

Targeted Therapy Delivered

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> > <u>www.lisata.com</u>



Forward-looking statements advisory

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Lisata at a Glance

Company Overview





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 fieldleading 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

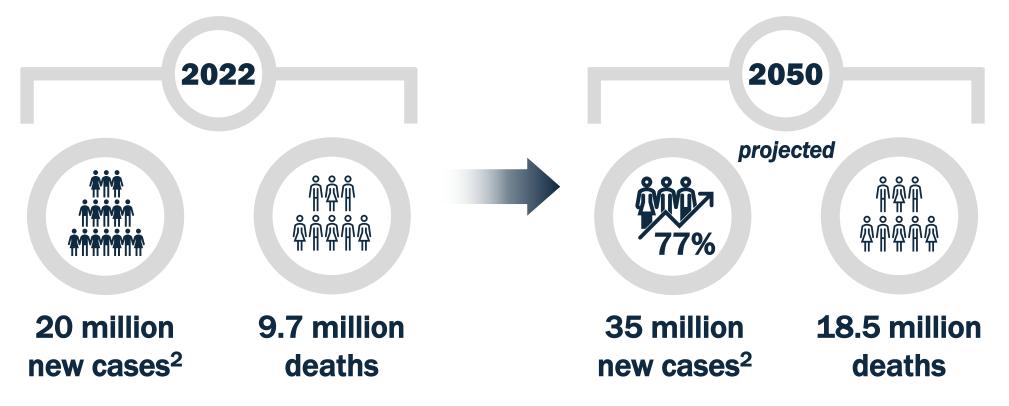
Problem, Solution and Approach





Improved solid tumor cancer treatment is a vital global need

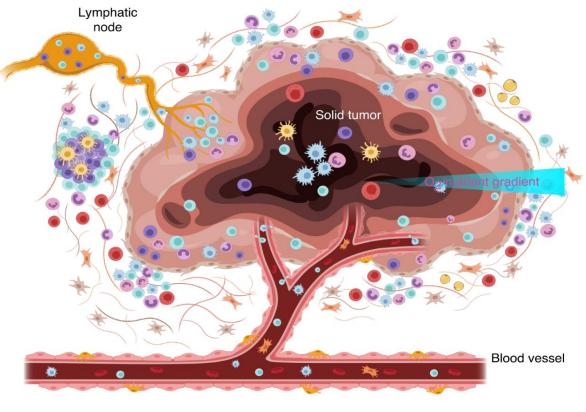
In 2023, in the U.S. alone, of ~2 million newly diagnosed cancer cases, >90% were solid tumor cancers¹

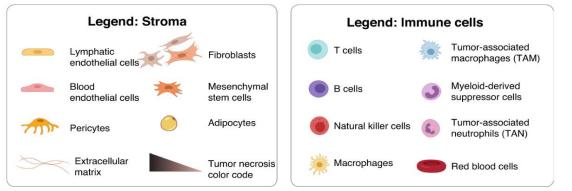


Examples of solid tumor cancers include cancers of the lung, breast, pancreas, liver, bile duct, kidneys, ovaries, brain, colon, prostate, esophagus, and head & neck

¹ <u>https://seer.cancer.gov/statfacts/html/common.html;</u> data retrieved November 2, 2023. ² https://gco.jarc.who.int/tomorrow/en/dataviz/tables?mode=population&vears=2050&types=1&populations=903 904 905 908 909 935 900; data retrieved Feb 12, 2024.

Current solid tumor treatments are suboptimal





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 nontargeted anti-cancer therapy generally leads to intolerable off-target side effects

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

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 metastases¹
 - 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

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 mortality¹

- 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

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Partnerships

Noteworthy existing relationships and potential for many more





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)



- 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

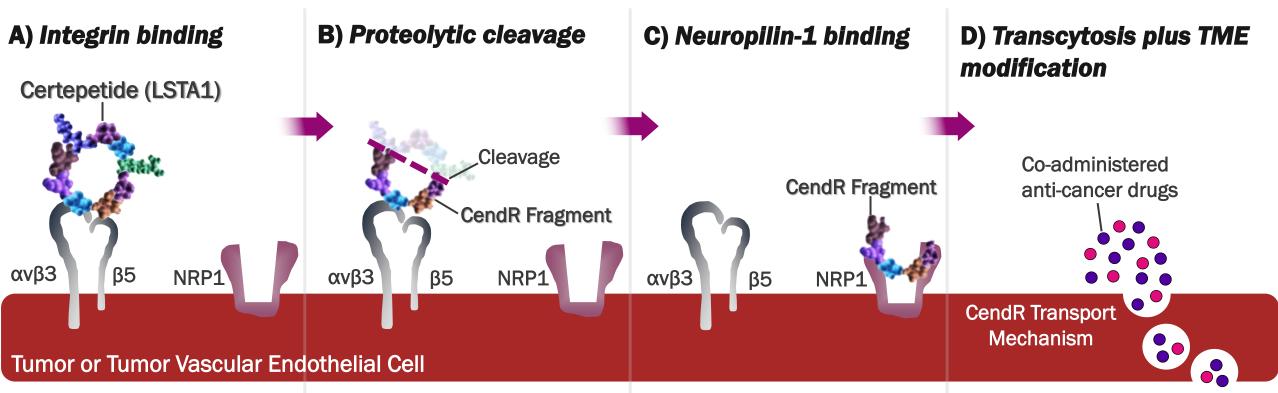
By indication, modality of co-administered drug(s), and/or geography

