moreover, our comparison to clones of clinical-stage molecules demonstrates CTIM-76's ability to address potential target density and toxicity challenges associated with first-generation approaches, as well as highlights CTIM-76's pharmacologically distinct profile and broad therapeutic potential."

The data will be presented during a poster session (Abstract #1183) at the Society for Immunotherapy of Cancer's (SITC) 38th Annual Meeting on Friday, November 3, 2023, in San Diego. To view the abstract, visit the SITC meeting website for details.

"The preclinical data at this year's SITC meeting will illustrate the potential of CTIM-76 to target CLDN6," said Lehr. "We believe these findings collectively support CTIM-76 as a promising

CLDN6-targeting candidate, and we look forward to filing an Investigational New Drug Application late in the first quarter of 2024."

About Context Therapeutics®
Context Therapeutics Inc. (Nasdaq: CNTX) is a biopharmaceutical company advancing medicines for solid tumors. Context is developing CTIM-76, a selective CLDN6 x CD3 bispecific antibody for CLDN6-positive tumors, currently in preclinical development. CLDN6 is a tight junction membrane protein target expressed in multiple solid tumors, including ovarian, lung, and testicular, and absent from or expressed at low levels in healthy adult tissues. Context is headquartered in Philadelphia. For more information, please visit www.contexttherapeutics.com or follow the Company on Twitter and LinkedIn.

About Integral Molecular
Integral Molecular (integralmolecular.com) is the industry leader in developing and applying innovative technologies that advance the discovery of therapeutics against difficult protein targets. With 20 years of experience focused on membrane proteins and antibodies, Integral Molecular's technologies have been integrated into the drug discovery pipelines of over 500 biotech and pharmaceutical companies to help discover new therapies for cancer, diabetes, autoimmune disorders, and viral threats such as SARS-CoV-2, Ebola, Zika, and dengue viruses. Follow Integral Molecular on LinkedIn.

Forward-looking Statements
This press release contains "forward-looking statements" that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. Any statements, other than statements of historical fact, included in this press release regarding strategy, future operations, prospects, plans and objectives of management, including words such as "may," "will," "expect," "anticipate," "plan," "intend," and similar expressions (as well as other words or expressions referencing future events, conditions, or circumstances) are forward-looking statements. These include, without limitation, statements regarding (i) the ability of the Company, its employees and certain SITC presenters to participate in and present at conferences, (ii) the potential benefits, characteristics, and side effect profile of our product candidate, (iii) the likelihood data will support future development, (iv) the ability of our product candidate to have benefits, characteristics, and a side effect profile that is differentiated and/or better than third party product candidates, (v) the likelihood of obtaining regulatory approval of our product candidate, and (vi) our expectation of filing an Investigational New Drug Application for CTIM-76 late in the first quarter of 2024. Forward-looking statements in this release involve substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by the forward-looking statements, and we therefore cannot assure you that our plans, intentions, expectations, or strategies will be attained or achieved. Other factors that may cause actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in our filings with the U.S. Securities and Exchange Commission, including the section titled "Risk Factors" contained therein. Except as otherwise required by law, we disclaim any intention or obligation to update or revise any forward-looking statements, which speak only as of the date they were made, whether as a result of new information, future events, or circumstances or otherwise.

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Context Therapeutics
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context
therapeutics
Advancing Medicines for Solid Tumors
Corporate Presentation
November 2023
context

Forward Looking Statement

Except for statements of historical fact, any information contained in this presentation may be a forward-looking statement that reflects the Company's current views about future events and are subject to risks, uncertainties, assumptions and changes in circumstances that may cause events or the Company's actual activities or results to differ significantly from those expressed in any forward-looking statement. In some cases, you can identify forward-looking statements by terminology such as "may", "will", "should", "plan", "predict", "expect", "estimate", "anticipate", "intend", "goal", "strategy", "believe", "could", "would", "potential", "project", "continue" and similar expressions and variations thereof.

Forward-looking statements may include statements regarding the Company's business strategy, cash flows and funding status, potential growth opportunities, clinical development activities, the timing and results of preclinical research, clinical trials and potential regulatory approval and commercialization of product candidates.

Although the Company believes that the expectations reflected in such forward-looking statements are reasonable, the Company cannot guarantee future events, results, actions, levels of activity, performance or achievements.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described under the heading "Risk Factors" in documents the Company has filed with the SEC. These forward-looking statements speak only as of the date of this presentation and the Company undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof.

Important Notice and Disclaimers

Certain information contained in this Presentation relates to or is based on studies, publications, surveys and other data obtained from third-party sources and the Company's own internal estimates and research. While the Company believes these third-party sources to be reliable as of the date of this Presentation, it has not independently verified, and makes no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. In addition, all of the market data included in this Presentation involves a number of assumptions and limitations, and there can be no guarantee as to the accuracy or reliability of such assumptions.

This presentation discusses product candidates that are under preclinical and clinical study, and which have not yet been approved for marketing by the U.S. Food and Drug Administration. No representation is made as to the safety or effectiveness of these product candidates for the use for which such product candidates are being studied. While the Company believes its internal research is reliable, such research has not been verified by any independent source. All the scientific, preclinical and clinical data presented within this presentation are – by definition prior to completion of the clinical trial and a clinical study report – preliminary in nature and subject to further quality checks including customary source data verification.

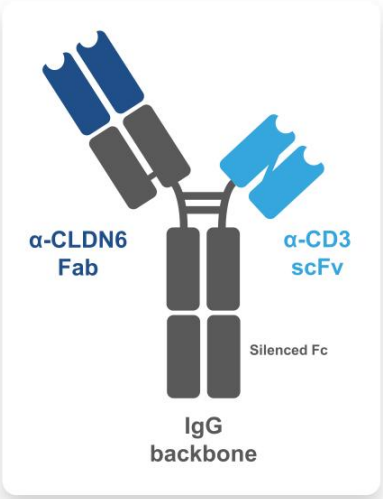
The trademarks included herein are the property of the owners thereof and are used for reference purposes only. Such use should not be construed as an endorsement of such products.

