LISATA THERAPEUTICS

Targeted Therapy *Delivered*

David J. Mazzo, Ph.D.
President and Chief Executive Officer

Corporate Presentation | December 3, 2024
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 29, 2024, 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)

WHAT WE ARE

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

OUR 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

Projected cash runway into early 2026, funding all current development programs through data

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
VP of BD and Operations and Corporate Counsel

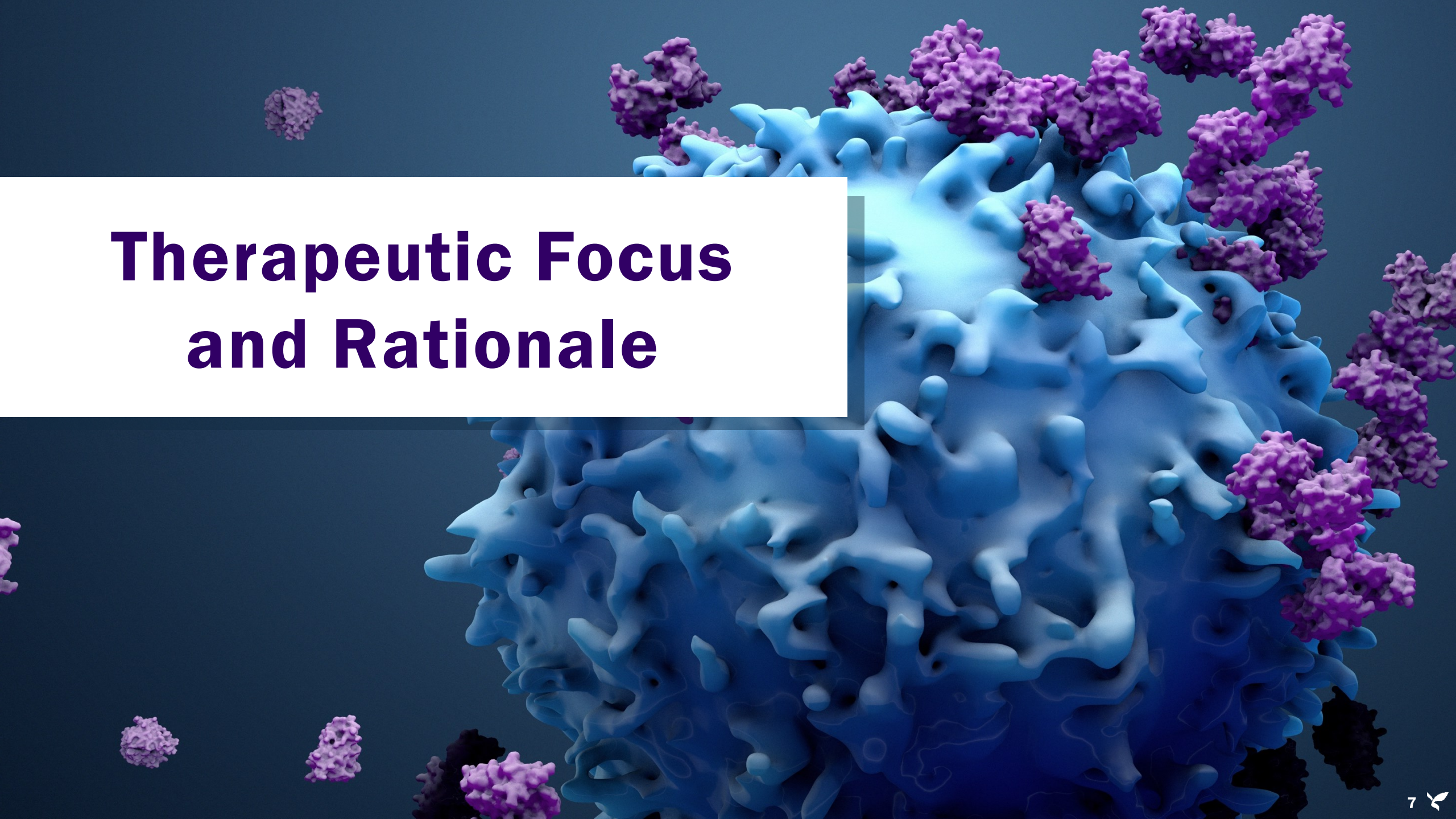
John Menditto
VP of Investor Relations and Corporate Communications

Bill Sietsema, PhD
VP of Global Regulatory Affairs

Ryan Quick
VP of Chemistry, Manufacturing and Controls

Detailed bios can be found at www.lisata.com

Therapeutic Focus and Rationale

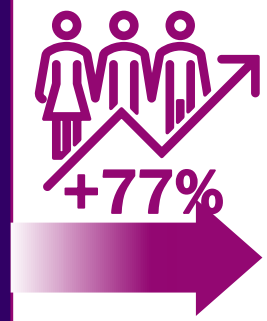


Improved solid tumor treatment remains a vital, growing global need

Over the next 30 years, cancer will cost the world $25 trillion[1]

Globally in 2022[2],[3]

- 20 million new cancer cases
- 10 million deaths
- >90% solid tumors



Globally in 2050[4]

- 35 million new cancer cases
- 18.5 million deaths
- >90% solid tumors

Examples of solid tumors: Lung, breast, pancreas, liver, bile duct (cholangiocarcinoma), kidneys, ovaries, brain, colon, prostate, esophagus, and head & neck.

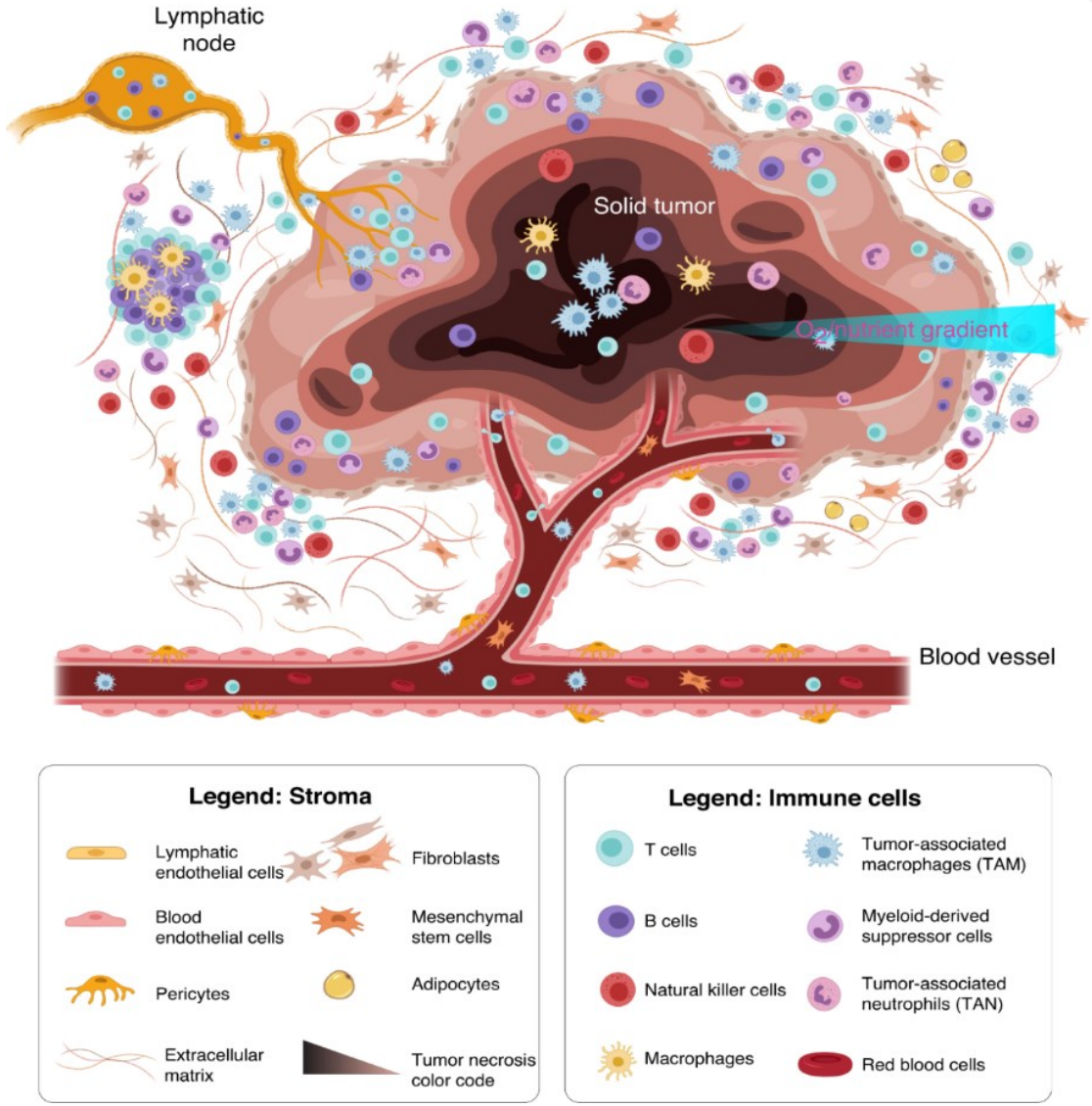
Pancreatic Cancer Stats

- By 2030, PDAC* is predicted to be the second most common cause of cancer mortality[5]
- Today, only 3% of PDAC patients survive for 5 years, with life expectancy at diagnosis of just 4.6 months

**Pancreatic ductal adenocarcinoma (PDAC)*

[1] Cancer will cost the world $25 trillion over next 30 years (nature.com)
[2] 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.
[3] https://seer.cancer.gov/statfacts/html/common.html; data retrieved Nov 2, 2023.
[4] https://www.who.int/news/item/01-02-2024-global-cancer-burden-growing--amidst-mounting-need-for-services; data retrieved Oct 14, 2024.
[5] 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) present major obstacles to optimized 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 designed to optimize solid tumor treatment outcomes

CHALLENGE	APPROACH
Dense stromal barrier physically inhibiting drug entry	Employ *internalizing* RGD* (iRGD) peptide to target tumor and trigger CendR active transport
Immunosuppressive TME which impedes the immune system	Employ specific iRGD that reduces immunosuppressive T cells and recruits cytotoxic T cells
Frequent metastases	Employ specific iRGD that inhibits the metastatic cascade

SOLUTION: *Certepetide*

- In late-stage clinical development in several solid tumors based on strong preclinical and early clinical evidence
- **Converts tumor stroma from a barrier to a conduit for anti-cancer drugs**
- **Selectively reduces immunosuppressive T cells and increases cytotoxic T cells[(1)]**
- **Inhibits the metastatic cascade[(2)]**
- Agnostic to the anti-cancer modality with which it is applied; can be co-administered or molecularly bound (tethered)

*internalizing Arginylglycylaspartic acid (iRGD)

