LISATA THERAPEUTICS

Targeted Therapy *Delivered*

Corporate Presentation | May 8, 2025

Nasdaq: LSTA

www.lisata.com

Forward-looking statements advisory

This presentation 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. All statements, other than statements of historical facts, included in this communication regarding strategy, future operations, future financial position, future revenue, projected expenses, prospects, plans and objectives of management are forward-looking statements. In addition, when or if used in this communication, the words “may,” “could,” “should,” “anticipate,” “believe,” “estimate,” “expect,” “intend,” “plan,” “predict”, “target” and similar expressions and their variants, as they relate to Lisata or its management, may identify forward-looking statements. Examples of forward-looking statements include, but are not limited to, statements relating to Lisata’s continued listing on the Nasdaq Capital Market; expectations regarding the capitalization, resources and ownership structure of Lisata; the approach Lisata is taking to discover, develop and commercialize novel therapeutics; the adequacy of Lisata’s capital to support its future operations and its ability to successfully initiate and complete clinical trials; and the difficulty in predicting the time and cost of development of Lisata’s product candidates. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation: the safety and efficacy of Lisata’s product candidates, decisions of regulatory authorities and the timing thereof, the duration and impact of regulatory delays in Lisata’s clinical programs, Lisata’s ability to finance its operations, the likelihood and timing of the receipt of future milestone and licensing fees, the future success of Lisata’s scientific studies, Lisata’s ability to successfully develop and commercialize drug candidates, the timing for starting and completing clinical trials, rapid technological change in Lisata’s markets, the ability of Lisata to protect its intellectual property rights and legislative, regulatory, political and economic developments. The foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors included in Lisata’s Annual Report on Form 10-K filed with the SEC on February 27, 2025, and in other documents filed by Lisata with the Securities and Exchange Commission. Except as required by applicable law, Lisata undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise.

Lisata at a Glance

Company Overview

Lisata Therapeutics (Nasdaq: LSTA)

OVERVIEW

Clinical-stage therapeutics company rapidly developing a novel solid tumor targeting and penetration technology with tumor microenvironment (TME) modifying properties.

MISSION

To enhance the treatment benefits of existing and emerging therapies for solid tumors and similar diseases without additional side effects utilizing an approach that is patient-friendly and pharmacoeconomically attractive.

Lisata Therapeutics (Nasdaq: LSTA): Key attributes

Seasoned management with successful international drug development experience and expertise

Proprietary field-leading technology with global IP protection extending beyond 2040

Multiple product and business milestones projected over the next 12 - 18 months

Platform technology validated by existing partnerships with potential for many others

Cash runway extending into 3Q2026 with no debt, funding current clinical programs

Seasoned leadership with proven history of drug approvals worldwide

David J. Mazzo, PhD

President and Chief Executive Officer, Member of the Board of Directors

With >40 years of experience, Dr. Mazzo is a global pharmaceutical executive noted for his strategic prowess and his vast experience developing and launching new products across all therapeutical areas. He recently was recognized as a *2024 PharmaVoice Top 100 Standout Leader*.

RegadoBiosciences · ÆTERNA ZENTARIS · CHUGAI (Roche Group) · Schering-Plough · Hoechst Marion Roussel · RHÔNE-POULENC RORER

Kristen K. Buck, MD

Executive Vice President of R&D and Chief Medical Officer

Dr. Buck is a board certified and licensed physician with >20 years of strategic global drug development, drug/device safety/epidemiology, FDA, and clinical practice experience.

ICON · IQVIA · FDA · OPTUMInsight · AstraZeneca · B|BRAUN

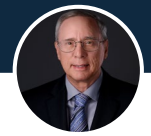
Gregory Berkin
Chief Information Officer and Data Protection Officer

James Nisco
SVP of Finance and Treasury and Chief Accounting Officer

Tariq Imam
SVP of BD and Operations and General Counsel

John Menditto
VP of Investor Relations and Corporate Communications

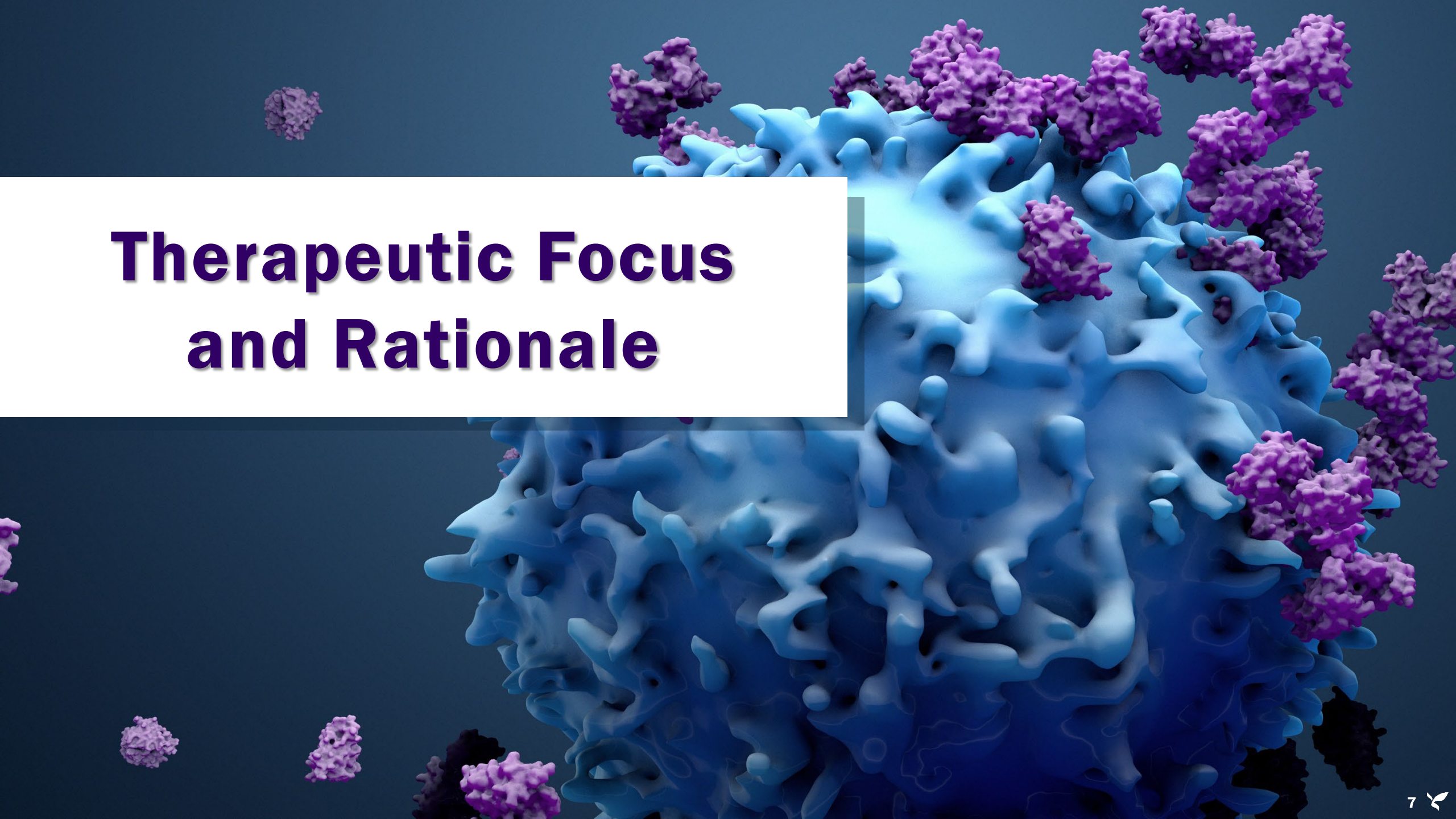
Bill Sietsema, PhD
VP of Global Regulatory Affairs



Ryan Quick
VP of Chemistry, Manufacturing and Controls

Detailed management bios can be found at www.lisata.com

Therapeutic Focus and Rationale



Improved solid tumor treatment remains a vital, growing global need

Worldwide Cancer Incidence

2022

20 million new cases with **10 million** deaths[1-2]

2050

35 million new cases with **18.5 million** deaths[3]

Solid tumors account for more than 90% of all diagnosed cancers

Pancreatic Cancer Incidence

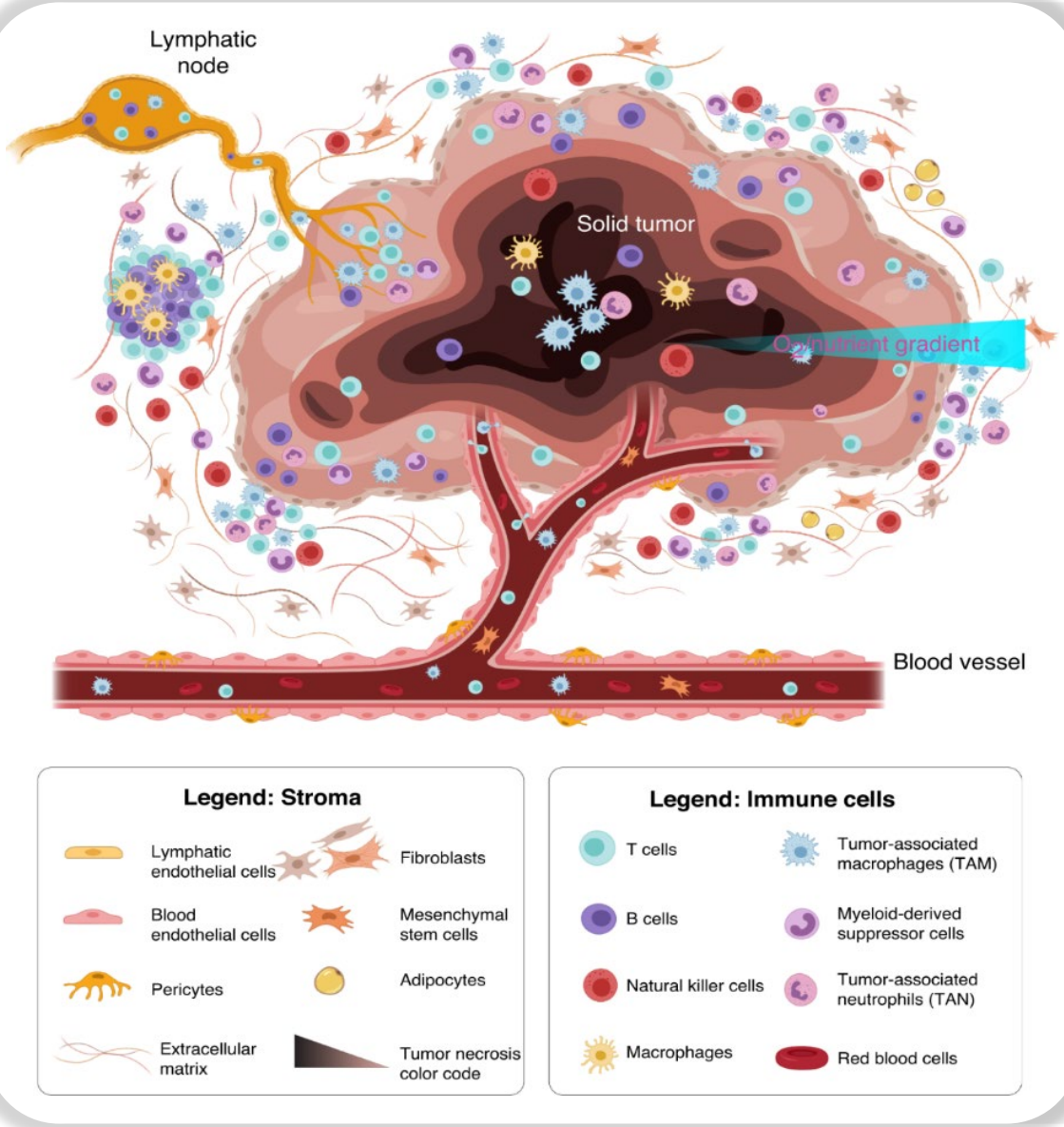
By 2030, PDAC* is predicted to be the second most common cause of cancer mortality[4]

Immunotherapy is generally ineffective in improving outcomes

**Pancreatic ductal adenocarcinoma (PDAC)*

[1] https://gco.iarc.who.int/tomorrow/en/dataviz/tables?mode=population&years=2050&types=1&populations=903_904_905_908_909_935_900; data retrieved Feb 12, 2024.
[2] https://seer.cancer.gov/statfacts/html/common.html; data retrieved Nov 2, 2023.
[3] https://www.who.int/news/item/01-02-2024-global-cancer-burden-growing--amidst-mounting-need-for-services; data retrieved Oct 14, 2024.
[4] Europe Is Facing a Pancreatic Cancer Emergency - Medscape - January 25, 2024.

Current solid tumor treatments & patient outcomes are suboptimal



Challenging tumor morphology and tumor microenvironment (TME) pose significant barriers to effective treatment and outcomes

Tumor stroma acts as a physical barrier to anti-cancer agents

An immunosuppressive TME contributes to tumor resistance and/or metastases

Prolonged or escalated dosing of non-targeted anti-cancer therapies generally leads to intolerable off-target side effects

Diagram source: Abizanda-Campo, S. et al, *Microsyst Nanoeng* **9**, 154 (2023)

Certepetide is designed to optimize solid tumor treatment

Certepetide: a proprietary internalizing RGD* (iRGD) cyclic peptide with tumor specific targeting & penetration activity and tumor microenvironment modifying properties

- Converts tumor stroma from a barrier to a conduit for anti-cancer drugs
- Selectively reduces TME immunosuppressive T cells and recruits cytotoxic T cells[1]
- Inhibits the metastatic cascade[2]
- Works with any modality of anti-cancer therapeutics
  - Via co-administration or molecular tethering
- Approaching Phase 3-ready readiness in mPDAC**
  - In mid-stage clinical development in multiple solid tumors

**internalizing RGD (iRGD): Arginylglycylaspartic acid*
***mPDAC: metastatic pancreatic ductal adenocarcinoma*

[1] Sugahara, et al. Mol Cancer Ther; 14(1) January 2015; Hamilton, et al., J MolMed. April 2015; and Miyamura, et al., bioRxiv. May 2023.
[2] Yuan, D., Duda, D., et al. CCA Foundation Conf. 2024 Poster. *Enhancing the efficacy of standard therapy in intrahepatic cholangiocarcinoma using LSTA1, a novel tumor targeting and penetration agent.*

Partnerships

Noteworthy existing relationships and potential for many more

Existing partnerships support certepetide's promise and broad applicability

R&D alliances contribute resources with minimal commercial interest in certepetide

- ***Australasian Gastro-Intestinal Trials Group*** - Clinical Trialists Consortium (Australia & New Zealand)
- ***WARPNINE*** - Foundation (Australia)

Existing strategic partnerships

Qilu Pharmaceutical

- Qilu granted exclusive rights in China, Taiwan, Hong Kong and Macau
- Qilu assumes all development and commercialization responsibilities/costs in licensed territories
- Lisata collected $15 million in milestones to date
- Potential for additional $221 million in milestones plus royalties on sales to Lisata

Kuva Labs

- Kuva granted exclusive worldwide rights to certepetide as a targeting agent/delivery vehicle in combination with Kuva's NanoMark technology for diagnostic tumor imaging
- Kuva assumes all development and commercialization responsibilities/costs
- Includes a $1 million upfront fee and potential ~$20 million in milestones plus royalties on sales to Lisata