Lead Program: CTIM-76, a Claudin 6 x CD3 Bispecific Antibody

Opportunity	• Claudin 6 (CLDN6) is a **tumor-specific protein** that is present at high surface density across many adult cancers[1] • CLDN6 is expressed at **very low levels or absent** in normal adult tissue
Challenge	• CLDN6 antigen is **conformationally dependent,** which limits access to antibody-antigen binding and antibody development • The CLDN6 antigen binding region is **highly conserved** with CLDN3, CLDN4, and CLDN9, which increases the risk of off-target binding and potential side effects associated with CLDN3 (pancreas), CLDN4 (liver), and CLDN9 (liver, ear)
Target Validation	• TORL's TORL-1-23 ADC and BioNTech's BNT211 CAR-T cell therapy establishes CLDN6-targeting **Proof of Concept**[2,3]: – Efficacy: TORL-1-23 demonstrated **75% ORR** (3/4 pts) at 2.4 mg/kg; BNT211 demonstrated **75% ORR** (6/8 pts) at DL2 – Safety: TORL-1-23 exhibited MMAE-related toxicities; BNT211 exhibited CRS that was adequately managed with anti-IL6
CTIM-76 Claudin 6 x CD3 bispecific antibody	• **Selective for CLDN6:** limited off-target effects • **Potent:** effective CLDN6-positive tumor killing at low doses • **Wide therapeutic window:** decreased risk of dangerous immune response • **IND Filing:** on track for late Q1 2024

DL2 = dose level 2; **CRS** = cytokine release syndrome. **1** Faber MS, et al. Bispecific claudin-6 x CD3 antibodies AACR Annual Meeting; 2021; Virtual. Abstract 1860 , **2** Sahin U, et al. TORL1-23: Initial results of a dose finding Phase 1 study. ASCO 2023; Chicago, IL. Abstract 3082, **3** Haanen JB, et al. BNT211: A Phase I trial. ASCO; 2023; Chicago, IL. Abstract 2518

CTIM-76: Claudin 6 x CD3 Bispecific Antibody



Established bispecific format

- Highly selective CLDN6 binding fragment antibody-binding (Fab) arm
- Immunostimulatory CD3 binding single-chain fragment variable (scFv) domain is designed to be functionally monovalent to avoid aberrant T-cell activation, potentially enhancing safety profile
- The fragment crystallizable region (Fc region) is the tail region of an antibody that interacts with cell surface receptors called Fc receptors. A mutation has been inserted into the Fc domain to silence the Fc domain function and avoid T-cell activation by Fc-gamma receptor positive cells

Potentially wide therapeutic window

- 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

Bispecific Antibody T Cell Engagers (bsAb TCE) in Solid Tumors

CTIM-76 and other 2nd generation assets are addressing toxicity and dosing challenges associated with 1st generation products

Innovation Driving Clinical Success

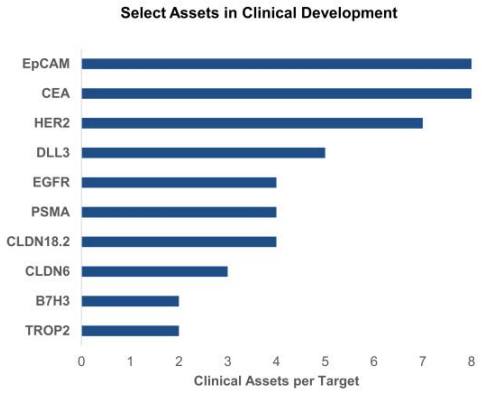
Limitations of 1st generation bsAb TCE:

1) Poor pharmacokinetics, continuous dosing
2) Cytokine release syndrome (CRS)
3) On-target/off-tumor toxicity

Advantages of 2nd generation bsAb TCE:

1) Potential for dosing every 1-3 weeks
2) Improved TCE engineering to mitigate CRS
3) Better target selection and/or enhanced avidity

Over 50 TCE in Clinical Development[1]



1 Data as of August 1, 2023

Claudin-targeted Therapeutics are Gaining Momentum

$263 million raised in 2023 for early-stage programs from TORL and Alentis

TORL Biotherapeutics (Private)

$158 million Financing

Description
Funding to advance TORL-1-23, a first-in-class, clinical-stage ADC targeting Claudin 6 and other novel clinical and preclinical stage programs.

Participating Investors

Goldman Sachs, vertex VENTURES, MOORE VENTURES, DEEP TRACK CAPITAL, Bristol Myers Squibb, PERCEPTIVE ADVISORS, COWEN HEALTHCARE INVESTMENTS

Alentis Therapeutics (Private)

$105 million Financing

Description
Funding to advance clinical programs ALE.F02 and ALE.C04 – two first-in-class anti-Claudin-1 (CLDN1) antibodies for organ fibrosis and CLDN1 positive tumors.

Participating Investors

RACAPITAL, novo holdings, Jeito, Schroders capital, PUREOS BIOVENTURES

Selected information presented is for illustrative purposes only

Claudin-targeted Therapeutics are Gaining Momentum

Internal and competitor milestones

Internal Milestone	
November:	CTIM-76 preclinical update at SITC conference
Q1 2024:	CTIM-76 IND filing

Competitor Milestones	
October:	TORL Biotherapeutics TORL-1-23 Phase 1 data update at ESMO conference
October:	BioNTech BNT211 Phase 1 data update (Late-Breaker) at ESMO conference
November:	Chugai SAIL66 preclinical update at SITC conference


Claudin 6 (CLDN6)
Target biology and therapeutic rationale
context
therapeutics
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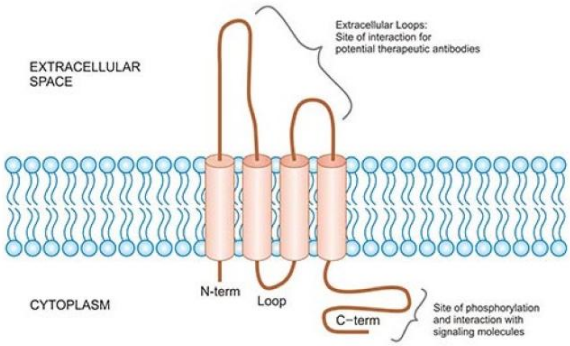
CLDN6 is an Oncofetal Protein