[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 commercial partnerships

Qilu Pharmaceutical

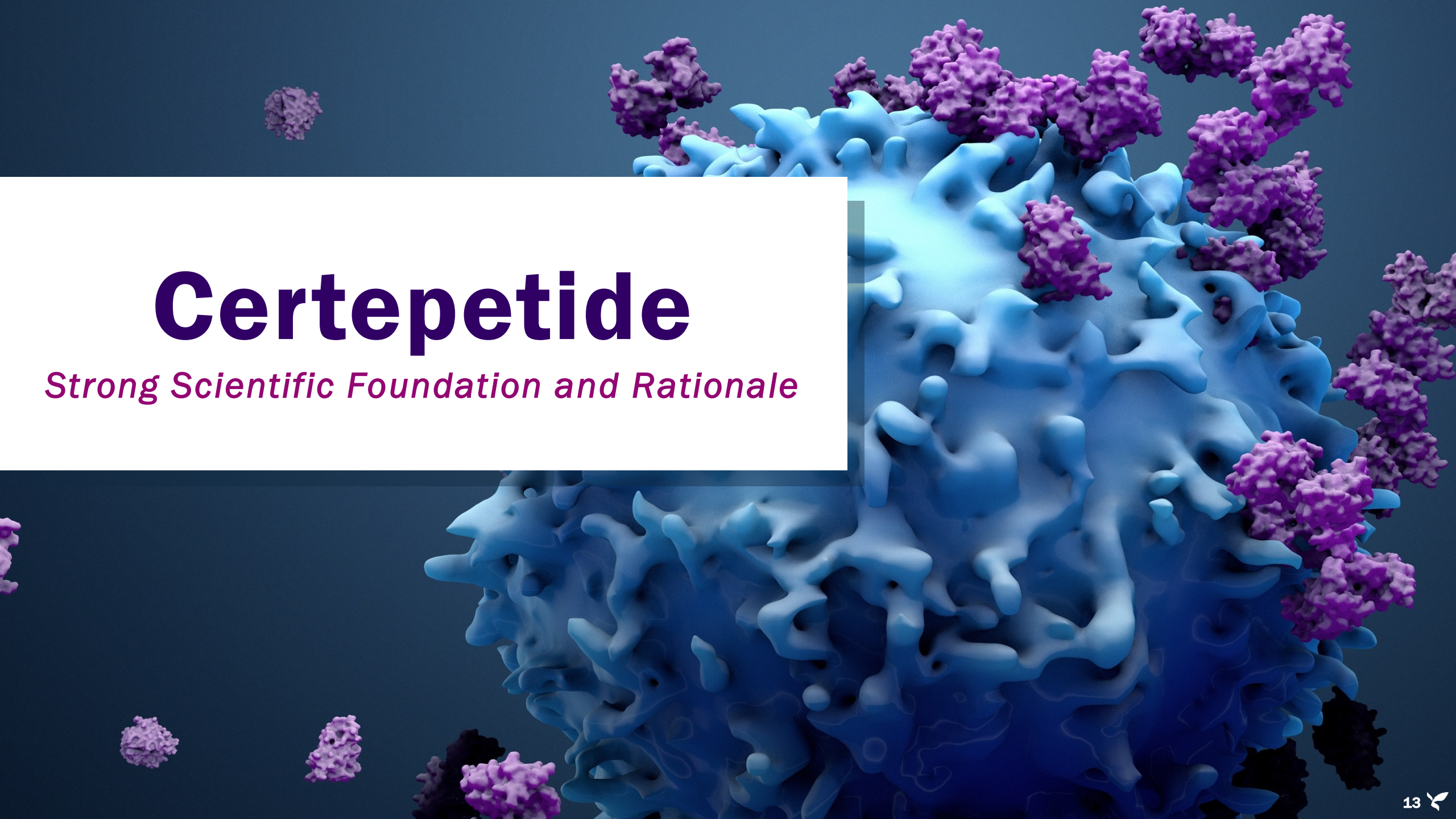
- Qilu granted exclusive rights in China, Taiwan, Hong Kong and Macau
- Qilu assumes all development and commercialization responsibilities/costs in licensed territories
- Lisata collected $15 million in milestones to date
- Potential for additional $221 million in milestones plus royalties on sales 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
- Includes a $1 million upfront license fee and potential for ~$20 million in milestones plus royalties on sales to Lisata
- Kuva assumes all development and commercialization responsibilities/costs

Additional partnership opportunities exist for many combinations with certepetide

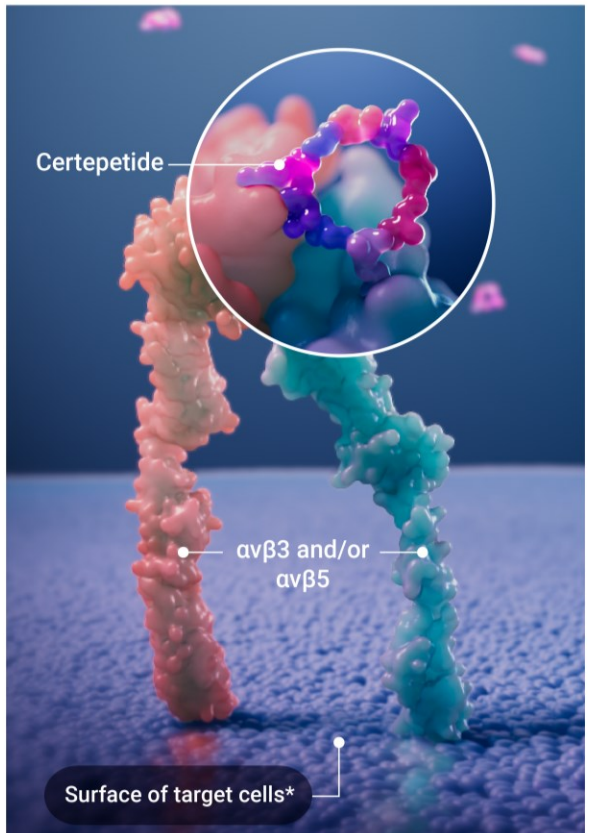
- By indication, modality of co-administered drug(s), and/or geography



Certepetide

Strong Scientific Foundation and Rationale

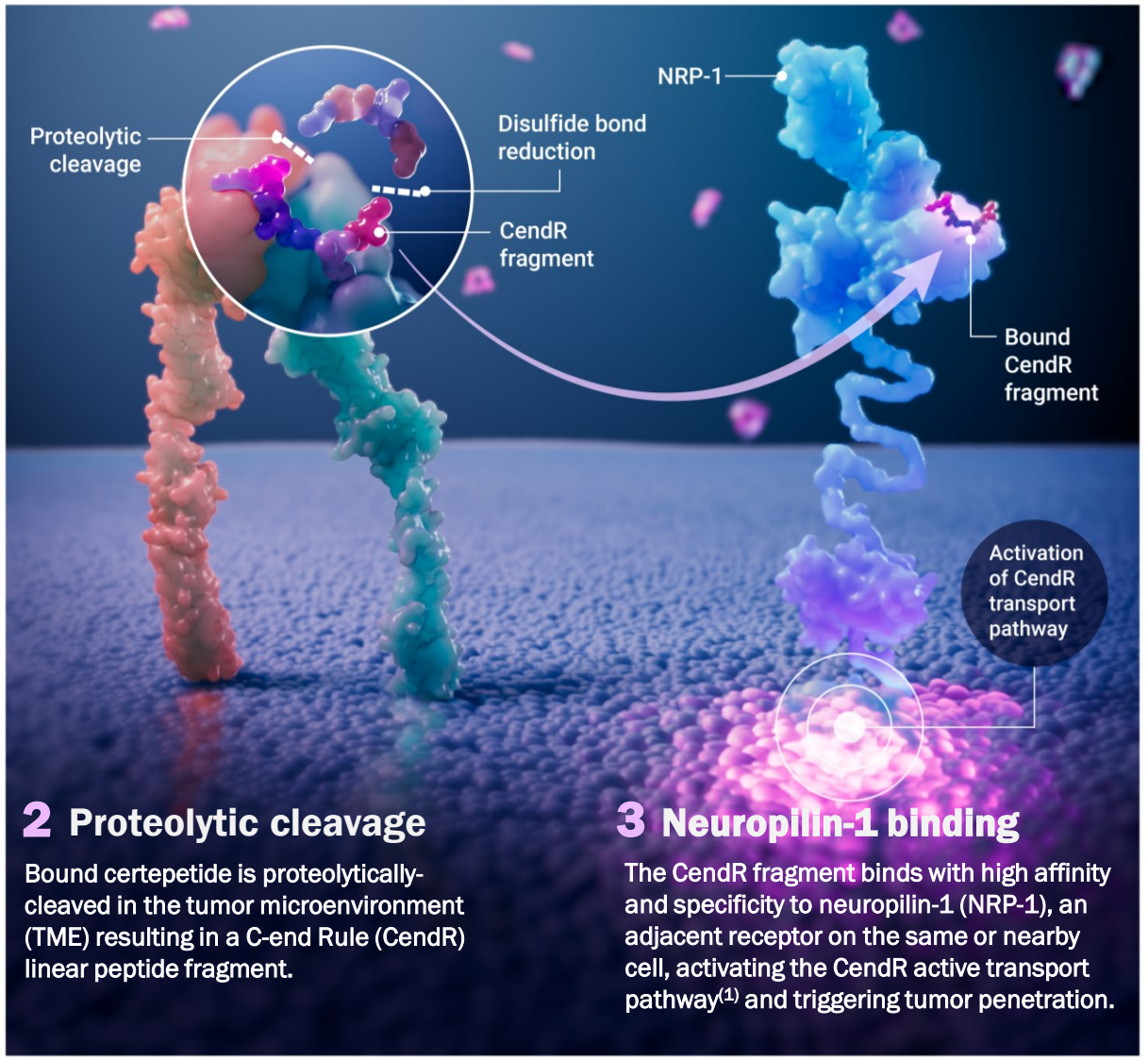
Certepetide mechanism of action: Unique, multi-step approach



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)*

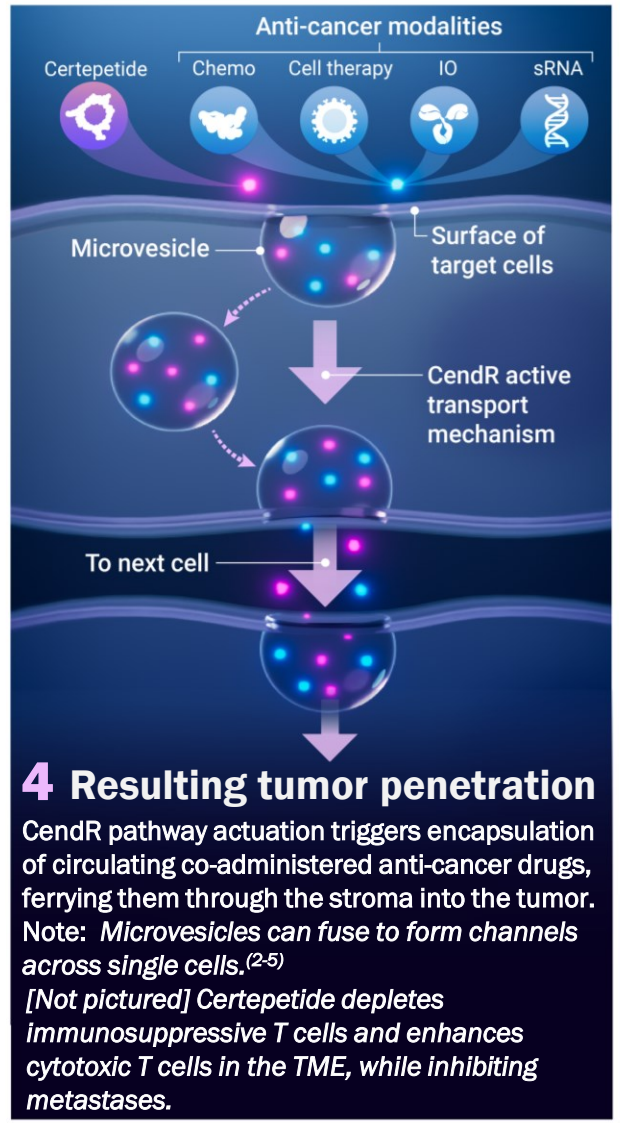


2 Proteolytic cleavage

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.*[2-5]
[Not pictured] Certepetide depletes immunosuppressive T cells and enhances cytotoxic T cells in the TME, while inhibiting metastases.

