UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 8-K

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

May 9, 2024
Date of Report (date of earliest event reported)

LISATA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-33650**	**22-2343568**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

110 Allen Road, Second Floor, Basking Ridge, NJ 07920
(Address of Principal Executive Offices)(ZipCode)
(908) 842-0100
Registrant's telephone number, including area code

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

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

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

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

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	LSTA	The Nasdaq Capital Market

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

☐ Emerging growth company

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

Item 2.02 Results of Operations and Financial Condition.

The information in Item 7.01 is incorporated by reference.

Item 7.01 Regulation FD Disclosure.

On May 9, 2024, Lisata Therapeutics, Inc. (the "Company") issued a press release in connection with its financial results for the first quarter ended March 31, 2024. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated into this Item 7.01 by reference.

A copy of a slide presentation that the Company will use at investor and industry conferences and presentations is attached to this Current Report as Exhibit 99.2 and is incorporated herein solely for purposes of this Item 7.01 disclosure.

The information in this Item 7.01, including Exhibits 99.1 and 99.2 attached hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this Item 7.01, including Exhibits 99.1 and 99.2 attached hereto, shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, except as otherwise expressly stated in such filing.

Item 9.01. Financial Statement and Exhibits.

Exhibit No.	Description
99.1	Press Release, dated May 9, 2024
99.2	Lisata Therapeutics, Inc. Corporate Presentation, May 9, 2024

SIGNATURES

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

LISATA THERAPEUTICS, INC.

By: /s/ David J. Mazzo
Name: David J. Mazzo, PhD
Title: President & Chief Executive Officer

Dated: May 9, 2024

Exhibit 99.1

Lisata Therapeutics Reports First Quarter 2024 Financial Results and Provides Business Update

Seminal Phase 2b ASCEND trial top-line data expected in fourth quarter of 2024

Projected available cash to fund planned operations into early 2026 covering all studies through data

Conference call scheduled for today at 4:30 p.m. Eastern Time

BASKING RIDGE, NJ (May 9, 2024) – Lisata Therapeutics, Inc. (Nasdaq: LSTA) ("Lisata" or the "Company"), a clinical-stage pharmaceutical company developing innovative therapies for the treatment of advanced solid tumors and other serious diseases, provided a business update and reported financial results for the three months ended March 31, 2024.

"2024, a pivotal year for Lisata, is off to a very strong start," stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Lisata. "Although we project multiple data readouts over the next 18 months, topline results from the Phase 2b ASCEND trial later this year have transformative potential for the Company. These results will be instrumental in determining the future of Lisata, and we plan to use them to explore conditional approvals with various regulatory agencies and/or to design an optimized Phase 3 program in pancreatic ductal adenocarcinoma. Since the start of the year, we have received both U.S. FDA Orphan Drug and Rare Pediatric Disease designations for certepetide, previously known as LSTA1, in osteosarcoma, further validating the broad therapeutic potential of this innovative therapy. We are energized by the progress we are making and excited about Lisata's prospects."

Dr. Mazzo added, "Our continued prudent financial management allows us to reaffirm our projection that currently available cash will fund operations into early 2026, providing a solid foundation to fund all ongoing and planned trials through to completion. More than ever, we remain confident in our ability to execute our development activities with the goal of reaching critical milestones at the earliest possible juncture."

Development Portfolio Highlights

Certepetide as a treatment for solid tumors in combination with other anti-cancer agents

Certepetide is an investigational drug designed to activate the CendR uptake pathway that allows co-administered or molecularly bound anti-cancer drugs to target and penetrate solid tumors more effectively. Certepetide is designed to actuate this active transport system in a tumor-specific manner, resulting in systemically co-administered anti-cancer drugs more efficiently penetrating and accumulating in the tumor, to the exclusion of normal tissues. In preclinical models, certepetide has also shown the ability to modify the tumor microenvironment, leading to the expectation that tumors will become more susceptible to immunotherapies and inhibiting the metastatic cascade (i.e., the spread of cancer to other parts of the body). Lisata and its development partners have amassed significant non-clinical data demonstrating enhanced delivery of a range of existing and emerging anti-cancer therapies, including chemotherapeutics, immunotherapies, and RNA-based therapeutics. To date, certepetide has also demonstrated favorable safety, tolerability and activity in completed and ongoing clinical trials designed to test its ability to enhance delivery of standard-of-care ("SOC") chemotherapy for metastatic pancreatic cancer ("mPDAC"). Certepetide has been granted orphan drug designation for pancreatic cancer in the U.S. and Europe as well as for glioblastoma multiforme ("GBM") and osteosarcoma in the U.S. It also received a Fast Track designation from the FDA for pancreatic cancer and, just recently, a Rare Pediatric Disease designation from the FDA for osteosarcoma. Currently, certepetide is the subject of multiple ongoing or planned Phase 2a and 2b clinical studies being conducted globally in a variety of solid tumor types in combination with a variety of anti-cancer regimens:

- ASCEND: Phase 2b double-blind, randomized, placebo-controlled clinical trial evaluating two dosing regimens of certepetide in combination with gemcitabine/nab-paclitaxel SOC chemotherapy in patients with mPDAC. Cohort A of the study receives a single dose of 3.2 mg/kg certepetide essentially simultaneously with SOC, while Cohort B is identical to Cohort A, but with a second dose of 3.2mg/kg of certepetide given four hours after the first. The trial is being conducted at 25 sites in Australia and New Zealand led by the Australasian Gastro-Intestinal Trials Group in collaboration with the University of Sydney and with the National Health and Medical Research Council Clinical Trial Centre at the University of Sydney as the Coordinating Centre. The conclusion of a planned interim futility analysis in 2023 by the Independent Data Safety Monitoring Committee was that the conditions for futility were not met and that the study should proceed to completion. With trial enrollment completed in the fourth quarter of 2023, Lisata expects topline data from the 95 patients assigned to Cohort A of the study to be reported in the fourth quarter of 2024 and the complete data set of all 158 patients from the study to be available by mid-2025.
- BOLSTER: Phase 2a double-blind, placebo-controlled, multi-center, randomized trial in the U.S. evaluating certepetide in combination with SOC in first-line cholangiocarcinoma. The trial is actively enrolling with enrollment completion expected by the end of the third quarter of 2024.
- CENDIFOX: Phase 1b/2a open-label trial in the U.S. of certepetide in combination with neoadjuvant FOLFIRINOX based therapies in pancreatic, colon and appendiceal cancers. The trial continues to make steady progress with enrollment completion for all three arms expected by the end of 2024.
- Qilu Pharmaceutical, the licensee of certepetide in the Greater China territory, is currently evaluating certepetide in combination with gemcitabine and nab-paclitaxel as a treatment for mPDAC. During the 2023 ASCO Annual Meeting, Qilu Pharmaceutical presented an abstract sharing preliminary data from the study which corroborated previously reported findings from the Phase 1b/2a trial of certepetide plus gemcitabine and nab-paclitaxel conducted in Australia in patients with mPDAC. As recently announced, Qilu has begun treating patients in their Phase 2 placebo-controlled trial in mPDAC. The study is planned to take approximately 18 months to complete enrollment and another 13 months for patient follow-up and data analysis and reporting.
- iLSTA: Phase 1b/2a randomized, single-blind, single-center, safety and pharmacodynamic trial in Australia evaluating certepetide in combination with the checkpoint inhibitor, durvalumab, plus standard-of-care gemcitabine and nab-paclitaxel chemotherapy versus standard-of-care alone in patients with locally advanced non-resectable PDAC. Enrollment completion is expected in the second half of 2024.
- A Lisata-funded Phase 2a, double-blind, placebo-controlled, randomized, proof-of-concept study evaluating certepetide in combination with standard-of-care temozolomide versus temozolomide alone in patients with newly diagnosed GBM is being conducted across multiple sites in Estonia and Latvia and is targeted to enroll 30 patients with a randomization of 2:1 in favor of the certepetide treatment group.

First Quarter 2024 Financial Highlights

For the three months ended March 31, 2024, operating expenses totaled $6.6 million, compared to $6.8 million for the three months ended March 31, 2023, representing a decrease of $0.2 million or 3.6%.