Valo Therapeutics

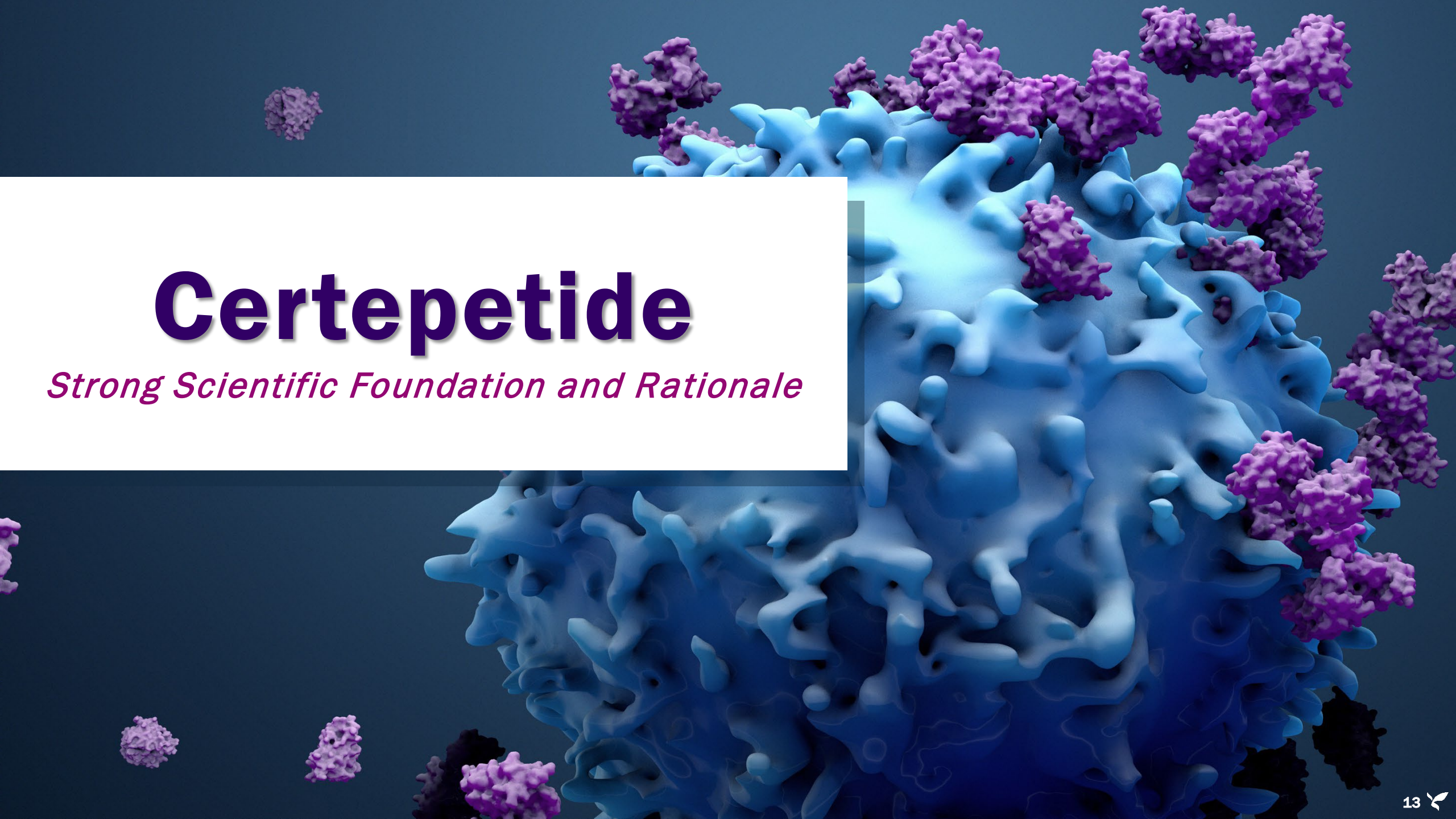
- Valo to investigate the benefits of combining certepetide with ValoTx's PeptiCRAd, a customizable oncolytic adenovirus platform technology, and a checkpoint inhibitor in a preclinical murine model for the treatment of melanoma

Catalent, Inc.

- Catalent to evaluate, in a preclinical setting, the efficacy of certepetide as a payload on Catalent's SMARTag® antibody-drug conjugate dual-payload technology platform for the treatment of difficult-to-treat diseases
- Catalent assumes all R&D responsibilities/costs; Lisata to provide consulting support
- Lisata to receive an upfront payment with the possibility of future considerations contingent upon the results of the preclinical evaluation

Additional partnership opportunities exist for many combinations with certepetide

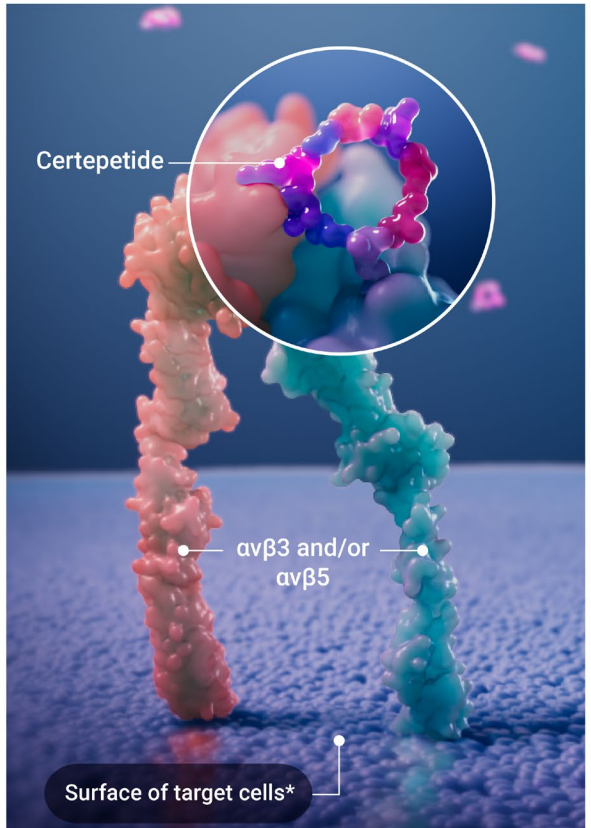
- By indication, modality of co-administered drug(s), and/or geography



Certepetide

Strong Scientific Foundation and Rationale

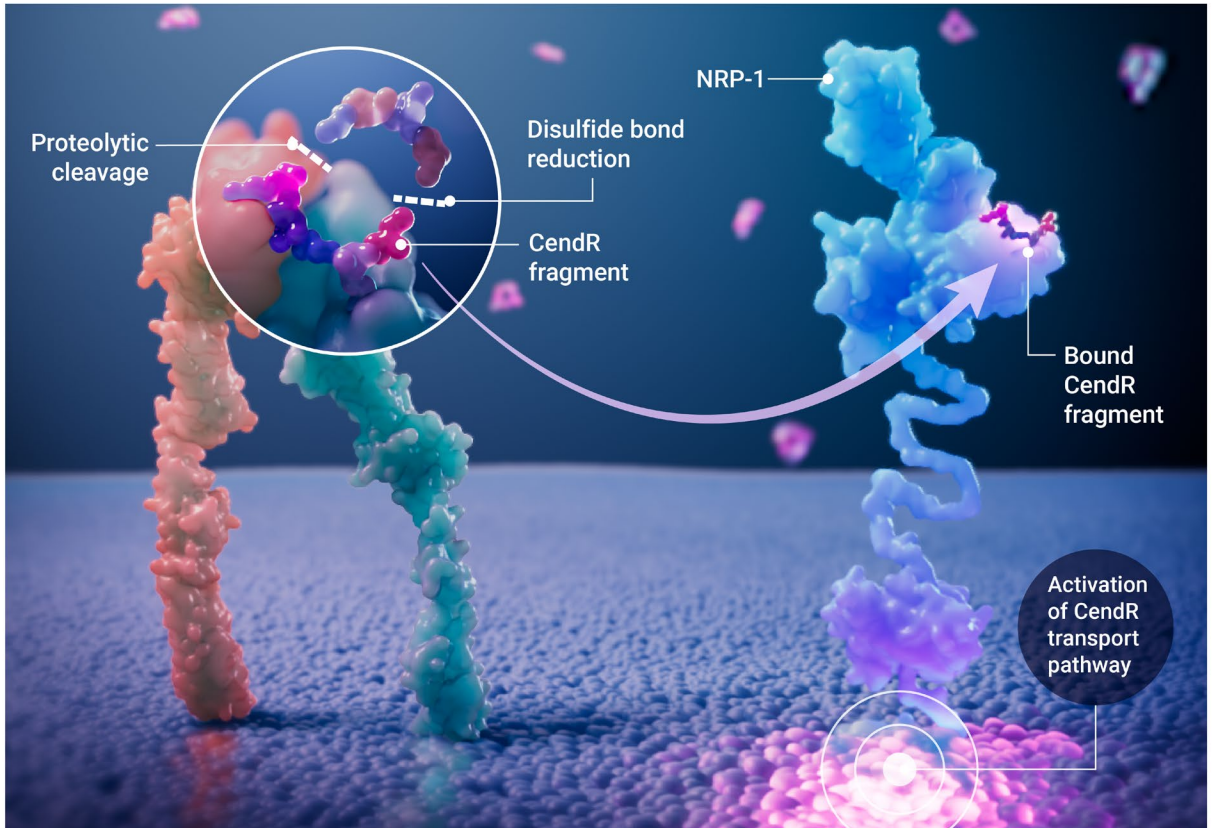
Certepetide mechanism of action: Unique, multi-step approach



1 Integrin binding

Certepetide is a 9-amino acid cyclic iRGD peptide with high binding specificity and affinity for αvβ3 and/or αvβ5 integrins that are upregulated on target cells.

**Tumor cells and tumor vascular endothelial cells (components of the tumor stroma)*

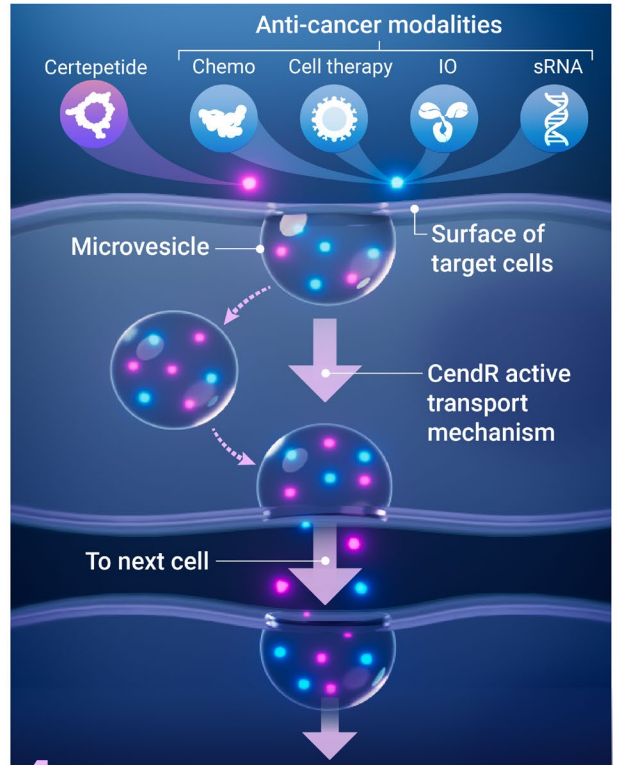


2 Proteolytic cleavage

Bound certepetide is proteolytically-cleaved in the tumor microenvironment (TME) resulting in a C-end Rule (CendR) linear peptide fragment.

3 Neuropilin-1 binding

The CendR fragment binds with high affinity and specificity to neuropilin-1 (NRP-1), an adjacent receptor on the same or nearby cell, activating the CendR active transport pathway[1] and triggering tumor penetration.



4 Resulting tumor penetration

CendR pathway actuation triggers encapsulation of circulating co-administered anti-cancer drugs, ferrying them through the stroma into the tumor.
Note: *Microvesicles can fuse to form channels across single cells.*[2-6]
[Not pictured] Certepetide depletes immunosuppressive T cells and enhances cytotoxic T cells in the TME, while inhibiting metastases.

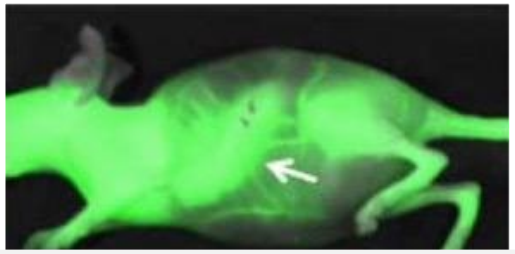
Illustration is a simplified rendition of MOA

[1] Ding et al., *Nature Comm*, 2019.
[2] Ruoslahti E. *The Journal of clinical investigation.* 2017;127(5), 1622–1624.
[3] Liu, X., et al. *J Clin Invest.* 2017;127(5):2007-2018.
[4] De Mendoza, T. H., Suzuki, K., et al. *Nature Comm,* 2021;12, 1541.
[5] Wang, C., et al. *International Journal of Nanomedicine,* 2024;19, 12633–12652.
[6] Saifi, M. A., et al. *Biochimica Et Biophysica Acta (BBA) - Reviews on Cancer*, 2023; 1878(3), 188895.

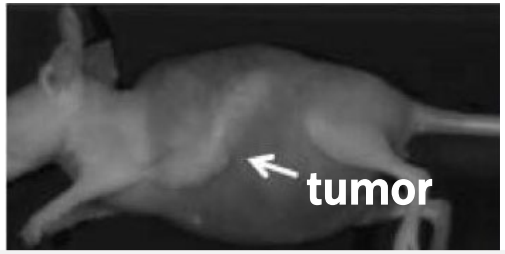
Certepetide/iRGD selectively promotes intratumoral penetration

Whole body imaging of mice with pancreatic ductal adenocarcinoma (arrow) dosed with Fluorescent Quantum Dots (FQDs) with and without certepetide[1],[2]

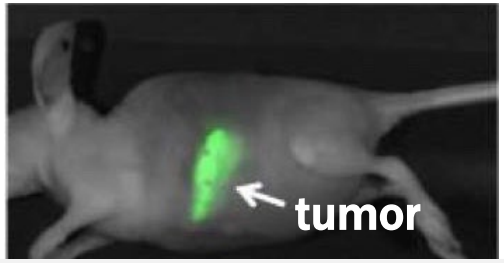
- Circulating FQDs result in whole body fluorescence
- Etching solution quenches fluorescence in circulation



FQDs

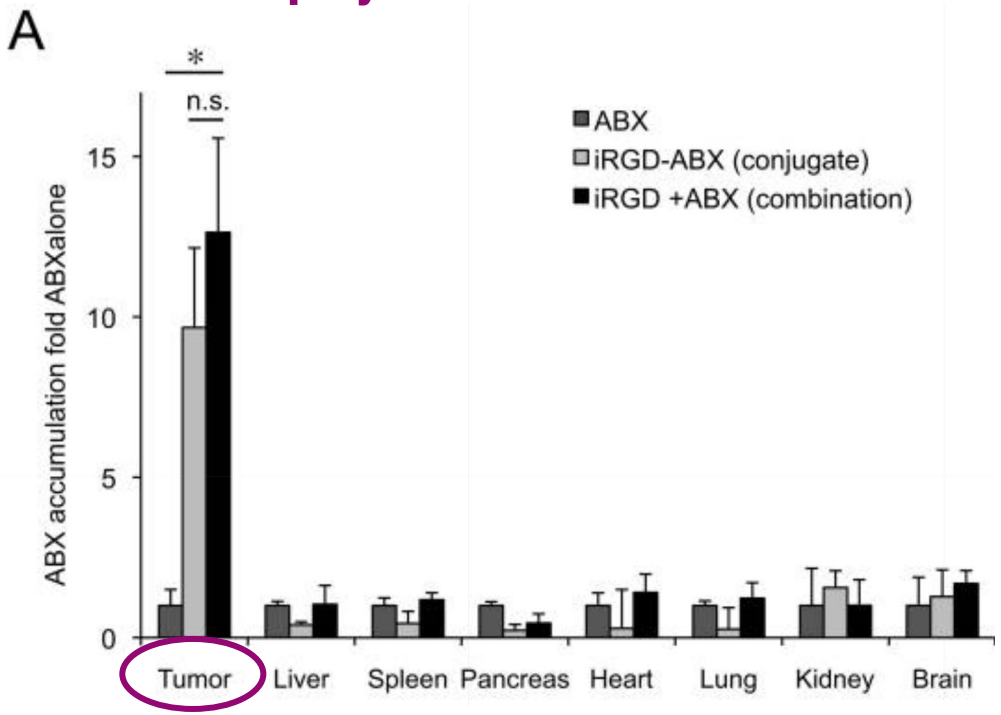


FQDs + Etching solution



Certepetide + FQDs + Etching solution

When co-administered with iRGD, nab-paclitaxel (Abraxane or ABX) is preferentially taken up by tumor tissue in mice[3]



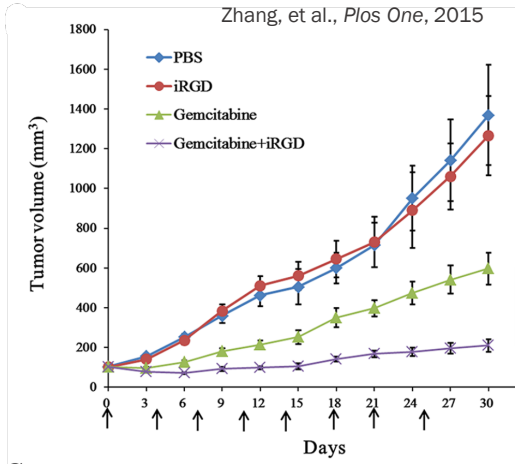
[1] Braun et al., Nature Mater. 2014.
[2] Liu, Braun et al., Nature Comm. 2017.
[3] Sugahara et al 2010.