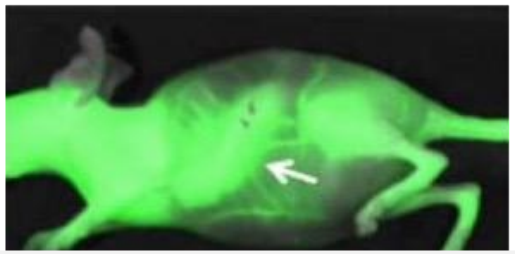
Illustration is a simplified rendition of MOA

[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.

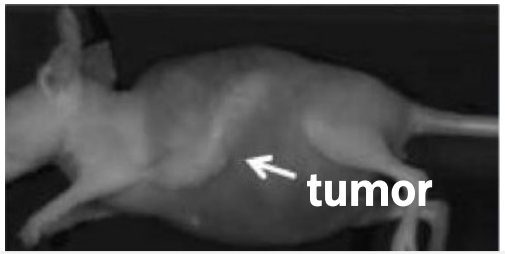
Certepetide/iRGD selectively promotes intratumoral penetration

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

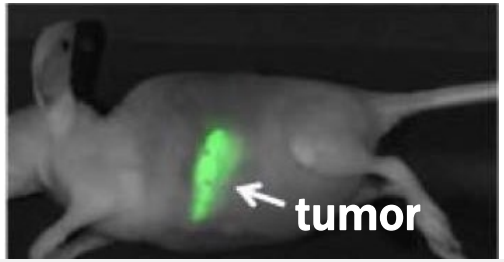
- Circulating FQDs result in whole body fluorescence
- Etching solution quenches fluorescence in circulation



FQDs

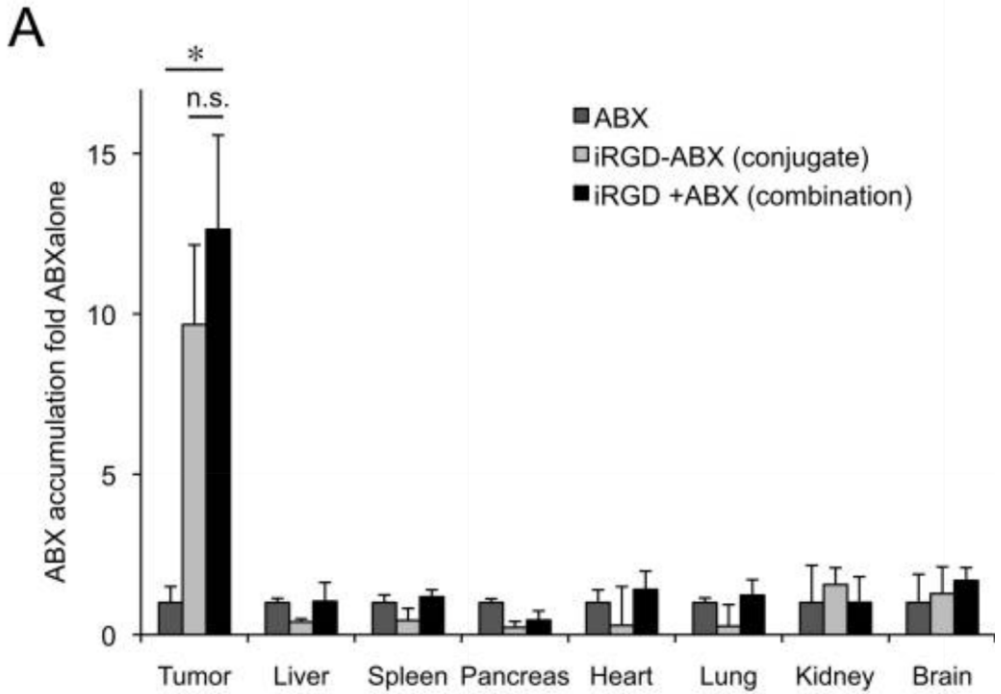


FQDs + Etching solution



Certepetide + FQDs + Etching solution

In the presence of iRGD, Abraxane (ABX) is selectively 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.

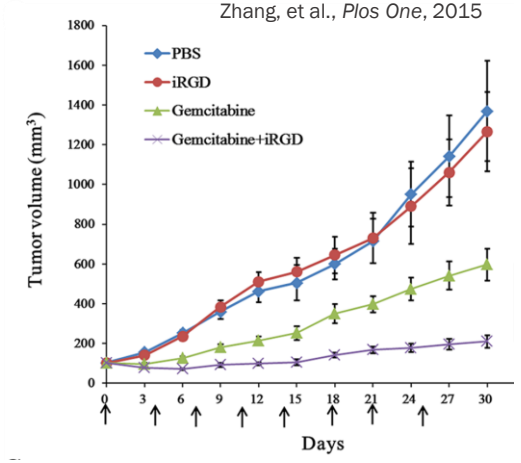
Certepetide is a proprietary iRGD; experiments denoting iRGD use a non-proprietary certepetide analog with differs in structure by a single acetyl group.

Broad applicability & activity of certepetide/iRGD consistently demonstrated

Sampling of >350 scientific publications showing improved survival

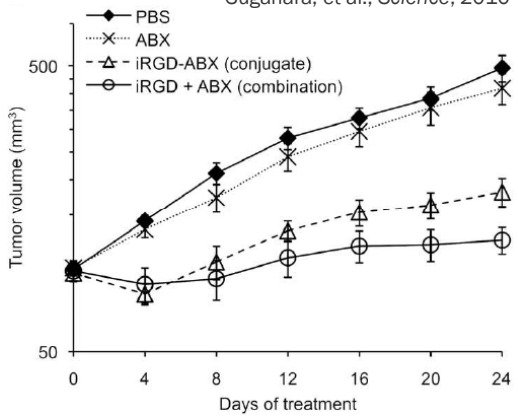
Lung cancer + gemcitabine

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



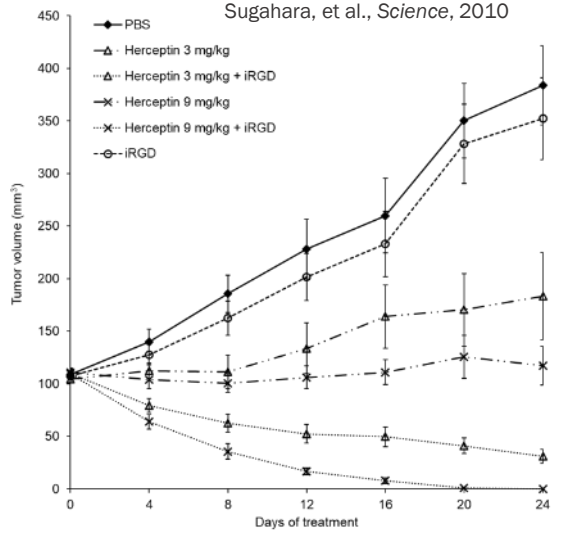
Breast cancer + nanoparticle nab-paclitaxel

Sugahara, et al., *Science*, 2010



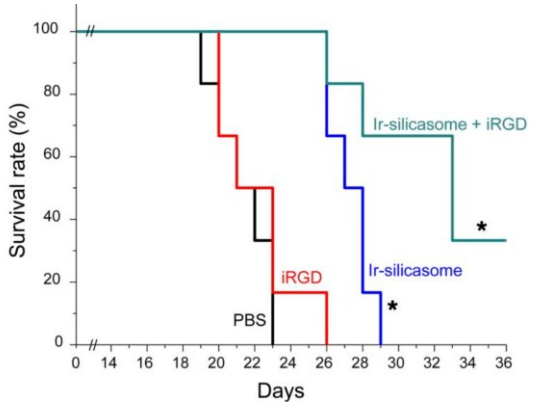
Breast cancer + Herceptin®

Sugahara, et al., *Science*, 2010



PDAC + irinotecan nanoparticles

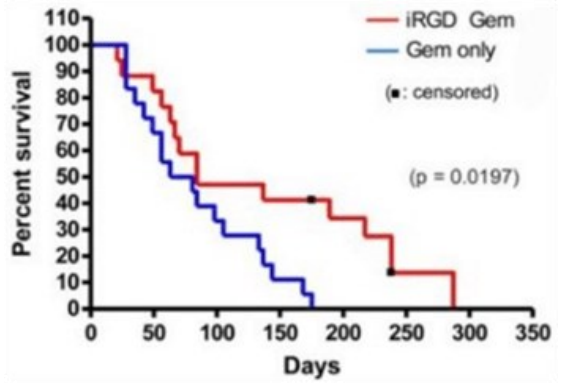
Liu X et al., J Clin Invest, 2017



Orthotopically transplanted KPC PDAC tumors
iRGD + irinotecan nanoparticles (i.v. co-admin)

PDAC + gemcitabine

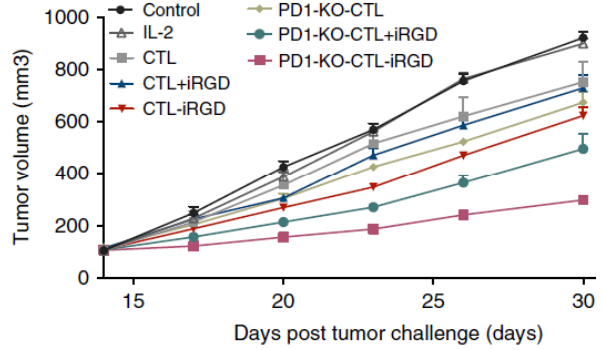
Hurtado de Mendoza et al, Nature Comms, 2021



KPC mice genetically engineered to develop
PDAC iRGD + gemcitabine (i.v. co-admin)

GI cancer + adoptive cell therapy

Ding, et al., *Nature*, 2019



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

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

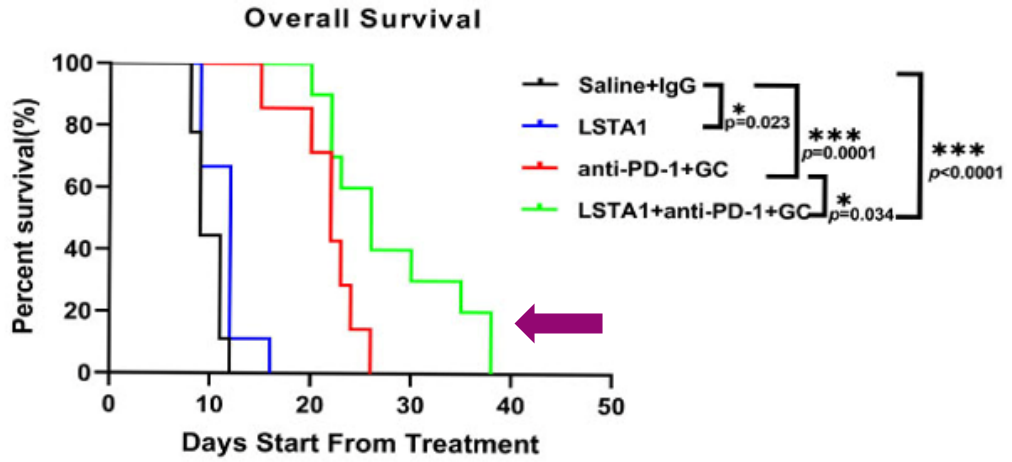
Study Description	Certepetide/iRGD vs. Control Group
▪ **Intrahepatic cholangiocarcinoma (ICC)** murine model ▪ Certepetide + anti-PD-1 + cytotoxics vs. controls	→ Significantly improved overall survival → Significantly reduced tumor volume → Significantly reduced metastases
▪ **Pancreatic adenocarcinoma (PDAC)** murine model ▪ Certepetide + anti-PD-L1 + cytotoxics vs. controls	
▪ **Prostate cancer** murine model ▪ iRGD vs. scrambled iRGDD control	→ Significantly reduced tumor size
▪ **Breast cancer** (human BT474) murine model ▪ Trastuzumab + iRGD vs. trastuzumab control	
▪ **Non-Small Cell Lung Cancer (NSCLC)** murine model ▪ Cetuximab + iRGD vs. cetuximab and iRGD control	
▪ **Gastric cancer** HGC27 tumor spheroids ▪ iRGD + natural killer T cells (NKT cells vs. NKT cells alone)	→ Significantly increased NKT cell penetration → Significantly reduced tumor size
▪ **Hepatocellular carcinoma (HCC)** murine model ▪ iRGD + NKT cells vs. NKT cells alone	