Certepetide (formerly LSTA1)

Strong Scientific Foundation and Rationale



Certepetide selective tumor targeting & penetration mechanism of action



Certepetide is a 9 amino acid cyclic peptide with high binding affinity and specificity to $\alpha\nu\beta3/\beta5$ integrins that are upregulated on tumor cells and tumor endothelial cells (i.e., tumor stroma)

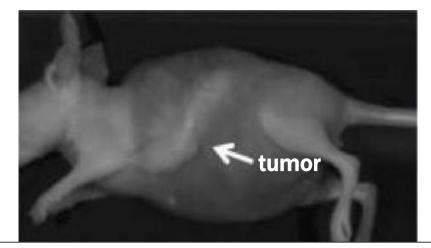
Once bound to αvβ3 & β5 integrins, certepetide is cleaved by proteases in the tumor microenvironment (TME) releasing a C-end Rule (CendR) linear peptide fragment The CendR fragment binds with high affinity and specificity to neuropilin-1 (NRP1), an adjacent receptor on the same or nearby cell, activating the CendR transport pathway¹ 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

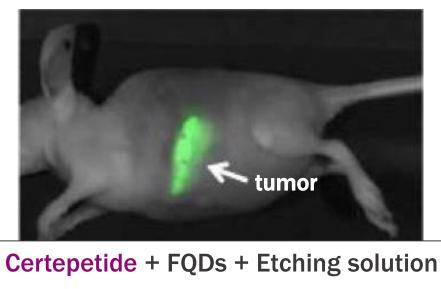
Certepetide selectively and efficiently facilitates intratumoral penetration

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



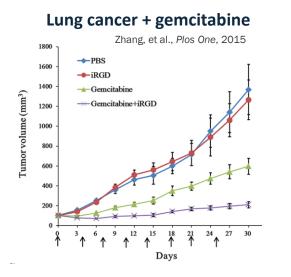
All FQDs in tumor

Certepetide provides targeted tumor penetration

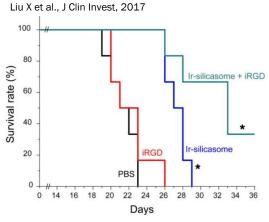
¹Braun et al., Nature Mater. 2014. ²Liu, Braun et al., Nature Comm. 2017.

Certepetide/iRGD activity & broad applicability consistently demonstrated

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

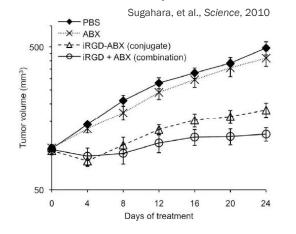






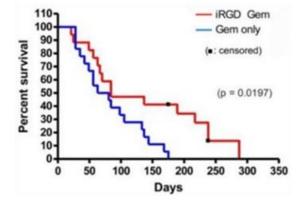
Orthotopically transplanted KPC PDAC tumors iRGD + irinotecan nanoparticles (i.v. co-admin)

Breast cancer + nanoparticle Abraxane

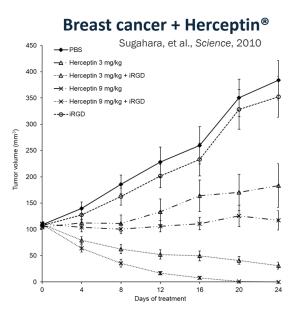


PDAC + gemcitabine

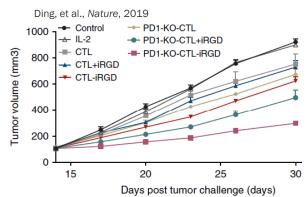
Hurtado de Mendoza et al, Nature Comms, 2021