Research and development expenses were approximately $3.2 million for the three months ended March 31, 2024, compared to $3.2 million for the three months ended March 31, 2023, representing an essentially unchanged spend. The minor increase of $62,000 or 2.0% was primarily due to an increase in expenses associated with enrollment activities in the current year for the BOLSTER trial, partially offset by a reduction in expenses associated with the Phase 2b ASCEND trial which completed enrollment in the prior year.

General and administrative expenses were approximately $3.4 million for the three months ended March 31, 2024, compared to $3.7 million for the three months ended March 31, 2023, representing a decrease of $0.3 million or 8.3%. This was primarily due to a decrease in staffing costs associated with the elimination of the Chief Business Officer position on May 1, 2023, a reduction in option assumption equity expense in connection with the Company’s merger with Cend Therapeutics, Inc., a decrease in directors and officers insurance premiums, and a reduction in spend on consulting and legal fees partially offset by one-off settlement-related costs.

Overall, net losses were $5.4 million for the three months ended March 31, 2024, compared to $6.2 million for the three months ended March 31, 2023.

Balance Sheet Highlights

As of March 31, 2024, Lisata had cash, cash equivalents, and marketable securities of approximately $43.3 million. Based on its current expected capital needs, the Company believes that its projected capital will fund its current proposed operations into early 2026, encompassing anticipated data milestones from all its ongoing and planned clinical trials.

Conference Call Information

Lisata will hold a live conference call today, May 9, 2024, at 4:30 p.m. Eastern Time to discuss financial results, provide a business update and answer questions.

Those wishing to participate must register for the conference call by way of the following link: **CLICK HERE TO REGISTER**. Registered participants will receive an email containing conference call details with dial-in options. To avoid delays, we encourage participants to dial into the conference call 15 minutes ahead of the scheduled start time.

A live webcast of the call will also be accessible under the **Investors & News** section of Lisata's website and will be available for replay beginning two hours after the conclusion of the call for 12 months.

About Lisata Therapeutics

Lisata Therapeutics is a clinical-stage pharmaceutical company dedicated to the discovery, development and commercialization of innovative therapies for the treatment of advanced solid tumors and other major diseases. Lisata's lead product candidate, certepetide, is an investigational drug designed to activate a novel uptake pathway that allows co-administered or tethered anti-cancer drugs to target and penetrate solid tumors more effectively. Based on Lisata's CendR Platform® Technology, Lisata has already established noteworthy commercial and R&D partnerships. The Company expects to announce numerous clinical study and business milestones over the next two years and has projected that its current business and development plan is funded with available capital through these milestones and into early 2026. For more information on the Company, please visit www.lisata.com.

Forward-Looking Statements

This communication 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 and capital, 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" 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, the potential efficacy of certepetide as a treatment for patients with metastatic pancreatic ductal adenocarcinoma and other solid tumors, 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 and develop 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: results observed from a single patient case study are not necessarily indicative of final results and one or more of the clinical outcomes may materially change following more comprehensive reviews of the data and as more patient data becomes available, including the risk that unconfirmed responses may not ultimately result in confirmed responses to treatment after follow-up evaluations; the risk that product candidates that appeared promising in early research and clinical trials do not demonstrate safety and/or efficacy in larger-scale or later clinical trials; 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.

Contact:

Investors and Media:
Lisata Therapeutics, Inc.
John Menditto
Vice President, Investor Relations and Corporate Communications
Phone: 908-842-0084
Email: jmenditto@lisata.com

- Tables to Follow -

Lisata Therapeutics, Inc.

Selected Financial Data

(in thousands, except per share data)

	Three Months Ended March 31,	
	2024	**2023**
	(unaudited)	**(unaudited)**
Statement of Operations Data:		
Research and development	$ 3,241	$ 3,179
General and administrative	3,360	3,665
Total operating expenses	**6,601**	**6,844**
Operating loss	**(6,601)**	**(6,844)**
Investment income, net	589	670
Other expense, net	(187)	(13)
Net loss before benefit from income taxes and noncontrolling interests	**(6,199)**	**(6,187)**
Benefit from income taxes	(798)	—
Net loss	**(5,401)**	**(6,187)**
Less - net income attributable to noncontrolling interests	—	—
Net loss attributable to Lisata Therapeutics, Inc. common stockholders	**$ (5,401)**	**$ (6,187)**
Basic and diluted loss per share attributable to Lisata Therapeutics, Inc. common stockholders	**$ (0.65)**	**$ (0.77)**
Weighted average common shares outstanding	**8,294**	**7,987**

	March 31, 2024	**December 31, 2023**
	(unaudited)	
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$43,349	$50,535
Total assets	48,240	54,694
Total liabilities	5,497	6,800
Total equity	42,743	47,894

# # #

Exhibit 99.2

LISATA THERAPEUTICS

Targeted Therapy *Delivered*

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

Corporate Presentation | May 9, 2024
Nasdaq: LSTA

www.lisata.com

Forward-looking statements advisory

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Lisata at a Glance
Company Overview
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Lisata Therapeutics (Nasdaq: LSTA)

A clinical stage therapeutics development company rapidly advancing a novel solid tumor targeting and penetration technology to improve the efficacy of anti-cancer drugs

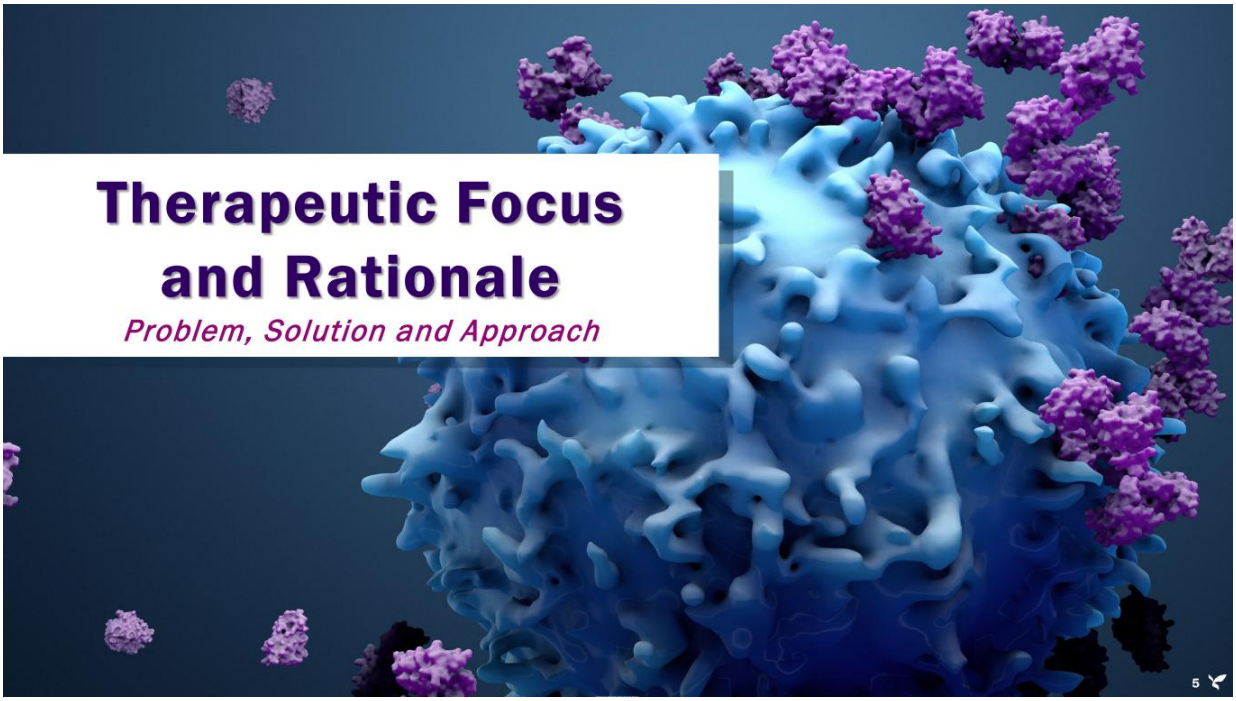
Seasoned management with successful international drug development experience and expertise