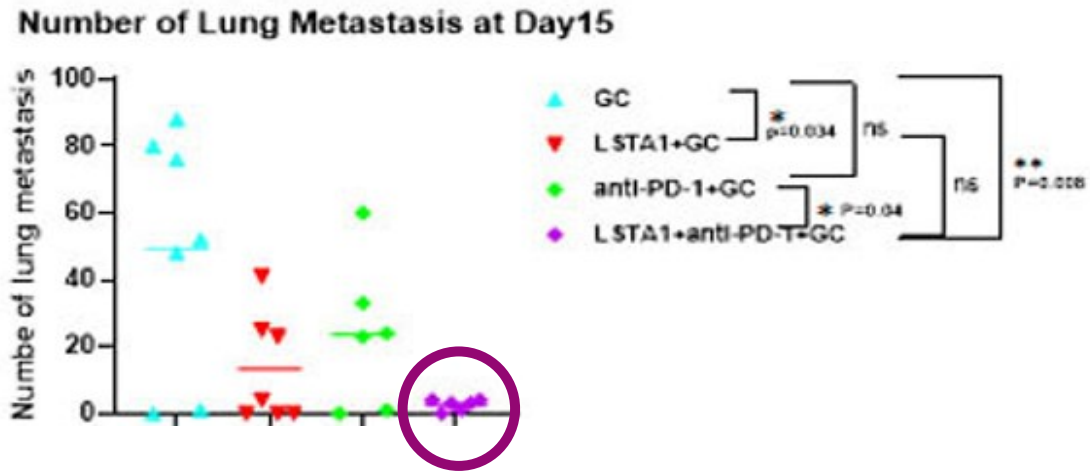
Certepetide is a proprietary iRGD; experiments denoting iRGD use a non-proprietary certepetide analog with differs in structure by a single acetyl group.

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*

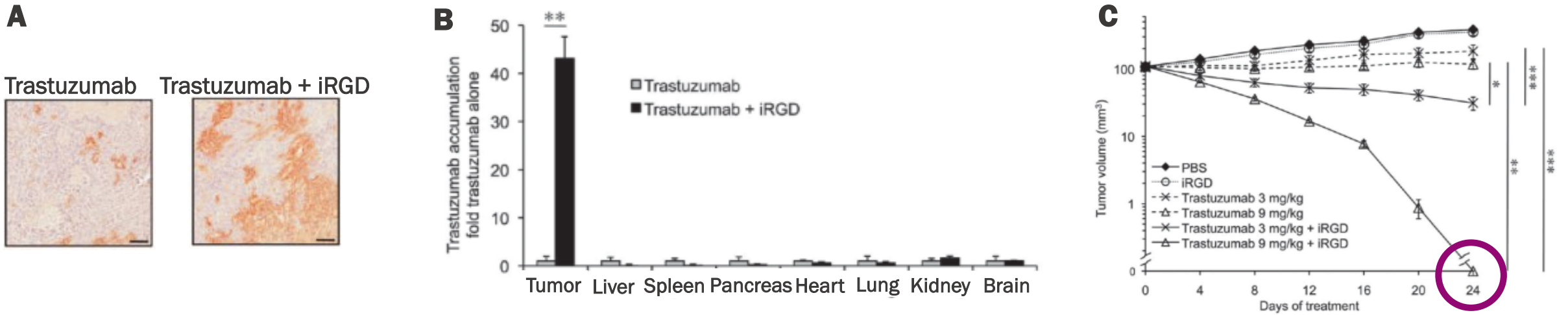
Certepetide combined with chemo- and immunotherapy improves survival, reduces morbidity and inhibits metastasis in cholangiocarcinoma mouse model

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 is composed of two main pillars

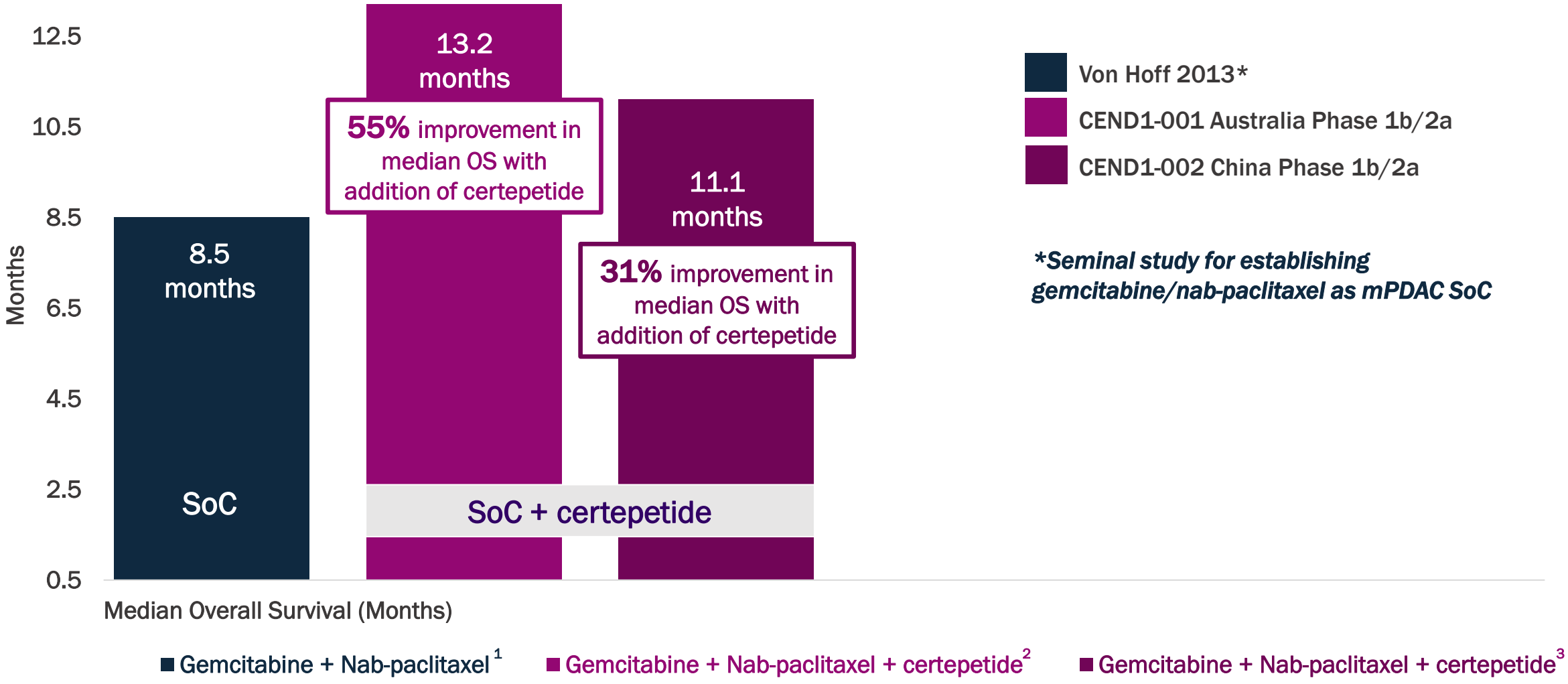
Pursue rapid global registration in pancreatic ductal adenocarcinoma (mPDAC), initially combined with gemcitabine/nab-paclitaxel standard-of-care (SoC)

- *Phase 2b 100% enrolled*
- *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

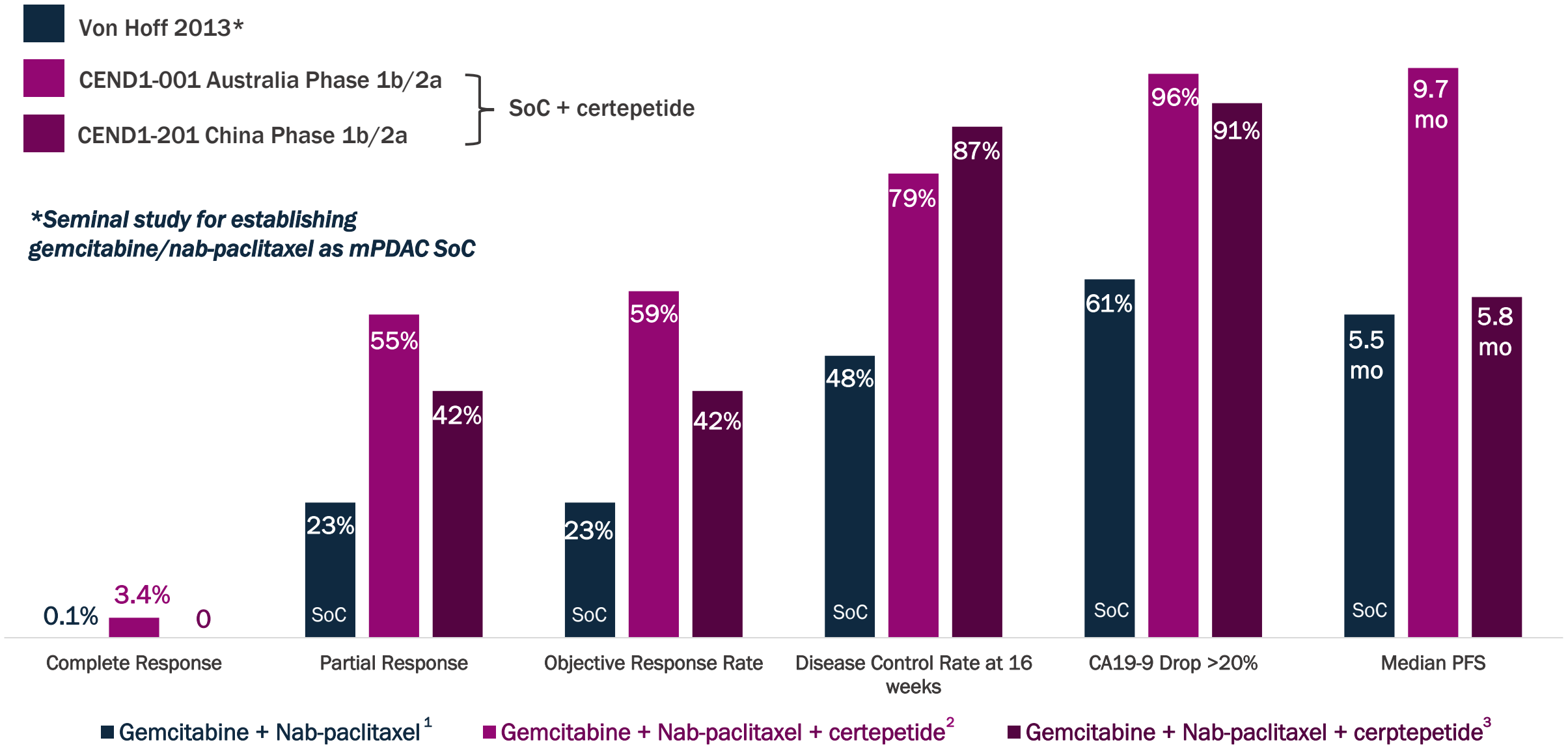
- *Multiple Phase 1b/2a studies underway*

