



# Targeted Therapy *Delivered*

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*President and Chief Executive Officer*

Corporate Presentation | April 9, 2024

Nasdaq: LSTA

[www.lisata.com](http://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.



# Company Overview

*Lisata at a Glance*

# 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 projected product and business milestones 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***



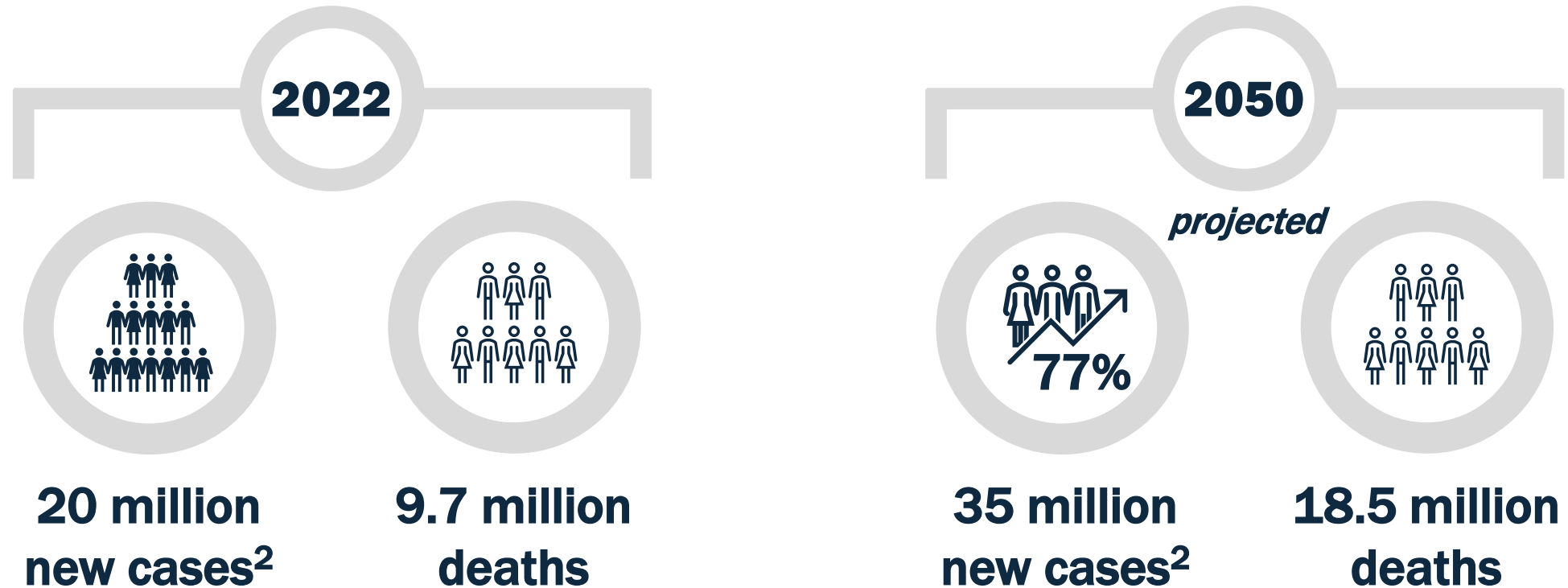
A 3D molecular model of a protein surface, rendered in a light blue color. The surface is highly textured with various protrusions and indentations. Several purple, ball-and-stick molecular models are shown interacting with the protein surface, particularly concentrated in a deep blue binding pocket. The background is a dark blue gradient.

# 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, there were ~2 million newly diagnosed cancer cases, with solid tumors comprising over 90% of these newly reported cases<sup>1</sup>



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

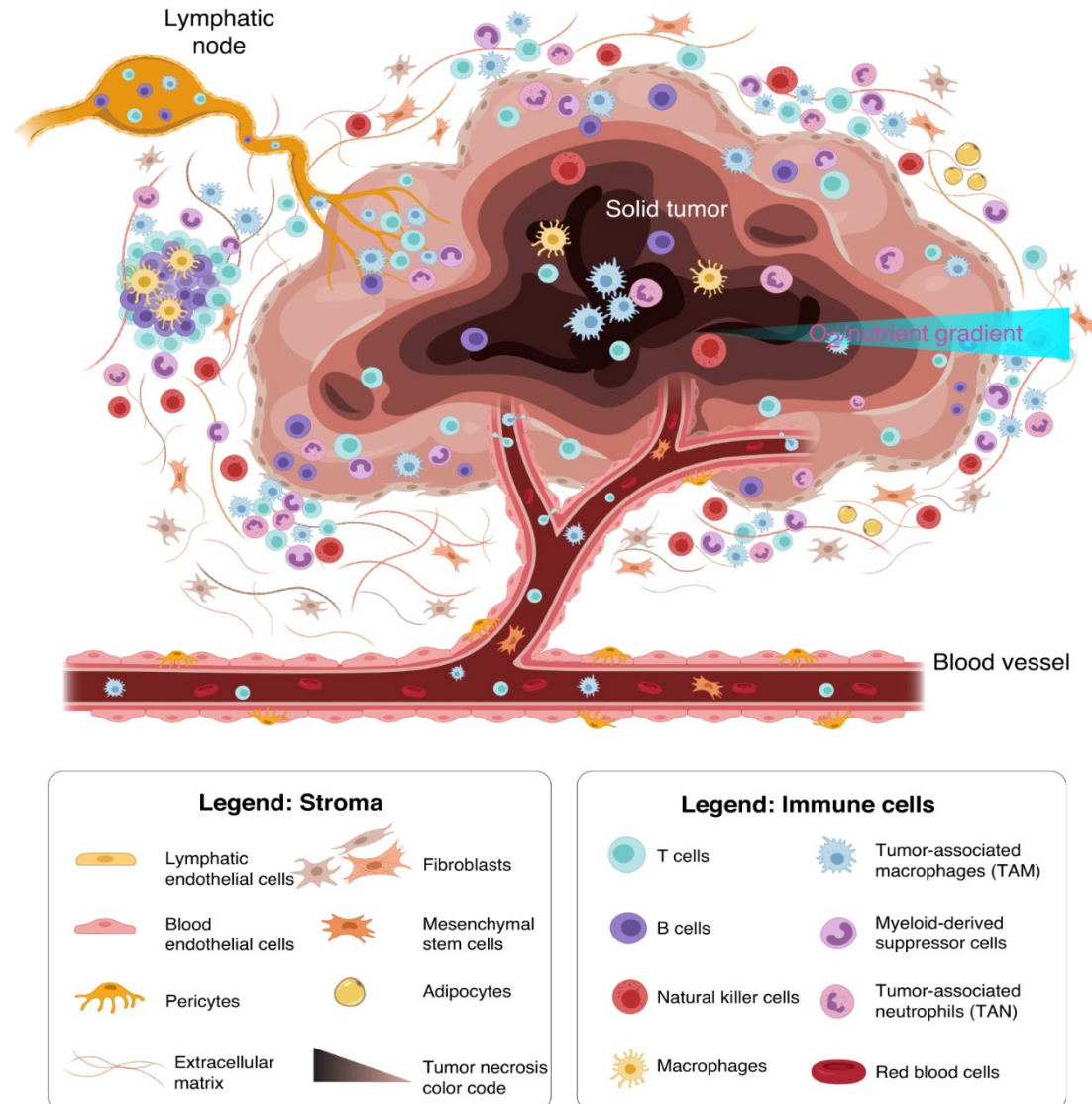
<sup>1</sup> <https://seer.cancer.gov/statfacts/html/common.html>; data retrieved November 2, 2023.