Broad applicability & activity of certepetide/iRGD consistently demonstrated

Sampling of >370 scientific publications showing improved survival

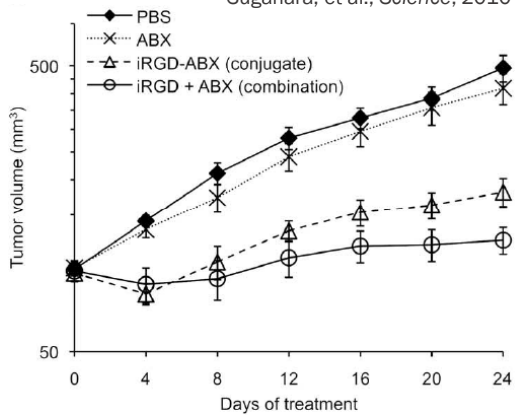
Lung cancer + gemcitabine

Zhang, et al., *Plos One*, 2015



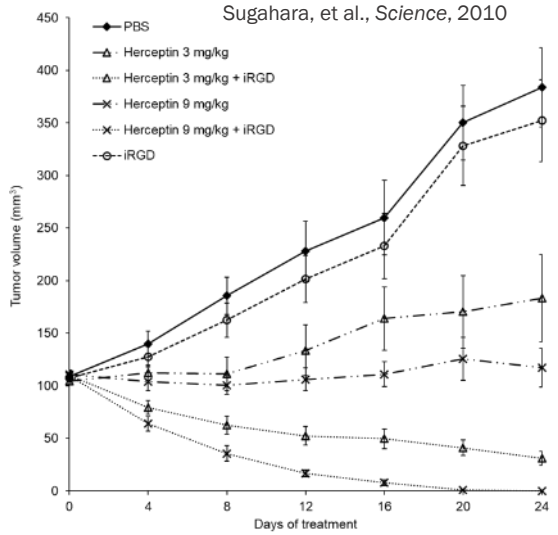
Breast cancer + nanoparticle nab-paclitaxel

Sugahara, et al., *Science*, 2010



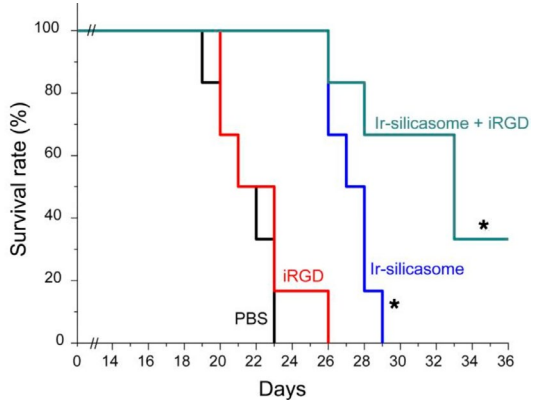
Breast cancer + Herceptin®

Sugahara, et al., *Science*, 2010



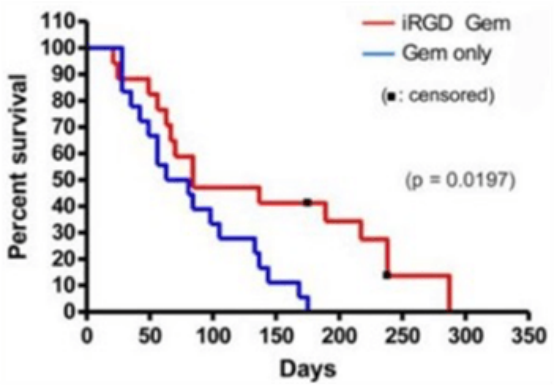
PDAC + irinotecan nanoparticles

Liu X et al., J Clin Invest, 2017



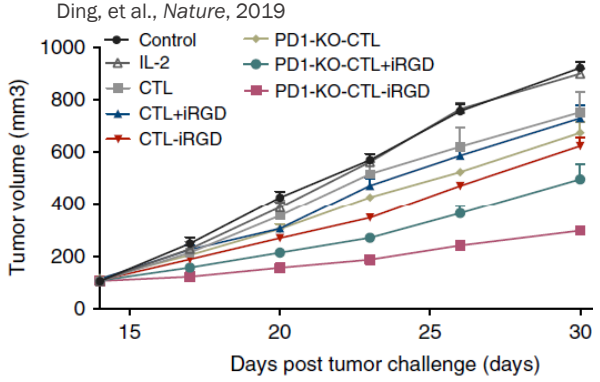
PDAC + gemcitabine

Hurtado de Mendoza et al, Nature Comms, 2021



GI cancer + adoptive cell therapy

Ding, et al., *Nature*, 2019



Certepetide/iRGD consistently improves *immunotherapy* efficacy in multiple preclinical solid tumor models

Solid Tumor Types

- Intrahepatic cholangiocarcinoma
- Pancreatic adenocarcinoma
- Prostate cancer
- Breast cancer
- Non-Small Cell Lung Cancer
- Gastric cancer
- Hepatocellular carcinoma

Preclinical Observations

- Improved overall survival
- Reduced tumor size
- Reduced and/or inhibited metastases

AACR 2025 Abstracts:

- Kim, M., Sugahara, K., et al. *iRGD peptide therapy transforms immunosuppressive microenvironment to immune-favorable state in pancreatic ductal adenocarcinoma* (https://www.abstractsonline.com/pp8/#!/20273/presentation/5422).
- Miyamura, N., Sugahara, K., et al. *A cytotoxic peptide designed for tumor-targeted delivery of co-injected molecules* (https://www.abstractsonline.com/pp8/#!/20273/presentation/3881).
- Kuroda, Y., Sugahara, K., et al. *The iRGD tumor-penetrating peptide inhibits TGF-β activation mediated by an αvβ5 integrin-rich tumor microenvironment in pancreatic cancer* (https://www.abstractsonline.com/pp8/#!/20273/presentation/5404).
- Choi, Y., Sugahara, K., et al. *Altered collagen morphology in pancreatic cancer treated with the iRGD tumor-penetrating peptide* (https://www.abstractsonline.com/pp8/#!/20273/presentation/5419).

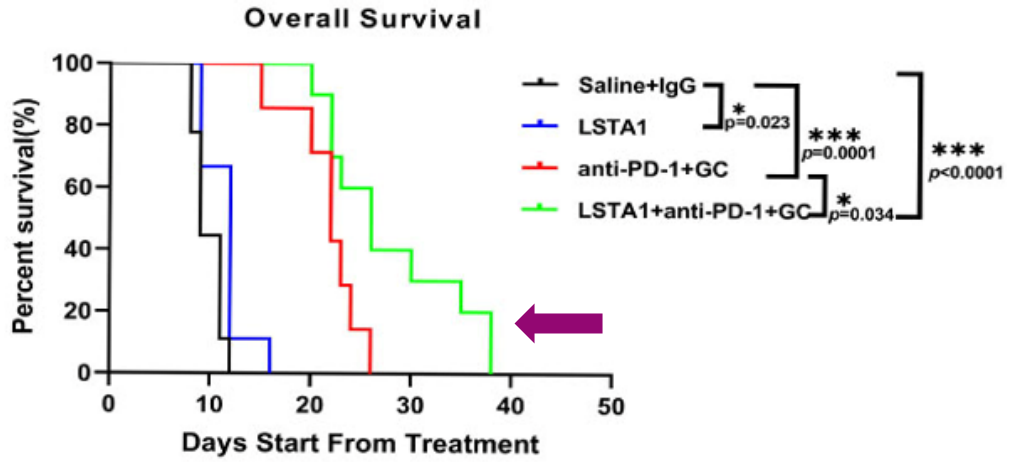
Sugahara, K., et al. bioRxiv 2023.05.24.542137; doi: https://doi.org/10.1101/2023.05.24.542137
Yuan, D., Duda, D., et al. 2024 CCA Foundation Conference. Poster: *Enhancing the efficacy of standard therapy in intrahepatic cholangiocarcinoma using LSTA1, a novel tumor targeting and penetration agent.*

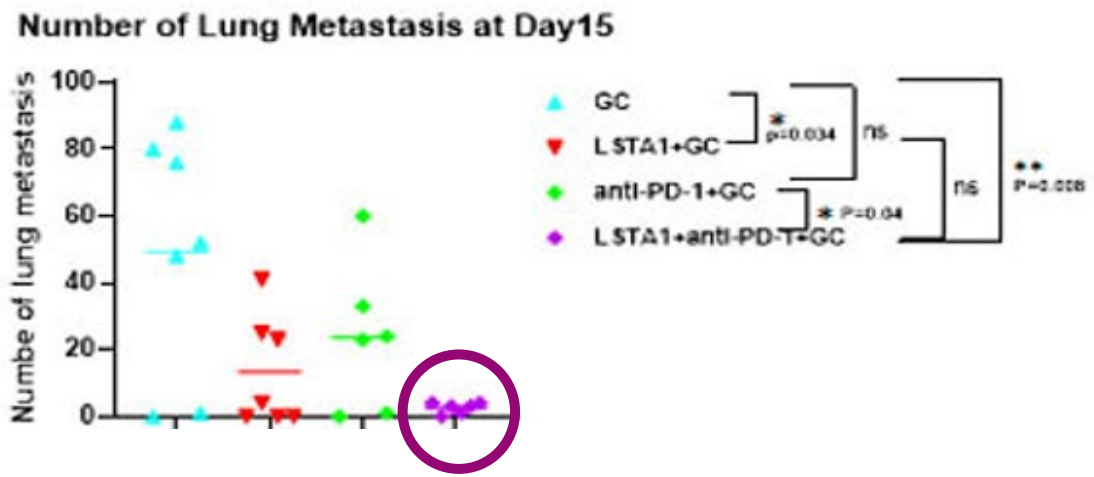
Sugahara, et al. 2015; Sugahara, et al. 2010
Yang, et al. 2019a; Yang, et al. 2019b
Zhang et al 2016b
Dong, et al. 2023

Certepetide improves immunotherapy impact in cholangiocarcinoma

- Intrahepatic cholangiocarcinoma (ICC) has an immunosuppressive TME and a dense desmoplastic stroma with abnormal vasculature which together impede anti-cancer agent efficacy
- Lung metastases often lead to a significant decline in survival
- Human ICC SoC (gemcitabine/cisplatin/durvalumab) efficacy improved with certepetide in murine model

ICC mouse model





**Certepetide was formerly known as LSTA1*

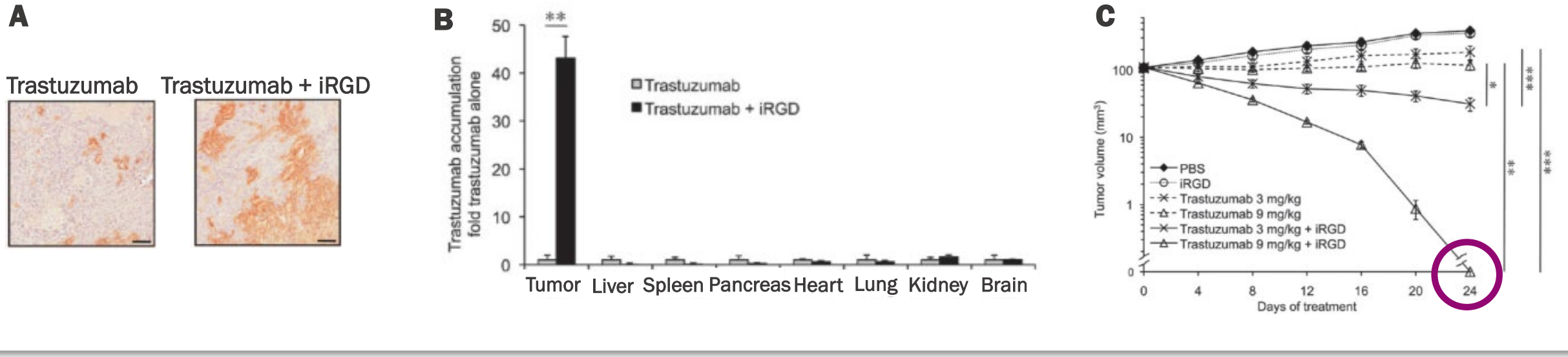
Certepetide combined with chemo- and immunotherapy improves survival, reduces morbidity and inhibits metastasis in cholangiocarcinoma mouse model

Yuan, D., Duda, D., et al. CCA Foundation Conf. (2024) Poster. *Enhancing the efficacy of standard therapy in intrahepatic cholangiocarcinoma using LSTA1, a novel tumor targeting and penetration agent*

iRGD enhances selective tumor penetration of trastuzumab

Mouse model injected with human BT474 breast tumors

Trastuzumab is a monoclonal Ab that inhibits HER2



- Panel A shows greater staining for trastuzumab in breast cancer tissue with iRGD
- Panel B shows remarkable selectivity for tumor tissue with iRGD
- Panel C shows iRGD co-administered with trastuzumab leads to **tumor shrinkage**

Sugahara, et al. 2010

Certepetide is a proprietary iRGD; experiments denoting iRGD use a non-proprietary certepetide analog with differs in structure by a single acetyl group.

Certepetide development strategy: A two-pillar approach

Pursue rapid global registration in mPDAC, initially combined with gemcitabine/nab-paclitaxel standard-of-care (SoC)

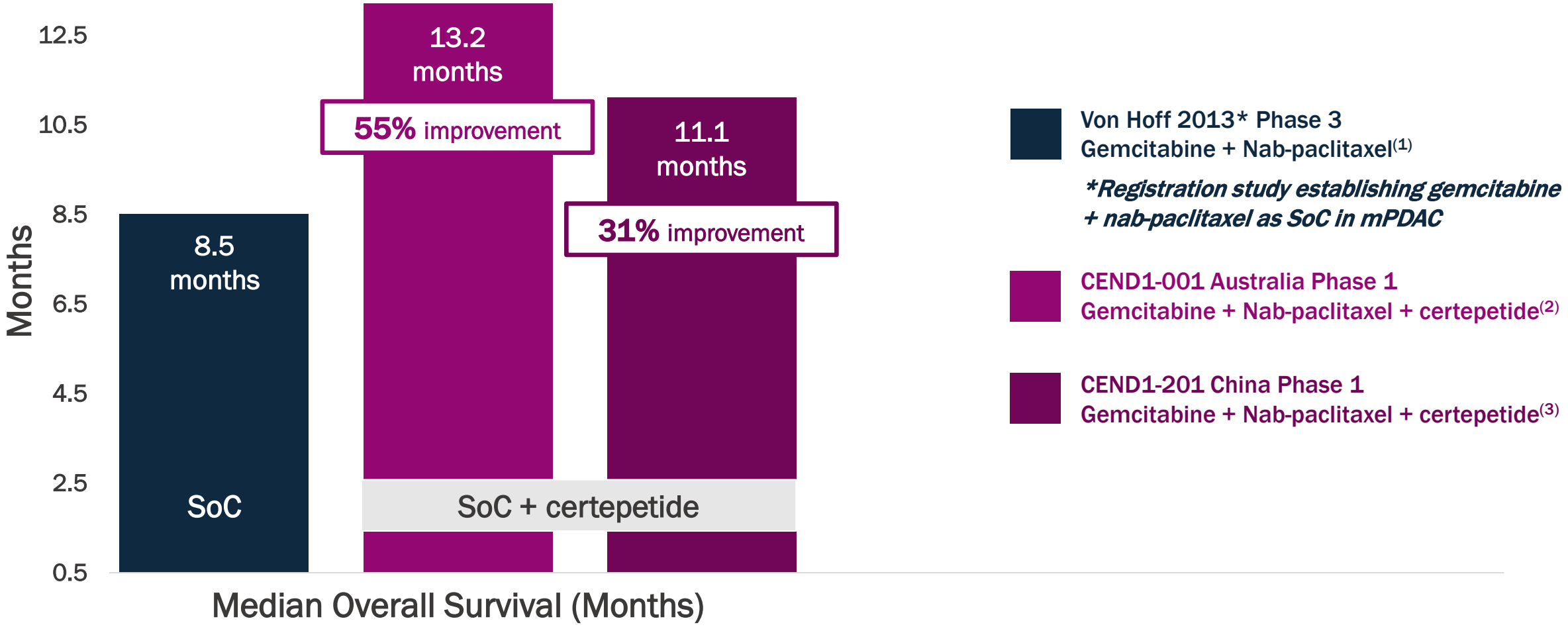
- ***Positive ASCEND Phase 2b preliminary results***
- ***Phase 3 preparation underway***

Demonstrate certepetide effectiveness when combined with a variety of other SoC regimens (e.g., chemotherapy, immunotherapy, etc.) in a variety of solid tumors