Oncofetal proteins are considered favorable candidates for immunotherapy

Oncofetal Characteristics of CLDN6

- Normally present at higher levels during embryonic development
- Turned off or have low levels of expression in adult tissues
- Increased expression known to occur in some tumor cells, including non-small cell lung cancer (NSCLC), ovarian, and testicular



Huan, Mol Med Reports, 2021

CLDN6 Has the Potential to Reach a Large Patient Population

~70,000 patients per year in the US only in Relapse/Refractory Setting

Initial indications of interest based on:

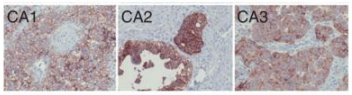
- CLDN6 prevalence
- Patient population size
- Observed clinical responses
- Eligibility for Orphan Designation

Selected Cancer indications	Incidence	R/R Incidence	CLDN6 Positive	Patient Population Based on R/R Incidence
Non-Small Cell Lung	201,229	110,653	6-50%[3,4,5]	**35,221**
Ovarian	19,900	12,800	91%[14]	**11,648**
Testicular	9,910	400	100%[14]	**400**
Breast	290,600	43,800	2-41%[1,10,11]	9,417
Gastric	26,380	11,090	13-55%[8,9]	3,771
Endometrial	65,900	12,500	20-31%[1,12,13]	3,188
Sarcoma	17,100	12,390	20%[14]	2,478
Glioma	19,000	10,000	21%[8]	2,100
Bladder	81,180	17,100	2-8%[1,13]	855
Small Cell Lung	35,511	19,527	2%[1]	391
Malignant Rhabdoid	50	500	29-44%[1,2,6,7]	183

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; 14 Mackensen, Nature Medicine, 2023. 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.

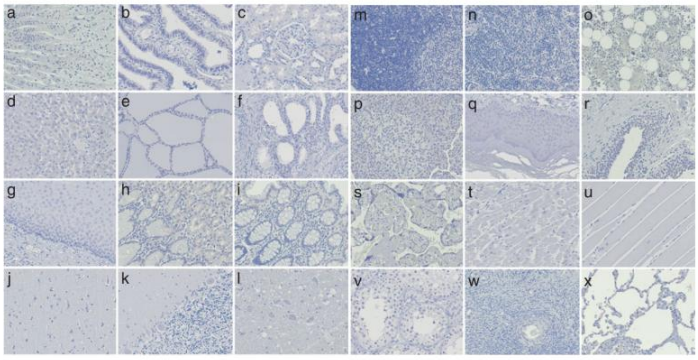
CLDN6 is Selectively Expressed on Cancer Cells

Cancer Tissue



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

Normal Tissue

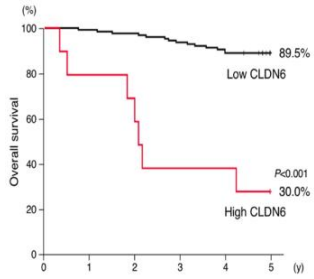


(a) adrenal gland, (b) fallopian tube, (c) kidney, (d) liver, (e) thyroid, (f) prostate, (g) esophagus, (h) stomach, (i) colon, (j) cerebrum, (k) cerebellum, (l) spinal cord. (m) thymus, (n) spleen, (o) bone marrow, (p) pancreas, (q) skin, (r) bladder, (s) placenta, (t) heart muscle, (u) striated muscle,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

Reinhard, Science, 2020

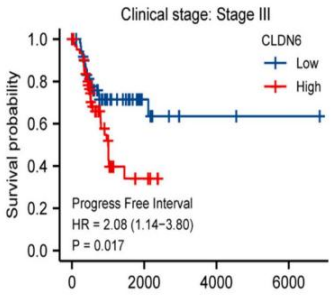
High CLDN6 Associated with a Worsened Prognosis in Cancer Patients

Endometrial Cancer[1]



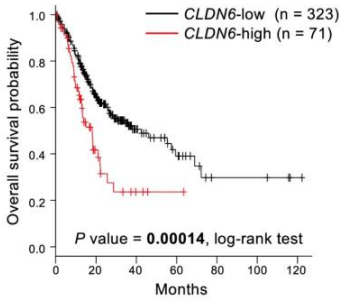
Overexpression of CLDN6 is associated with worse overall survival in endometrial cancer patients

Bladder Cancer[2]



Overexpression of CLDN6 is associated with worse overall survival and higher disease stage (more aggressive) in bladder cancer patients

Stomach Cancer[3]

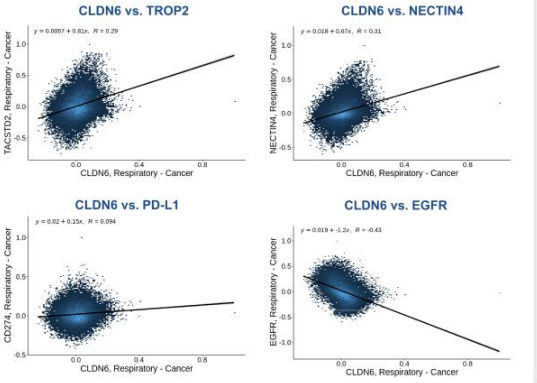


Overexpression of CLDN6 is associated with worse overall survival in stomach cancer patients

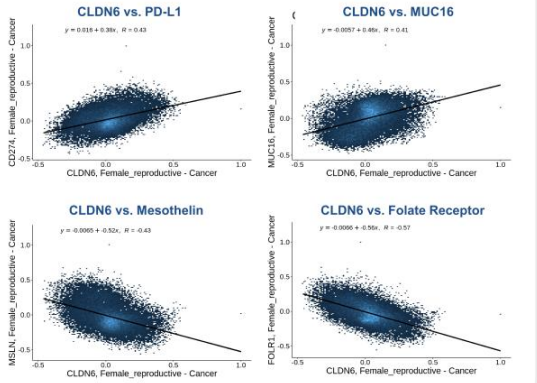
1 Kojima, Cancers, 2020; **2** Zhang, Front. Cell Dev. Biol., 2021; **3** Kohmoto, Gastric Cancer, 2020