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



GI cancer + adoptive cell therapy



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%

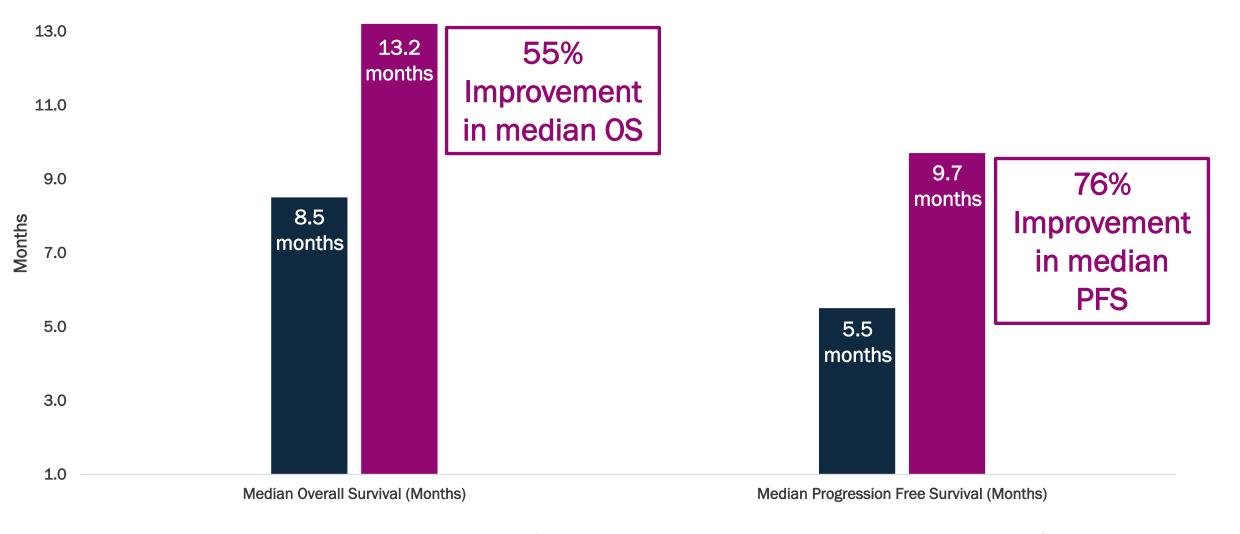


First-line, mPDAC patients from 3 sites in Australia

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

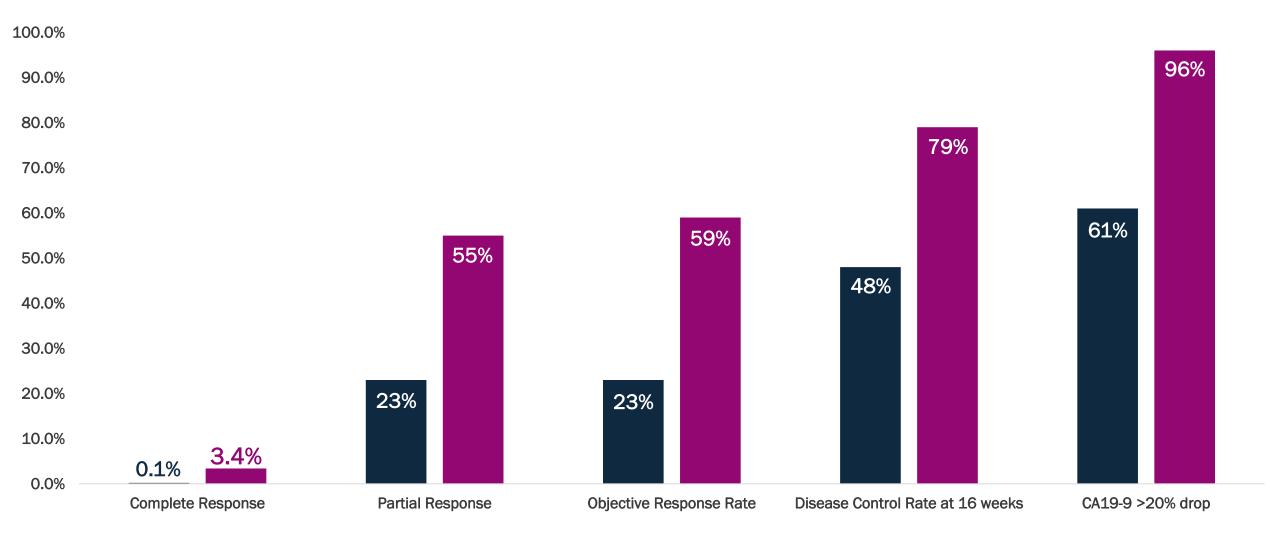
Certepetide Ph 1b/2a results: Improved survival vs. SoC alone



■ Gemcitabine + Nab-paclitaxel¹

■ Gemcitabine + Nab-paclitaxel + certepetide²

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



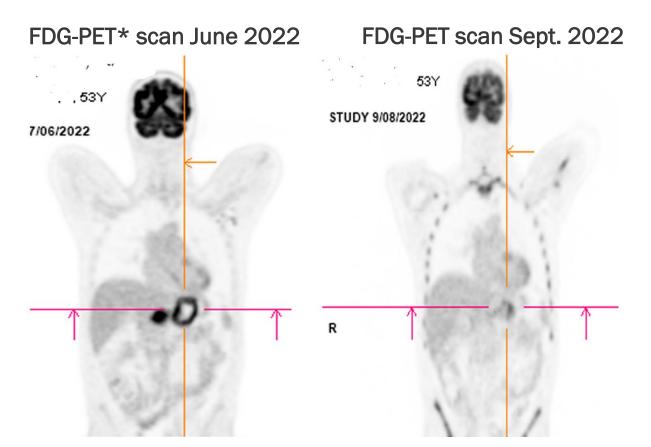
■ Gemcitabine + Nab-paclitaxel¹

Gemcitabine + Nab-paclitaxel + certepetide²

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 – <u>complete response</u>



Reduction in FDG activity demonstrated¹

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

Certepetide

Clinical/Regulatory Development Portfolio



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 <u>Fast</u> <u>Track Designation</u> from FDA for pancreatic cancer