- ***Multiple Phase 2a studies underway***

**TGA: Therapeutic Goods Administration (Australia)*

Certepetide improved survival in mPDAC in two independent, multicenter Phase 1 trials



[1] Von Hoff D, et al., *New England Journal of Medicine,* 2013.
[2] Dean A, et al., *The Lancet Gastroenterology & Hepatology*, 2022
[3] QILU Pharmaceutical

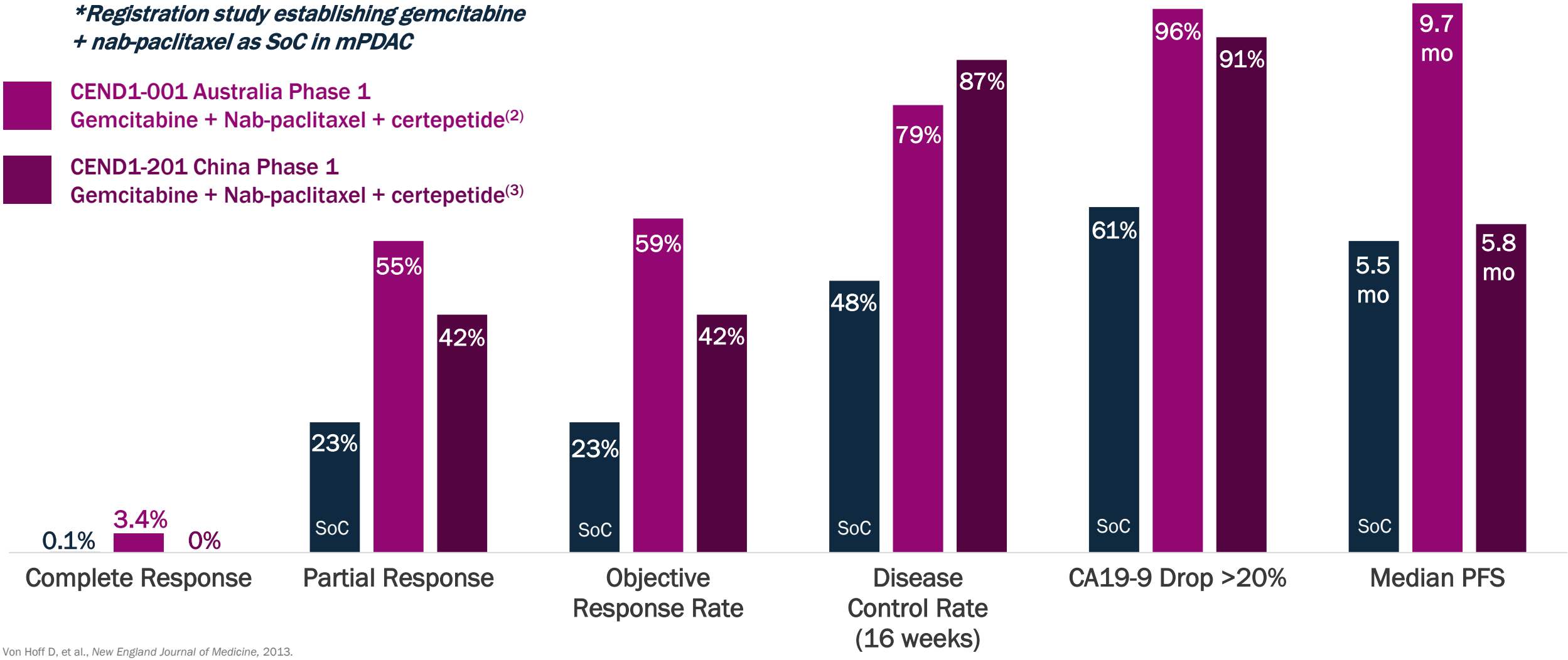
Certepetide demonstrated internal consistency of response in two Phase 1 trials

Von Hoff 2013* Phase 3
Gemcitabine + Nab-paclitaxel[1]

Registration study establishing gemcitabine + nab-paclitaxel as SoC in mPDAC

CEND1-001 Australia Phase 1
Gemcitabine + Nab-paclitaxel + certepetide[2]

CEND1-201 China Phase 1
Gemcitabine + Nab-paclitaxel + certepetide[3]



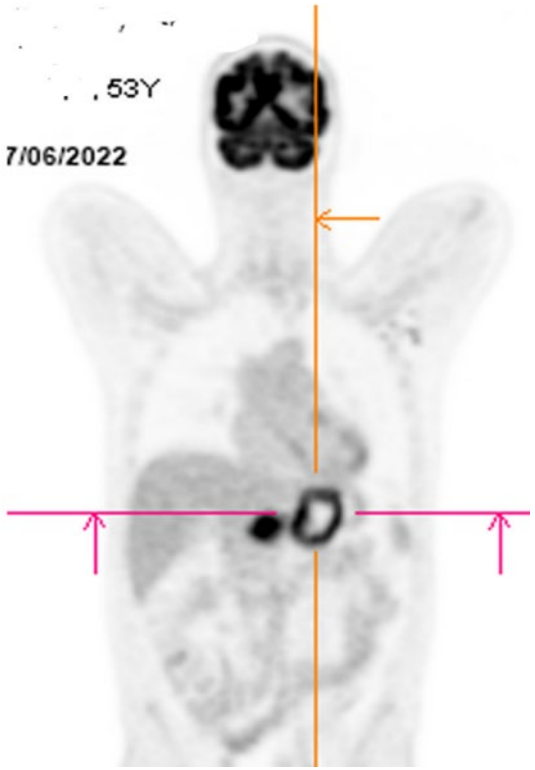
[1] Von Hoff D, et al., *New England Journal of Medicine*, 2013.
[2] Dean A, et al., *The Lancet Gastroenterology & Hepatology*, 2022
[3] QILU Pharmaceutical

Remarkable evidence of certepetide activity in other solid tumors

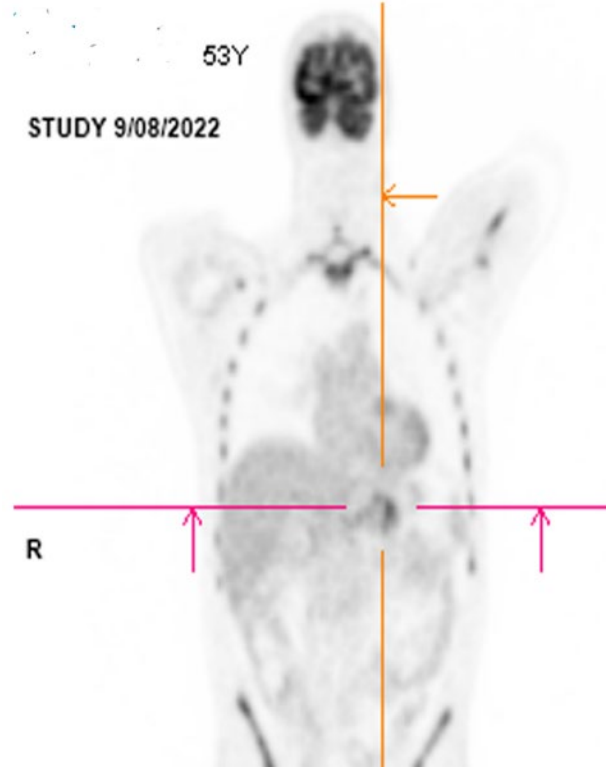
Certepetide potentiated a complete response in metastatic gastroesophageal adenocarcinoma (mGEAC)

- 53-year-old male with mGEAC with significant (> 5cm) nodal metastases (June 2022)
- SoC combination chemotherapy (FOLFIRINOX) and radiotherapy, with immunotherapy (pembrolizumab) later added, resulting in partial response
- Certepetide added to above regimen at cycle 7 and exploratory laparoscopy after cycle 18 (September 2022) showed **no discernable disease**
- **31+ months with sustained complete response**

FDG-PET* scan June 2022



FDG-PET scan Sept. 2022



Reduction in FDG activity demonstrated[1]

**Fluorodeoxyglucose (FDG)-positron emission tomography (PET)*

[1] Buck, K.K, Dean, A., McSweeney, T. LSTA1 Potentiates Complete Response in Metastatic Gastroesophageal Adenocarcinoma. Oncol Cancer Case Rep. 2023, 9(6), 001-003

ASCEND: Phase 2 study of certepetide in mPDAC

Investigator initiated trial *inherited* through acquisition of Cend Therapeutics

- **Sponsor:** Australasian Gastro-Intestinal Trials Group (AGITG) and NHMRC Clinical Trials Centre of University of Sydney (Australia)
  - Lisata-funded, data contractually sponsor-controlled
    - Restricts initial public results announcements to scientific meetings or publications
- **'Academic design'** overlooked global regulatory standards supporting eventual approval, e.g.;
  - **Powered for 6-mos. PFS primary endpoint**
  - **Single cohort with one IV push of certepetide 3.2 mg/kg + SoC vs. SoC alone**

Lisata *amended* protocol to ensure trial data will support global registration strategy

- **Lisata** clinical trial data rights defined/expanded
- **'Product development design'** considers eventual regulatory review and approval
  - **Median overall survival (precedent registration endpoint)** added for both cohorts
  - **Second cohort (Cohort B) added with two IV pushes of certepetide 3.2 mg/kg administered 4 hours apart** to further evaluate pharmacodynamics of certepetide consistent with FDA Project Optimus

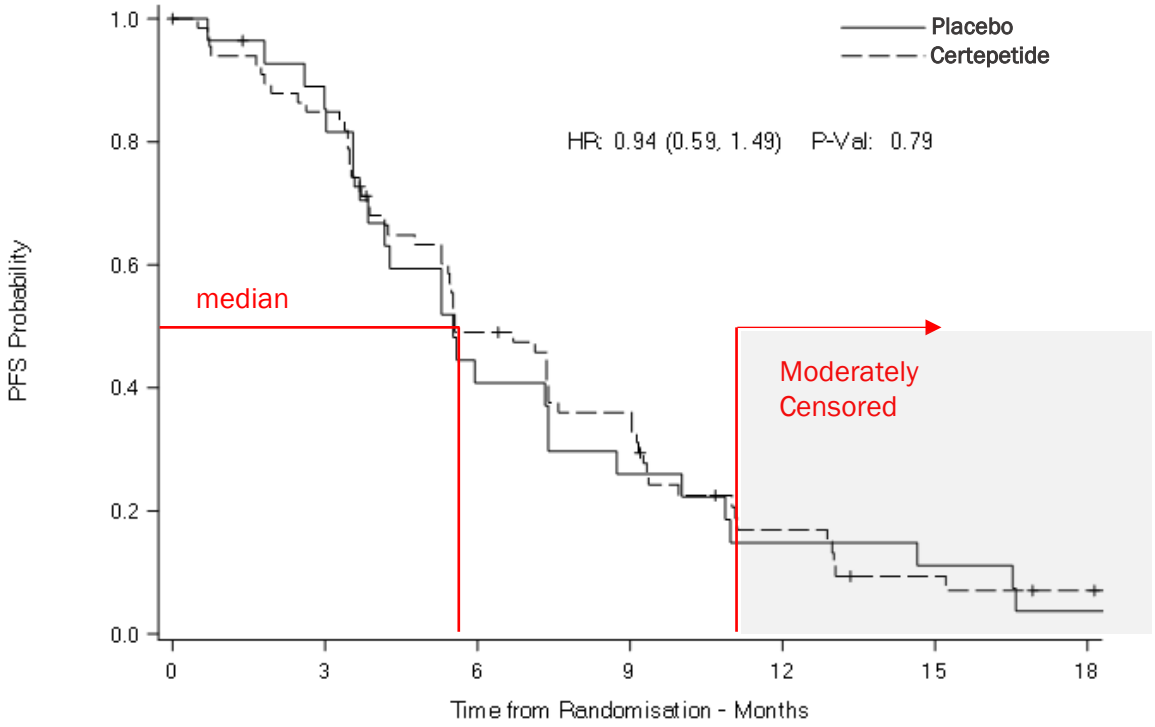
ASCEND: Preliminary Cohort A progression-free survival data

Cohort A

ONE IV PUSH OF CERTEPETIDE + SoC

- Cohort A ***powered*** for 6-month PFS
- No statistically significant improvement shown with certepetide
- *Data mature* - 91% (86 out of 95 patients with Progressive Disease or Death)

Cohort A: Progression-Free Survival (PFS) Data



Treatment arm	N	Median PFS in months (95% CI)
Certepetide	66	5.55 (5.29, 7.39)
Placebo	21	5.52 (3.68, 7.39)

ASCEND: Preliminary Cohort A overall survival data

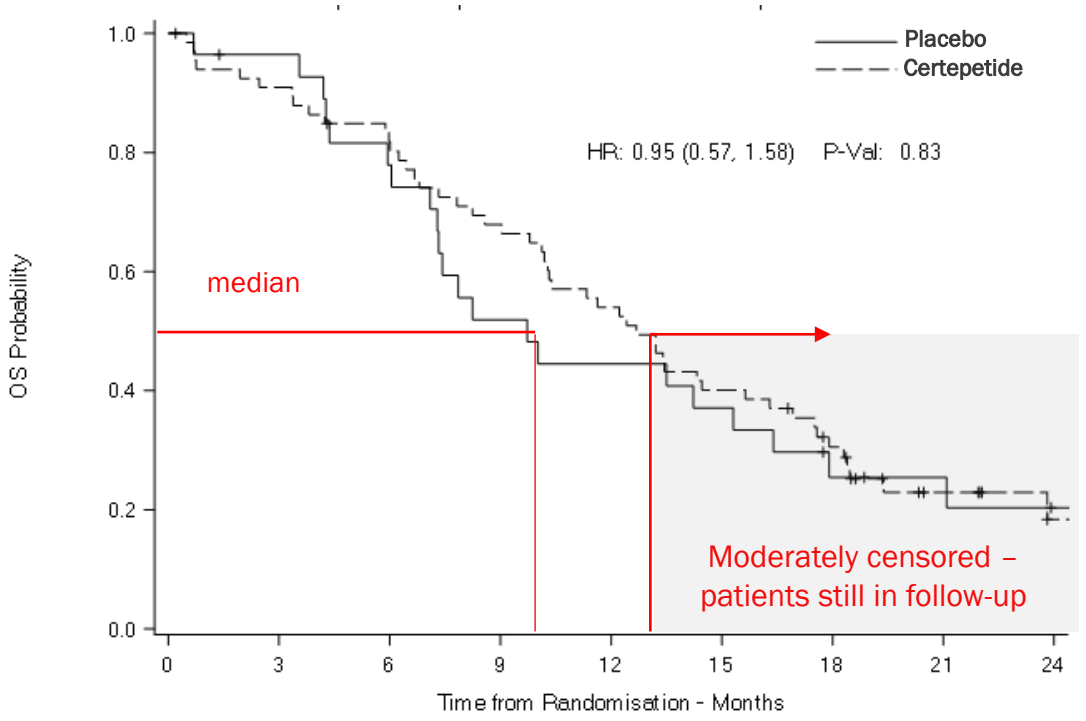
Cohort A

ONE IV PUSH OF CERTEPETIDE + SoC

- Cohort A ***not powered*** for OS
- *Data mature* - 76% (72 deaths out of 95)
- mOS numerically favors certepetide (12.68 vs. 9.72 months); separation occurs at 7 months similar to NAPOLI-3
- Cohort A ORR* data favors certepetide
  - Certepetide – 4 complete responses
  - Placebo – 0 complete responses