Proprietary field-leading technology in underserved global indications

Multiple product and business milestones projected over the next 24 months

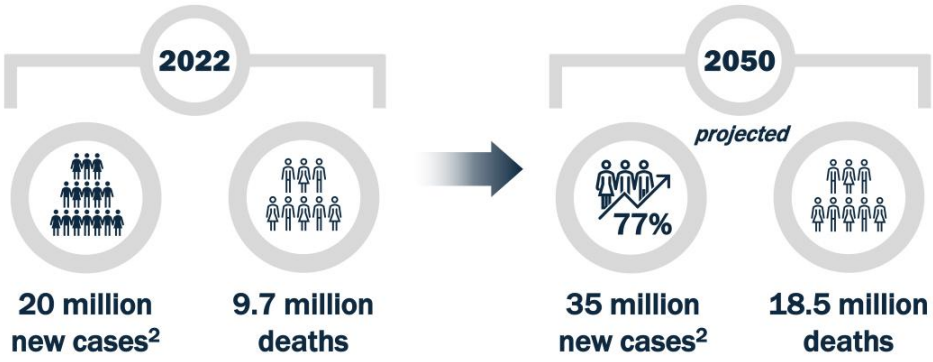
Platform technology "validated" by existing partnerships with potential for many others

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


Therapeutic Focus
and Rationale
Problem, Solution and Approach
5

Improved solid tumor cancer treatment is a vital global need

In 2023, in the U.S. alone, of ~2 million newly diagnosed cancer cases, >90% were solid tumor cancers[1]



Examples of solid tumor cancers include cancers of the lung, breast, pancreas, liver, bile duct, kidneys, ovaries, brain, colon, prostate, esophagus, and head & neck

[1] https://seer.cancer.gov/statfacts/html/common.html; data retrieved November 2, 2023.
[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.

Current solid tumor treatments are suboptimal

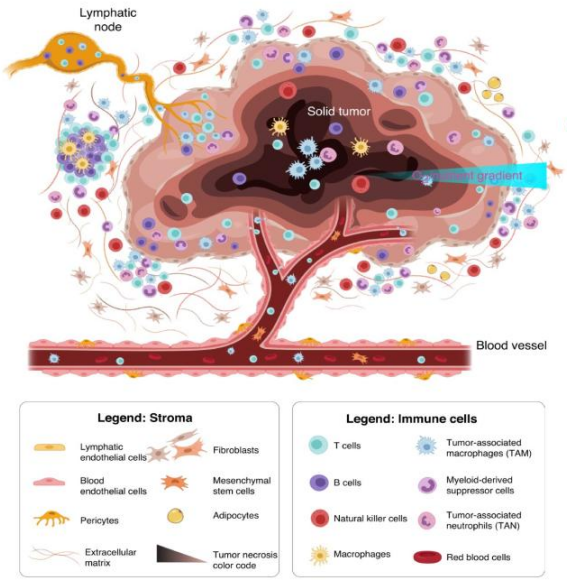


Diagram: Abizanda-Campo, S. et al, *Microsyst Nanoeng* 9, 154 (2023)

A challenging tumor microenvironment complicates "targeting" and "penetration"

- Tumor stroma acts as a physical barrier to anti-cancer agents
- An immunosuppressive tumor microenvironment (TME) contributes to tumor resistance and/or metastases
- Prolonged or escalated dosing of non-targeted anti-cancer therapy generally leads to intolerable off-target side effects

Improving selective solid tumor penetration to maximize treatment effects

Harnessing the C-end Rule (CendR) transport mechanism for solid tumor penetration

- RGD peptides target tumor cells, but do not enhance penetration and delivery
- *Internalizing* RGD (iRGD) peptides combine targeting and penetration enhancement
- Certepetide (LSTA1) is an iRGD peptide that triggers the CendR active transport mechanism to selectively target and deliver anti-cancer drugs to solid tumors
- Certepetide is in mid- to late-stage clinical development for solid tumor treatment

Certepetide promises optimized solid tumor treatment

- **Certepetide converts tumor stroma from a barrier to a conduit for anti-cancer drugs**
  - **Certepetide combats resistance and metastases[1]**
    - Preclinically, certepetide selectively depletes immunosuppressive T cells, enhances cytotoxic T cells, and inhibits the metastatic cascade
  - **Certepetide is agnostic to the modality of the companion anti-cancer therapy**
    - Effective with co-administered or molecularly bound (tethered) anti-cancer therapies
      - Co-administration presents an initial streamlined development path to registration
      - Tethering creates a new chemical entity providing prolonged compound exclusivity

[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.

Certepetide development strategy is composed of two main pillars

Focus on Pancreatic & Other Advanced Solid Tumor Cancers

- By 2030, pancreatic cancer is predicted to become the second most common cause of cancer mortality[1]
  - Today, only 3% of people diagnosed with pancreatic cancer will survive for 5 years
    - Current life expectancy at the time of diagnosis is just 4.6 months

- Pursue rapid global registration in pancreatic ductal adenocarcinoma (mPDAC), initially combined with gemcitabine/nab-paclitaxel standard-of-care (SoC)
  - *Phase 2b 100% enrolled*

- Demonstrate certepetide effectiveness when combined with a variety of SoC regimens (e.g., chemotherapy, immunotherapy, etc.) in a variety of solid tumor cancers
  - *Multiple Phase 1b/2a studies underway*

[1] Europe Is Facing a Pancreatic Cancer Emergency - Medscape - January 25, 2024.


Partnerships
Noteworthy existing relationships and potential for many more
11

Existing partnerships support certepetide's promise and broad applicability

Development alliances contribute resources without commercial interest in certepetide

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

*Strategic commercial partnership in China with **Qilu Pharmaceutical***

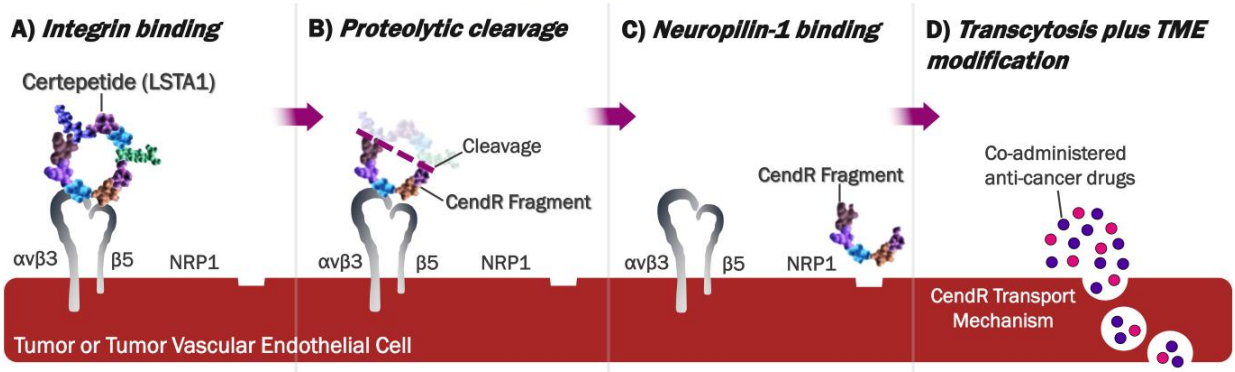
- Exclusive rights to certepetide in China, Taiwan, Hong Kong and Macau
- Qilu assumes all development and commercialization responsibilities/costs in licensed territories
  - Strategy and activities under the auspices of a Joint Steering Committee with Lisata executives
- Collected $15 million in milestones to date
- Potential for additional $221 million in milestones plus royalties on sales

Additional partnership opportunities exist for many combinations with certepetide

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


Certepetide
(formerly LSTA1)
Strong Scientific Foundation and Rationale
13

Certepetide selective tumor targeting & penetration mechanism of action



Certepetide is a 9 amino acid cyclic peptide with high binding affinity and specificity to αvβ3/β5 integrins that are upregulated on tumor cells and tumor endothelial cells (i.e., tumor stroma)

Once bound to αvβ3 & β5 integrins, certepetide is cleaved by proteases in the tumor microenvironment (TME) releasing a C-end Rule (CendR) linear peptide fragment

The CendR fragment binds with high affinity and specificity to neuropilin-1 (NRP1), an adjacent receptor on the same or nearby cell, activating the CendR transport pathway[1] and triggering tumor penetration

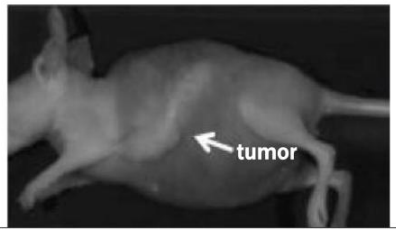
- CendR pathway actuation triggers tumor penetration of circulating co-administered anti-cancer drugs
- Certepetide-induced TME modification provokes reduction of immunosuppressive T cells, augmentation of cytotoxic T cells, and inhibition of metastases

[1] Ding et al., Nature Comm, 2019.