CLDN6 Has Limited Overlap with Competing Drug Targets in Solid Tumors

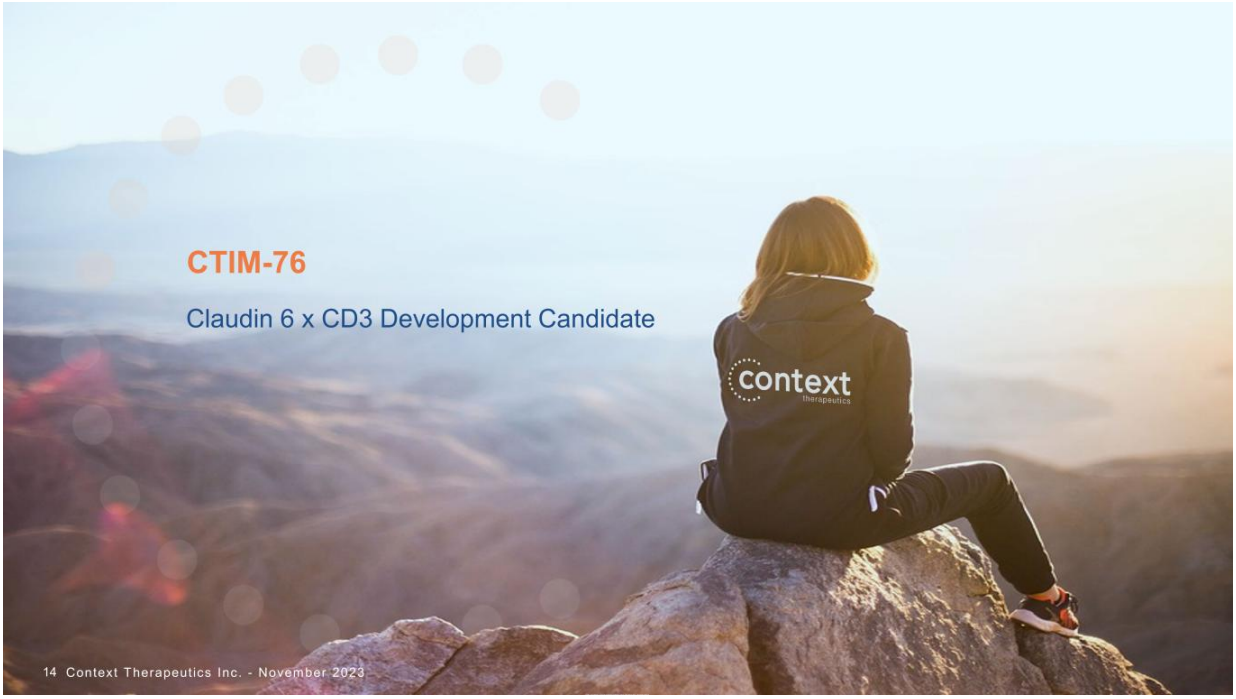
Respiratory Cancer
Limited correlation with TROP2 and Nectin-4,
no correlation with PD-L1 and EGFR



Female Reproductive Cancer
Limited correlation with PD-L1 and MUC16,
no correlation with Mesothelin and Folate Receptor Alpha



Bishop, AnalyzeR [Data Set] Accessed August 1, 2023


CTIM-76
Claudin 6 x CD3 Development Candidate
context
therapeutics
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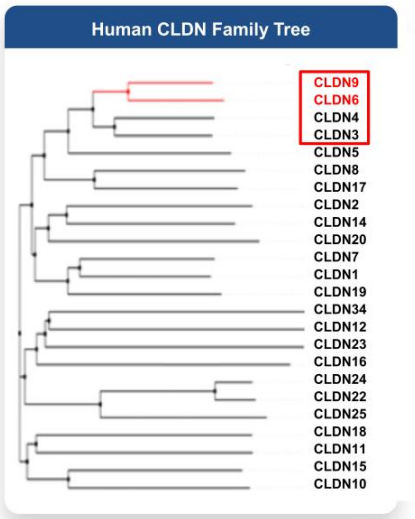
Developing a Highly Selective CLDN6 Antibody is Challenging

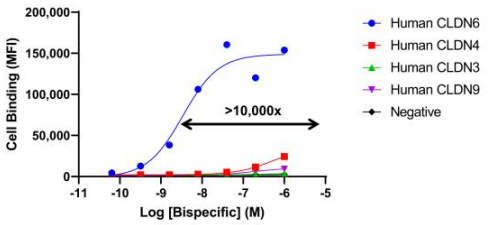


- CLDN6 antigen is **conformationally dependent**, which limits access to antibody-antigen binding
- Antigen binding region is **highly conserved** with CLDN3, CLDN4, and CLDN9, making CLDN6-selective binding a challenge[1]
- CLDN6 **selectivity is required** to avoid off-target liabilities identified in murine knockout and knockdown studies with CLDN3 (intestine)[2], CLDN4 (liver, pancreas)[3], and CLDN9 (liver, ear)[4]

1 Screnci, Cancer Res, 2022; **2** Tanaka, J Hepatol, 2018; **3** Cordat, Physiology, 2019; Li, FEBS Open Bio, 2020; **4** Nakano, PLoS Genet, 2009

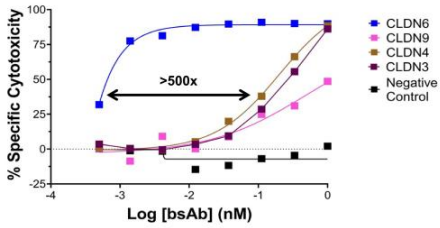
CTIM-76 Exhibits Excellent Selectivity and Potency

CLDN6 Selectivity



- CTIM-76 **CLDN6 EC50 of 3.41 nM (binding)**
- 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)