<sup>2</sup> [https://gco.iarc.who.int/tomorrow/en/dataviz/tables?mode=population&years=2050&types=1&populations=903\\_904\\_905\\_908\\_909\\_935\\_900](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

*A challenging tumor microenvironment complicates “targeting” and “penetration”*



- Tumor stroma acts as a physical barrier, limiting the penetration and distribution of anti-cancer agents into the tumor
- Tumor microenvironment (TME) immunosuppressive cells contribute 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 can target tumor cells, but do not enhance penetration and delivery
- *Internalizing* RGD (iRGD) peptides combine targeting and penetration enhancement
- LSTA1 (certepetide) is an iRGD that triggers the CendR active transport mechanism for selective enhancement of delivery of anti-cancer therapy into solid tumors
- LSTA1 is in mid- to late-stage clinical development for solid tumor treatment



# LSTA1 promises optimized solid tumor treatment

- **LSTA1 converts tumor stroma from a barrier to a conduit for anti-cancer drugs**
- **LSTA1 combats resistance and metastases<sup>1</sup>**
  - Preclinical data demonstrate that LSTA1 selectively depletes immunosuppressive T cells, enhances cytotoxic T cells, and inhibits the metastatic cascade
- **LSTA1 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

<sup>1</sup>Sugahara, et al. Mol Cancer Ther; 14(1) January 2015;  
Hamilton, et al., J MolMed. April 2015; and  
Miyamura, et al., bioRxiv. May 2023.

# LSTA1 development strategy is composed of two main pillars

## Pancreatic & Other Advanced Solid Tumor Focus

- By 2030, pancreatic cancer is predicted to become the second most common cause of cancer mortality<sup>1</sup>
  - Only 3% of people diagnosed with pancreatic cancer will survive for 5 years
  - 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 LSTA1 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*

<sup>1</sup> Europe Is Facing a Pancreatic Cancer Emergency - Medscape - January 25, 2024.

# Partnerships

*Noteworthy existing relationships and  
potential for many more*



# Existing partnerships support LSTA1 promise and broad applicability



## *Development alliances contribute resources without commercial interest in LSTA1*

- LSTA1/gemcitabine/nab-paclitaxel treatment regimen with **AGITG (AUS & NZ)**
- LSTA1/gemcitabine/nab-paclitaxel treatment regimen ± durvalumab with **WARPNINE (AUS)**
- LSTA1/FOLFIRINOX treatment regimen ± nivolumab with **WARPNINE (AUS)**



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

- Exclusive rights to LSTA1 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
- Potential for up to \$221 million to Lisata for milestones & tiered double-digit royalties on sales



## *Additional partnership opportunities exist for many combinations with LSTA1*

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

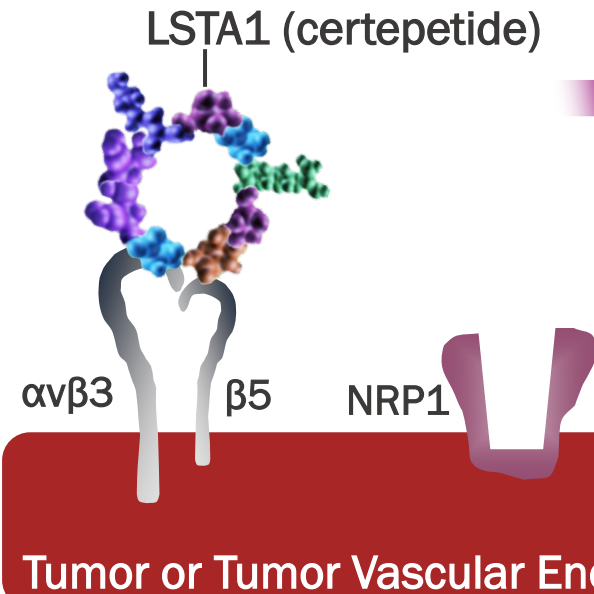
A 3D molecular model of a protein surface. The main body of the protein is colored in a light blue/cyan hue, showing a complex, wavy, and irregular surface. Attached to this main body are several smaller, distinct clusters of atoms or residues, colored in a vibrant purple/magenta. These clusters are distributed across the surface, some appearing more isolated and others more integrated into the larger structure. The background is a dark, gradient blue, providing a high contrast for the protein model.

# LSTA1

*Strong Scientific Foundation and Rationale*

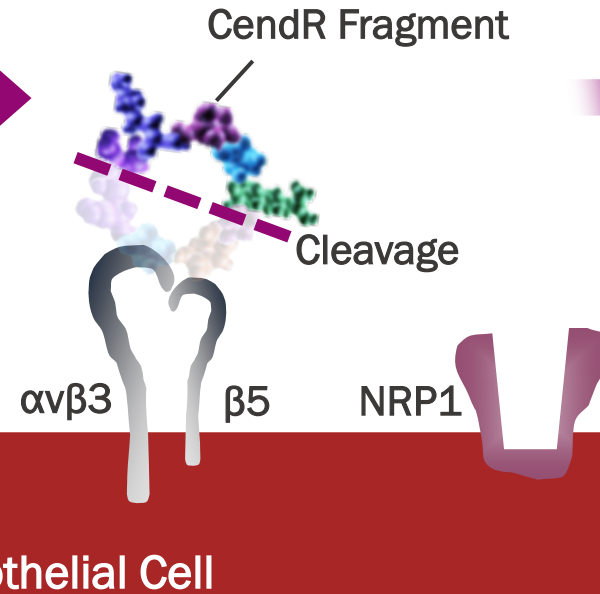
# LSTA1 Selective Tumor Targeting & Penetration Mechanism of Action

## A) Integrin binding



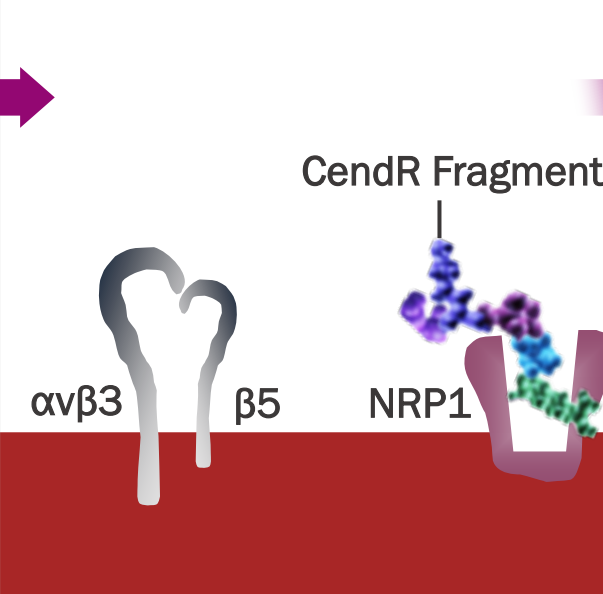
LSTA1: 9 amino acid cyclic peptide; high binding affinity and specificity to  $\alpha v \beta 3 / \beta 5$  integrins that are upregulated on tumor endothelial cells and tumor cells (i.e. tumor stroma)