Certepetide selectively and efficiently facilitates intratumoral penetration

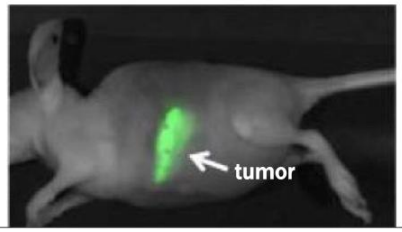
Whole body imaging of mice with pancreatic ductal adenocarcinoma (arrow) dosed with Fluorescent Quantum Dots (FQDs) with and without certepetide

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



FQDs + Etching solution

All FQDs in circulation



Certepetide + FQDs + Etching solution

All FQDs in tumor

Certepetide provides targeted tumor penetration

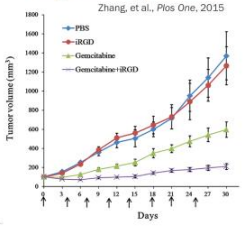
[1] Braun et al., Nature Mater. 2014.
[2] Liu, Braun et al., Nature Comm. 2017.

Certepetide/iRGD activity & broad applicability consistently demonstrated

Sampling of >350 scientific publications showing improved survival with certepetide/iRGD

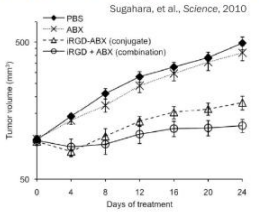
Lung cancer + gemcitabine

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



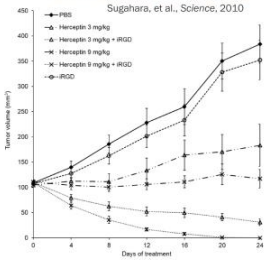
Breast cancer + nanoparticle Abraxane

Sugahara, et al., *Science*, 2010



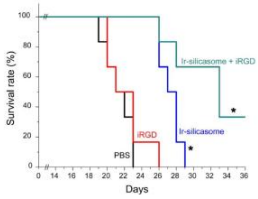
Breast cancer + Herceptin®

Sugahara, et al., *Science*, 2010



PDAC + irinotecan nanoparticles

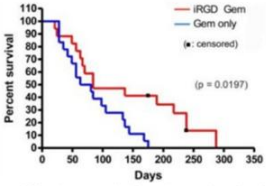
Liu X et al., J Clin Invest, 2017



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

PDAC + gemcitabine

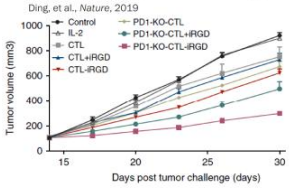
Hurtado de Mendoza et al, Nature Comms, 2021



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

GI cancer + adoptive cell therapy

Ding, et al., *Nature*, 2019



Certepetide Ph 1b/2a results: Compelling improvement of SoC efficacy

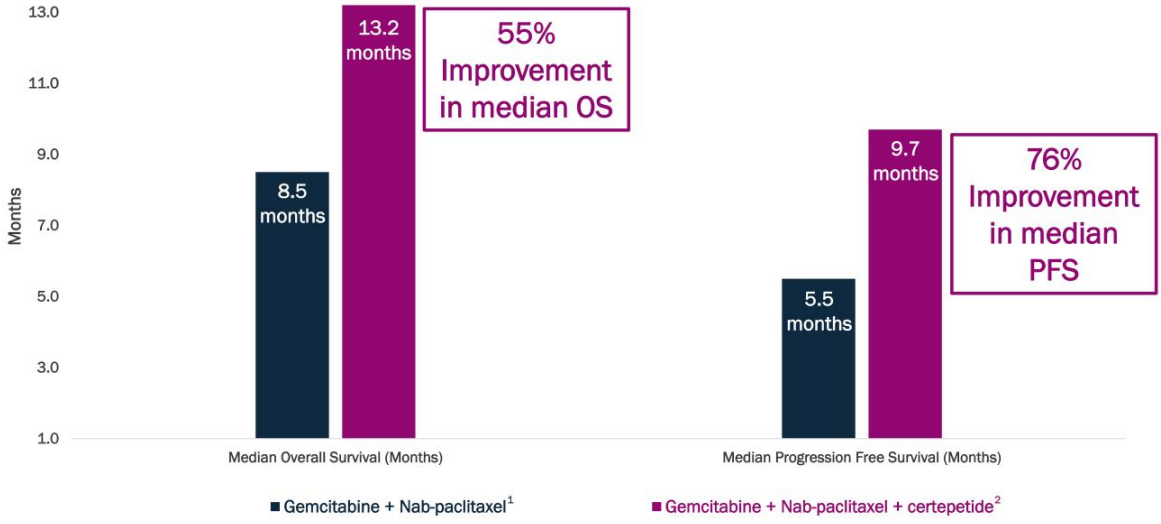
Endpoints	Gemcitabine + Nab-paclitaxel[1]	Certepetide + Gemcitabine + Nab-paclitaxel[2]
N= # of study participants	N=431	N=31
Median Overall Survival	8.5 mos.	13.2 mos.
Median Progression-Free Survival	5.5 mos.	9.7 mos.
Objective Response Rate	23% (99)	59% (17)
Complete Response	0.2% (1)	3.4% (1)
Partial Response	23% (98)	55% (16)
Stable Disease	27% (118)	31% (9)
Progressive Disease	20% (86)	10.3% (3)
Disease Control Rate 16 weeks	48%	79%
CA19-9 >20% drop	61%	96%

First-line, mPDAC patients from 3 sites in Australia

Certepetide well-tolerated, no dose-limiting toxicities; safety of certepetide + SoC consistent with SoC alone

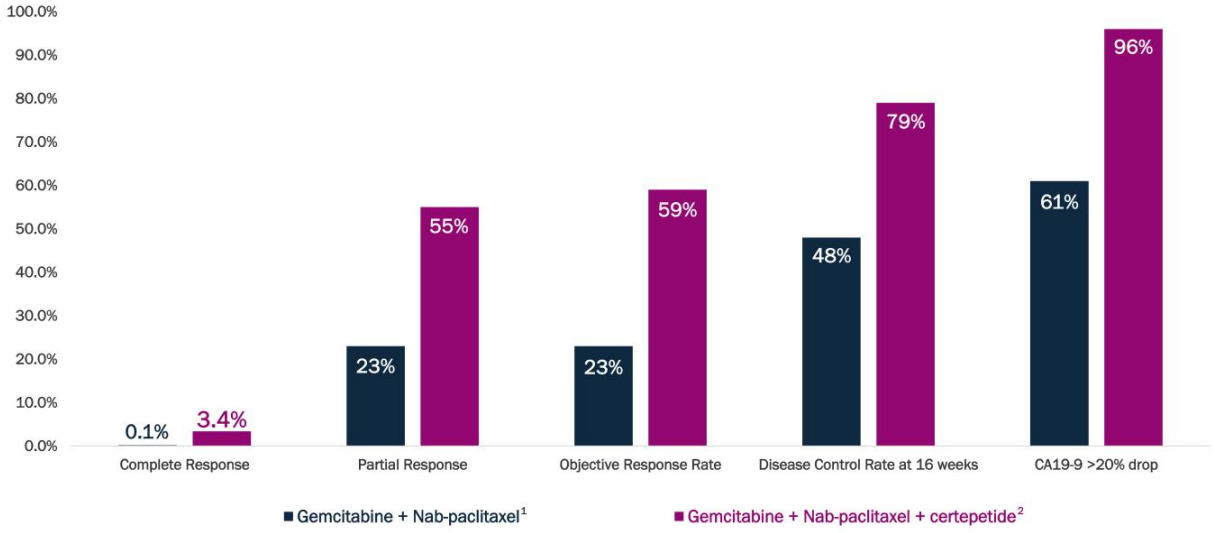
[1] Von Hoff D, et al., *New England Journal of Medicine*, 2013.
[2] Dean A, et al., *The Lancet Gastroenterology & Hepatology*, 2022.