FDA Rare Pediatric Disease Designation

- Eligible for <u>Priority Review Voucher</u> 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 <u>Rare</u> <u>Pediatric Disease Designation</u> 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 <u>Orphan</u> <u>Drug Designations</u> 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 <i>Enrolling</i>
KUCC/Lisata	USA	Pancreatic, Colon, & Appendiceal Cancers FOLFIRINOX + panitumumab* with certepetide N=50	Phase 1b/2a (CENDIFOX) Open-label <i>Enrolling</i>
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 <i>Enrolling</i>

Certepetide capital efficient development plan

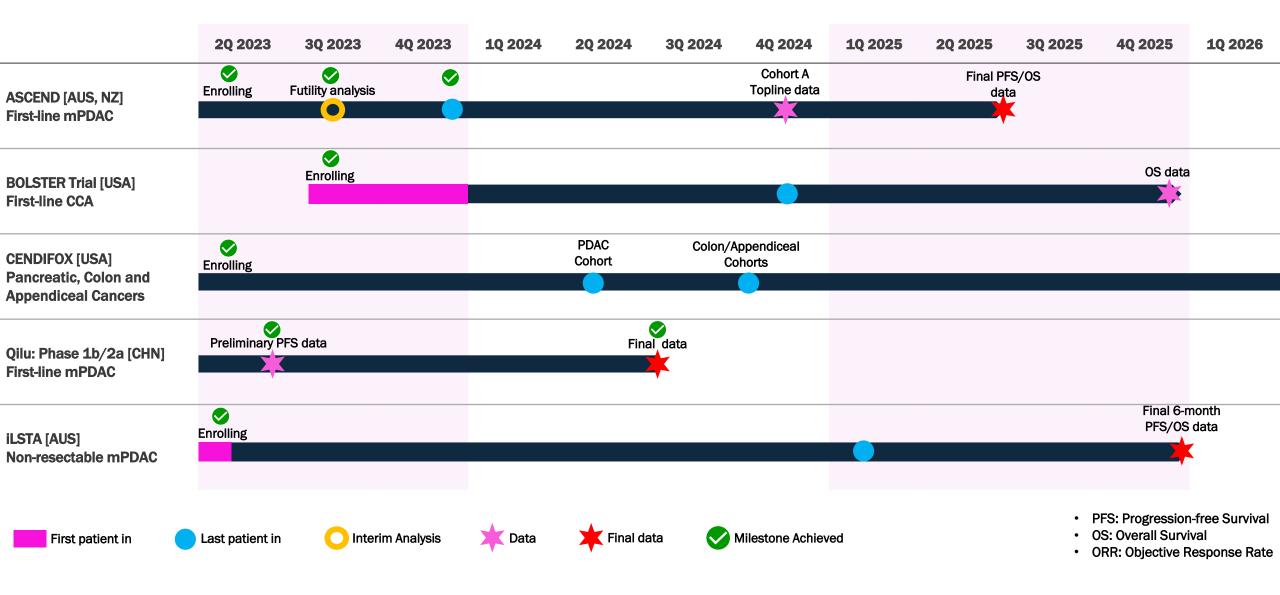
Sponsors/Partners	Region	Indication and Test Articles	Status
Tartu University/ Lisata	Estonia & Latvia	First-line Glioblastoma Multiforme (GBM) Temozolomide +/- certepetide N=30	Phase 2a Placebo-controlled <i>Enrolling</i>
UCSD/Lisata	USA	Peritoneal Carcinomatosis (Colon & Ovarian) HIPEC* intraoperative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