## B) Proteolytic cleavage



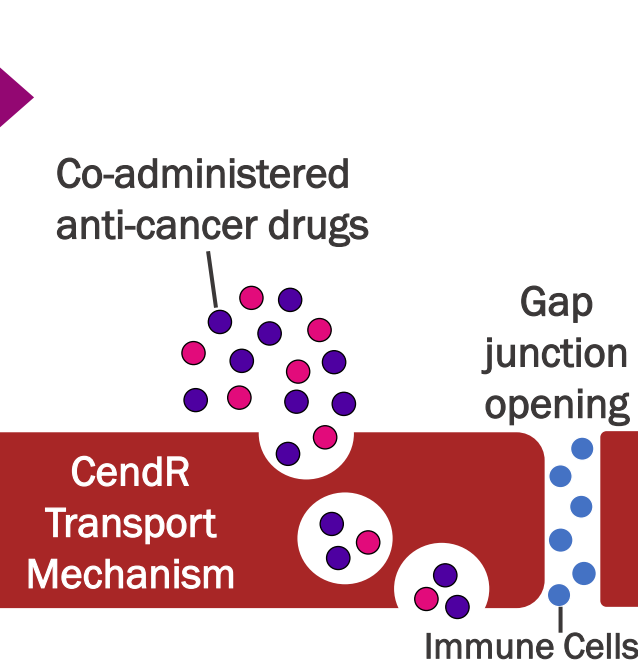
Once bound to  $\alpha v \beta 3$  &  $\beta 5$  integrins, LSTA1 is cleaved by proteases in the tumor microenvironment, releasing a C-end Rule (CendR) linear peptide fragment

## C) Neuropilin-1 binding



The CendR fragment then binds to an adjacent receptor, neuropilin-1 (NRP1), with high affinity and specificity, activating the CendR transport pathway<sup>1</sup> and triggering penetration into the tumor tissue

## D) Transcytosis



CendR transport mechanism activation triggers:

- Tumor penetration of circulating moieties including any unbound LSTA1 & CendR fragments and co-administered anti-cancer drugs
- Infiltration of immune cells due to intratumoral gap junction opening

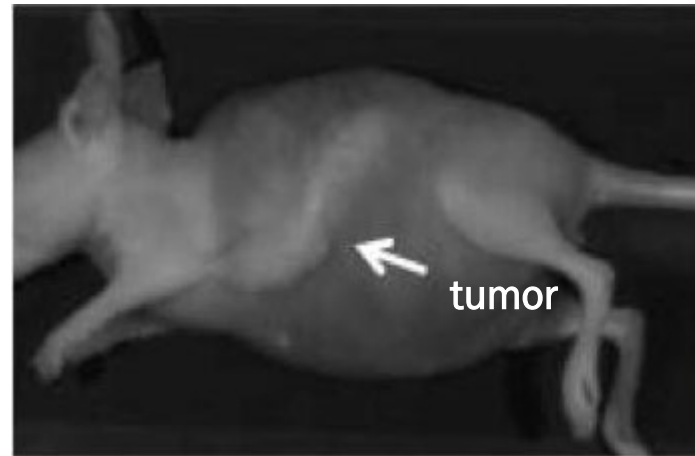
<sup>1</sup> Ding et al., Nature Comm, 2019.



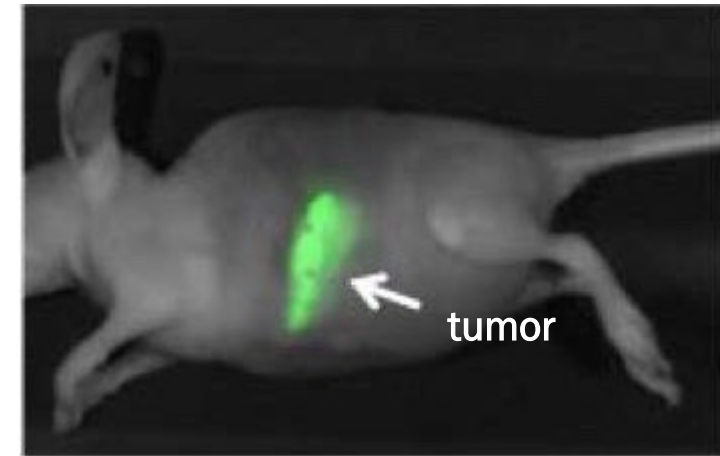
# LSTA1 selectively and efficiently facilitates intratumoral penetration

**Whole body imaging of mice with pancreatic ductal adenocarcinoma (arrow) dosed with Fluorescent Quantum Dots (FQDs) with and without LSTA1**

**FQD + Etching solution**



**LSTA1 + FQD + Etching solution**



- Circulating FQDs result in whole body fluorescence
- Etching solution quenches fluorescence in circulation
- **LSTA1 provides targeted tumor penetration**

<sup>1</sup> Braun et al., Nature Mater. 2014.

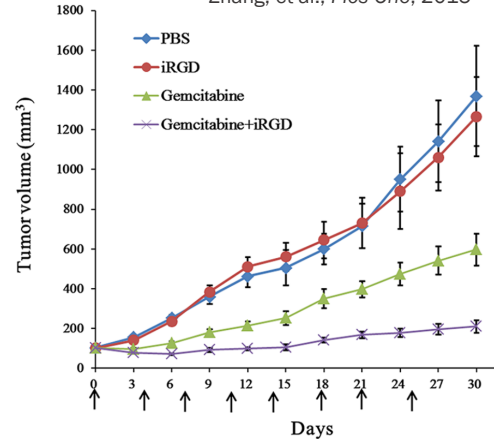
<sup>2</sup> Liu, Braun et al., Nature Comm. 2017.

# LSTA1/iRGD activity & broad applicability consistently demonstrated

*Sampling of >350 scientific publications showing improved survival with LSTA1/iRGD*

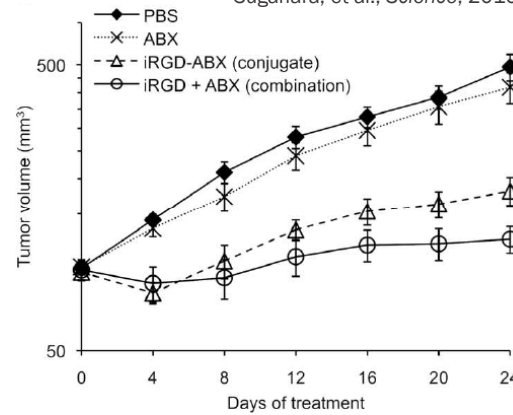
## Lung cancer + gemcitabine

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



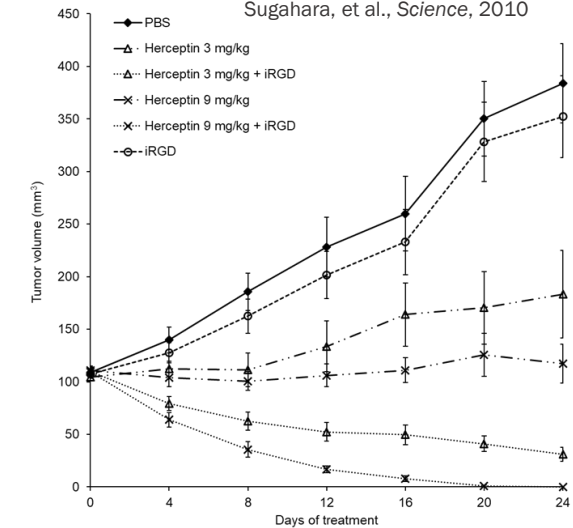
## Breast cancer + nanoparticle Abraxane