Certepetide Ph 1b/2a results: Improved survival vs. SoC alone



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

Certepetide Ph 1b/2a results: Consistent improvement across associated endpoints

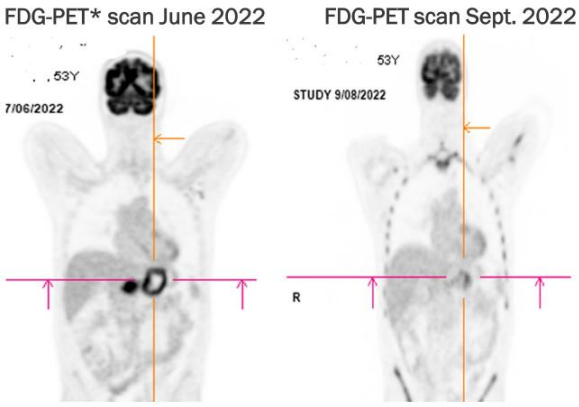


[1] Von Hoff D. et al., *New England Journal of Medicine*, 2013.
[2] Dean A. et al., *The Lancet Gastroenterology & Hepatology*, 2022

Clinical evidence of certepetide activity in other solid tumors

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

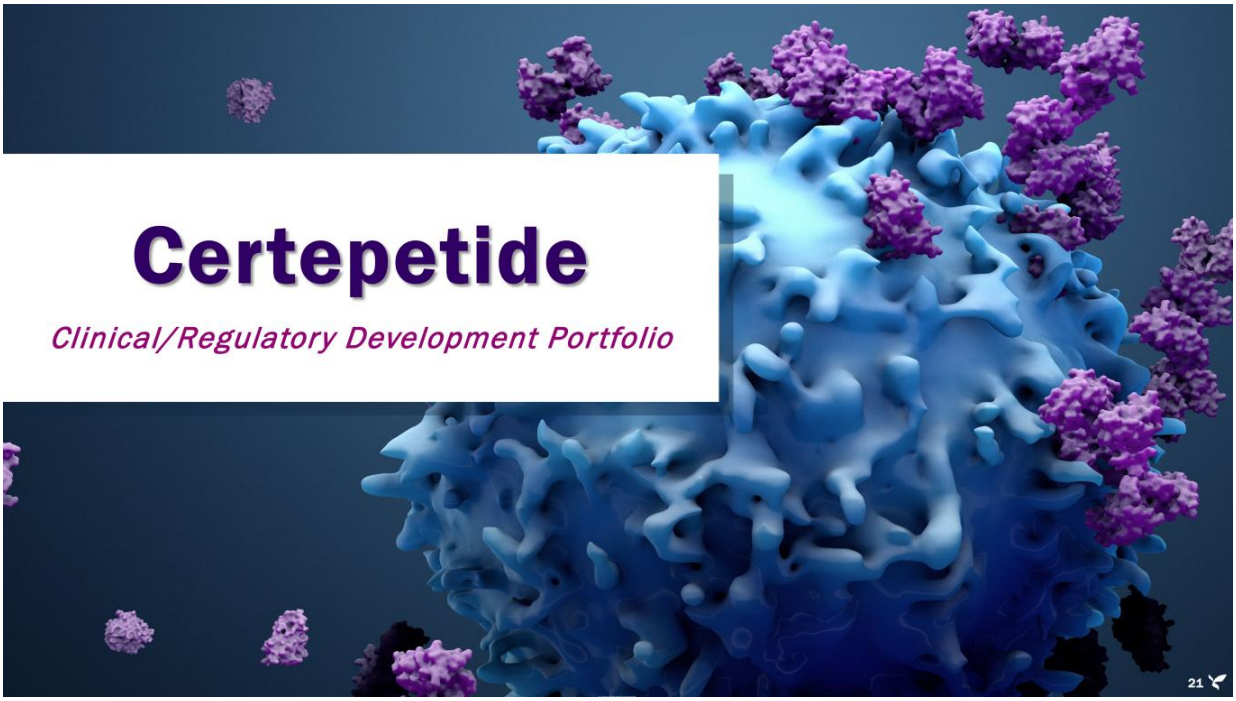
- 53-year-old male with mGEAC with significant (> 5cm) nodal metastases (June 2022)
- SoC combination radiotherapy, chemotherapy (FOLFIRINOX), and immunotherapy (pembrolizumab) resulted in partial response
- Certepetide added to SoC regimen at cycle 7
- Exploratory laparoscopy after cycle 18 (September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



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


Certepetide
Clinical/Regulatory Development Portfolio
21

Certepetide regulatory designations and implications

FDA Fast Track Designation

- More frequent communication with and program-specific guidance from FDA
- Eligible for *Accelerated Approval, Priority Review and Rolling Review*
- ***Certepetide received Fast Track Designation from FDA for pancreatic cancer***

FDA Rare Pediatric Disease Designation

- Eligible for *Priority Review Voucher* that can be redeemed to receive a priority review for any subsequent marketing application, or may be sold or transferred
- Historically, vouchers have sold for $350 million USD and, more recently, have sold for $75-$100 million USD
- ***Certepetide received Rare Pediatric Disease Designation from FDA for osteosarcoma***

Orphan Drug Designation

- Incentives such as *tax credits, marketing exclusivity, fee waivers and grant eligibility* to support clinical trials
- Specialized regulatory assistance from FDA's Office of Orphan Products Development
- ***Certepetide received Orphan Drug Designations from FDA and EMA for pancreatic cancer, from FDA for malignant glioma, and from FDA for osteosarcoma***

Certepetide capital efficient development plan

Sponsors/Partners	Region	Indication and Test Articles	Status
AGITG/Lisata	Australia & New Zealand	**First-line mPDAC** Gemcitabine/nab-paclitaxel with certepetide or placebo N=158	Phase 2b (**ASCEND**) Placebo-controlled ***Enrollment complete***
Lisata	USA	**First-line Cholangiocarcinoma (CCA)** Gemcitabine/cisplatin/durvalumab with certepetide or placebo N=40	Phase 2a (**BOLSTER**) Placebo-controlled *Enrolling*
KUCC/Lisata	USA	**Pancreatic, Colon, & Appendiceal Cancers** FOLFIRINOX + panitumumab* with certepetide N=50	Phase 1b/2a (**CENDIFOX**) Open-label *Enrolling*
Qilu/Lisata	China	**First-line mPDAC** Gemcitabine/nab-paclitaxel + certepetide N=41	Phase 1b/2a Open-label ***Enrollment complete***
WARPNINE/Lisata	Australia	**Locally advanced, non-resectable PDAC** Gemcitabine/nab-paclitaxel/durvalumab + certepetide N=30	Phase 1b/2a (**iLSTA**) Open-label *Enrolling*