Certepetide improved survival in *metastatic* pancreatic cancer in two independent multicenter, Phase 1b/2a studies



[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 1b/2a studies



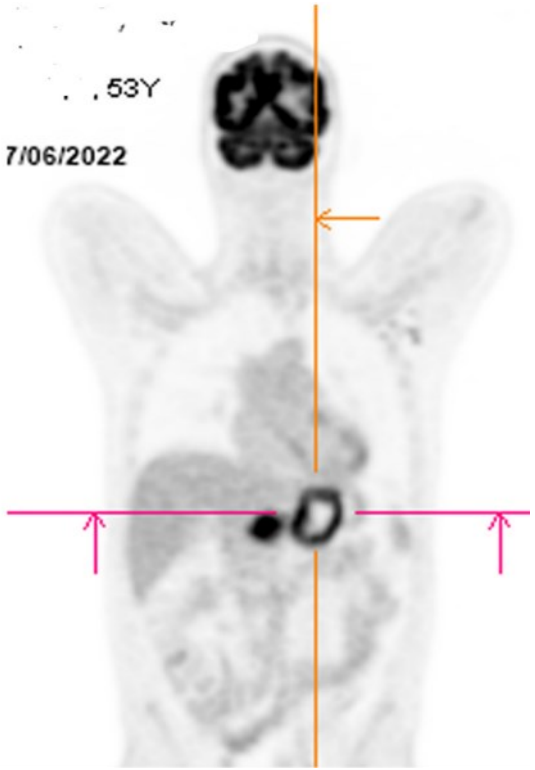
[1] Von Hoff D, et al., *New England Journal of Medicine*, 2013.
[2] Dean A, et al., *The Lancet Gastroenterology & Hepatology*, 2022
[3] QILU Pharmaceutical

Remarkable evidence of certepetide activity in other solid tumors

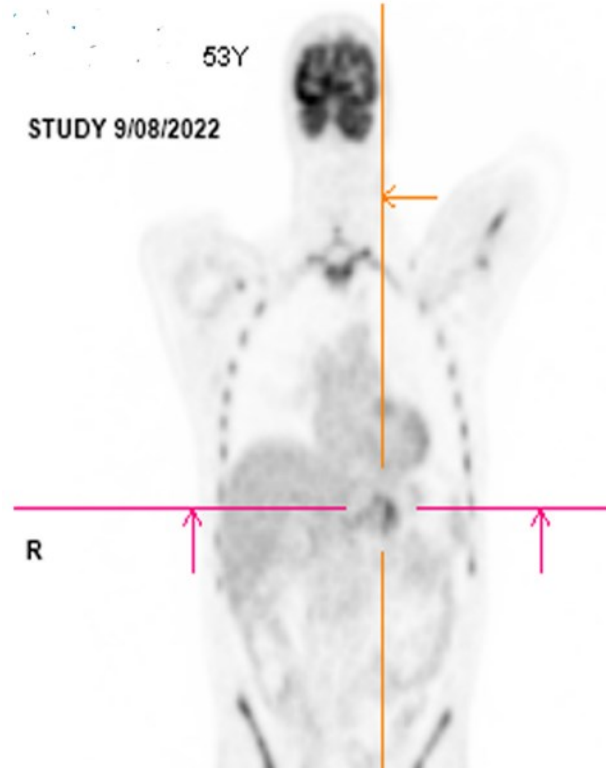
Certepetide potentiated a complete response in metastatic gastroesophageal adenocarcinoma (mGEAC)

- 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**
- **25+ months with sustained <u>complete response</u>**

FDG-PET* scan June 2022



FDG-PET scan Sept. 2022



Reduction in FDG activity demonstrated(1)

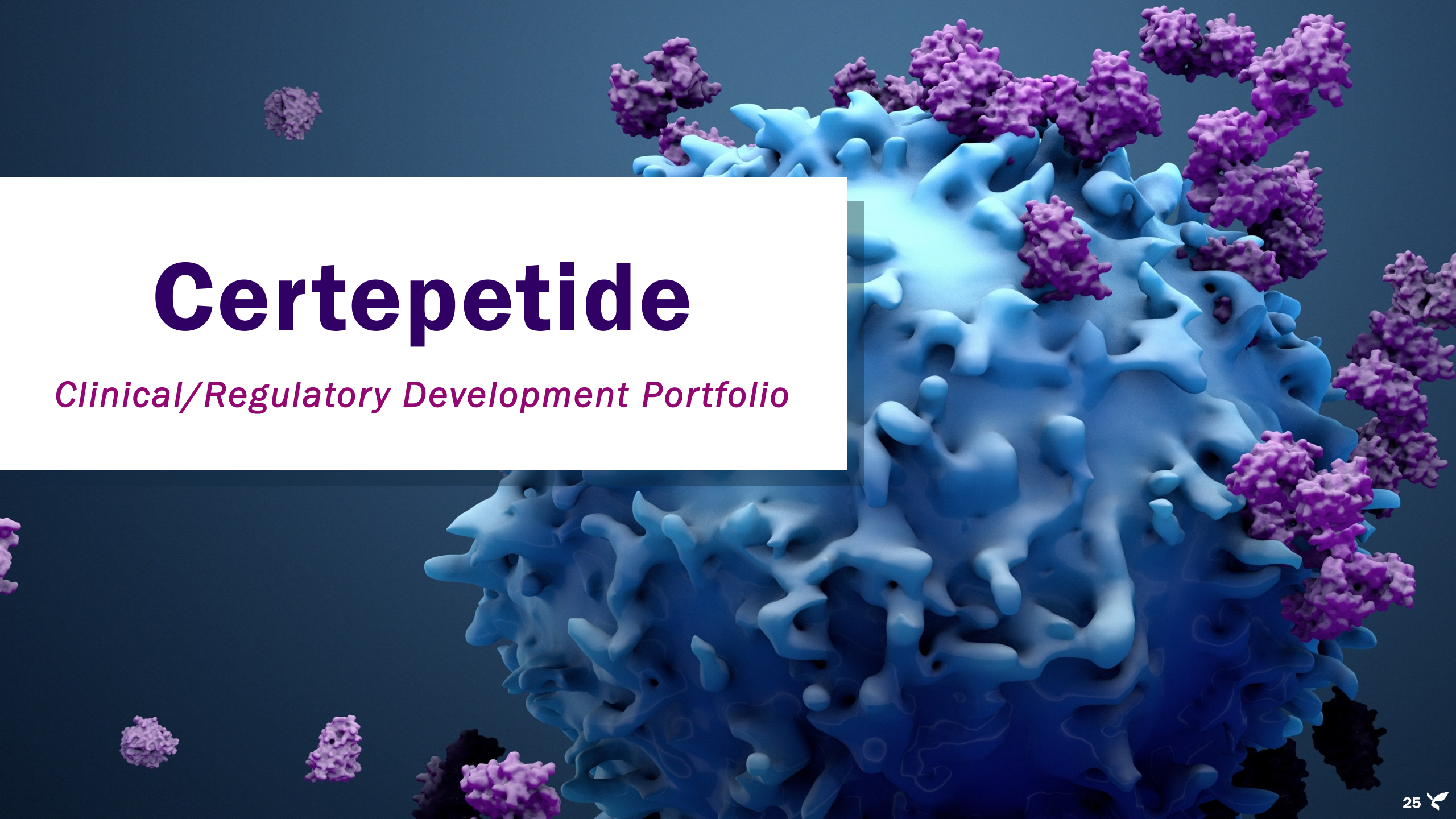
**Fluorodeoxyglucose (FDG)-positron emission tomography (PET)*

[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

Accumulating clinical data demonstrate certepetide's ability to augment anti-cancer efficacy of chemotherapy alone and with immunotherapy

Certepetide Clinical Data Summary to Date

- Two Phase 1b/2a clinical trials (CEND1-001 – Australia and CEND1-201 - China) demonstrate that certepetide plus chemotherapy SoC **improves overall survival in *metastatic* PDAC**
- Well-tolerated with no dose-limiting toxicity; AEs similar to companion therapy alone
- Sustained complete response in patient with metastatic gastroesophageal cancer
- Phase 1b/2a trial (iLSTA): randomized, patient-blinded interim data demonstrate:
  - Certepetide plus chemotherapy SoC and immunotherapy ***improves clinical outcomes in locally advanced* PDAC**



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

Certepetide capital efficient clinical development plan

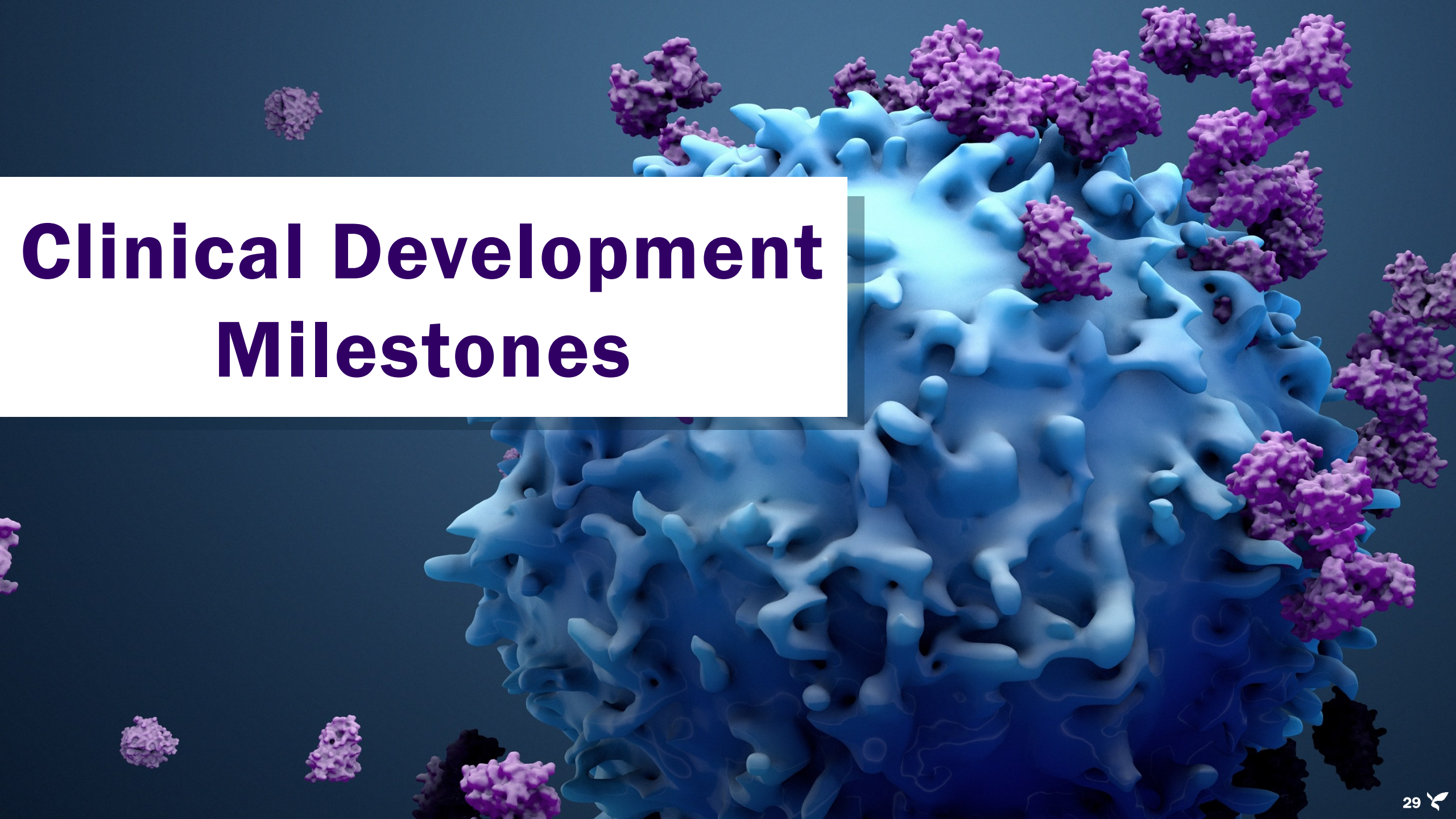
Sponsor(s)	Indication	Description	Current Phase
			Phase 1 / Phase 2 / Phase 3
AGITG/Lisata	*First-line mPDAC*	▪ **ASCEND:** Phase 2b, placebo-controlled trial (N=158) ▪ *Gemcitabine/nab-paclitaxel + certepetide or placebo* ▪ Australia/New Zealand	Enrollment complete
Lisata	*First- and Second-line Cholangiocarcinoma (CCA)*	▪ **BOLSTER:** Phase 2a, placebo-controlled trial (N=80) ▪ *1L CCA: Gemcitabine/cisplatin/durvalumab with certepetide or placebo* ▪ *2L CCA: FOLFOX with certepetide or placebo* ▪ United States	1L CCA Enrollment complete 2L CCA Enrolling
KUCC/Lisata *Investigator-initiated trial*	*Pancreatic, Colon, and Appendiceal Cancers*	▪ **CENDIFOX:** Phase 1b/2a, open-label trial (N=51) ▪ *FOLFIRINOX + panitumumab* + certepetide* ▪ United States	Enrolling
Qilu/Lisata	*First-line mPDAC*	▪ Phase 1b/2a, open-label trial (N=41) ▪ *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=120) ▪ *Gemcitabine/nab-paclitaxel + certepetide* ▪ China	Enrolling
Lisata	*Second-line mPDAC*	▪ **FORTIFIDE:** Phase 1b/2a placebo-controlled trial (N=30) ▪ Gemcitabine/nab-paclitaxel + continuous infusion of certepetide/placebo ▪ United States	Enrolling soon