Development Milestones



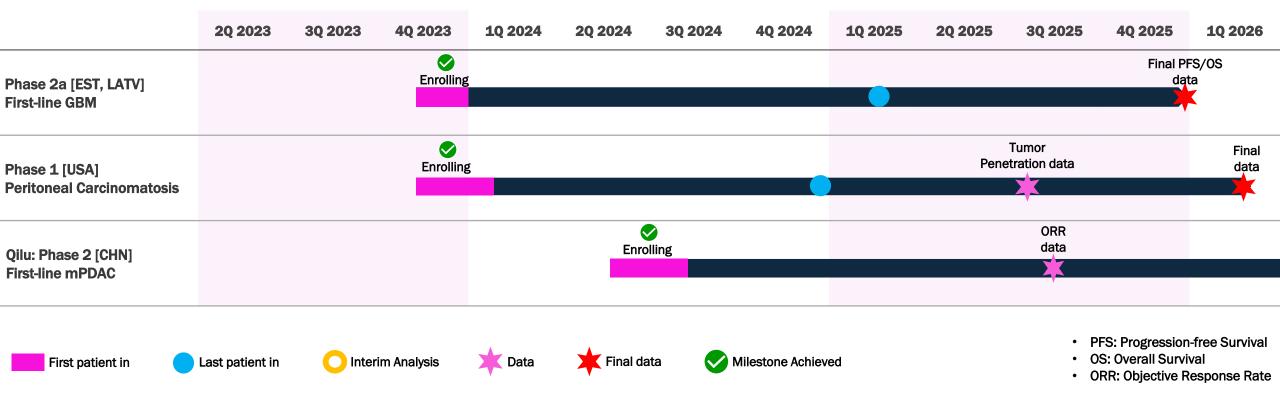


A wealth of anticipated key milestones



*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.)





Financial Highlights







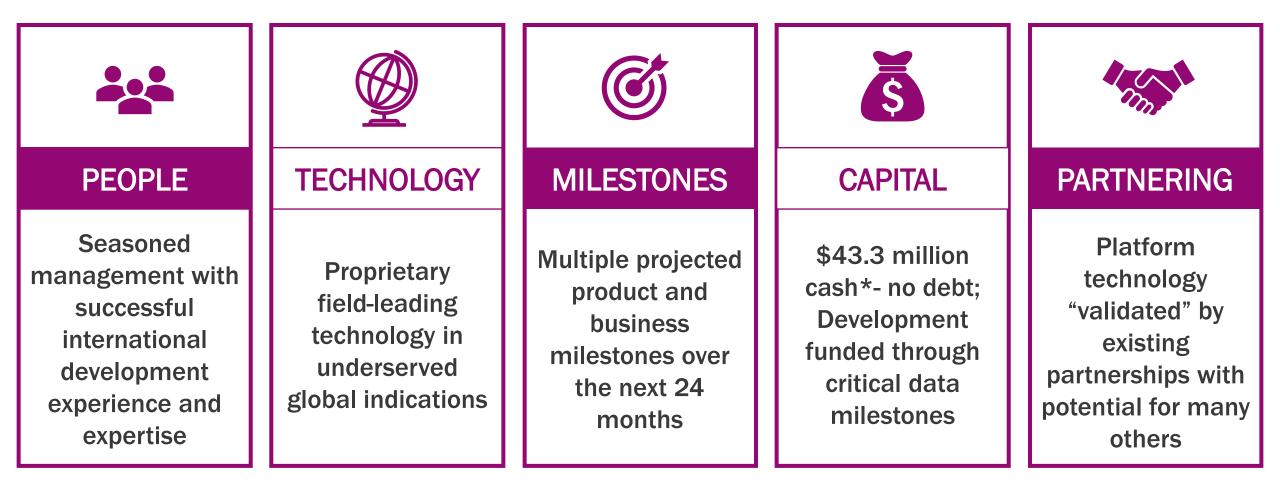
Capital projected to fund all clinical programs to data

Cash & Investments As of 3/31/2024	Debt	Projected Cash Runway Into	
\$43.3M	\$0	1Q2026	
Common Shares Outstanding (3/31/20	24):	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