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

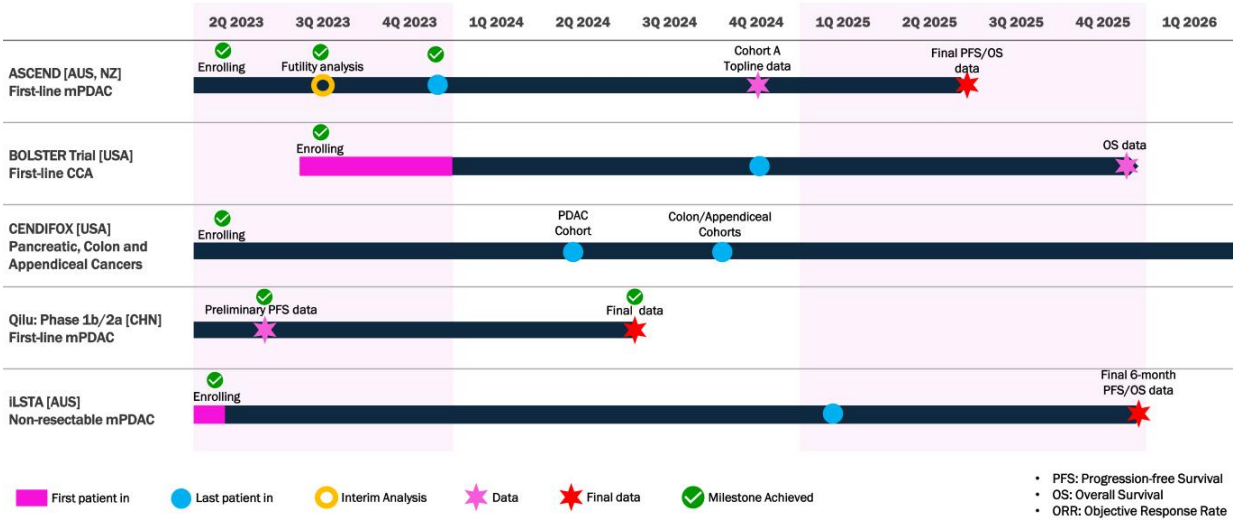
Certepetide capital efficient development plan

Sponsors/Partners	Region	Indication and Test Articles	Status
Tartu University/ Lisata	Estonia & Latvia	**First-line Glioblastoma Multiforme (GBM)** Temozolomide +/- certepetide N=30	Phase 2a Placebo-controlled *Enrolling*
UCSD/Lisata	USA	**Peritoneal Carcinomatosis (Colon & Ovarian)** HIPEC* intraoperative intraperitoneal lavage + certepetide N=21	Phase 1 Open-label *Enrolling*
Qilu/Lisata	China	**First-line mPDAC** Gemcitabine/Nab-paclitaxel + certepetide N=120	Phase 2 Placebo-controlled *Enrolling*
WARPNINE/Lisata	Australia	**Locally advanced, non-resectable Gastroesophageal Adenocarcinoma** Nivolumab/FOLFIRINOX + certepetide N=40	Phase 1b/2a (**iGoLSTA**) Open-label *Pending initiation*

*Hyperthermic intraperitoneal chemotherapy


Development
Milestones
25

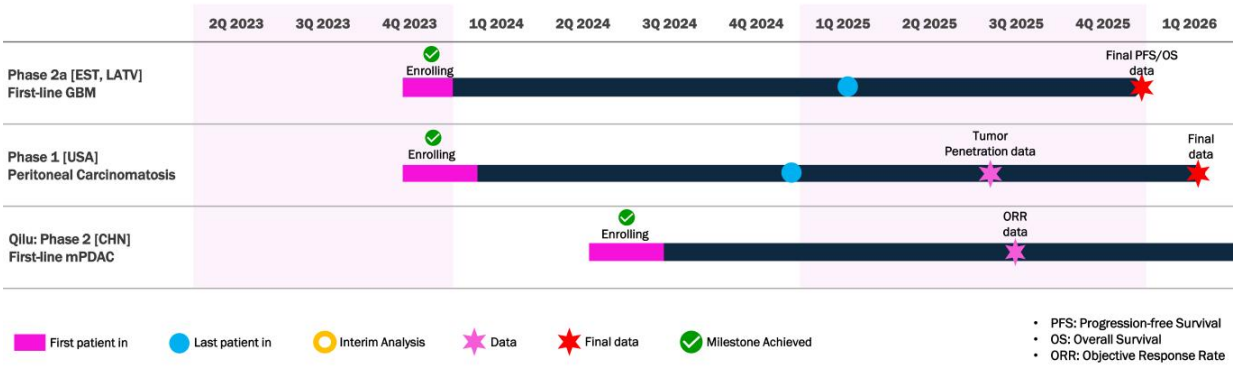
A wealth of anticipated key milestones



- 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.*

A wealth of anticipated key milestones (contd.)



- 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
28

Capital projected to fund all clinical programs to data

Cash & Investments *As of 3/31/2024*	Debt	Projected Cash Runway Into
$43.3M	**$0**	**1Q2026**

Common Shares Outstanding (3/31/2024):	8.3 million shares
Options Outstanding (3/31/2024): Exercise Price: $0.02 - $4.22 = 1,216,100 shares Exercise Price: > $4.22 = 237,800 shares	1.5 million shares
Warrants Outstanding (3/31/2024): Weighted Average Exercise Price: $42.51	1.4 million shares


Investment Thesis
Rational and focused development program
Highly experienced management team
Derisked asset based on a body of data
Fiscally stable company
30

Key factors supporting investment in Lisata Therapeutics

PEOPLE	TECHNOLOGY	MILESTONES	CAPITAL	PARTNERING
Seasoned management with successful international development experience and expertise	Proprietary field-leading technology in underserved global indications	Multiple projected product and business milestones over the next 24 months	$43.3 million cash*- no debt; Development funded through critical data milestones	Platform technology "validated" by existing partnerships with potential for many others

* As of 3/31/2024; includes investments

LISATA THERAPEUTICS

Targeted Therapy *Delivered*

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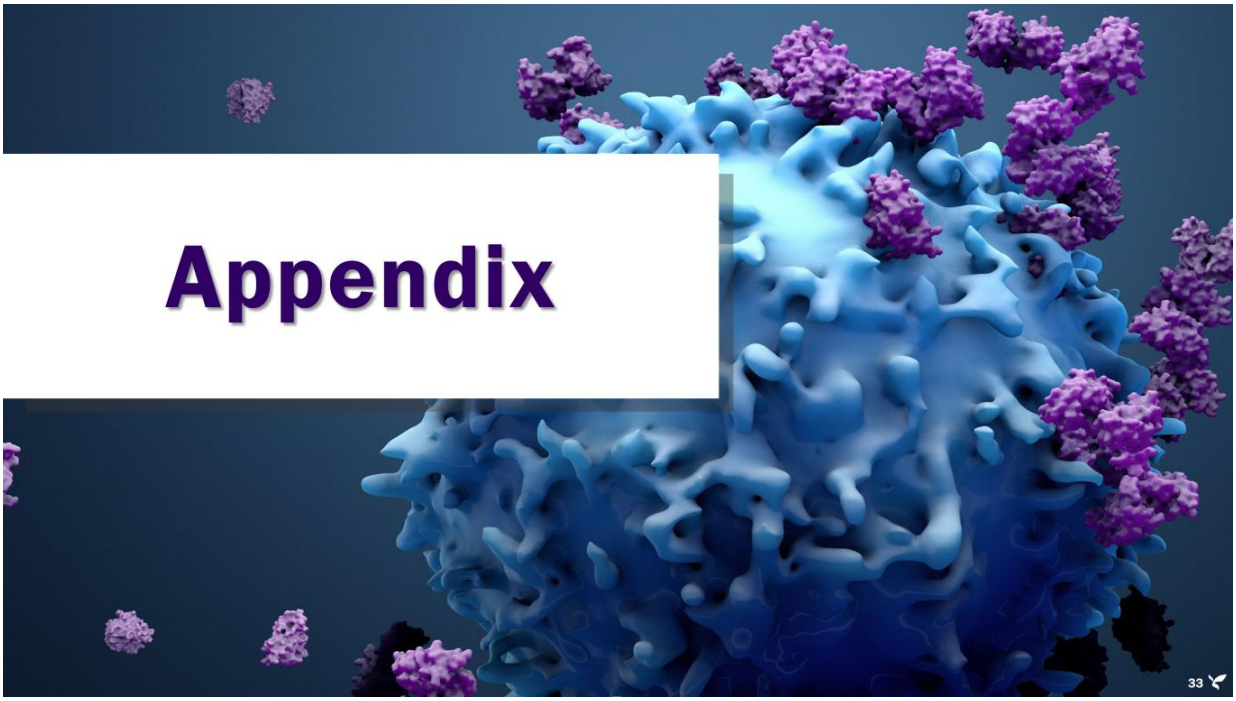
Nasdaq: LSTA | *www.lisata.com*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Certepetide capital efficient development plan