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

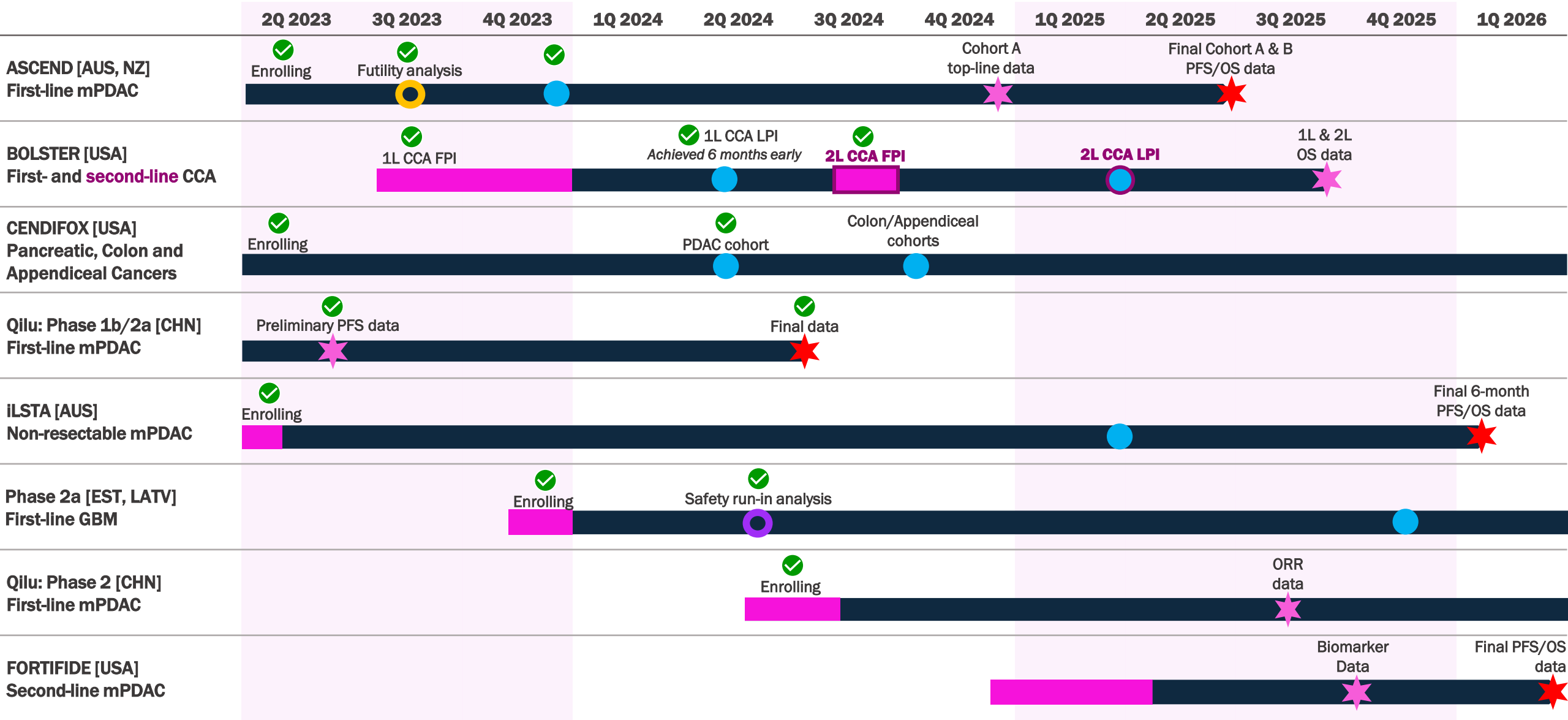
Certepetide preclinical activities and milestones

Sponsor(s)	Indication	Objective and Description	Upcoming Milestones
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	Target date for data: 1Q2025
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: 2Q2025

Clinical Development Milestones



A wealth of anticipated key certepetide clinical milestones



First patient in | Last patient in | Interim analysis | Safety run-in analysis | Data | Final data | Milestone achieved

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

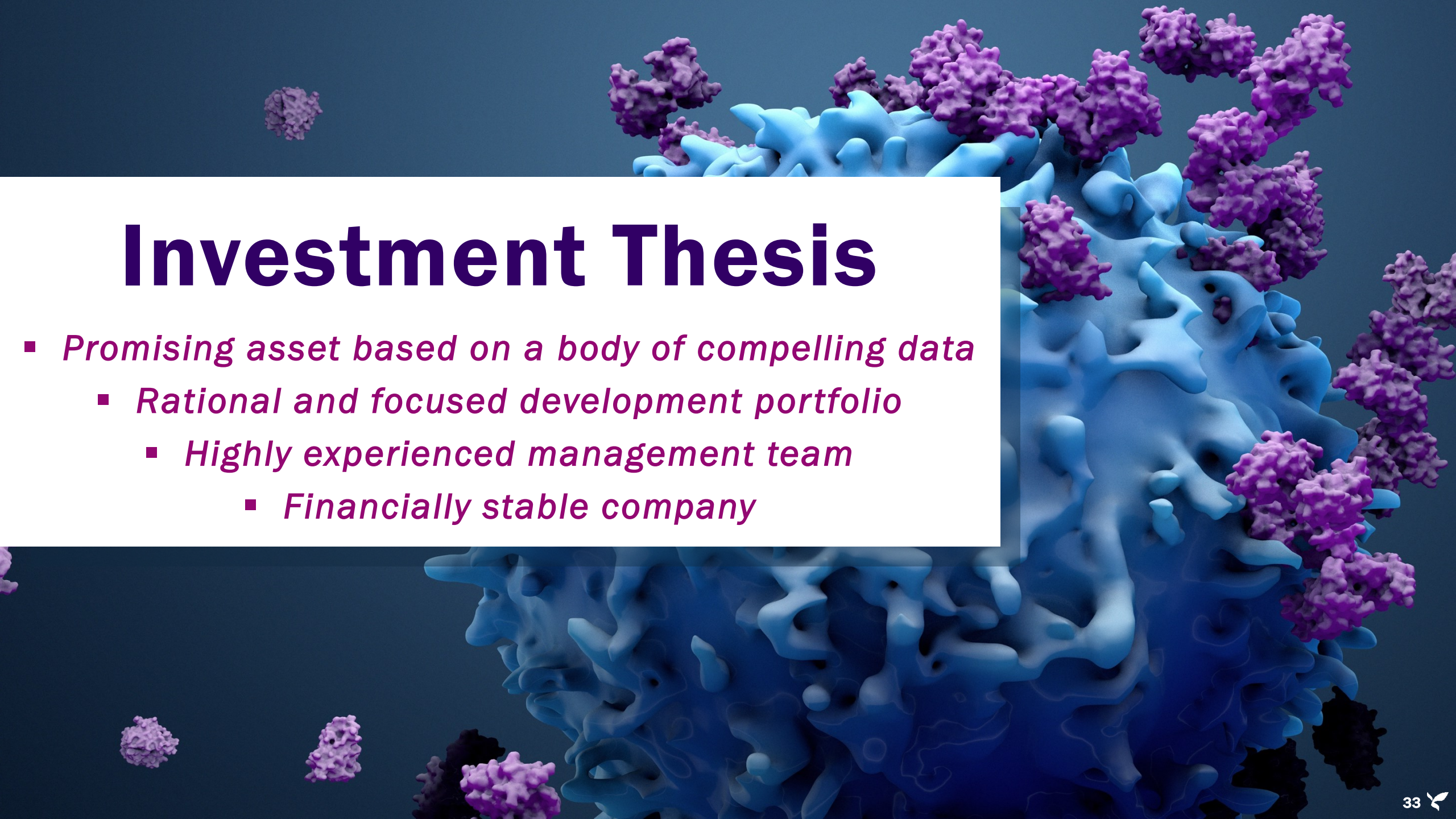
**Several of these studies are investigator-initiated trials. Lisata has limited control and thus, timelines and expectations may be subject to change.*

Financial Highlights

Capital projected to fund all clinical programs to data

Cash & Investments As of 9/30/2024	Debt	Projected Cash Runway Into
$35.9M	**$0**	**1Q2026**

Common Shares Outstanding (9/30/2024):	8.3 million shares
Options Outstanding (9/30/2024): Exercise Price: $0.02 - $4.22 = 1,217,400 shares Exercise Price: > $4.22 = 237,100 shares	1.5 million shares
Warrants Outstanding (9/30/2024): Weighted Average Exercise Price: $40.52	1.5 million shares



Investment Thesis

- *Promising asset based on a body of compelling data*
  - *Rational and focused development portfolio*
    - *Highly experienced management team*
      - *Financially stable company*

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

$35.9 million cash*- no debt; Current development funded through critical data milestones

PARTNERING

Platform technology validated by existing partnerships with potential for many others