Key factors supporting investment in Lisata Therapeutics



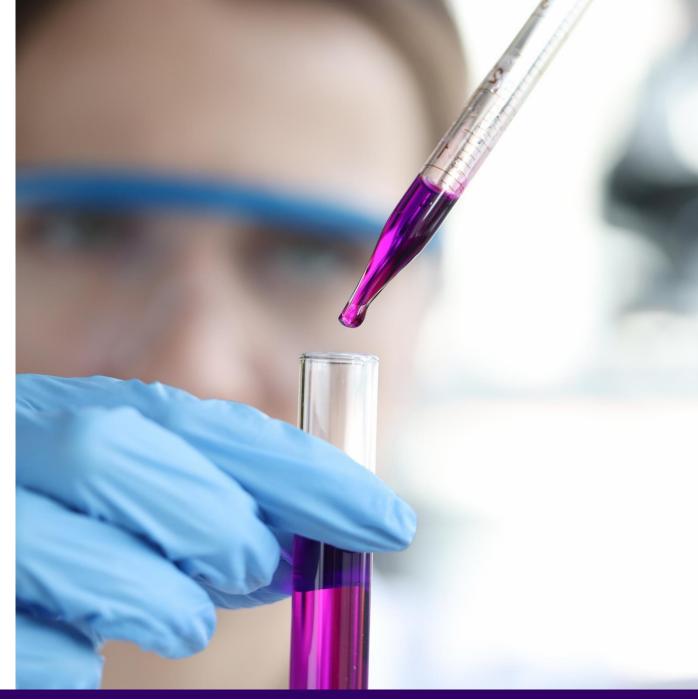


Targeted Therapy Delivered

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Appendix









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

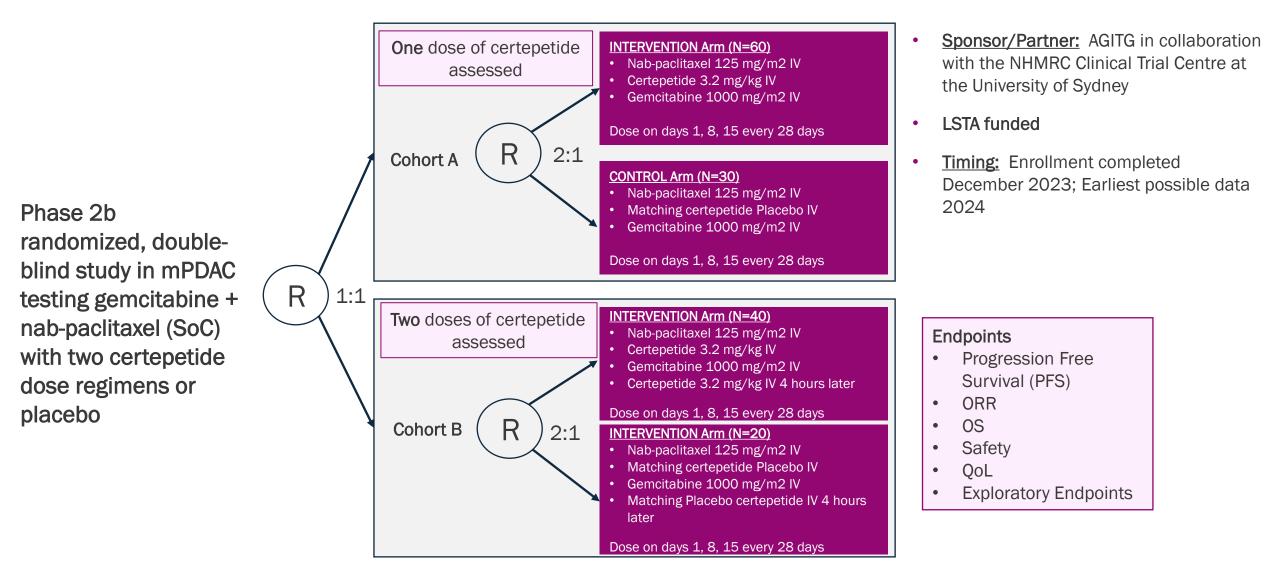
Certepetide capital efficient development plan

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 2023Earliest possible data 2024

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



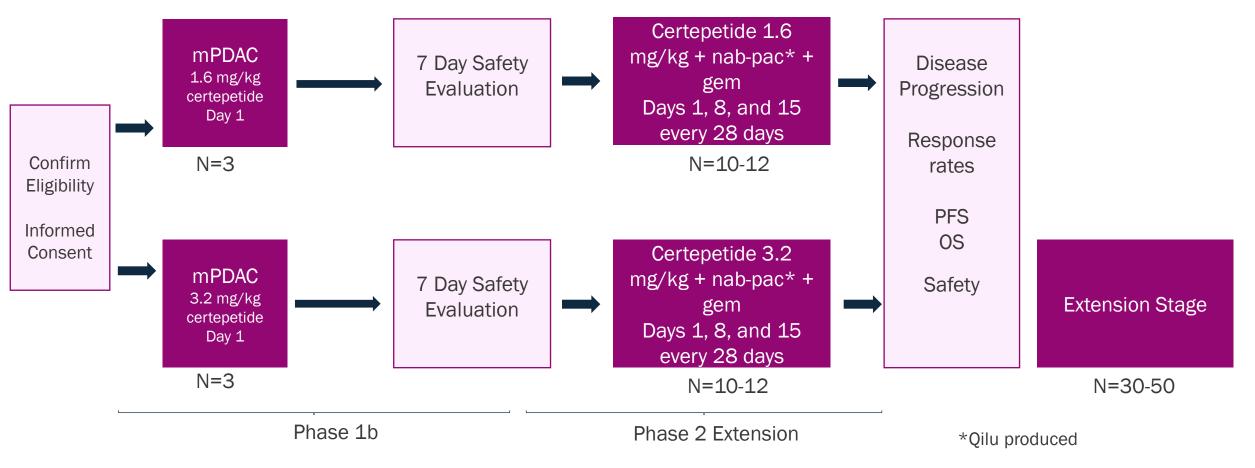
Phase 1b/2a open-label trial in mPDAC in China