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-line Cholangiocarcinoma (CCA);** Gemcitabine/cisplatin/durvalumab with 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)
WARPNINE/Lisata [Australia]	**Locally advanced non-resectable Gastroesophageal (GE) adenocarcinoma;** Nivolumab/FOLFIRINOX + certepetide	**Phase 1b/2a (iGoLSTA)**	Assess certepetide safety and effectiveness in combination with IO & chemo in locally advanced GE AdenoCa; determine if inoperable tumors can become operable (open label)

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

Certepetide capital efficient development plan

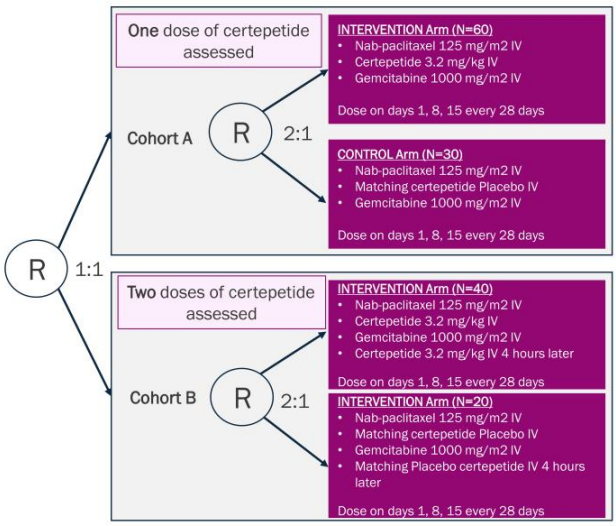
Development Partner(s) [Development Venue]	Indication and Trial Product/Comparator	Stage of Development	Strategic Rationale
Tartu University/Lisata [Estonia/Latvia]	**First-line Glioblastoma Multiforme;** Temozolomide +/- certepetide	Phase 2a	Assess certepetide safety and effectiveness in additional tumor type (GBM) in a placebo-controlled trial
UCSD/Lisata [United States]	**Peritoneal Carcinomatosis** HIPEC* intraoperative intraperitoneal lavage + certepetide	Phase 1	Assess safety and intraoperative tumor penetration of HIPEC in combination with certepetide (open label)
Qilu [China]	**First-line mPDAC;** Gemcitabine/Nab-paclitaxel + certepetide	Phase 2b	Continue development of certepetide in China (placebo controlled)

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 2024

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 2024

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

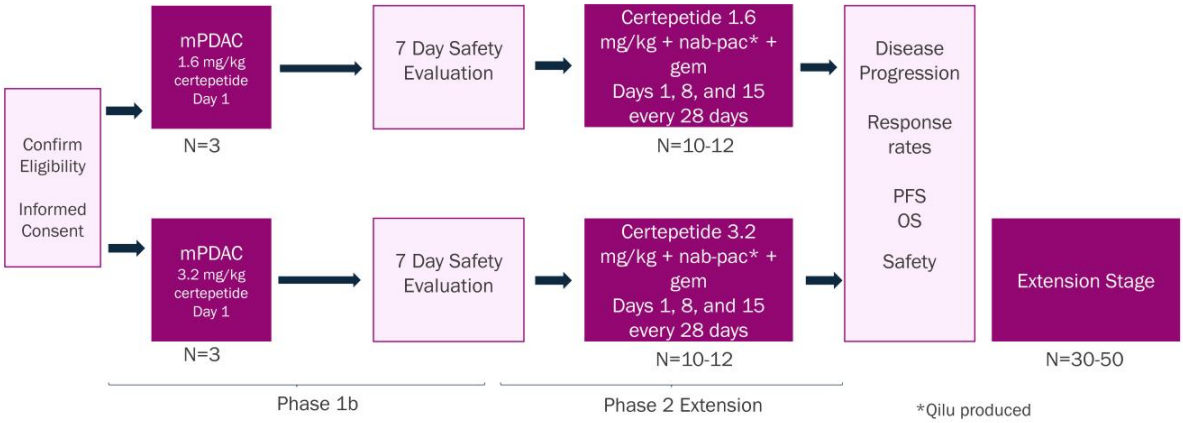
Phase 1b/2a open-label trial in mPDAC in China

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	▪ Preliminary data expected 1H23

Phase 1b/2a open-label trial in mPDAC in China

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 expected 1H23

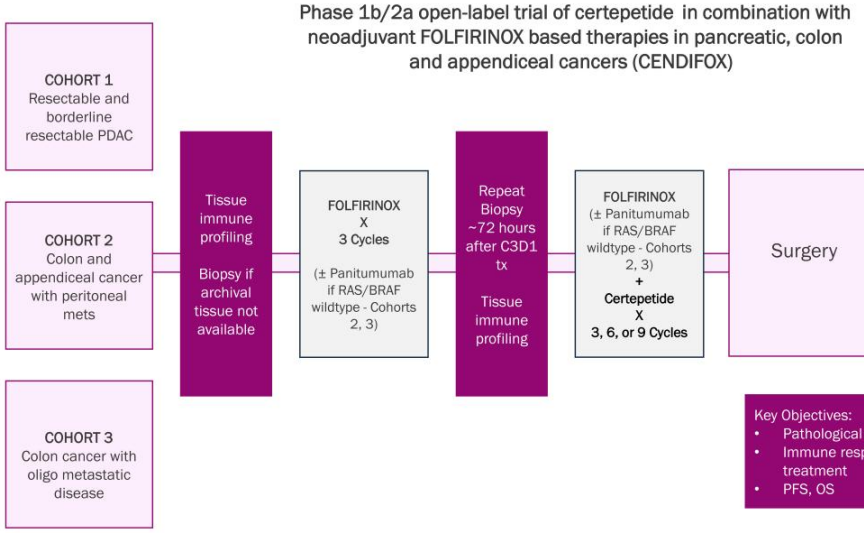


*Qilu produced

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 (20 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 4Q23 ▪ Data readouts possible throughout 2023 with complete results expected 2024

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 4Q23; data readouts possible throughout 2023; complete results expected 2024

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-line cholangiocarcinoma
Design	▪ Phase 2 randomized, double-blind, placebo-controlled, proof-of-concept trial in first-line cholangiocarcinoma testing corresponding SoC with certepetide or placebo
Study Size	▪ N=40 (1:1 SoC + certepetide or SoC + placebo)
Endpoints	▪ Primary: OS ▪ Secondary: Safety, ORR, PFS
Timing	▪ Trial initiation target: 2Q23 ▪ Enrollment commenced September 2023

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-line cholangiocarcinoma

- Sponsor: Lisata
- Timing: Trial initiation target 2Q23

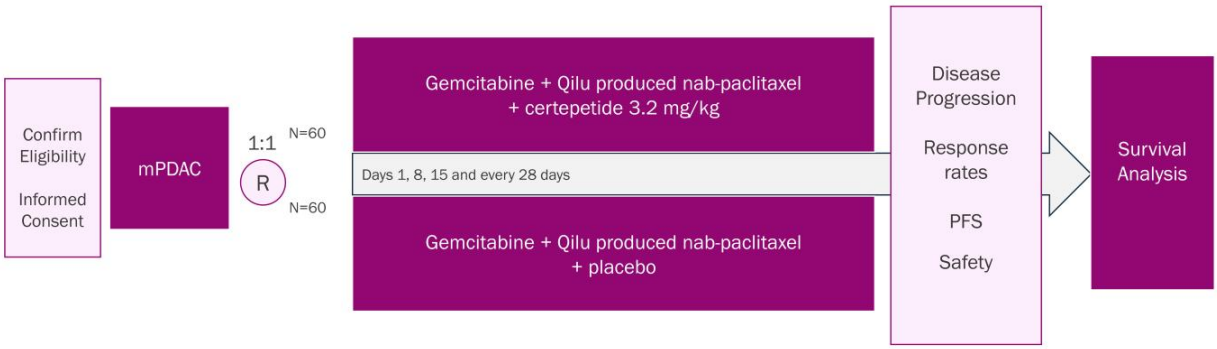
Phase 2 double-blind, placebo-controlled trial in mPDAC in China