Sugahara, et al., *Science*, 2010



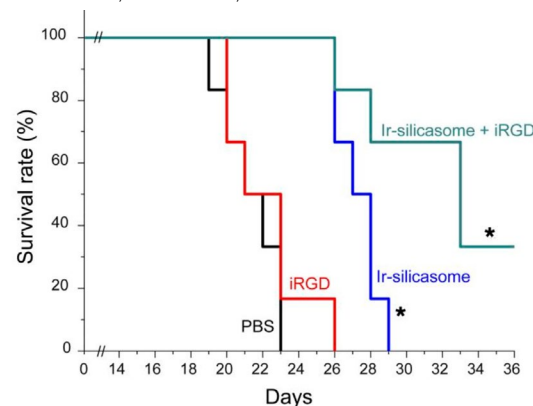
## Breast cancer + Herceptin®

Sugahara, et al., *Science*, 2010



## PDAC + irinotecan nanoparticles

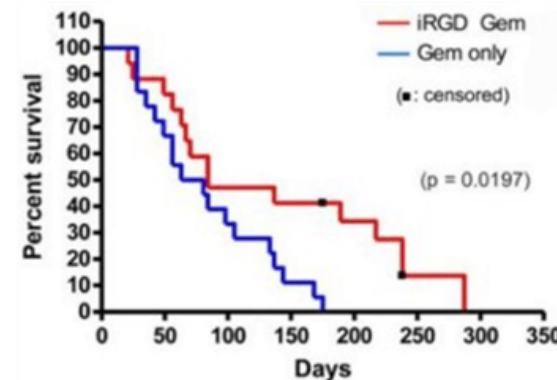
Liu X et al., *J Clin Invest*, 2017



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

## PDAC + gemcitabine

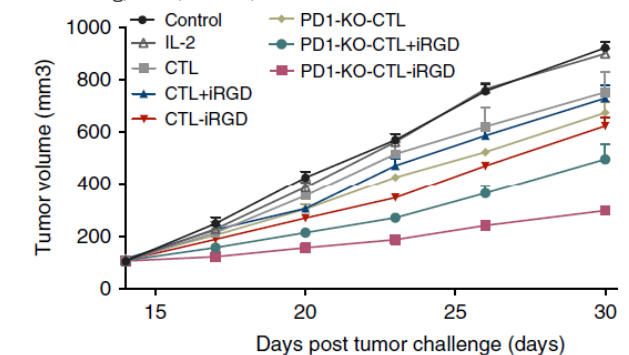
Hurtado de Mendoza et al, *Nature Comms*, 2021



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

## GI cancer + adoptive cell therapy

Ding, et al., *Nature*, 2019



# LSTA1 Phase 1b/2a results: Compelling improvement of SoC efficacy

Endpoints	Gemcitabine + Nab-paclitaxel <sup>1</sup>	LSTA1 + Gemcitabine + Nab-paclitaxel <sup>2</sup>
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



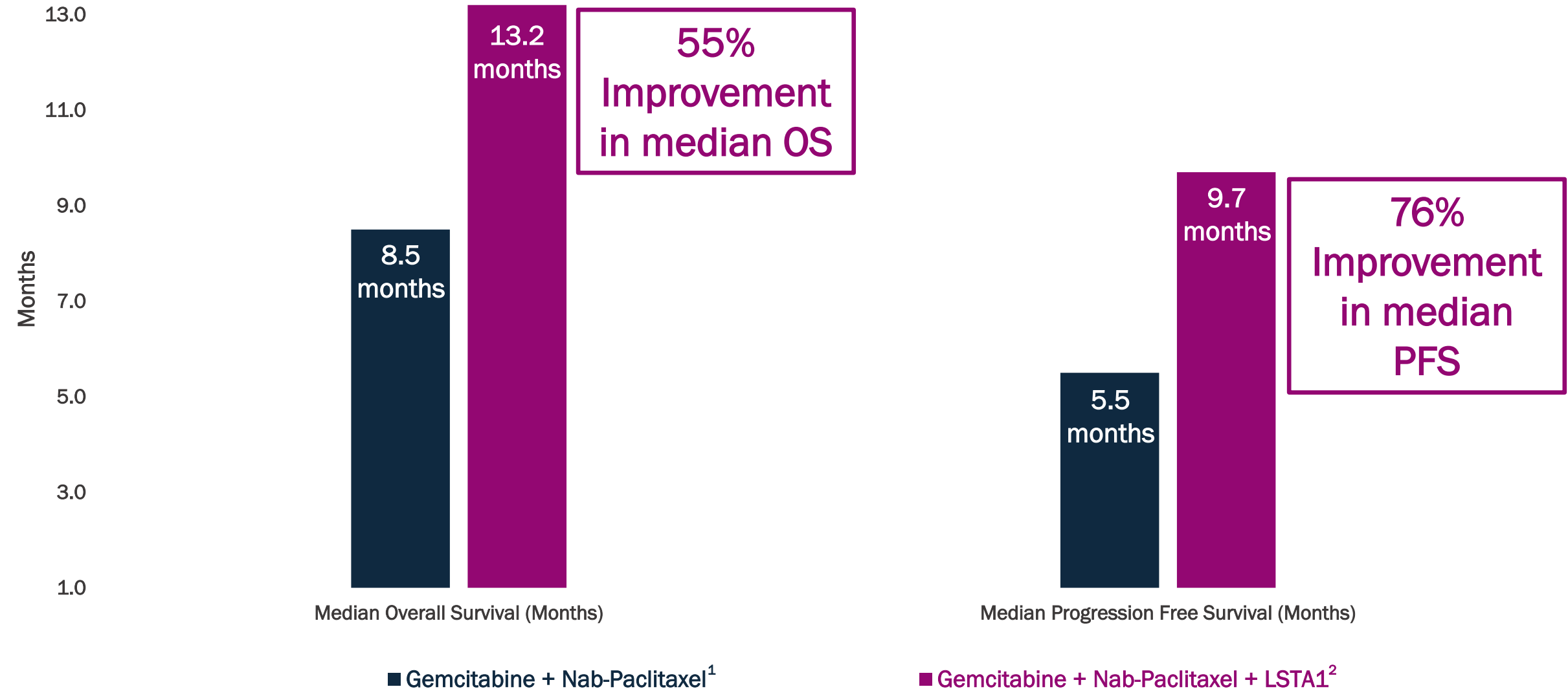
LSTA1 well-tolerated, no dose-limiting  
toxicities; safety of LSTA1 + SoC  
consistent with SoC alone

<sup>1</sup> Von Hoff D, et al., *New England Journal of Medicine*, 2013.

<sup>2</sup> Dean A, et al., *The Lancet Gastroenterology & Hepatology*, 2022.