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

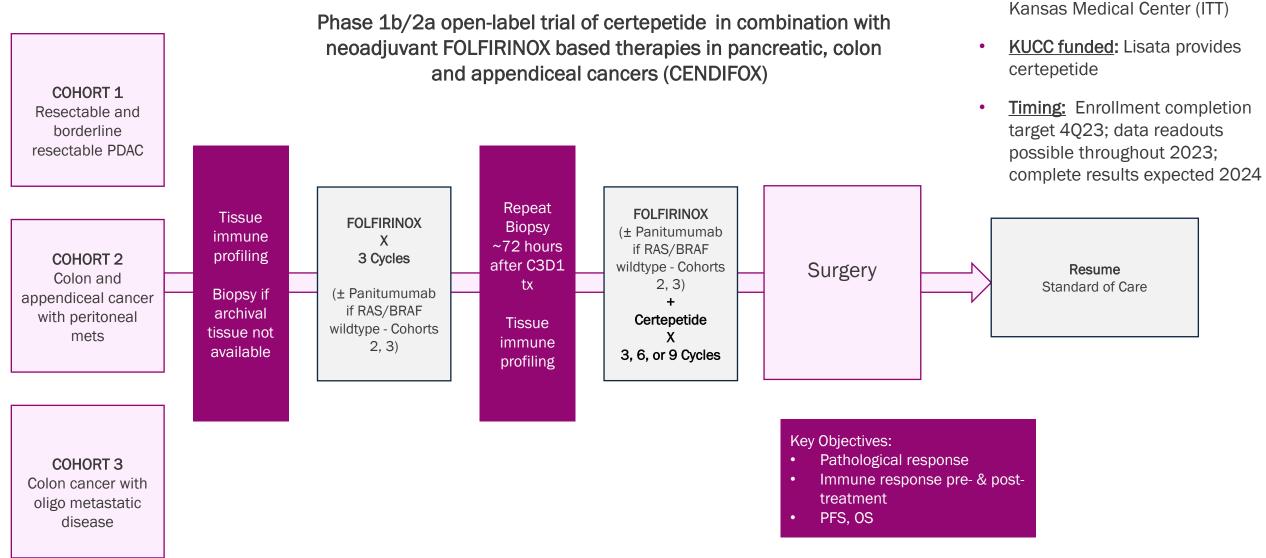
- Sponsor/Partner: Qilu Pharmaceutical (funds all development in China)
- <u>Timing:</u> Preliminary data expected 1H23



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



Appendix

Sponsor/Partner: University of

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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

 Phase 2 randomized, double-blind, placebo-controlled, proof-of-concept trial in first-line cholangiocarcinoma testing corresponding SoC with certepetide or placebo

Study SizeN=40 (1:1 SoC + certepetide or SoC + placebo)