*ORR: Objective Response Rate

Cohort A: Overall Survival (OS) Data

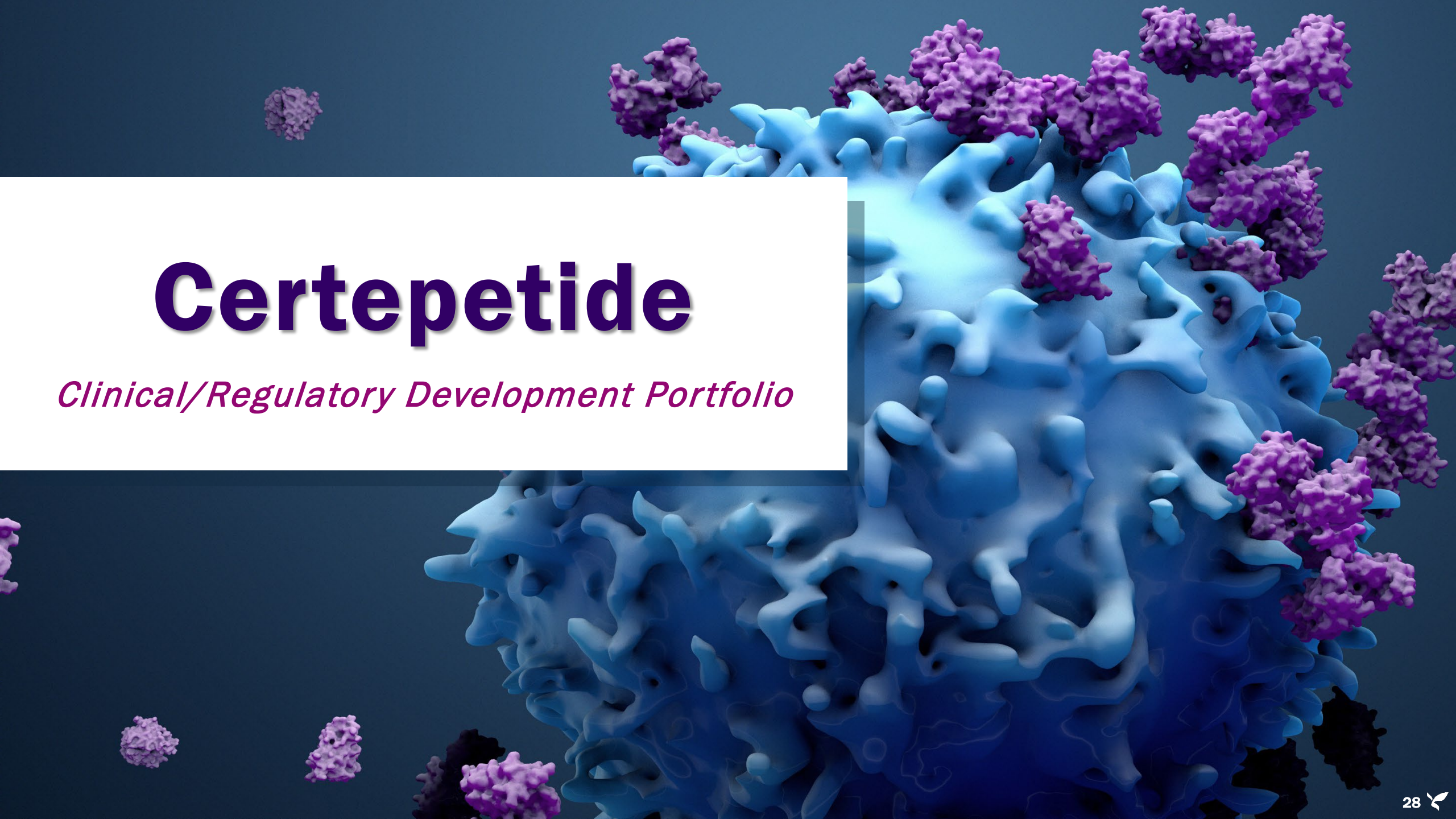


Treatment arm	Participants	Median OS in months (95% CI)
Certepetide	66	12.68 (10.18, 16.30)
Placebo	29	9.72 (7.10, 16.39)

Certepetide improves clinical outcomes in mPDAC with benign safety profile

Certepetide Clinical Data Summary to Date

- Two Phase 1 clinical trials (CEND1-001 in Australia and CEND1-201 in China) demonstrate that **certepetide plus SoC chemotherapy improves overall survival in *metastatic* PDAC akin to the recently FDA-approved NALIRIFOX triplet therapy**
- Certepetide is well tolerated with **no dose-limiting toxicity**
- Cumulative certepetide adverse events reflect companion therapy with which it is administered
- **ASCEND Phase 2 trial Cohort A data demonstrate positive trend in overall survival, including 4 complete responses observed in certepetide treatment group compared to none in placebo group**
  - Preliminary information suggests that Cohort B data will support a benefit of certepetide + SoC versus SoC alone; however, final, definitive data are expected by mid-2025
- **Phase 3 trial preparation underway**



Certepetide

Clinical/Regulatory Development Portfolio

Certepetide special regulatory designations and benefits

FDA Fast Track Designation

- ***Pancreatic cancer (FDA)***

- Eligible for *Accelerated Approval, Priority Review and Rolling Review*
- Provides for program-specific guidance from and frequent communication with FDA

FDA Rare Pediatric Disease Designation

- ***Osteosarcoma (FDA)***

- Eligible for *Priority Review Voucher* upon approval; redeemable for a priority review for any subsequent marketing application, or may be sold or transferred
- Vouchers have sold recently for $75-$100 million and, historically, for up to $350 million

Orphan Drug Designations

- ***Pancreatic cancer (FDA & EMA)***
- ***Malignant glioma (FDA)***
- ***Osteosarcoma (FDA)***
- ***Cholangiocarcinoma (FDA)***

- Eligible for tax credits, marketing exclusivity, fee waivers and development grants
- Provides for specialized regulatory assistance from FDA's Office of Orphan Products Development

**Priority Review Voucher program expires September 2026 and may not be renewed*

Certepetide capital efficient clinical development plan

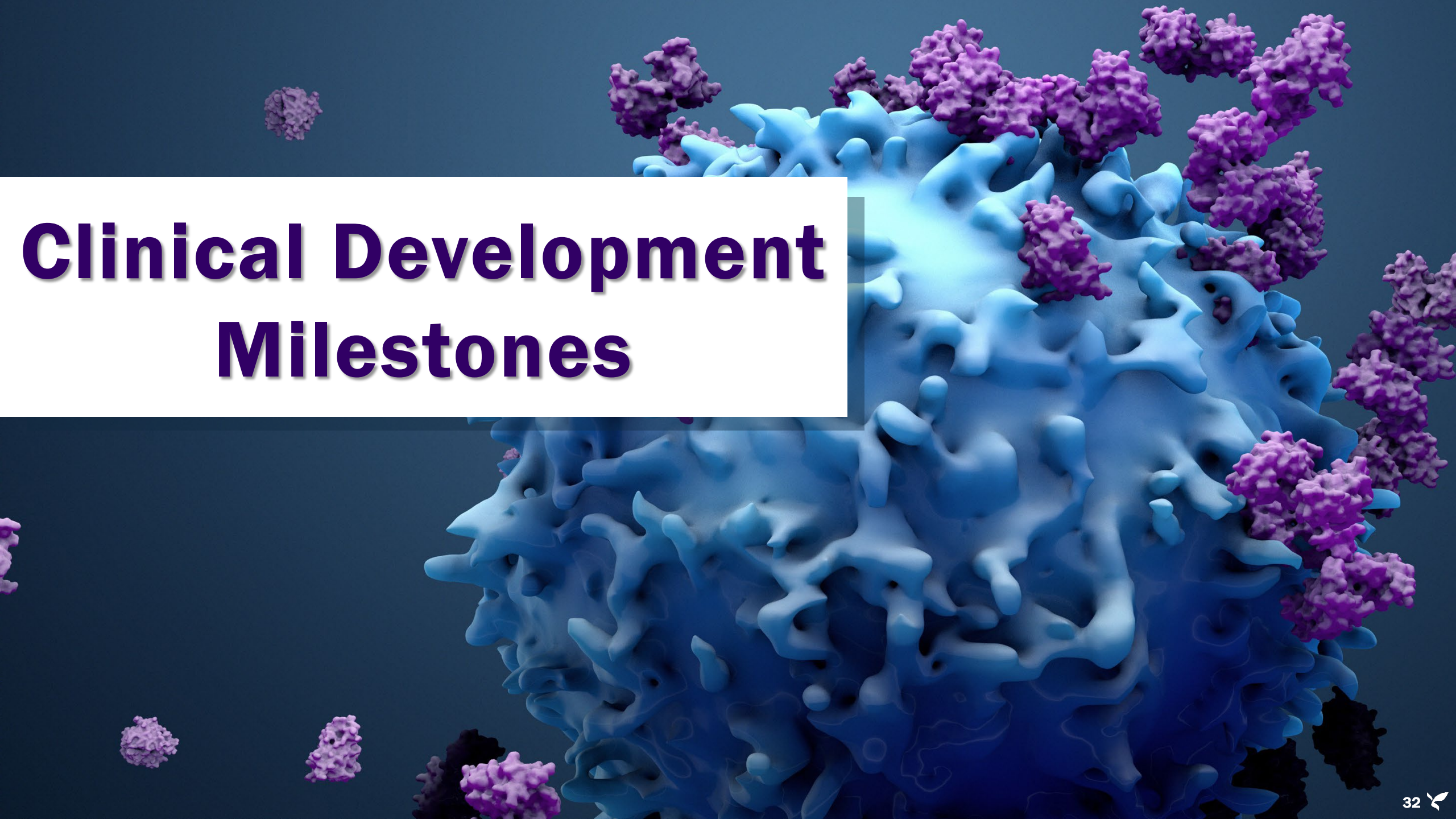
Sponsor(s)	Indication	Description	Current Phase
			Phase 1 / Phase 2 / Phase 3
AGITG/Lisata	*First-line mPDAC*	▪ **ASCEND:** Phase 2b, placebo-controlled trial (N=158) ▪ *Gemcitabine/nab-paclitaxel + certepetide or placebo* ▪ Australia/New Zealand	Enrollment complete
Lisata	*First- and Second-line Cholangiocarcinoma (CCA)*	▪ **BOLSTER:** Phase 2a, placebo-controlled trial ▪ *1L: Gemcitabine/cisplatin/durvalumab + certepetide or placebo* (N=47) ▪ *2L: FOLFOX with certepetide or placebo* (N=22) ▪ United States	1L CCA Enrollment complete 2L CCA Enrollment complete
KUCC/Lisata *Investigator-initiated trial*	*Pancreatic, Colon, and Appendiceal Cancers*	▪ **CENDIFOX:** Phase 1b/2a, open-label trial (N=50) ▪ *FOLFIRINOX + panitumumab* + certepetide* ▪ United States	Enrollment complete
Qilu/Lisata	*First-line mPDAC*	▪ Phase 1b/2a, open-label trial (N=55) ▪ *Gemcitabine/nab-paclitaxel + certepetide* ▪ China	Enrollment complete
WARPNINE/Lisata	*Locally advanced, non-resectable PDAC*	▪ **iLSTA:** Phase 1b/2a, open-label trial (N=30) ▪ *Gemcitabine/nab-paclitaxel/durvalumab + certepetide* ▪ Australia	Enrolling
Tartu University/Lisata *Investigator-initiated trial*	*First-line Glioblastoma Multiforme (GBM)*	▪ Phase 2a, placebo-controlled trial (N=30) ▪ *Temozolomide +/- certepetide* ▪ Estonia/Latvia	Enrolling
Qilu/Lisata	*First-line mPDAC*	▪ Phase 2, placebo-controlled trial (N=96) ▪ *Gemcitabine/nab-paclitaxel + certepetide* ▪ China	Enrollment complete
Lisata	*First-line mPDAC*	▪ **FORTIFIDE:** Phase 1b/2a placebo-controlled trial (N=30) ▪ Gemcitabine/nab-paclitaxel + continuous infusion of certepetide/placebo ▪ United States	Enrollment pending

**Panitumumab may be added for colorectal or appendiceal patients without Ras mutation.*

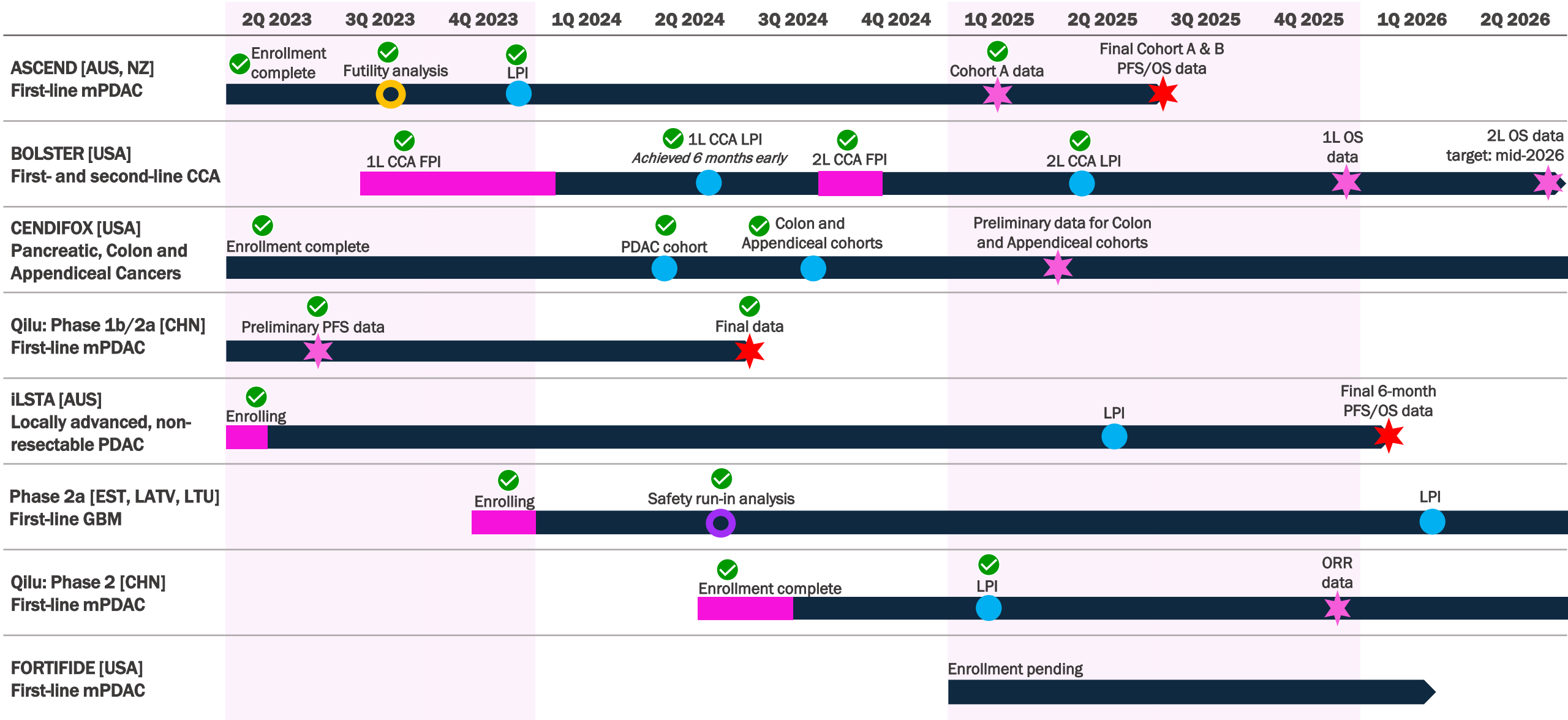
Certepetide preclinical activities and results

Sponsor(s)	Indication	Objective and Description	Results
University of Cincinnati/Lisata	*Endometriosis*	**Assess the therapeutic effect of adding certepetide to bevacizumab (VEGF inhibitor) on the size and number of endometriotic lesions.** ▪ Certepetide + bevacizumab ▪ Murine endometriosis model C57BL/6J ▪ United States	▪ Encouraging early signals suggest further investigation ▪ Next steps contingent on funding
Valo Therapeutics/Lisata	*Melanoma*	**Assess the therapeutic effects of PeptiCRAd (oncolytic virus), certepetide, and a checkpoint inhibitor (CPI) on systemic T cell responses, T cell infiltration into tumors, and impact on tumor growth control.** ▪ Certepetide + PeptiCRAd + CPI ▪ Murine melanoma model B16-OVA ▪ Finland	▪ Target date for data: 2H2025
Catalent/Lisata	*Solid tumors*	▪ Assess the therapeutic effects of certepetide and Catalent's SMARTag® antibody-drug conjugate dual-payload technology platform for the treatment of difficult-to-treat-diseases.	▪ Target date for data: 2H2025

Clinical Development Milestones



A wealth of anticipated key certepetide clinical milestones



- PFS: Progression-free Survival
- OS: Overall Survival
- ORR: Objective Response Rate

**Several of these studies are investigator-initiated trials. Lisata has limited control and thus, timelines and expectations may be subject to change.*

Financial Highlights

Capital projected to fund all clinical programs to data

Cash & Investments As of 3/31/2025	Debt	Projected Cash Runway into
$25.8M	**$0**	**3Q2026**

Common Shares Outstanding (3/31/2025):	8.6 million shares
Options Outstanding (3/31/2025): Exercise Price: $0.02 - $4.22 = 1,310,700 shares Exercise Price: > $4.22 = 218,700 shares	1.5 million shares
Warrants Outstanding (3/31/2025): Weighted Average Exercise Price: $40.52	1.5 million shares

Key factors supporting investment in Lisata Therapeutics

PEOPLE

Seasoned management with successful international drug development experience and expertise