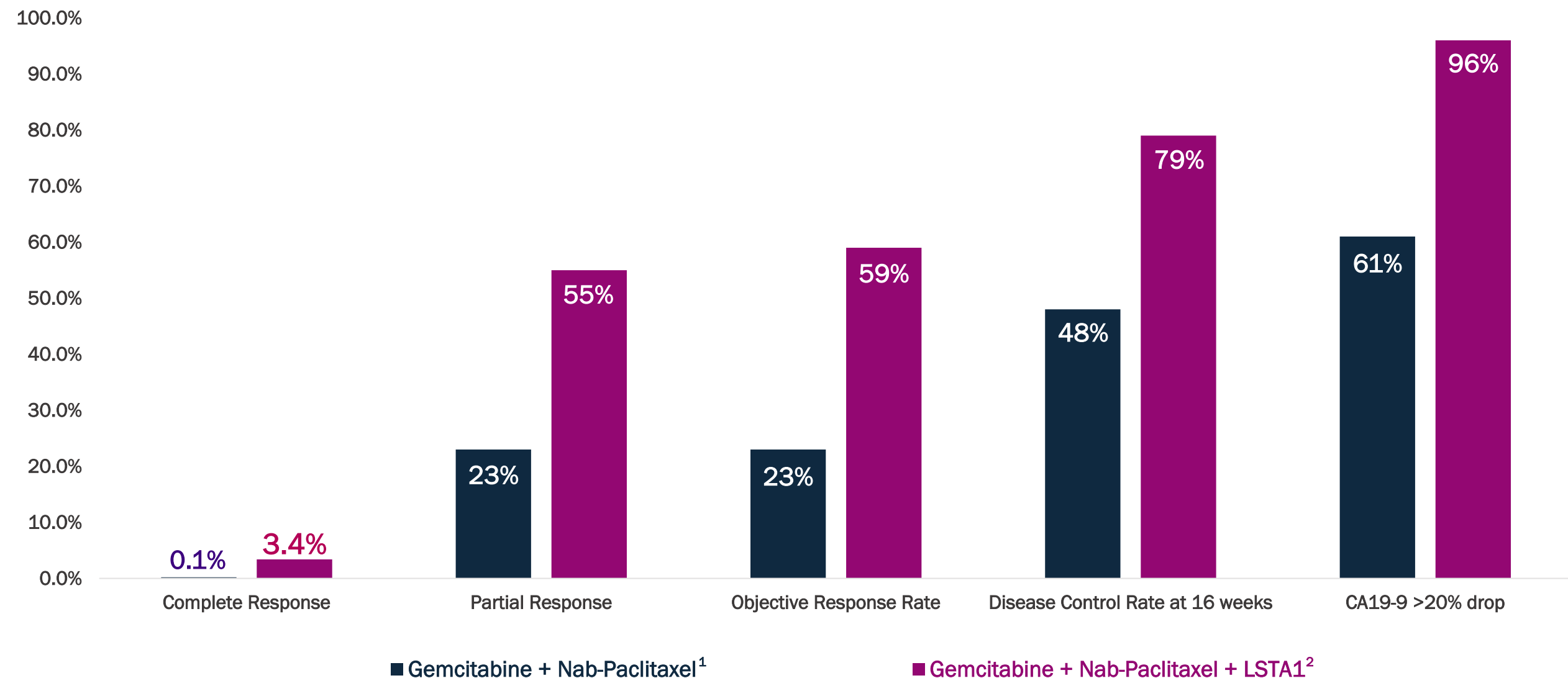
# LSTA1 Phase 1b/2a results: Improved survival vs. SoC alone



<sup>1</sup> Von Hoff D, et al., *New England Journal of Medicine*, 2013.

<sup>2</sup> Dean A, et al., *The Lancet Gastroenterology & Hepatology*, 2022

# LSTA1 Phase 1b/2a results: Consistent improvement across associated endpoints



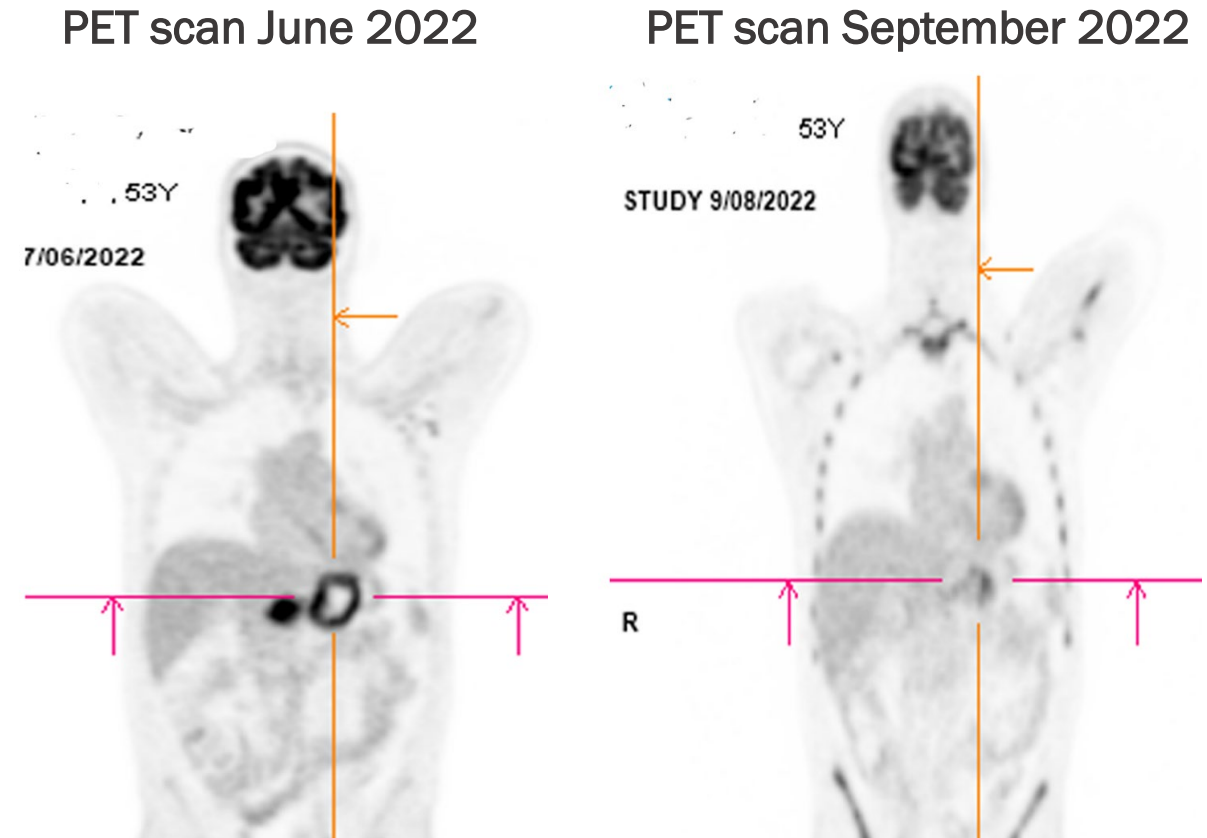
<sup>1</sup> Von Hoff D, et al., *New England Journal of Medicine*, 2013.