Endpoints

Design

- 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

- <u>Sponsor:</u> Lisata
- <u>Timing:</u> Trial initiation target 2Q23

Appendix



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

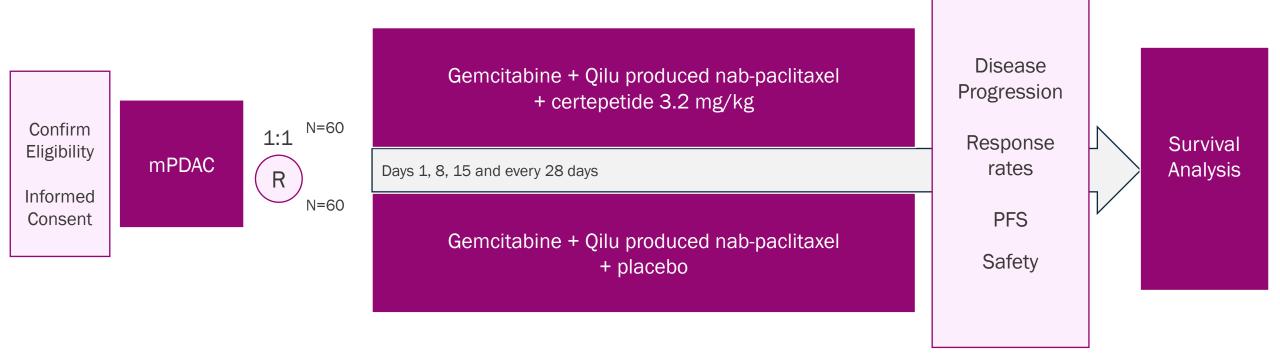
Timing

Trial initiation target 2Q24

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

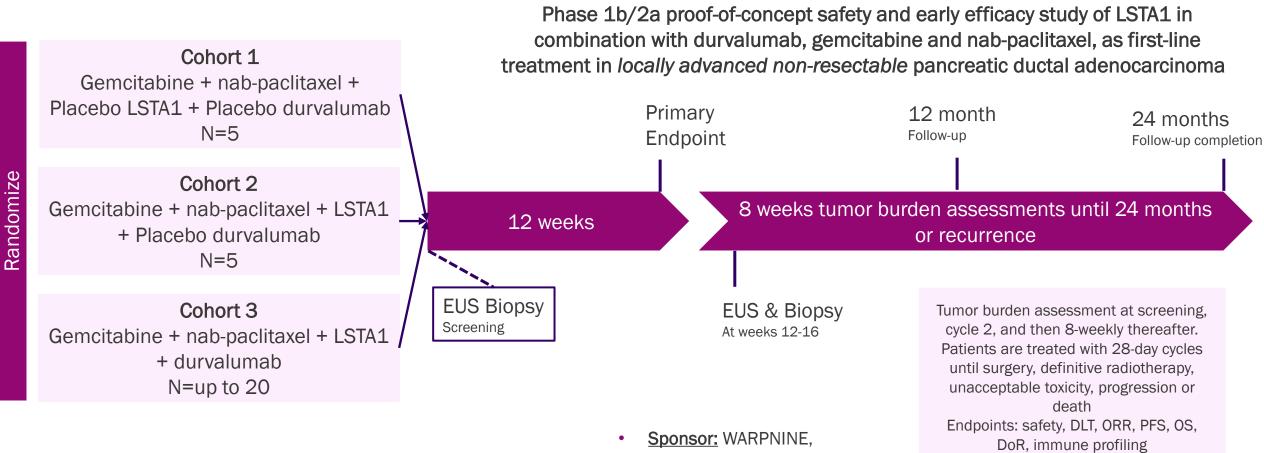
Phase 2b, double-blind, placebo-controlled, randomized, multicenter study evaluating the safety and efficacy of certepetide when added to standard of care (nab-paclitaxel and gemcitabine) vs. standard of care alone and placebo in Chinese subjects with locally advanced unresectable mPDAC

- Sponsor/Partner: Qilu Pharmaceutical (funds all development in China)
- <u>Timing</u>: 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 <i>locally advanced</i> 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



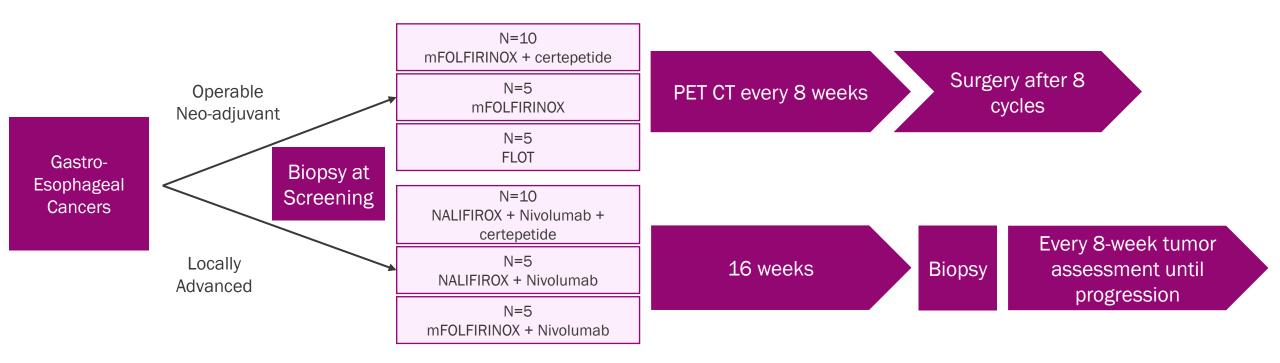
- Inc. funding trial
- **Timing:** Trial initiation target 2Q23

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 <i>resectable</i> GE cancers as well as in combination with chemotherapy and immunotherapy in <i>advanced non-resectable</i> 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



Appendix

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) 	ng
Study Size	 N=40 	
Endpoints	 Safety, tolerability ORR, PFS, OS, disease control rate 	
Timing	 Trial initiation target 3Q23 Enrollment commenced December 2023 	50 🏹

Sponsor: Tartu University

Hospital; Estonia

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

Phase 2a proof-of-concept double-blind, placebo-controlled, randomized, proof-of-Funding: Lisata concept study evaluating certepetide when added to standard of care (temozolomide) versus temozolomide and matching certepetide placebo in subjects with newly Timing: Trial initiation diagnosed GBM target 3Q23 Disease Progression Temodar[®] + certepetide N=20 Confirm 1:1 Newly Survival 72-hour Eligibility Response Diagnosed Analysis Days 1, 2, 3, 4, 5 and every 28 days for 6 cycles Run-in R rates GBM without SoC Informed N=20 Temodar[®] + certepetide matching placebo Consent Safety

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

First patient treated target 4Q23

Sponsor: Tartu University

Phase 1 trial of certepetide + HIPEC in Peritoneal Carcinomatosis

Hospital; Estonia A Phase I, single center, unblinded, randomized controlled trial of Intraperitoneal Certepetide in Patients Undergoing Cytoreductive Surgery and Funding: Lisata **HIPEC for Peritoneal Surface Malignancy** Timing: Trial initiation target 4023 Candidate for **CRS-HIPEC** Non-5-year Safety mucinous Patient CRS-HIPEC + certepetide Confirm N=14 appendiceal, 2:1 Record Tumor drug Eligibility colorectal, Day Review for concentration R 30 ovarian Survival Informed N=7 carcinoma **CRS-HIPEC** Analysis Consent **PFS** with \geq 5 mm peritoneal 0S nodule(s)