* As of 9/30/2024; includes investments

LISATA THERAPEUTICS

Targeted Therapy *Delivered*

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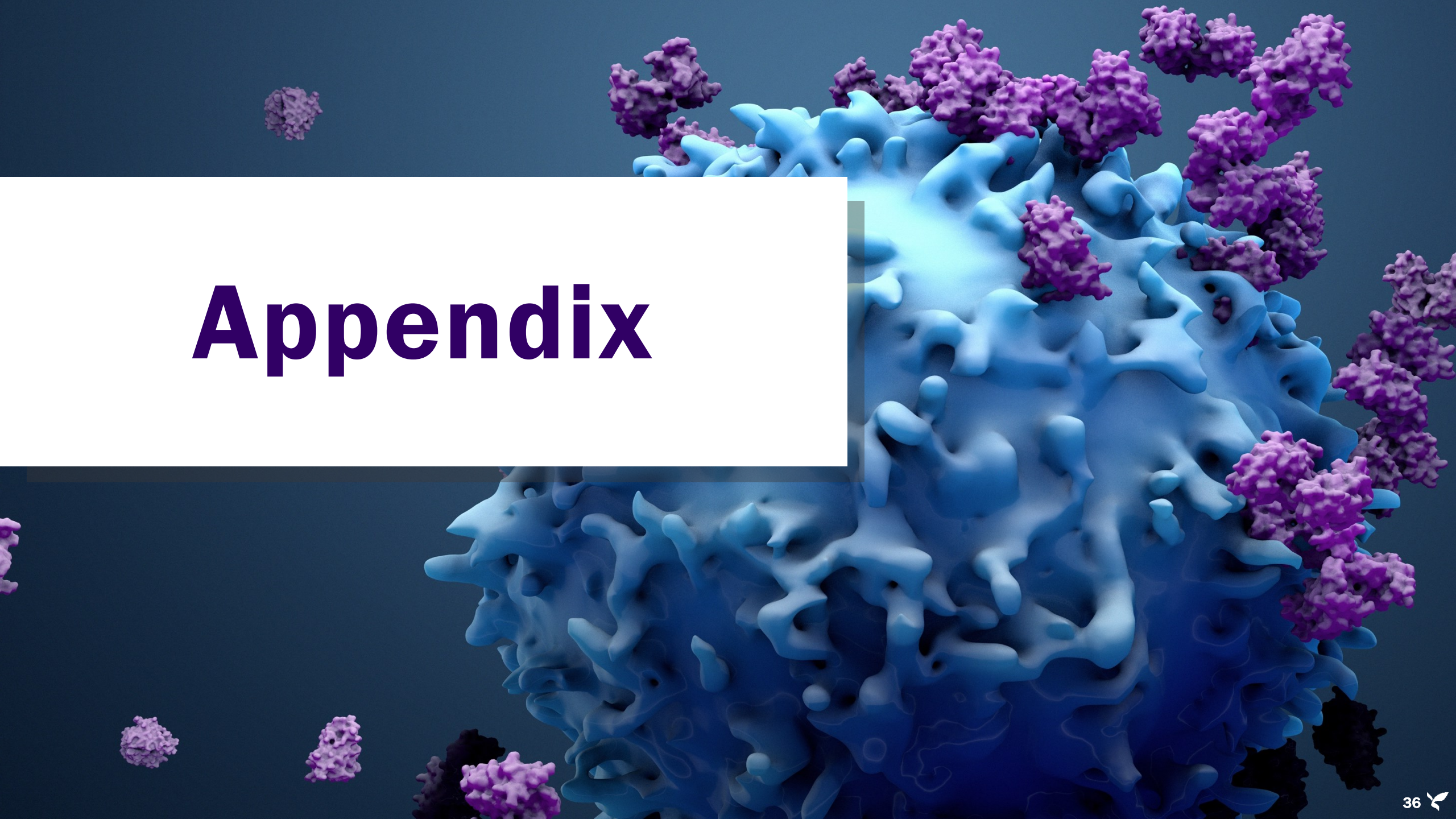
Nasdaq: LSTA | *www.lisata.com*



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]	**Second-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.

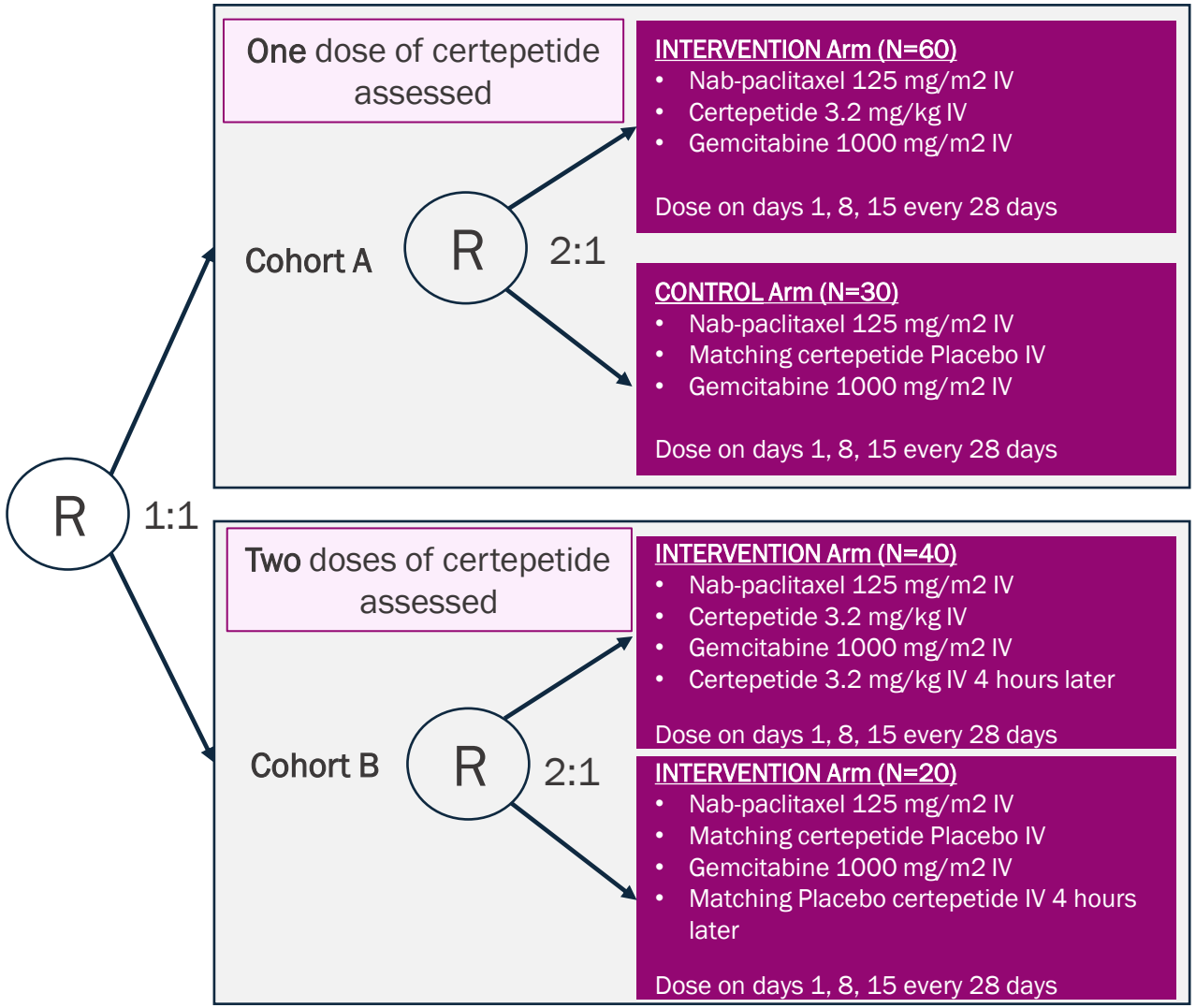
**Investigator-initiated trial*
***Panitumumab may be added for colorectal or appendiceal patients without Ras mutation*

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 ▪ Earliest possible data 4Q24

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; Earliest possible data 4Q24

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

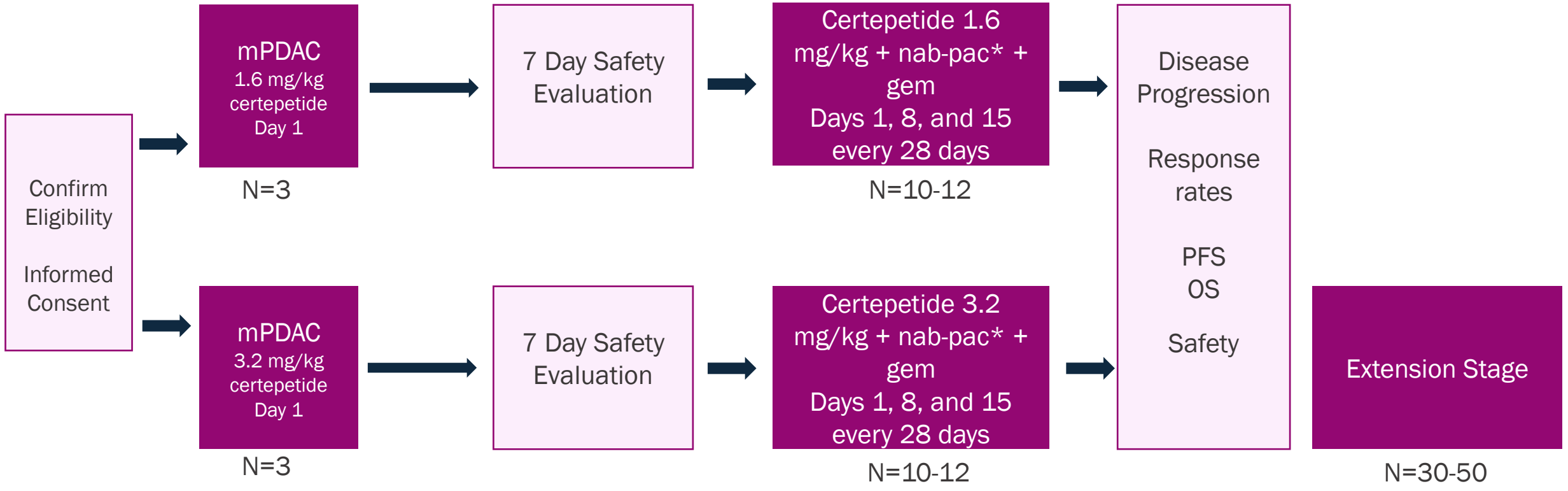
Phase 1b/2a open-label trial in mPDAC in China (CEND1-201)

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=50 (~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	▪ Final data anticipated 2H2024

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:** Final data anticipated 2H2024