<sup>2</sup> Dean A, et al., *The Lancet Gastroenterology & Hepatology*, 2022

# Growing evidence of LSTA1 activity in other solid tumors

## *LSTA1 potentiated a complete response in metastatic gastroesophageal adenocarcinoma*

- 53-year-old male diagnosed with metastatic gastroesophageal adenocarcinoma in June 2022 with significant (> 5cm) nodal metastases
- Neoadjuvant chemotherapy with radiotherapy including FOLFIRINOX and pembrolizumab resulted in partial response
- At cycle 7, LSTA1 was added to the FOLFIRINOX/pembrolizumab regimen
- After cycle 18, patient underwent an exploratory laparoscopy for surgical resection
  - **no disease present** – only scar tissue



Reduction in FDG activity demonstrated<sup>1</sup>

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





# LSTA1

## *Clinical Development Portfolio*

*Fast Track Designation (PDAC - USA)*

*Orphan Drug Designation (PDAC – USA/EU, GBM – USA &  
Osteosarcoma - USA)*

*Rare Pediatric Disease Designation (Osteosarcoma – USA)*

# Implications of Fast Track, Rare Pediatric Disease & Orphan Drug designations

## FDA Fast Track Designation

- More frequent communication with and program-specific guidance from FDA
- Eligible for *Accelerated Approval*, *Priority Review* and *Rolling Review*
- ***LSTA1 received fast track designation from the U.S. 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
- ***LSTA1 received rare pediatric disease designation from the U.S. 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
- ***LSTA1 received orphan drug designations for pancreatic cancer in the U.S. and EU, malignant glioma in the U.S., and osteosarcoma in the U.S.***

# LSTA1 capital efficient development plan; shared costs & selective geography

Sponsors/Partners	Region	Indication and Test Articles	Status
AGITG/Lisata	Australia & New Zealand	First-line mPDAC Gemcitabine/nab-paclitaxel with LSTA1 or placebo <b>N=158</b>	Phase 2b ( <b>ASCEND</b> ) Placebo-controlled <b>Enrollment complete</b>
Lisata	USA	First-line Cholangiocarcinoma Standard of Care with LSTA1 or placebo <b>N=40</b>	Phase 2a ( <b>BOLSTER</b> ) Placebo-controlled <b>Enrolling</b>
KUCC/Lisata	USA	Pancreatic, Colon, & Appendiceal Cancers LSTA1 + FOLFIRINOX + panitumumab* <b>N=50</b>	Phase 1b/2a ( <b>CENDIFOX</b> ) Open-label <b>Enrolling</b>
Qilu/Lisata	China	First-line mPDAC Gemcitabine/nab-paclitaxel + LSTA1 <b>N=41</b>	Phase 1b/2a Open-label <b>Enrollment complete</b>
WARPNINE/Lisata	Australia	Locally advanced, non-resectable PDAC Durvalumab/gemcitabine/nab-paclitaxel + LSTA1 <b>N=30</b>	Phase 1b/2a ( <b>iLSTA</b> ) Open-label <b>Enrolling</b>

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

# LSTA1 capital efficient development plan; shared costs & selective geography

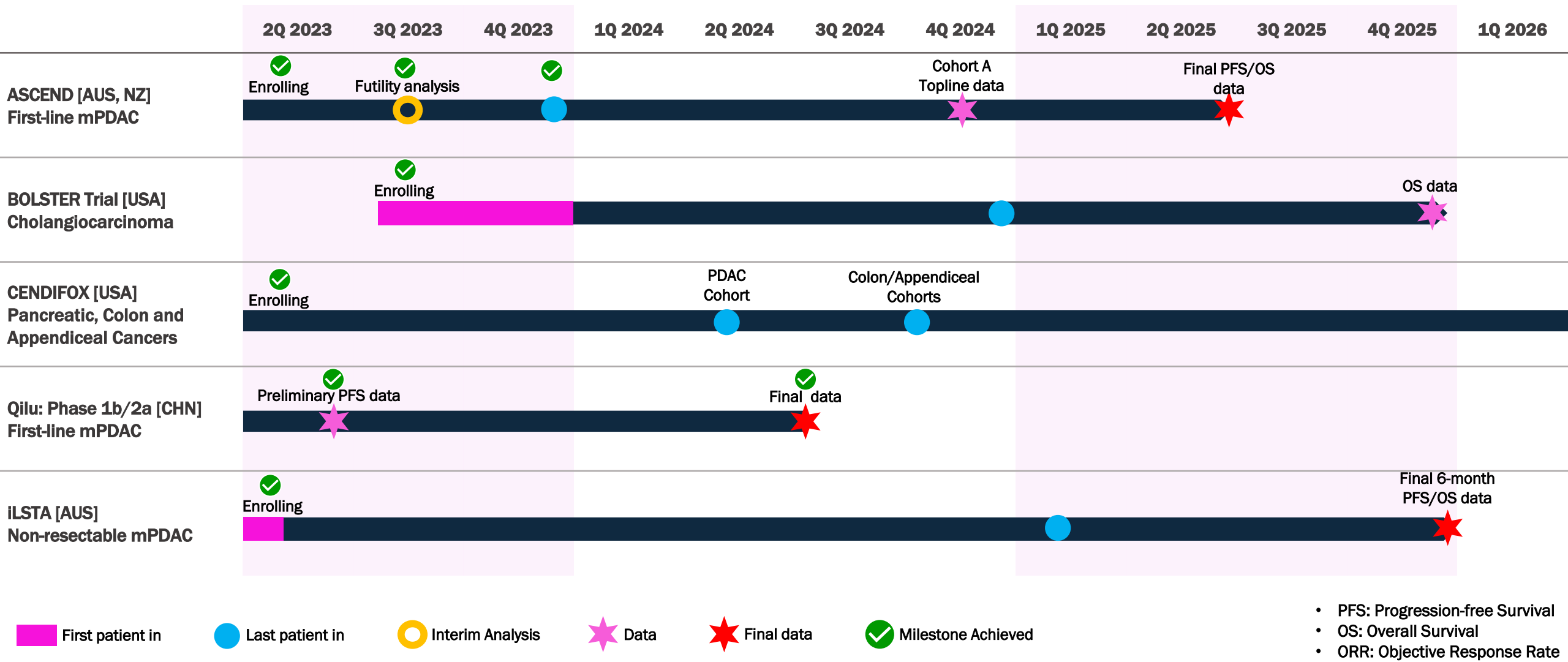
Sponsors/Partners	Region	Indication and Test Articles	Status
Tartu University/ Lisata	Estonia & Latvia	First-line Glioblastoma Multiforme (GBM) Temozolomide +/- LSTA1 <b>N=30</b>	Phase 2a Placebo-controlled <i>Enrolling</i>
UCSD/Lisata	USA	Peritoneal Carcinomatosis (Colon & Ovarian) LSTA1 + HIPEC* intraoperative intraperitoneal lavage <b>N=21</b>	Phase 1 Open-label <i>Enrolling</i>
Qilu/Lisata	China	First-line mPDAC Gemcitabine/Nab-paclitaxel + LSTA1 <b>N=120</b>	Phase 2 Placebo-controlled <i>Enrolling</i>
WARPNINE/Lisata	Australia	Locally advanced, non-resectable Gastroesophageal Adenocarcinoma Nivolumab/FOLFIRINOX + LSTA1 <b>N=40</b>	Phase 1b/2a ( <b>iGoLSTA</b> ) Open-label <i>Pending initiation</i>