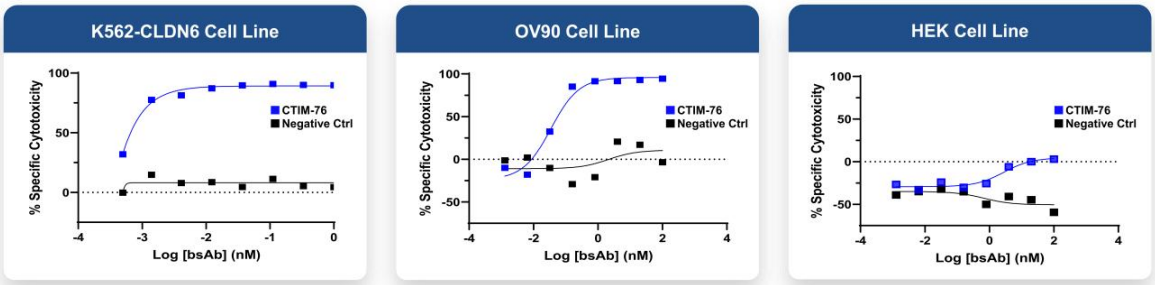
CLDN6 Potency



- Potency assay provides a better assessment than binding assays for off-target liabilities associated with CLDN3, CLDN4, or CLDN9
- CTIM-76 **CLDN6 EC50 of 0.0004 nM (cytotoxicity)**
- CTIM-76 **preferentially targets CLDN6**, with minimal binding and cytotoxicity against CLDN9-expressing cells

CTIM-76 Induces Specific Lysis

CTIM-76 showed potent and specific killing of even those cell lines with very low CLDN6 expression

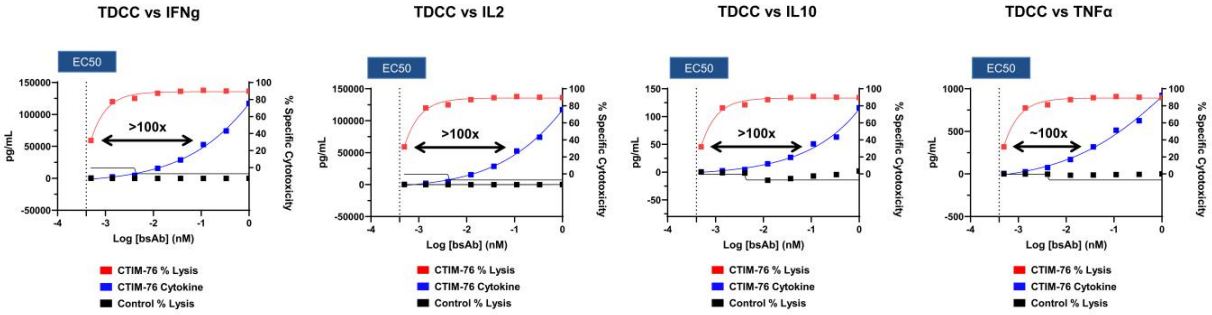


	K562-CLDN6	OV90	HEK
CLDN6 Expression	High	Medium	Low
CTIM-76 (EC50)	0.0004 nM	0.049 nM	2.79 nM

CTIM-76 Exhibits Limited Activation of Free Cytokines

- Data supports potential to dose at levels that promote cancer cell killing but have manageable levels of free cytokine production, thereby potentially reducing the risk of cytokine release syndrome
- Cytokine production evaluated in exogenous (CLDN6-K562) cell line model at 48 hours
- Cytokine production happens well above the concentration of maximal killing (TDCC EC50 = 0.0004 nM)

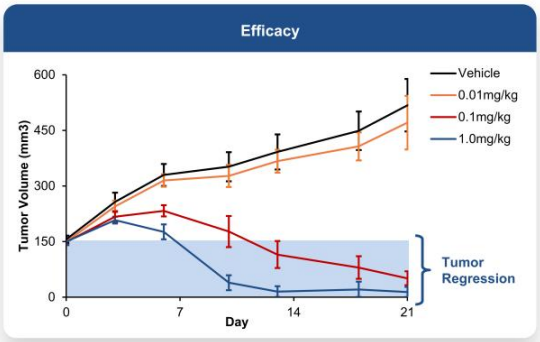
Comparison of T cell-dependent cellular cytotoxicity (TDCC) to Cytokine Production

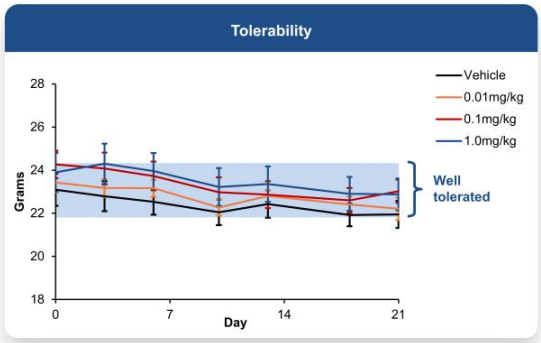


Study Design: K562 cells stably over-expressing CLDN6 and luciferase were co-cultured with human T cells at an E:T ratio of 10:1 for 48 hours. Cytotoxicity was determined by luminescence imaging.

CTIM-76 Inhibits Tumor Growth in a Mouse Xenograft Model

CTIM-76 induced regression of established subcutaneous OVCAR3 xenograft tumors



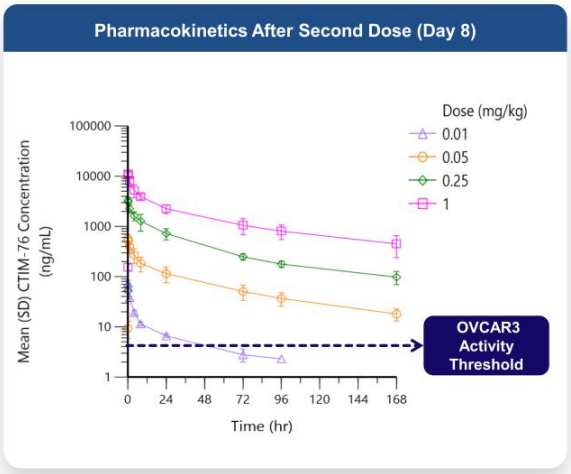


- CTIM-76 effectively engaged systemically administered human PBMC cells to promote significant tumor regression and complete responses in OVCAR3 ovarian xenograft models in mice
- NSG-b2m knockout mice (n=14/arm) engrafted with human PBMCs and bearing advanced subcutaneous OVCAR3 tumor xenografts (~150,000 CLDN6 copies per cell) were treated twice per week with vehicle or CTIM-76

- CTIM-76 was well tolerated in OVCAR3 xenograft study

NSG: NOD scid gamma immunodeficient mice; PBMC: peripheral blood mononuclear cells