INTELLECTUAL PROPERTY

Proprietary field-leading technology with global IP protection extending beyond 2040

MILESTONES

Multiple product and business milestones projected over the next 12 - 18 months

CAPITAL

$25.8 million cash*- no debt; Funds to support advancement of current clinical programs

PARTNERING

Platform technology validated by existing partnerships with potential for many others

* As of 3/31/2025; includes investments

LISATA THERAPEUTICS

Targeted Therapy *Delivered*

Investor Relations Contact:
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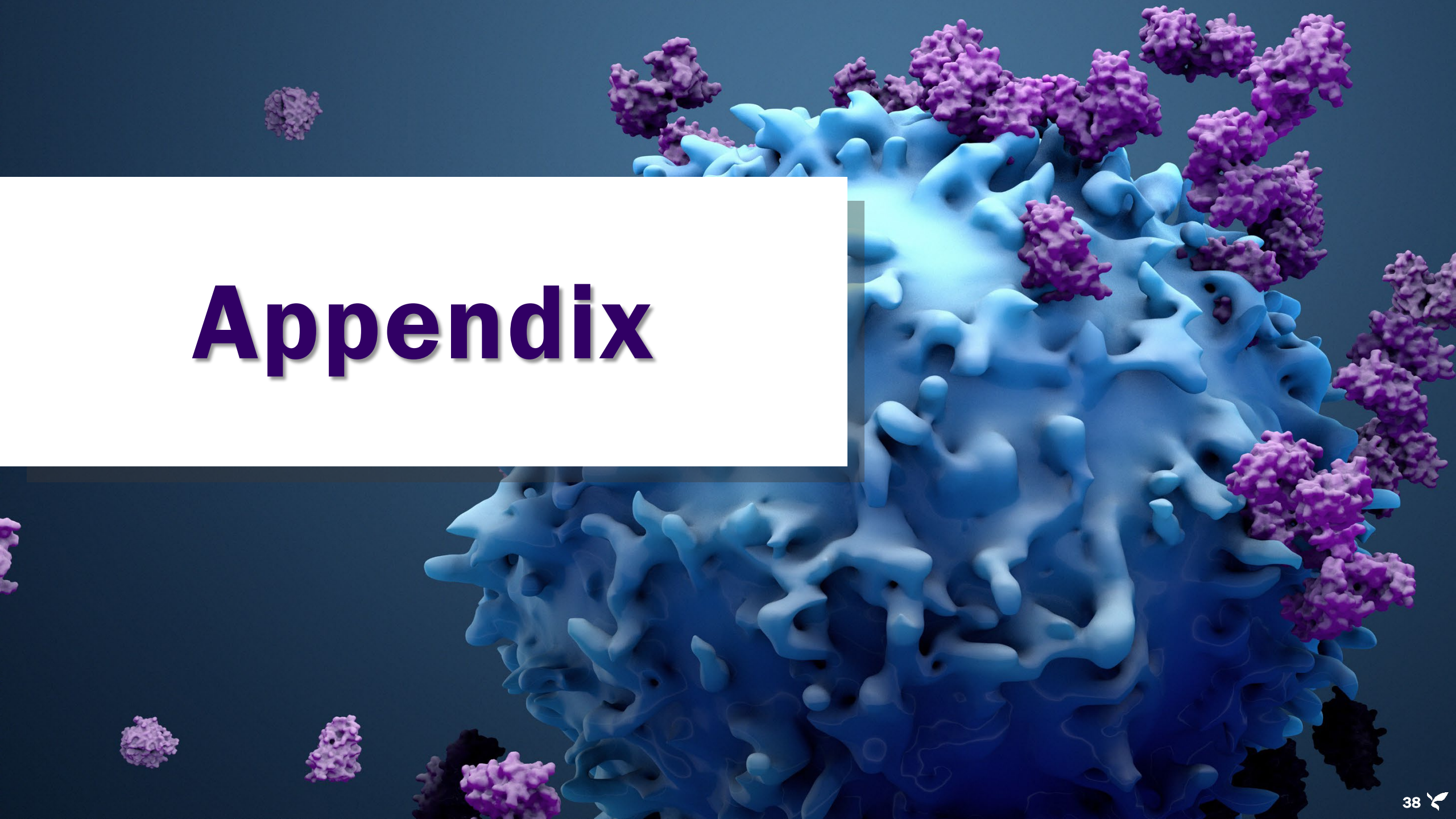
Nasdaq: LSTA | *www.lisata.com*



Appendix

Certepetide capital efficient clinical development plan

Development Partner(s) [Development Venue]	Indication and Trial Product/Comparator	Stage of Development	Strategic Rationale
Lisata/AGITG [Australia/New Zealand]	**First-line mPDAC;** Gemcitabine/nab-paclitaxel with certepetide or placebo	Phase 2b (**ASCEND**)	Corroborate Phase 1b results in a placebo-controlled trial and evaluate 2 dose regimens of certepetide for dose optimization
Lisata [United States]	**First- and Second-line Cholangiocarcinoma (CCA);** 1L CCA: Gemcitabine/cisplatin/durvalumab + certepetide or placebo 2L CCA: FOLFOX + certepetide or placebo	Phase 2a (**BOLSTER**)	Assess certepetide safety and effectiveness in cholangiocarcinoma in a placebo-controlled trial (proof-of-concept)
KUCC/Lisata* [United States]	**Pancreatic, Colon & Appendiceal Cancers;** FOLFIRINOX + panitumumab** with certepetide	Phase 1b/2a (**CENDIFOX**)	Tumor immuno-profiling pre- & post- treatment and certepetide effectiveness assessment in combination with chemo and an EGFR inhibitor (open-label)
Qilu [China]	**First-line mPDAC;** Gemcitabine/nab-paclitaxel + certepetide	Phase 1b/2a	Assess safety, PK and therapeutic effect of certepetide in Chinese patients (open-label)
WARPNINE/Lisata [Australia]	**Locally Advanced, Non-Resectable PDAC;** Gemcitabine/nab-paclitaxel/durvalumab + certepetide	Phase 1b/2a (**iLSTA**)	Assess certepetide safety and effectiveness in combination with IO & Chemo in locally advanced PDAC; determine if inoperable tumors can become operable (open-label)
Tartu University/Lisata* [Estonia/Latvia]	**First-line Glioblastoma Multiforme (GBM);** Temozolomide +/- certepetide	Phase 2a	Assess certepetide safety and effectiveness in additional tumor type (GBM) in a placebo-controlled trial
Qilu [China]	**First-line mPDAC;** Gemcitabine/Nab-paclitaxel + certepetide	Phase 2b	Continue development of certepetide in China (placebo controlled)
Lisata [United States]	**First-line mPDAC;** Gemcitabine/nab-paclitaxel + continuous infusion of certepetide or placebo	Phase 1b/2a (**FORTIFIDE**)	Evaluate the safety, tolerability, and efficacy of a 4-hour continuous infusion of certepetide in combination with SoC in subjects with mPDAC who have progressed on FOLFIRINOX. Haystack MRD™ technology to measure ctDNA for early efficacy exploration.

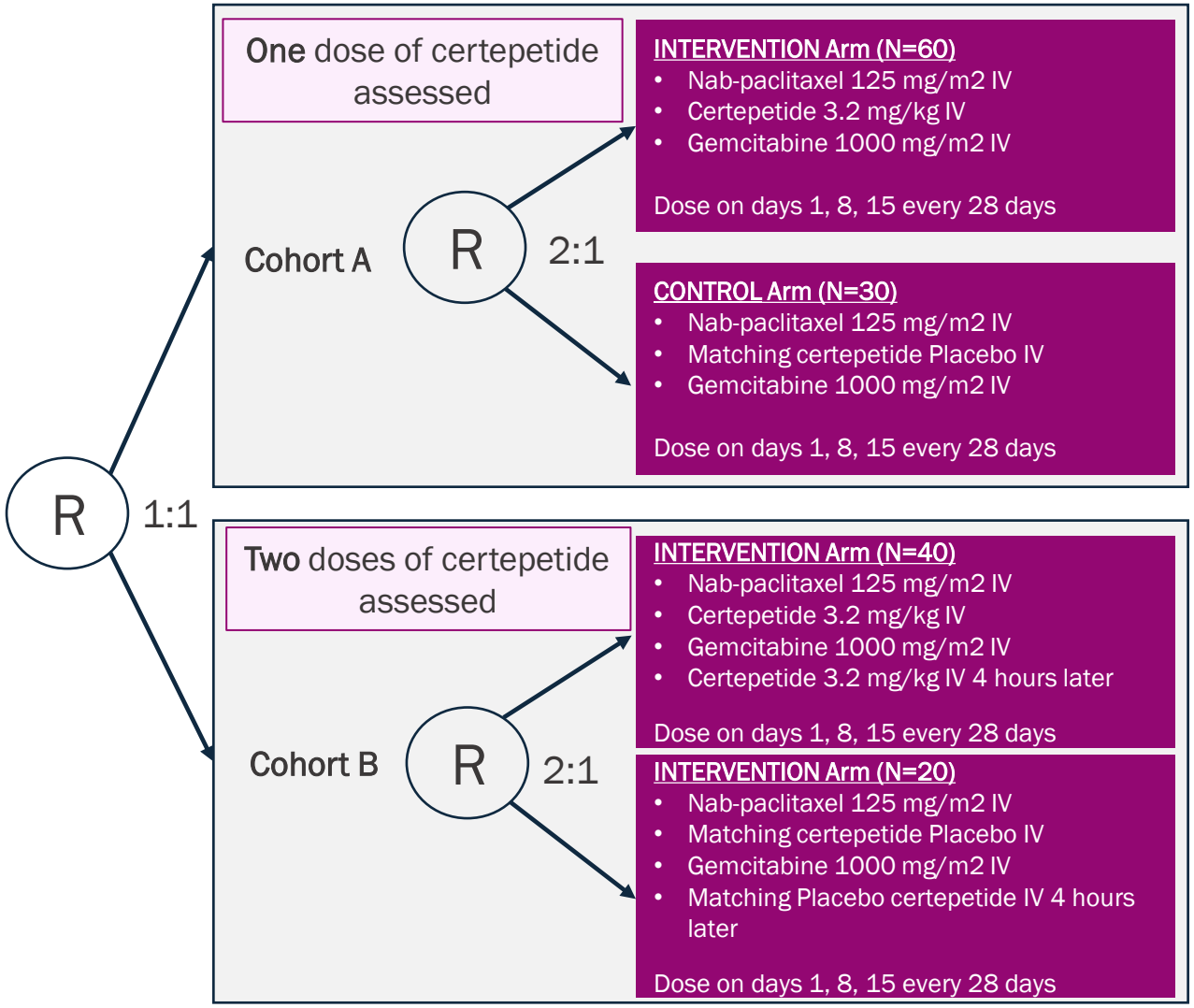
**Investigator-initiated trial*
***Panitumumab may be added for colorectal or appendiceal patients without Ras mutation*

ASCEND: Phase 2b, blinded, randomized trial in mPDAC

Sponsor/Partner	▪ Australasian Gastro-Intestinal Trials Group (AGITG) in collaboration with the NHMRC Clinical Trials Centre at the University of Sydney ▪ Lisata funded (LSTA eligible for ~43% rebate on all qualified R&D expenses in AUS)
Objective	▪ Corroborate Phase 1b results in a placebo-controlled study ▪ Determine if a second dose of certepetide further improves patient outcomes
Design	▪ Phase 2b randomized, double-blind study in mPDAC testing gemcitabine + nab-paclitaxel SoC with one of two certepetide dose regimens or placebo
Study Size	▪ N=158 (~30 sites in Australia and New Zealand)
Endpoints	▪ Primary: Progression Free Survival ▪ Secondary: AEs, SAEs, Overall Survival, Objective Tumor Response Rate
Timing	▪ Enrollment completed December 2023 ▪ Cohort A data released 1Q25 with Cohort B expected in 2Q25

ASCEND: Phase 2b, blinded, randomized trial in mPDAC

Phase 2b randomized, double-blind study in mPDAC testing gemcitabine + nab-paclitaxel (SoC) with two certepetide dose regimens or placebo



- **Sponsor/Partner:** AGITG in collaboration with the NHMRC Clinical Trial Centre at the University of Sydney
- **LSTA funded**
- **Timing:** Enrollment completed December 2023; Cohort A data released 1Q25 with Cohort B expected in 2Q25

Endpoints
- Progression Free Survival (PFS)
- ORR
- OS
- Safety
- QoL
- Exploratory Endpoints

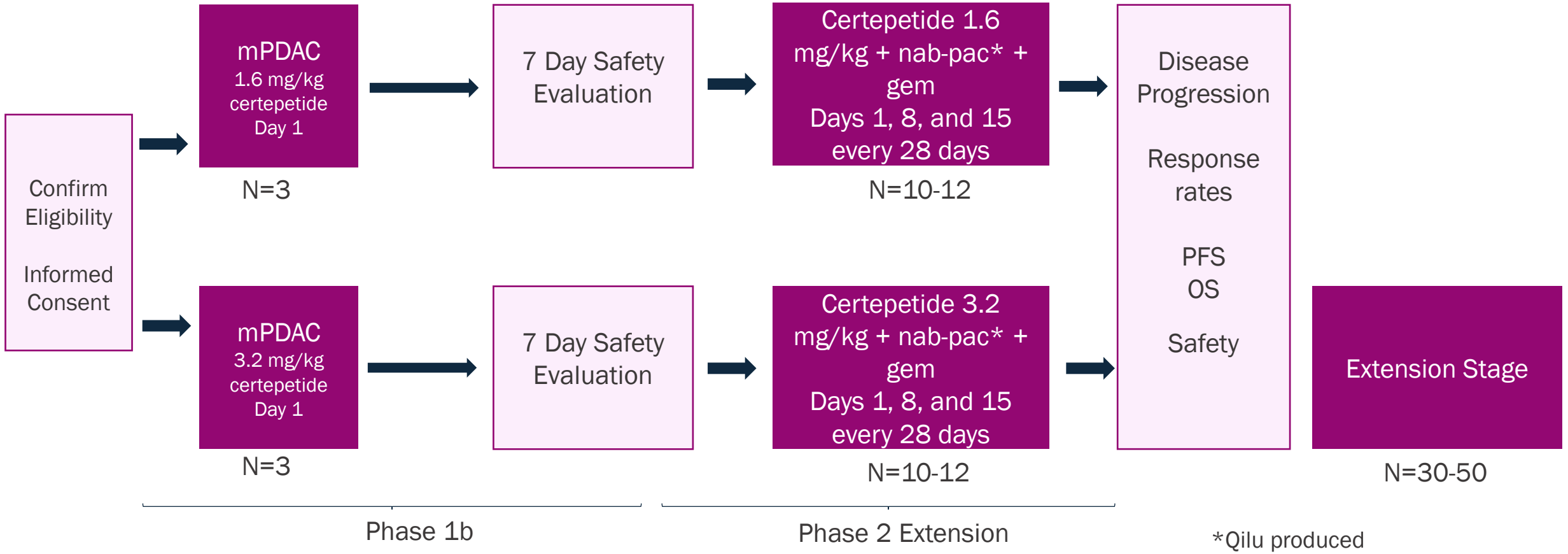
Phase 1b/2a open-label trial in mPDAC in China (CEND1-201)

Sponsor/Partner	▪ Qilu Pharmaceutical (funds all development in China)
Objective	▪ Evaluate safety, pharmacokinetics and preliminary efficacy of certepetide added to SoC in Chinese patients with mPDAC
Design	▪ Phase 1b/2a open-label study in advanced mPDAC patients of Chinese ethnicity testing SoC chemotherapy (gemcitabine + Qilu-produced nab-paclitaxel) in combination with certepetide
Study Size	▪ N=55 (~15 sites)
Endpoints	▪ Primary: AEs, SAEs, Objective Response Rate, Duration of Response, Disease Control Rate, Overall Survival, and Progression Free Survival ▪ Secondary: Pharmacokinetic parameters
Timing	▪ Preliminary data was presented at the 2023 ASCO Annual Meeting

Phase 1b/2a open-label trial in mPDAC in China (CEND1-201)

Phase 1b/2a study evaluating the safety, pharmacokinetics, and preliminary efficacy of certepetide for injection in Chinese patients with advanced metastatic pancreatic ductal adenocarcinoma

- **Sponsor/Partner:** Qilu Pharmaceutical (funds all development in China)
- **Timing:** Preliminary data was presented at the 2023 ASCO Annual Meeting