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 initiation target 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

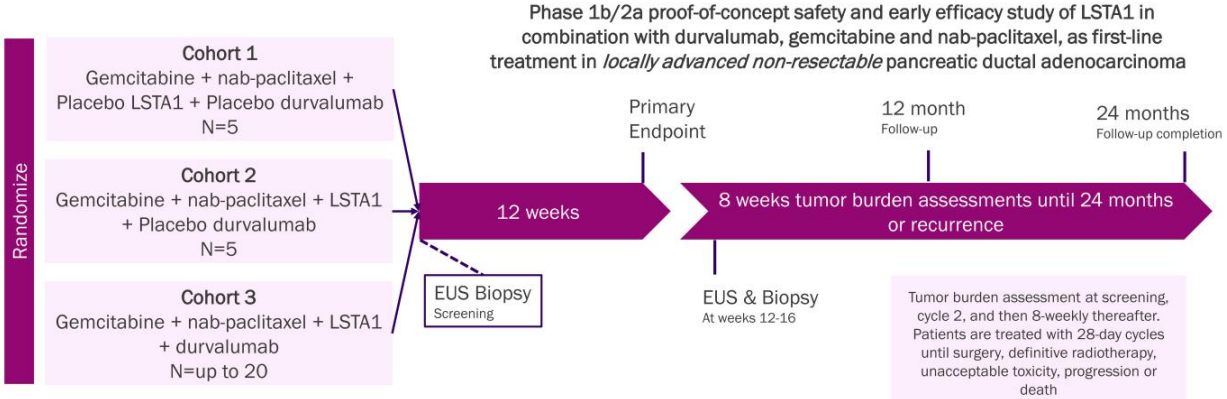
- Sponsor/Partner: Qilu Pharmaceutical (funds all development in China)
- Timing: Trial initiation target 2Q24



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	▪ Trial initiation target 2Q23 ▪ Enrollment commenced April 2023

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



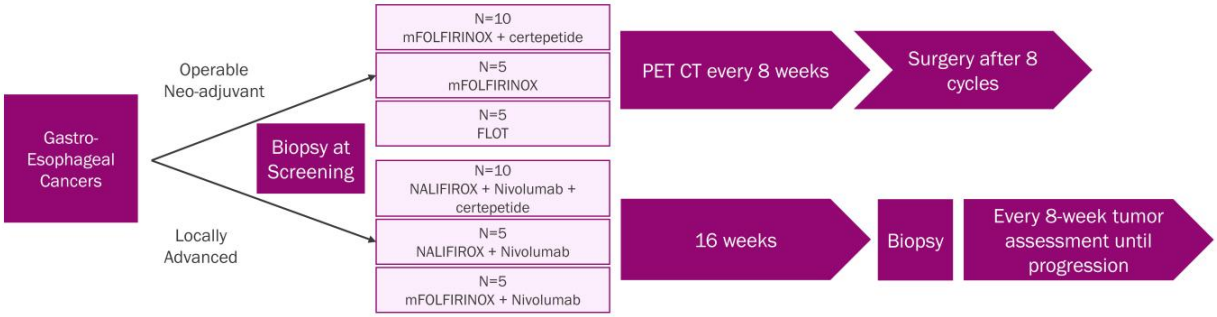
- Sponsor: WARPNINE, Inc. - funding trial
- Timing: Trial initiation target 2Q23

iGoLSTA: Phase 1b/2a trial in operable/inoperable GEC with chemo & IO

Sponsor/Partner	▪ WARPNINE, Inc. (registered charity in Australia) is funding trial ▪ Lisata providing study drug
Objective	▪ Evaluate certepetide safety & therapeutic effect in combination neoadjuvant chemo in operable gastroesophageal (GE) cancers. ▪ Evaluate certepetide safety and therapeutic effect in combination with immunotherapy and chemotherapy for advanced non-resectable GE cancers
Design	▪ Phase 1b/2a proof-of-concept, two cohort, 6 arm safety and early efficacy study of certepetide in combination with chemo as treatment in *resectable* GE cancers as well as in combination with chemotherapy and immunotherapy in *advanced non-resectable* GE cancers
Study Size	▪ N=40 (20 per cohort)
Endpoints	▪ Safety and tolerability ▪ Objective response rate, PFS, OS, duration of response, immune cell infiltration
Timing	▪ Trial initiation target 3Q23

iGoLSTA: Phase 1b/2a trial in operable/inoperable GEC with chemo & IO

Phase 1b/2a proof-of-concept safety and early efficacy study of certepetide in combination with chemotherapy and immunotherapy in *resectable* and *locally advanced non-resectable* gastroesophageal cancers



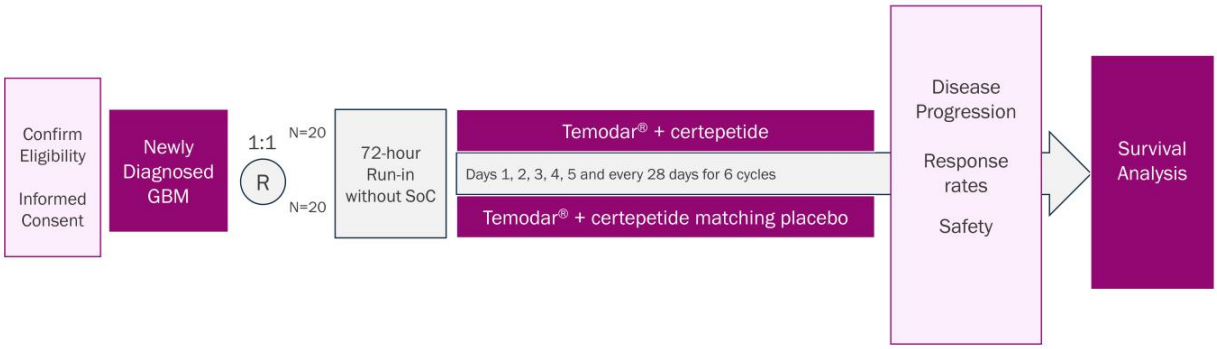
Phase 2a trial of certepetide with SoC in first-line GBM

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=40
Endpoints	▪ Safety, tolerability ▪ ORR, PFS, OS, disease control rate
Timing	▪ Trial initiation target 3Q23 ▪ 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: Trial initiation target 3Q23



Phase 1 trial of certepetide + HIPEC in Peritoneal Carcinomatosis

Sponsor/Partner	▪ University of California, San Diego (Investigator initiated trial)
Objective	▪ Evaluate safety of certepetide in combination with hyperthermic intraperitoneal chemotherapy (HIPEC) or HIPEC alone (without certepetide) in patients with peritoneal metastases
Design	▪ Phase 1 single-center, unblinded, randomized trial to determine the safety and tolerability of certepetide administered intraperitoneally in patients with peritoneal metastases from colorectal, appendiceal, or ovarian cancer undergoing Cytoreductive Surgery (CRS) and HIPEC. Participants will be randomized 2:1 to receive certepetide with HIPEC versus HIPEC alone after CRS.
Study Size	▪ N=21
Endpoints	▪ Safety and tolerability ▪ PFS, OS
Timing	▪ First patient treated target 4Q23

Phase 1 trial of certepetide + HIPEC in Peritoneal Carcinomatosis

A Phase I, single center, unblinded, randomized controlled trial of Intraperitoneal Certepetide in Patients Undergoing Cytoreductive Surgery and HIPEC for Peritoneal Surface Malignancy

- Sponsor: Tartu University Hospital; Estonia
- Funding: Lisata
- Timing: Trial initiation target 4Q23