\*Hyperthermic intraperitoneal chemotherapy



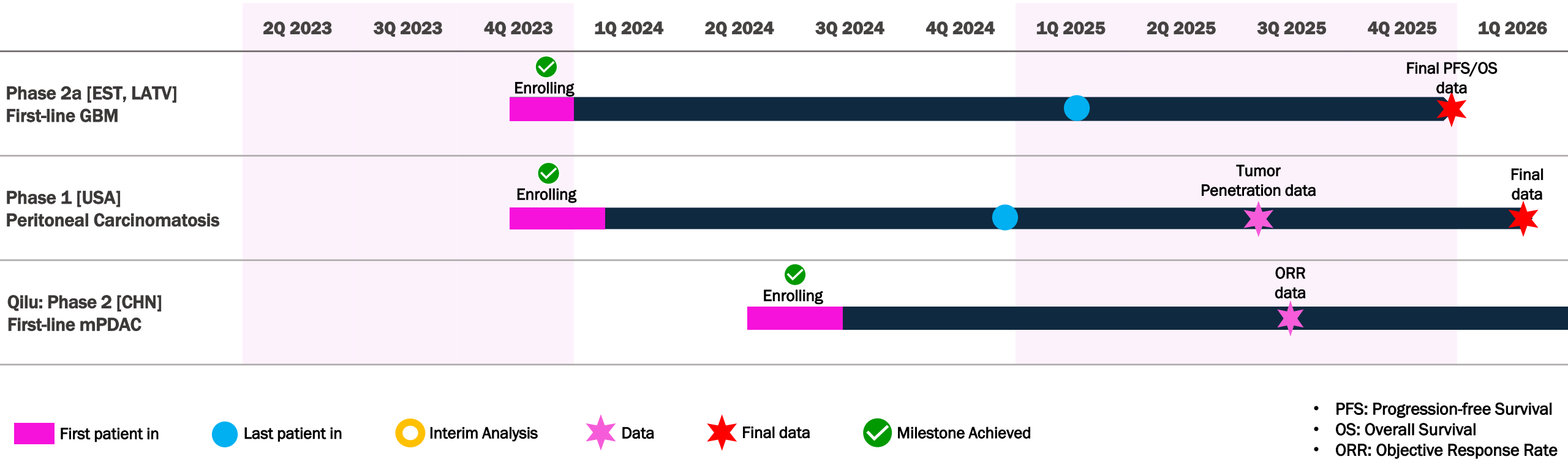
# Development Milestones

# 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.)



\*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 12/31/2023*

**\$50.5M**

Debt

**\$0**

Projected Cash Runway Into

**1Q2026**

Common Shares Outstanding (12/31/2023):

8.1 million shares

Options Outstanding (12/31/2023):

Exercise Price: \$0.02 - \$4.22 = 1,084,000 shares

Exercise Price: > \$4.22 = 239,000 shares

1.3 million shares

Warrants Outstanding (12/31/2023):

Weighted Average Exercise Price: \$42.51

1.4 million shares

# Strong Investment Rationale

# Key factors supporting investment in Lisata Therapeutics



## PEOPLE

Seasoned management with successful international development experience and expertise



## TECHNOLOGY

Proprietary field-leading technology in underserved global indications



## MILESTONES

Multiple projected product and business milestones over the next 24 months



## CAPITAL

\$50.5 million cash\*- no debt; Development funded through critical data milestones



## PARTNERING

Platform technology “validated” by existing partnerships with potential for many others





# Targeted Therapy *Delivered*

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Nasdaq: LSTA | [www.lisata.com](http://www.lisata.com)





# Appendix

# LSTA1 capital efficient development plan; shared costs & selective geography

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 LSTA1 or placebo	Phase 2b (ASCEND)	Corroborate Phase 1b results in a placebo-controlled trial and evaluate 2 dose regimens of LSTA1 for dose optimization
Lisata [United States]	First-line Cholangiocarcinoma; SoC with LSTA1 or placebo	Phase 2a (BOLSTER)	Assess LSTA1 safety and effectiveness in cholangiocarcinoma in a placebo-controlled trial (Proof-of-Concept)
KUCC/Lisata [United States]	Pancreatic, Colon & Appendiceal Cancers; LSTA1 + FOLFIRINOX + panitumumab*	Phase 1b/2a (CENDIFOX)	Tumor immuno-profiling pre- & post- treatment and LSTA1 effectiveness assessment in combination with chemo and an EGFR inhibitor (open label)
Qilu [China]	First-line mPDAC; Gemcitabine/nab-paclitaxel + LSTA1	Phase 1b/2a	Assess safety, PK and therapeutic effect of LSTA1 in Chinese patients (open label)
WARPNINE/Lisata [Australia]	Locally advanced non-resectable PDAC; Durvalumab/gemcitabine/nab-paclitaxel + LSTA1	Phase 1b/2a (iLSTA)	Assess LSTA1 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 + FFX + LSTA1	Phase 1b/2a (iGoLSTA)	Assess LSTA1 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

# LSTA1 capital efficient development plan; shared costs & selective geography

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 ± LSTA1	Phase 2a	Assess LSTA1 safety and effectiveness in additional tumor type (GBM) in a placebo-controlled trial
UCSD/Lisata [United States]	Peritoneal Carcinomatosis LSTA+HIPEC intraoperatively	Phase 1	Assess safety and intraoperative tumor penetration of HIPEC in combination with LSTA1 (open label)
Qilu [China]	First-line mPDAC; Gemcitabine/nab-paclitaxel + LSTA1	Phase 2b	Continue development of LSTA1 in China (placebo controlled)

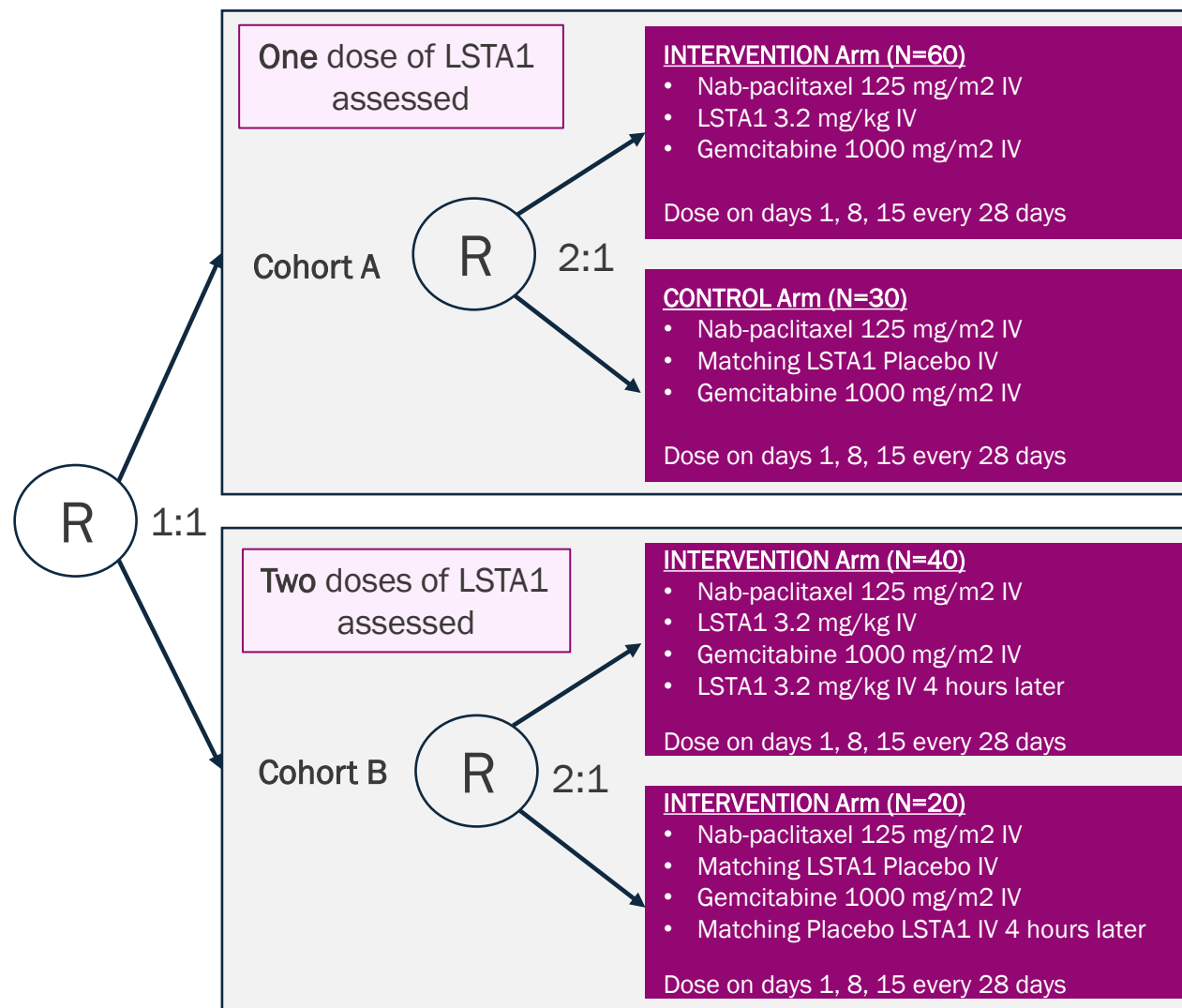
# ASCEND: Phase 2b, blinded, randomized trial in mPDAC