*Qilu produced

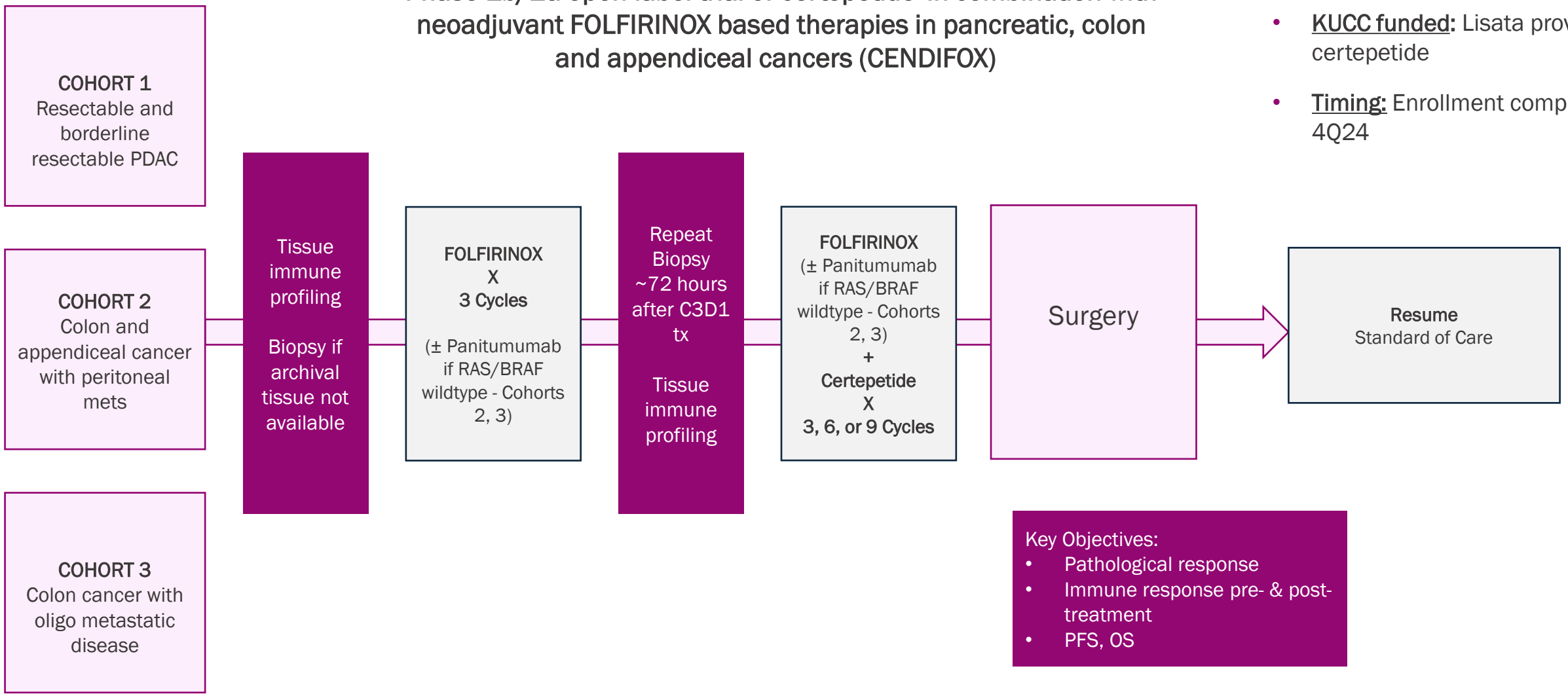
CENDIFOX: Phase 1b/2a open-label trial in PDAC and other cancers

Sponsor/Partner	▪ University of Kansas Medical Center (Investigator initiated trial in U.S.) ▪ KUCC funded; Lisata provides certepetide
Objective	▪ Evaluate the safety and therapeutic effect of certepetide in combination with neoadjuvant FOLFIRINOX-based therapies and an EGFR inhibitor for the treatment of pancreatic, colon and appendiceal cancers and determine immuno-profiling in tumor pre- & post- treatment
Design	▪ Phase 1b/2a open-label study in resectable pancreatic, colon with oligo metastases and appendiceal with peritoneal metastases cancers testing SoC chemotherapy (neoadjuvant FOLFIRINOX-based therapies) with certepetide ± panitumumab
Study Size	▪ N=50 (24 PDAC, 15 colon, and 11 appendiceal)
Endpoints	▪ Primary: Drug Safety ▪ Secondary: Overall Survival, Disease-free Survival, Overall Response Rate, RO Resection Rate, Pathological Response Rate
Timing	▪ Enrollment completed 4Q24

CENDIFOX: Phase 1b/2a open-label trial in PDAC and other cancers

- **Sponsor/Partner:** University of Kansas Medical Center (ITT)
- **KUCC funded:** Lisata provides certepetide
- **Timing:** Enrollment completed 4Q24

Phase 1b/2a open-label trial of certepetide in combination with neoadjuvant FOLFIRINOX based therapies in pancreatic, colon and appendiceal cancers (CENDIFOX)



Key Objectives:
- Pathological response
- Immune response pre- & post-treatment
- PFS, OS

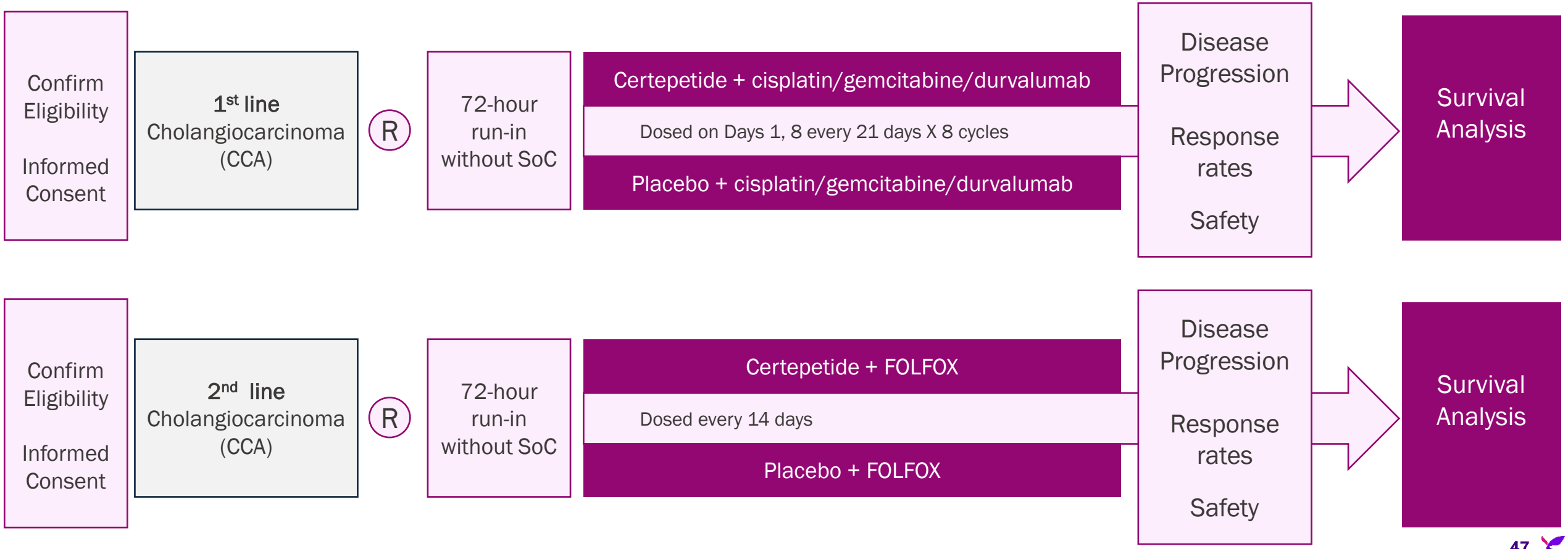
BOLSTER: Phase 2 blinded, randomized trial in cholangiocarcinoma

Sponsor/Partner	▪ Lisata (U.S.)
Objective	▪ Evaluate the preliminary efficacy, safety and tolerability of certepetide in combination with standards of care in subjects with first- and second-line cholangiocarcinoma
Design	▪ Phase 2 randomized, double-blind, placebo-controlled, proof-of-concept trial in first- and second-line cholangiocarcinoma testing corresponding SoC with certepetide or placebo
Study Size	▪ N=69 (1L: N=47, 2L: N=22) ▪ 1:1 SoC + certepetide or SoC + placebo
Endpoints	▪ Primary: OS ▪ Secondary: Safety, ORR, PFS
Timing	▪ Enrollment completed for 1L and 2L CCA

BOLSTER: Phase 2 blinded, randomized trial in cholangiocarcinoma

Phase 2a, double-blind, placebo-controlled, multi-center, randomized study evaluating certepetide when added to standard of care (SoC) versus standard of care alone in subjects with first- and second-line cholangiocarcinoma

- Sponsor: Lisata
- Timing:
  - Enrollment completed for 1L & 2L CCA



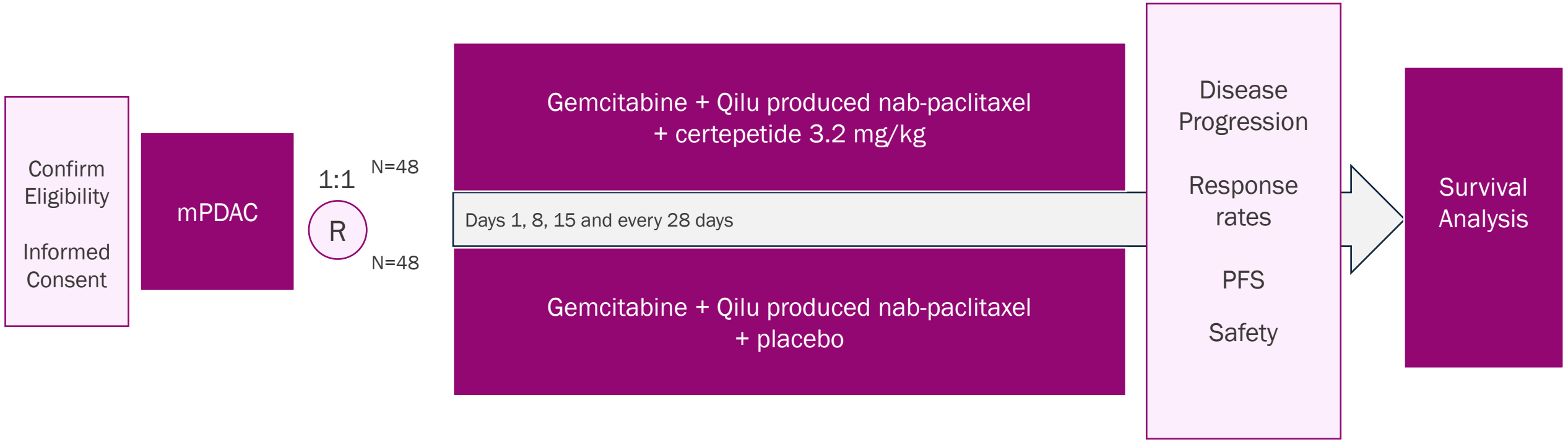
Phase 2 double-blind, placebo-controlled trial in mPDAC in China

Sponsor/Partner	▪ Qilu Pharmaceutical (funds all development in China)
Objective	▪ Further evaluate safety and therapeutic efficacy of certepetide when added to SoC in Chinese patients with locally advanced unresectable mPDAC
Design	▪ Phase 2b, double-blind, placebo-controlled, randomized study evaluating certepetide + SoC (Qilu-produced nab-paclitaxel and gemcitabine) vs. placebo + SoC
Study Size	▪ N=96 (1:1 SoC + certepetide or SoC + placebo)
Endpoints	▪ Objective response rate, progression free survival, duration of response, disease control rate, overall survival ▪ Safety
Timing	▪ Enrollment completed 1Q25

Phase 2 blinded, placebo-controlled trial in mPDAC in China

Phase 2b, double-blind, placebo-controlled, randomized, multicenter study evaluating the safety and efficacy of certepetide when added to standard of care (nab-paclitaxel and gemcitabine) vs. standard of care alone and placebo in Chinese subjects with locally advanced unresectable mPDAC

- **Sponsor/Partner:** Qilu Pharmaceutical (funds all development in China)
- **Timing:** Enrollment completed 1Q25



iLSTA: Phase 1b/2a trial in locally advanced PDAC with chemo & IO

Sponsor/Partner	▪ WARPNINE, Inc. (registered charity in Australia) is funding trial ▪ Lisata providing study drug
Objective	▪ Evaluate safety and therapeutic effect of LSTA1 in combination with IO & Chemo in locally advanced non-resectable pancreatic ductal adenocarcinoma (PDAC); determine if inoperable tumors can become operable
Design	▪ Phase 1b/2a proof-of-concept safety and early efficacy study of LSTA1 in combination with durvalumab, gemcitabine and nab-paclitaxel, as first-line treatment in *locally advanced* non-resectable pancreatic adenocarcinoma
Study Size	▪ N=30
Endpoints	▪ Safety and tolerability; 28-day DLTs ▪ Objective response rate, PFS, OS, duration of response, immune cell infiltration
Timing	▪ Enrollment completion target 1H25

iLSTA: Phase 1b/2a trial in locally advanced PDAC with chemo & IO

Phase 1b/2a proof-of-concept safety and early efficacy study of LSTA1 in combination with durvalumab, gemcitabine and nab-paclitaxel, as first-line treatment in *locally advanced non-resectable* pancreatic ductal adenocarcinoma

Randomize

Cohort 1
Gemcitabine + nab-paclitaxel + Placebo LSTA1 + Placebo durvalumab
N=5

Cohort 2
Gemcitabine + nab-paclitaxel + LSTA1 + Placebo durvalumab
N=5

Cohort 3
Gemcitabine + nab-paclitaxel + LSTA1 + durvalumab
N=up to 20

EUS Biopsy
Screening

12 weeks

Primary Endpoint

8 weeks tumor burden assessments until 24 months or recurrence

12 month
Follow-up

24 months
Follow-up completion

EUS & Biopsy
At weeks 12-16

Tumor burden assessment at screening, cycle 2, and then 8-weekly thereafter. Patients are treated with 28-day cycles until surgery, definitive radiotherapy, unacceptable toxicity, progression or death
Endpoints: safety, DLT, ORR, PFS, OS, DoR, immune profiling

- **Sponsor:** WARPNINE, Inc. - funding trial
- **Timing:** Enrollment completion target 1H25

Preliminary iLSTA Trial Results Poster at 2025 ASCO GI Symposium

ASCO
American Society of Clinical Oncology

Authors:
Andrew Peter Dean[1], Mikael Johansson[2], Ian Yusoff[2], Samarth Rao[2], Susan Sparrow[3], Priyanthi Kumarasinghe[3], Suresh Navadgi[1], Yuki Watanabe[2], Laurence Webber[1], Jenny Grew[3], Alice Talbot[1], Olivia Rose Comito[4].

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1. St John of God Hospital, Subiaco, WA.
2. Sir Charles Gairdner Hospital, Nedlands, WA.
3. Australian Clinical Labs, Subiaco, WA.
4. WARPNINE Incorporated.

iLSTA: Trial in Progress

A safety and early efficacy study of LSTA-1 in combination with durvalumab, gemcitabine and nab-paclitaxel, as first-line treatment in locally advanced pancreatic ductal adenocarcinoma (PDAC)

ASCO Gastrointestinal Cancers Symposium

Background

Pancreatic ductal adenocarcinoma (PDAC) is characterised by a dense, extracellular, matrix-rich stroma, which creates a physical barrier against drug penetration.

It is estimated that less than 1% of the administered chemotherapeutic agent can penetrate the stroma to reach the tumour.

LSTA-1 (formerly known as CEND-1) is an investigational drug that penetrates the dense outer stroma of PDAC, which leads to improved intratumoural delivery of therapeutic drugs, thus, enhancing their effect.

LSTA-1 is a cyclic peptide which selectively binds to αvβ3/β5 integrins that are overexpressed on a tumour's vascular endothelium, and once bound, it is cleaved by proteases into a linear peptide.

This peptide goes on to bind with neuropilin-1 (NRP-1) to increase vascular permeability and activate endocytic/exocytic uptake transport pathways. This leads to enhanced uptake of co-administered drugs.

Regulatory T cells (Tregs) are T cells that suppress immune response and are expressed in high levels in PDAC, further contributing to its resistance to treatment. Specifically, resistance to immunotherapy.

Tregs in PDAC express αvβ5 integrin and NRP-1 thus making them a target for LSTA-1.

Recent studies showed that LSTA-1 leads to a depletion of Tregs in mice, thereby enhancing the effects of immune checkpoint inhibitors such as durvalumab.