CTIM-76 was well tolerated in Toxicology Study in Cynomolgus Monkeys

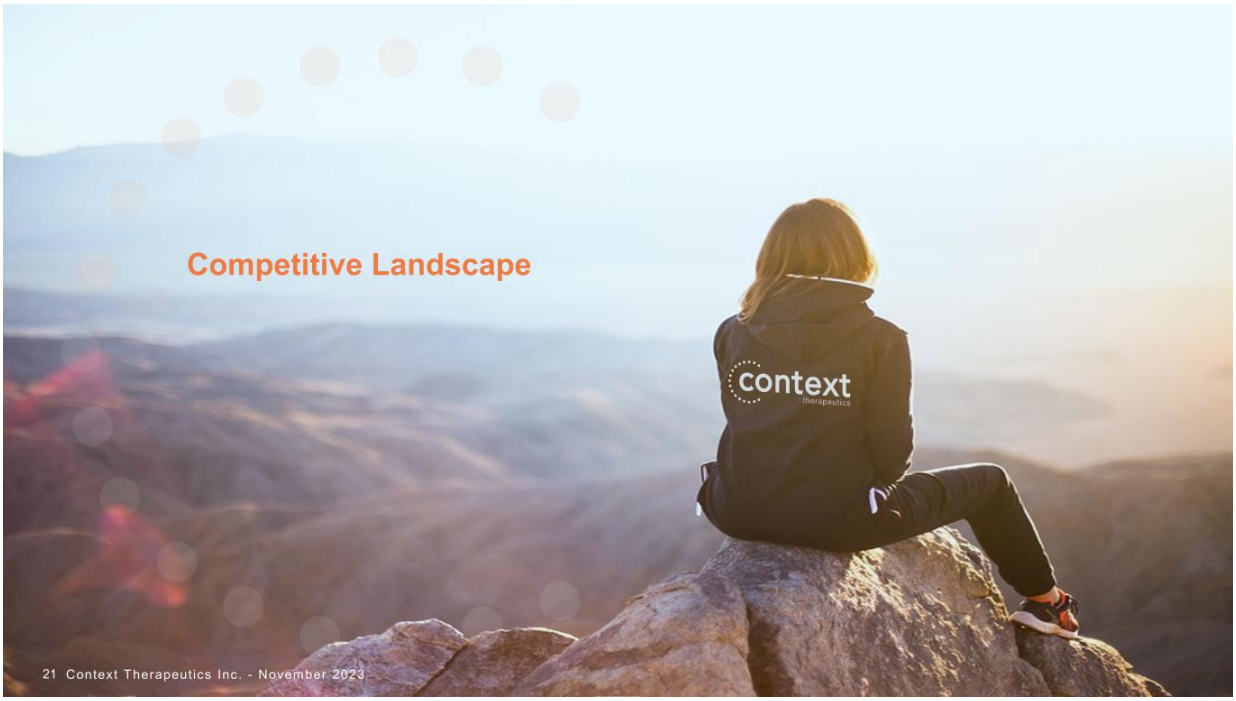


CTIM-76 is Cross-Reactive to Cynomolgus Monkey CLDN6 and CD3

- Exhibited linear pharmacokinetics
- Supports weekly dosing in Phase 1 study
- C_{min} above threshold required for therapeutic activity

CTIM-76 was well tolerated in Toxicology Study in Cynomolgus Monkey:

- well tolerated at projected therapeutic doses
- No major CRS-associated clinical symptoms or toxicity
- CLDN4/9 hepatobiliary effects were generally mild


Competitive Landscape
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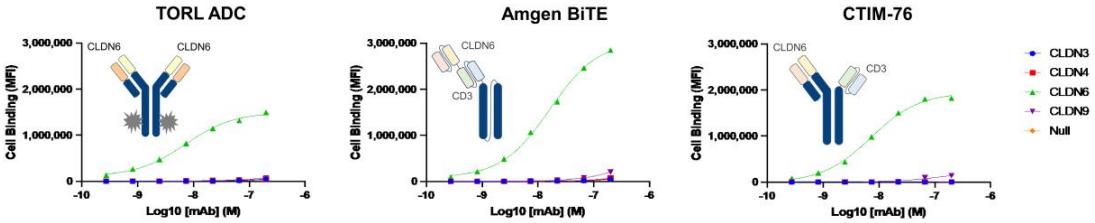
Few CLDN6 Programs Have Excellent CLDN6-Selectivity

CTIM-76, TORL-1-23, and AMG-794 are selective for CLDN6 vs CLDN3, CLDN4, CLDN9

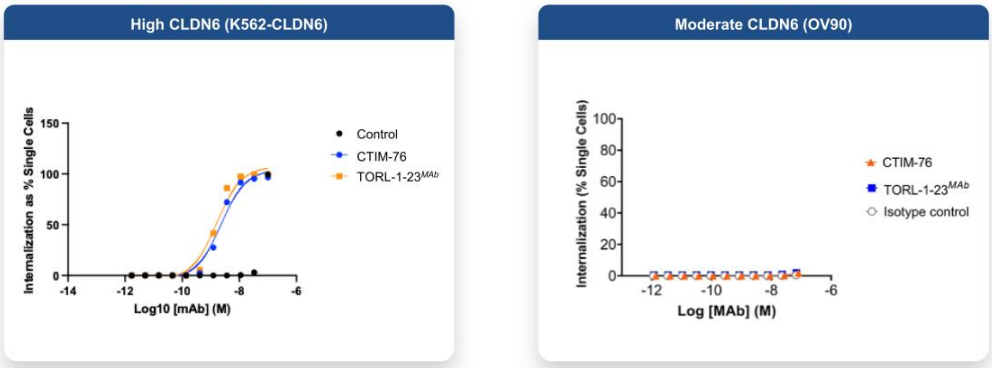


- **Clones of TORL-1-23 and AMG-794 were generated by Context for benchmarking purposes**
  - The clones are not derived from the original manufacturer and were produced for this research study based on the published sequence of their antibody variable chains, thus, the clones used in this study are biosimilars and may not be identical to the MAbs formulated for clinical development
- **TORL-1-23**
  - A clinical-stage CLDN6 antibody-drug conjugate (ADC) that incorporates a protease-labile linker and an MMAE payload
  - TORL-1-23 clone ("TORL ADC") was generated from CLDN6 antibody AB3-7 (WO2020/191342) with MMAE conjugated using AlphaThera's oYo link system with a 2:1 drug-antibody ratio
- **AMG-794**
  - A clinical-stage T cell engaging bispecific antibody that incorporates a BiTE® conjugated to an Fc domain to achieve half-life extension (HLE)
  - AMG-794 clone ("Amgen BiTE") was generated from CLDN6 antibody SEQ ID No: 21 (WO2022/096700) and conjugated to an Fc domain for HLE

HEK-293F cells were transfected with human CLDN6, CLDN9, CLDN3, or CLDN4 and stained with the indicated concentration of TORL ADC, Amgen BiTE, or CTIM-76.