*Qilu produced

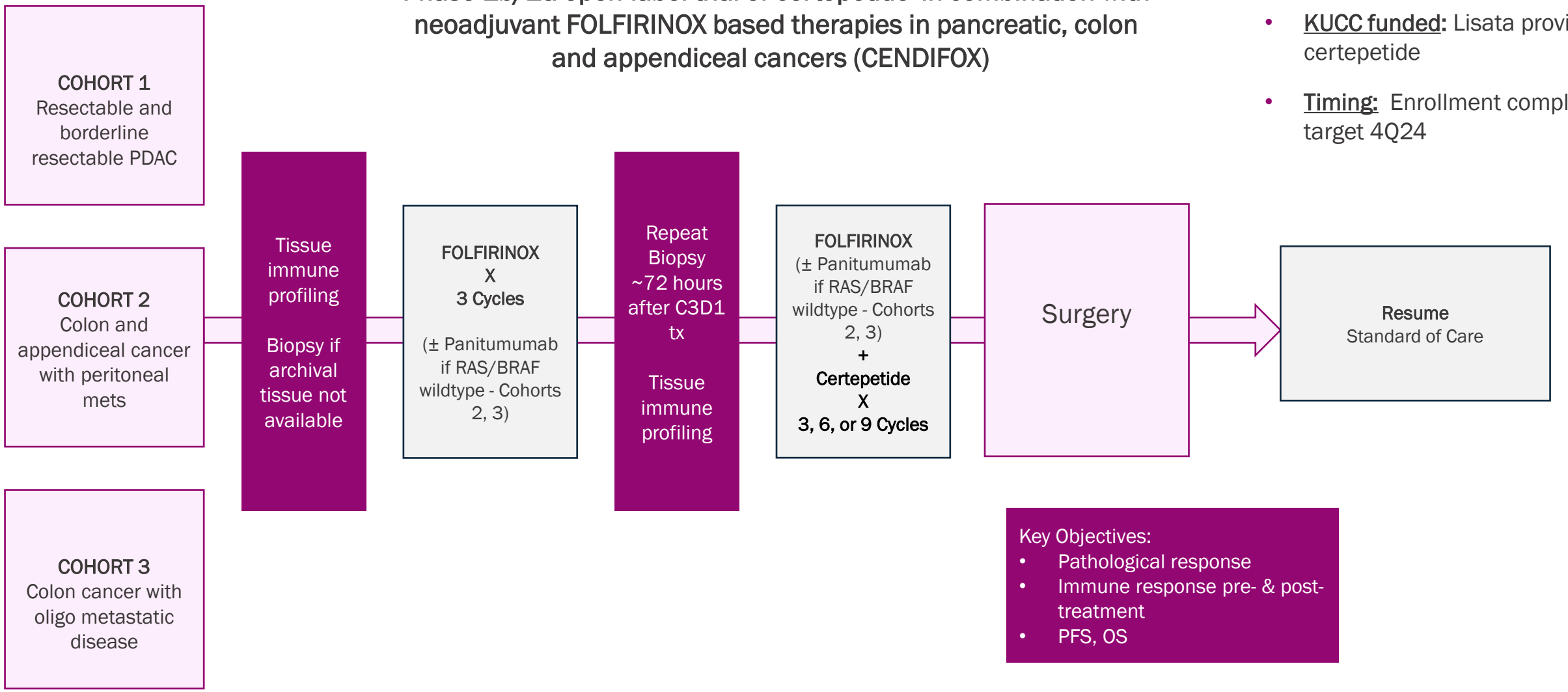
CENDIFOX: Phase 1b/2a open-label trial in PDAC and other cancers

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=51 (21 PDAC, 15 colon and 15 appendiceal)
Endpoints	▪ Primary: Drug Safety ▪ Secondary: Overall Survival, Disease-free Survival, Overall Response Rate, RO Resection Rate, Pathological Response Rate
Timing	▪ Enrollment completion target 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 completion target 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

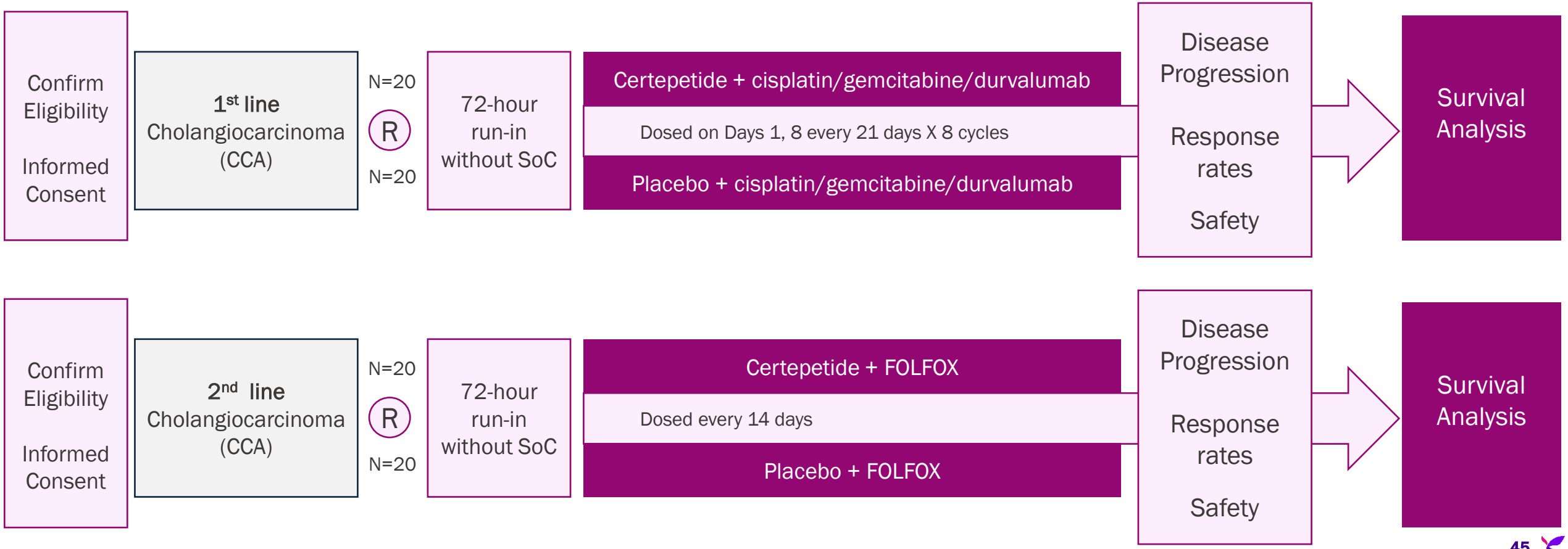
BOLSTER: Phase 2 blinded, randomized trial in Cholangiocarcinoma

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=80 (N=40 per tumor type) ▪ 1:1 SoC + certepetide or SoC + placebo
Endpoints	▪ Primary: OS ▪ Secondary: Safety, ORR, PFS
Timing	▪ Enrollment completed for 1L CCA ▪ Enrollment commenced July 2024 for 2L CCA

BOLSTER: Phase 2 blinded, randomized PoC trial in various cancers

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 CCA
  - Enrollment anticipated July 2024 for 2L CCA



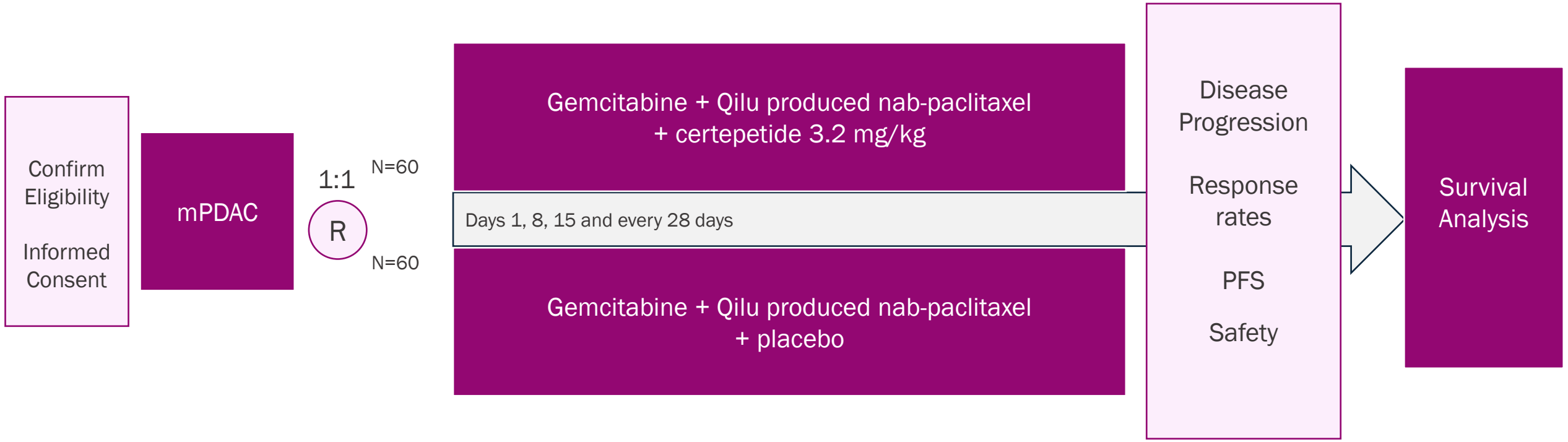
Phase 2 double-blind, placebo-controlled trial in mPDAC in China

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=120 (1:1 SoC + certepetide or SoC + placebo)
Endpoints	▪ Objective response rate, progression free survival, duration of response, disease control rate, overall survival ▪ Safety
Timing	▪ Trial initiated 2Q24

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:** Trial initiated 2Q24



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 commenced April 2023

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 commenced April 2023

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

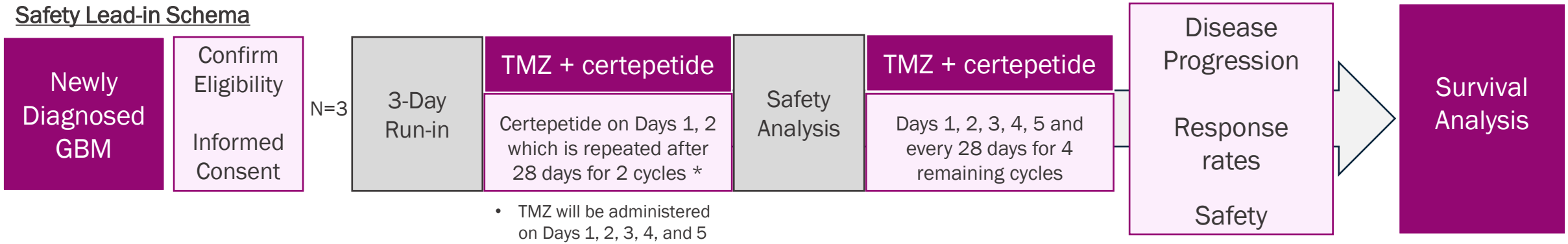
Sponsor/Partner	▪ Tartu University Hospital (Investigator initiated trial in Estonia) ▪ Lisata providing study drug and funding trial
Objective	▪ Evaluate safety, tolerability, and therapeutic effect of certepetide in combination with standard-of-care (temozolomide) in patients with previously untreated 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

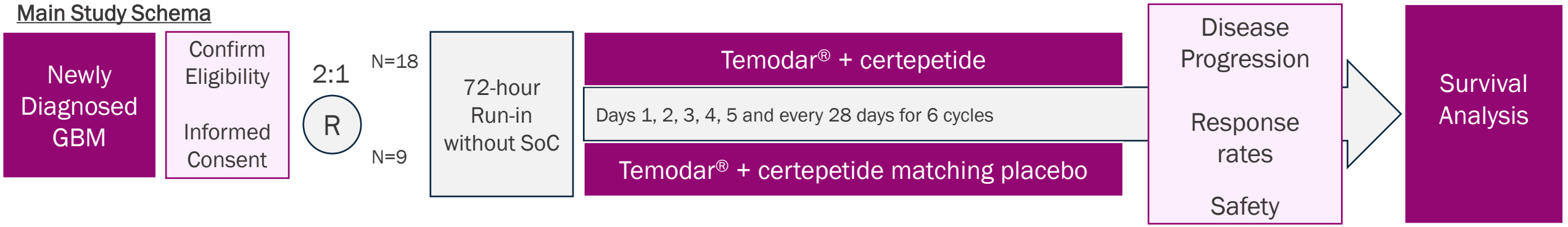
- **Sponsor:** Tartu University Hospital; Estonia
- **Funding:** Lisata
- **Timing:** Enrollment commenced December 2023

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 second-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 second-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	▪ First patient treated target 4Q24

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