Finally, LSTA-1 increases the CD8+ to CD4+ T cell ratio, thus priming the tumour immune landscape. This study will assess the effect of adding immunotherapy to LSTA-1 and standard chemotherapy as first-line treatment in locally advanced PDAC.

Inclusion Criteria

1. Have histologically confirmed, locally advanced pancreatic ductal adenocarcinoma
2. Capable of giving signed informed consent.
3. Age > 18 years.
4. Eastern Cooperative Oncology Group (ECOG) score of 0 or 1.
5. Have either adequate archival tissue from prior biopsy or willingness to undergo tumour biopsy before treatment starts and willing to have tumour biopsy during treatment at 12-16 weeks.
6. Have a negative serum pregnancy test (if premenopausal female). Men and women of child-bearing potential must use effective barrier contraceptive methods during the study.
7. Adequate normal organ and marrow function:
   i. Haemoglobin ≥9.0 g/dL, absolute neutrophil count (ANC) ≥1.5 × 109 /L,
   ii. Platelet count ≥100 × 109/L,
   iii. Serum bilirubin ≤1.5 x institutional upper limit of normal (ULN),
   iv. AST (SGOT)/ALT (SGPT) ≤ 2.5 x institutional upper limit of normal,
   v. Measured creatinine clearance (CL) >60 mL/min/1.73m2 or Calculated creatinine CL>40 mL/min by the Cockcroft-Gault formula (Cockcroft and Gault 1976) or by 24-hour urine collection for determination of creatinine clearance
8. Patient is willing and able to comply with the protocol for the duration of the study including undergoing treatment and scheduled visits and examinations including follow up.
9. Minimum life expectancy of 12 weeks.
10. No significant abnormalities in urinalysis.
11. Have acceptable coagulation status.
12. At least 1 lesion, not previously irradiated, that qualifies as a Response Evaluation Criteria in Solid Tumours (RECIST) 1.1 target lesion (TL) at baseline. Tumour assessment by computed tomography (CT) scan or magnetic resonance imaging (MRI) must be performed within 28 days prior to randomisation, and subsequent imaging should use the same modality.
13. Must be eligible for treatment with nab-paclitaxel and gemcitabine

Method

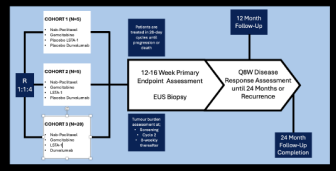
This is a phase I, randomised, single-blind, single-centre, safety and pharmacodynamics study evaluating the safety and tolerability of LSTA-1 in combination with durvalumab, nab-paclitaxel and gemcitabine versus standard of care chemotherapy in patients with locally advanced PDAC.

A total of 30 participants are randomised 4:1:1 in favour of cohort 3.

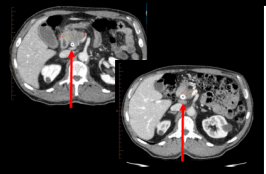
- Cohort 1 (N=5) will receive nab-paclitaxel 125mg/m2 and gemcitabine 1000mg/m2 on days 1, 8, and 15 with placebo durvalumab D1 and 15 and placebo LSTA-1 D1, 2, 8, 15 and 16 in 28-day cycles.
- Cohort 2 (N= 5) will receive nab-paclitaxel 125mg/m2, gemcitabine 1000mg/m2 and LSTA1 3.2mg/kg on days 1, 8, and 15 with placebo durvalumab D1, 15 and placebo LSTA-1 D2 and 16 in 28-day cycles.
- Cohort 3 (N=20) will receive nab-paclitaxel 125mg/m2 and gemcitabine 1000mg/m2 on days 1, 8, and 15 with durvalumab D1, 15 and LSTA1 3.2mg/kg D1, 2, 8, 15 and 16.

An EUS biopsy will be taken at 12-16 weeks and compared to diagnostic samples to ascertain the degree of immune cell infiltration of the tumour in each cohort.

Schema



CT Scan Images



Translational Research

Background: Recent research has identified that bacteria in the human gut microbiome may influence treatment response in patients with PDAC. These bacteria are present in faeces, and are thought to be representative of the bacteria in the pancreatic ductal system. Many bacteria in the *Firmicutes* phylum produce Butyrate, which is known to have several anti-cancer effects. Additionally, *gammaproteobacteria*, which belong to the *Proteobacteria* phylum, secrete the enzyme cytidine deaminase, which is capable of metabolising and deactivating gemcitabine.

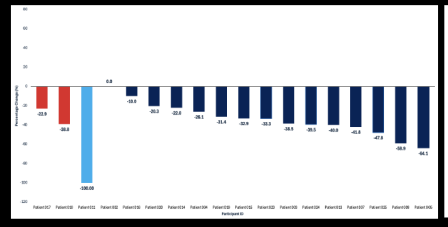
Aim: This study aimed to investigate the relationship between gut microbiome composition and patient response to PDAC anti-cancer therapy, and the effect of anti-cancer treatment on the gut microbiome.

Method: This study involved 14 individuals with locally advanced PDAC from the iLSTA trial. Participants received anti-cancer treatment, with patient response determined through analysis of CA19-9 levels and RECIST guidelines.

Results:
- 9 patients demonstrated strong treatment outcomes with high levels of Firmicutes (>80%) and low levels of Proteobacteria (<0.54%).
- 5 patients demonstrated a reduced treatment response with had low levels of Firmicutes (>44%) and high levels of Proteobacteria (<27%).
- 9/14 had an increase in Firmicutes (8 in C3).
- 10/14 had a decrease in Proteobacteria (9 in C3).
- 8/14 had both an increase in Firmicutes and a decrease in Proteobacteria (7 in C3).

Conclusion: This study revealed a trend towards shifting microbial composition and treatment response. High levels of Firmicutes and low levels of Proteobacteria were associated with improved treatment outcomes. Patients who received immunotherapy developed a more favourable microbiome composition during treatment.

Results: RECIST Classification After 4 Cycles of Treatment



Cohort 1
- 1 PR, 1 SD

Cohort 2
- 1 CR

Cohort 3
- 10 PR, 5 SD

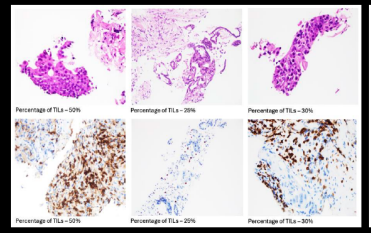
Response Rate: 67%
Disease Control Rate: 100%

6 of the first **7** participants had a major RECIST response after 2 cycles.

Toxicity

- Of the 20 participants on study, 16 participants have received immunotherapy
- 7 participants have experienced immune-related adverse events (irAEs).
- Examples of toxicities that have been observed:
  - Grade 2 hepatitis
  - Grade 2 myositis
  - Grade 2 autoimmune diabetes
  - Grade 2 pancreatitis
  - Grade 3 dermatitis
  - Grade 3 hepatitis
  - Grade 3 colitis (biopsy confirmed)
  - 2 participants discontinued immunotherapy due to toxicity (one of which withdrew consent from the trial following colitis)

Results: Tumour Infiltrating Lymphocytes



Patient biopsies were assessed for 'Tumour Infiltrating Lymphocytes' (TILs).

Of the 8 participants who had their baseline and secondary biopsies analysed for the presence of TILs;
- 6 patients had an increase in TILs (5% to 45%)
  i. 5 patients had a partial response (4 in C3)
  ii. 1 patient had stable disease (C3)
- 1 patient had no change in TILs
  i. Patient had stable disease (C3)
- 1 patient had a decrease in TILs (5%)
  i. Patient had stable disease (C3)

Objectives

Primary Objectives
1. To determine the safety and tolerability of adding LSTA-1 to the combination of durvalumab, gemcitabine, and nab-paclitaxel in subjects with locally advanced pancreatic ductal adenocarcinoma.

Secondary Objectives
1. Disease control rate (DCR).
2. The best overall response rate (ORR).
3. Median progression-free survival (mPFS) and mPFS at 6 months.
4. Duration of response for responding participants.
5. To determine levels of immune cell infiltration in tumour biopsies (pre-treatment and on treatment at 12-16 weeks) in each cohort.

Study Update

- Study Sponsor: WARPNINE Incorporated, Subiaco, WA 6008, Australia
- Contact: admin@warpnine.org.au
- Study Chair: Dr Andrew Dean
- Trial Identifier: ACTRN12623000223639
- Participating site(s): St John of God Subiaco Hospital, 12 Salvado Rd, Subiaco WA 6008
- Anticipated recruitment end date: End of first quarter 2025

Recruitment details:
- 20 participants enrolled
- 3 participants randomised to Cohort 1
- 1 participant randomised to Cohort 2
- 16 participants randomised to Cohort 3
- 4 participants underwent surgery after study

Results: Tumour Markers

		Participant ID																		
	Cycle	003-002	003-003	003-004	003-005	003-007	003-009	001-010	002-011	003-013	003-014	003-015	003-016	001-017	003-019	003-020	003-023	003-024	003-025
CA19-9	Screening	163	251	8435	<2	30208	30	8572	42	1567	3620	409	3008	23	3	8	1347	3106	54
	C1D1	179	-	8223	-	31916	-	-	33	627	-	553	3390	-	8	-	-	3813	6
	C2D1	290	61	6675	1	7835	27	5649	19	169	1102	273	1786	15	6	13	252	2059	12
	C3D1	271	33	3635	<2	948	15	1685	16	55	653	245	919	11	8	7	62	492	14
	C4D1	205	96	1625	4	137	12	411	19	28	1486	112	230	7	32	13	27	167	8
	C5D1	495	187	497	4	244	12	346	19	28	2862	101	148	11	7	11	13	131	15
	C6D1	-	1259	213	<2	220	14	541	15	17	4203	81	90	10	6	6	13	151	-

Summary

Notable early RECIST response rate in combination arms. 10/15 participants in C3 have demonstrated a RECIST partial response (PR) to treatment, 6 of whom had a PR after just 2 cycles.

An encouraging signal of immune engagement has been observed as 6/8 participants demonstrated an increase in TILs during treatment (5 in C3).

Early results suggest a a relationship between gut microbiome composition and response to anti-cancer treatment. Further analysis is ongoing.

Immune related toxicities have been observed in 7 of the 16 participants who received immunotherapy, all of which are recognised as irAEs .

4 participants proceeded to surgery having previously been deemed inoperable.

An abstract with a detailed summary of the poster presentation is also available on the ASCO GI website: https://meetings.asco.org/abstracts-presentations/241611

Phase 2a trial of certepetide with SoC in first-line GBM

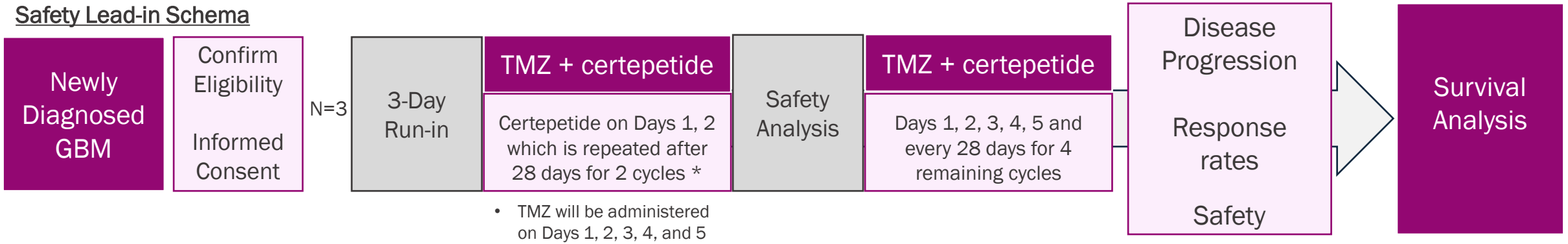
Sponsor/Partner	▪ Tartu University Hospital (Investigator initiated trial in Estonia, Latvia and Lithuania) ▪ Lisata providing study drug and funding trial
Objective	▪ Evaluate safety, tolerability, and therapeutic effect of certepetide in combination with standard-of-care (temozolomide) in patients with previously untreated Glioblastoma Multiforme
Design	▪ Phase 2a proof-of-concept, double-blind, placebo-controlled, randomized study evaluating certepetide when added to standard of care (temozolomide) versus SoC and placebo in subjects with newly diagnosed Glioblastoma Multiforme (GBM)
Study Size	▪ N=30 total (N=3 safety run-in, N=18 in main study schema)
Endpoints	▪ Safety, tolerability ▪ ORR, PFS, OS, disease control rate
Timing	▪ Enrollment commenced December 2023

Phase 2a trial of certepetide with SoC in first-line in GBM

Phase 2a proof-of-concept double-blind, placebo-controlled, randomized, proof-of-concept study evaluating certepetide when added to standard of care (temozolomide) versus temozolomide and matching certepetide placebo in subjects with newly diagnosed GBM

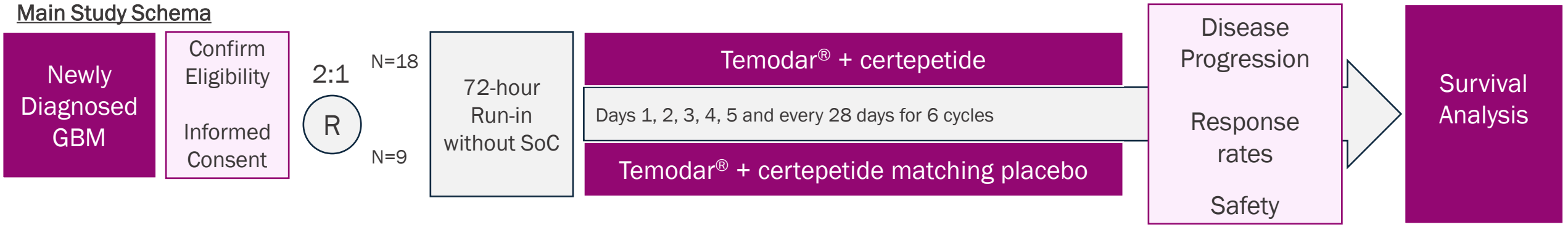
- **Sponsor:** Tartu University Hospital; Estonia
- **Funding:** Lisata
- **Timing:** Enrollment commenced December 2023

Safety Lead-in Schema



- TMZ will be administered on Days 1, 2, 3, 4, and 5 of each cycle

Main Study Schema



FORTIFIDE: Phase 1b/2a continuous infusion study of certepetide

Sponsor/Partner	▪ Lisata (U.S. only)
Objective	▪ Evaluate the safety, tolerability, pharmacodynamics, pharmacokinetics, and efficacy of certepetide when given as a 4-hour continuous infusion in combination with SoC in subjects with first-line mPDAC who have progressed on FOLFIRINOX. Haystack Oncology MRD™ technology to measure ctDNA for early efficacy exploration.

Design	▪ Phase 1b/2a, double-blind, placebo-controlled, three-arm, randomized study evaluating the following treatment arms in subjects with first-line mPDAC who have progressed on FOLFIRINOX:
	  ▪ an intravenous push of certepetide with continuous 4-hour infusion + SoC
	  ▪ a single intravenous push of certepetide with continuous infusion of matching placebo + SoC
	  ▪ an intravenous push of matching placebo with a continuous infusion of matching placebo + SoC

Study Size	▪ N=30
Endpoints	▪ Safety and tolerability ▪ PFS, OS
Timing	▪ Enrollment pending

FORTIFIDE: Phase 1b/2a continuous infusion study of certepetide

Subjects with 1L mPDAC

Obtain Informed Consent

Confirm Eligibility

R

N=10

72 hour Run-in without SoC

Gemcitabine, certepetide 3.2 mg/kg single IV push/4-hour continuous certepetide infusion + nab-paclitaxel Days 1, 8, and 15 every 28 days

N=10

72 hour Run-in without SoC

Gemcitabine, certepetide 3.2 mg/kg single IV push/ 4-hour continuous placebo infusion + nab-paclitaxel Days 1, 8, and 15 every 28 days

N=10

72 hour Run-in without SoC

Gemcitabine, certepetide placebo single IV push/ 4-hour continuous placebo infusion + nab-paclitaxel Days 1, 8, and 15 every 28 days

Primary Endpoint:

- Safety

Secondary Efficacy Endpoints:

- Mean change from baseline in CA19-9 and CEA
- Mean change from baseline in ctDNA (quantitative)
- Pharmacokinetics of certepetide
- ORR, PFS, OS

Secondary Efficacy Endpoints to be assessed:

- At baseline
- C1 Day 1 (2 and 4 hours after dosing)
- C1 Days 8, and 15 pre-dosing for Cycle 1
- Day 1 of each subsequent cycle *until disease progression*

Safety

Biomarkers

PK

Disease Progression

Response rates

PFS

OS