TORL ADC Internalization Restricted to Cells with High Levels of CLDN6

- TORL-1-23^{MAb} internalizes in a cell line where CLDN6 is overexpressed
- TORL-1-23^{MAb} does not internalize in a cell line with moderate CLDN6 expression
- TORL-1-23 is potentially best utilized in tumors with high levels of CLDN6 expression where the ADC can bathe the tumor, thereby enhancing the probability of a tumor response and decreasing the level of free MMAE in plasma

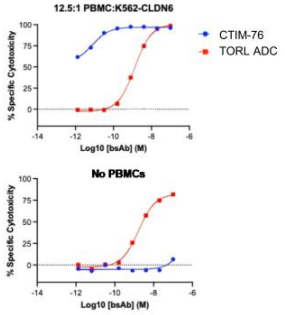


TORL-1-23 clones are not derived from the original manufacturer and were produced for this research study based on the published sequence of their antibody variable chains, thus, the clones used in this study are biosimilars and may not be identical to the MAbs formulated for clinical development. Monoclonal antibody (mAb) variant of TORL-1-23 was generated (TORL-1-23^{MAb}) for benchmarking purposes from CLDN6 antibody AB3-7 (WO2020/191342). Antibodies were labeled with a pH-sensitive dye, pHrodo, using pHrodo iFL Red Microscale Protein Labeling Kit (Thermo Fisher Scientific) and incubated in OV90 ovarian cancer cells for 2 hours and 24 hours (data not shown)

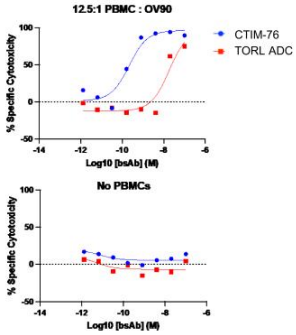
TORL ADC Potency Requires High Levels of CLDN6

- TORL ADC may be best utilized in cancers that express high levels of CLDN6, including testicular and ovarian cancers
- TORL ADC incorporates a functional Fc and is active in cells with moderate CLDN6 expression only when immune cells are present
- TORL-1-23 activity is likely derived primarily from ADC internalization and/or bystander killing in high CLDN6 cells and to a lesser extent from complement-mediated immune activation due to a functional Fc domain

High CLDN6 (K562-CLDN6)



Moderate CLDN6 (OV90)

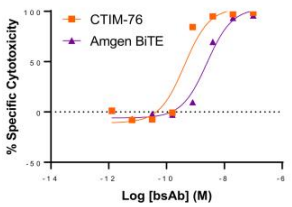


CTIM-76 is a More Potent Inducer of Cytotoxicity and T Cell Activation than AMG-794

- AMG-794 is a BiTE that incorporates a detuned CD3 (standard for BiTEs) and an Fc domain for half-life extension (HLE-BiTE)
- AMG-794 has exhibited dose-limiting side effects in murine and cynomolgus monkey studies[1,2]
- CTIM-76 is ~10x more potent than Amgen BiTE in *in vitro* cytotoxicity and cytokine activation assays

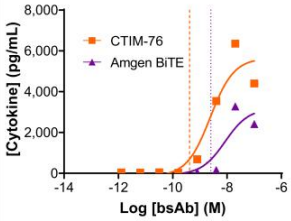
Cytotoxicity in OV90 Cell Line

12.5:1 Effector:Target



Cytokine Activation

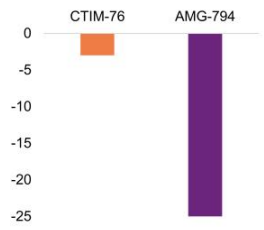
IL-6 at 24 Hours



Vertical lines represent cytotoxicity EC50

Percent Weight Loss in Xenograft[1,2]

1 mg/kg Dose in OVCAR3



1 Pham et al, AMG-794, a Claudin 6-targeted half-life extended (HLE) bispecific T cell engager (BITE®) , AACR 2022; 2 Amgen Patent WO2022096700

BNT211 and TORL-1-23 Phase 1 Data at ESMO 2023 and ASCO 2023

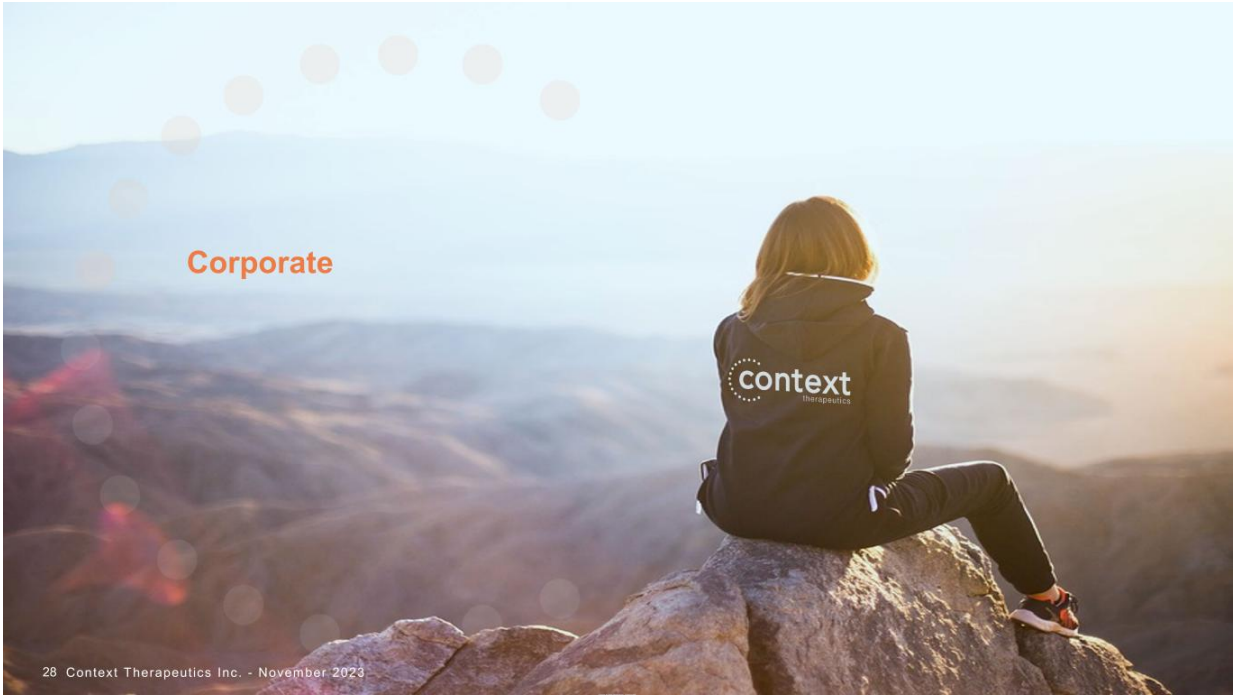
	BNT211		TORL-1-23	
Conference	ASCO	ESMO	ASCO	ESMO
Cutoff Date	March 10, 2023	September 10, 2023	May 3, 2023	September 29, 2023
Patients (n)	19 (17 evaluable) Ovarian = 8 Testicular = 6 Lung = 1 Other = 4	44 (38 evaluable) Ovarian = 17 Testicular = 16 Other =11 (4 lung, 3 round cell, 2 esophageal, 1 endometrial, 1 sinonasal)	25 Ovarian = 19 Testicular = 3 Endometrial = 3	42 (36 evaluable) 17 pts at 3 mg/kg Ovarian = 30 Testicular = 5 Endometrial = 7
Median Prior Treatments, n (range)	4 (2-9)	4 (2-9)	5 (1-10)	4 (1-9)
ORR, n (%)	Overall: 41% (7/17) Dose Level 0 or 1: 11% (1/9) Dose Level 2: 75% (6/8) Ovarian DL2: 80% (4/5)	Overall: 44% (17/38) Dose Level 0 or 1: 11% (1/9) Dose Level 2: 59% (13/22) Ovarian DL2: 77% (7/9) Testicular DL2: 38% (3/8) Other DL2: 60% (3/5)	Overall: 28% (7/25) Ovarian: 32% (6/19) Ovarian, 2.4mg/kg: 75% (3/4)	Overall: 31% (11/36) Ovarian: 33% (9/27) Other: 22% (2/9) Ovarian, ≥2.4mg/kg: 50% (6/12)
SAE	Grade 3: sepsis (1 pt)	Grade 4: CRS (1pt @ DL3) Grade 5: sepsis (1 pt)	Grade 4: lymphocytopenia (1 pt) Grade 5: pneumonia (1 pt)	Grade 4: blood counts at higher doses Grade 5: pneumonia (1 pt)
Treatment-Related AEs	LFT	Blood counts LFT Bilirubin	Alopecia Anemia Neuropathy Pneumonia	Alopecia Anemia Neuropathy Pneumonia

CLDN6 Competitive Landscape[1]

Selective, Potent, Scalable

	Scalable Manufacturing Process	Complex Manufacturing Process	Potential / Disclosed Safety Liabilities
Selectivity for CLDN6 vs CLDN3,4,9	**TORL-1-23** CLDN6 + MMAE *FPI Q4 21* **CTIM-76** bsAb CLDN6xCD3 *IND Q1 24*	**BNT211** CAR-T + CARVac *FPI Q3 20*	**AMG-794**[3] BiTE CLDN6xCD3 *FPI Q1 23*
Limited Information on Asset	**Undisclosed** bsAb CLDN6xCD3 *IND Q4 23*	**Undisclosed** CAR-NK *IND 2H 23* **CLDN6-CAR-NK** CAR-NK + IL7 *FPI Q2 22*	
Limited Selectivity	**XmAb541** 2+1 bsAb CLDN6xCD3 *IND 2H 23* **SAIL66** bsAb CLDN6xCD3 *FPI Q1 23*		**DS-9606a** CLDN6/CLDN9 + 2nd gen toxin *FPI Q2 22* **GB-7008-01** CLDN6/CLDN9 + MMAE *Status Unknown* **BNT142** mRNA BsAb CLDN6xCD3 *FPI Q1 22*
Deprioritized	**TJ-C64B**[2] 2+2 bsAb CLDN6x4IBB		**SC004**[4] CLDN6/CLDN9 + PBD *Ph 1 DLT*

1 Analysis based on current understanding of publicly available information compiled as of October 23, 2023 and internal benchmarking studies; **2** TJ-C64B deprioritization per Q2 2023 earnings guidance; **3** Pham et al, AMG 794, a Claudin 6-targeted half-life extended (HLE) bispecific T cell engager (BITE®), AACR 2022; **4** Hamilton, First-in-human study of SC-004, AACR 2020; **FPI** = First Patient In Phase 1 trial; **DLT** = Dose Limiting Toxicity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Tarek Sahmoud, MD, PhD
Chief Medical Officer

Novartis · H3 Biomedicine · Celgene

Priya Marreddy, MS
VP Clinical Operations

Spark Therapeutics · teva · PRA Health Sciences

Focus on Execution

Experienced team with deep oncology experience

Our CMO led the clinical development of multiple blockbuster drugs including Kisqali, Arimidex, and Afinitor

Our management team is supported by a Board with strong public company operating and governance experience

Investment Highlights (Nasdaq: CNTX)

Large Unmet Need

Solid Tumors

High-Value Target

Claudin 6

Milestones

November SITC Poster

Anticipated Late Q1 2024 IND filing

Strong Team

Deep Domain Experience, Track Record of Success

Financial Strength

Expected Cash Runway into late 2024


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Advancing Medicines
for Solid Tumors
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