Sponsor/Partner	<ul style="list-style-type: none"><li>■ Australasian Gastro-Intestinal Trials Group (AGITG) in collaboration with the NHMRC Clinical Trials Centre at the University of Sydney</li><li>■ Lisata funded (LSTA eligible for ~43% rebate on all qualified R&amp;D expenses in AUS)</li></ul>
Objective	<ul style="list-style-type: none"><li>■ Corroborate Phase 1b results in a placebo-controlled study</li><li>■ Determine if a second dose of LSTA1 further improves patient outcomes</li></ul>
Design	<ul style="list-style-type: none"><li>■ Phase 2b randomized, double-blind study in mPDAC testing gemcitabine + nab-paclitaxel SoC with one of two LSTA1 dose regimens or placebo</li></ul>
Study Size	<ul style="list-style-type: none"><li>■ N=158 (~30 sites in Australia and New Zealand)</li></ul>
Endpoints	<ul style="list-style-type: none"><li>■ Primary: Progression Free Survival</li><li>■ Secondary: AEs, SAEs, Overall Survival, Objective Tumor Response Rate</li></ul>
Timing	<ul style="list-style-type: none"><li>■ Enrollment completed December 2023</li><li>■ Earliest possible data 2024</li></ul>



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

Phase 2b  
randomized, double-  
blind study in mPDAC  
testing gemcitabine +  
nab-paclitaxel (SoC)  
with two LSTA1 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

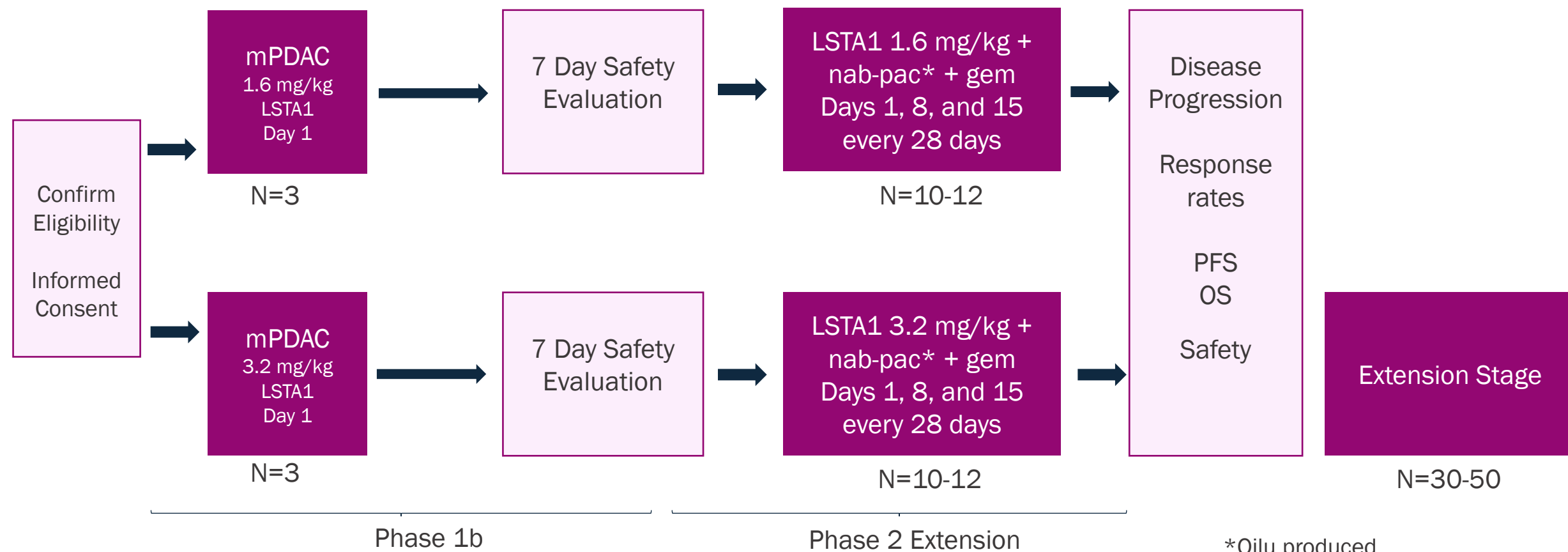
# Phase 1b/2a open-label trial in mPDAC in China

Sponsor/Partner	<ul style="list-style-type: none"><li>▪ Qilu Pharmaceutical (funds all development in China)</li></ul>
Objective	<ul style="list-style-type: none"><li>▪ Evaluate safety, pharmacokinetics and preliminary efficacy of LSTA1 added to SoC in Chinese patients with mPDAC</li></ul>
Design	<ul style="list-style-type: none"><li>▪ Phase 1b/2a open-label study in advanced mPDAC patients of Chinese ethnicity testing SoC chemotherapy (gemcitabine + Qilu-produced nab-paclitaxel) in combination with LSTA1</li></ul>
Study Size	<ul style="list-style-type: none"><li>▪ N=50 (~15 sites)</li></ul>
Endpoints	<ul style="list-style-type: none"><li>▪ Primary: AEs, SAEs, Objective Response Rate, Duration of Response, Disease Control Rate, Overall Survival, and Progression Free Survival</li><li>▪ Secondary: Pharmacokinetic parameters</li></ul>
Timing	<ul style="list-style-type: none"><li>▪ Preliminary data expected 1H23</li></ul>

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

Phase 1b/2a study evaluating the safety, pharmacokinetics, and preliminary efficacy of LSTA1 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



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

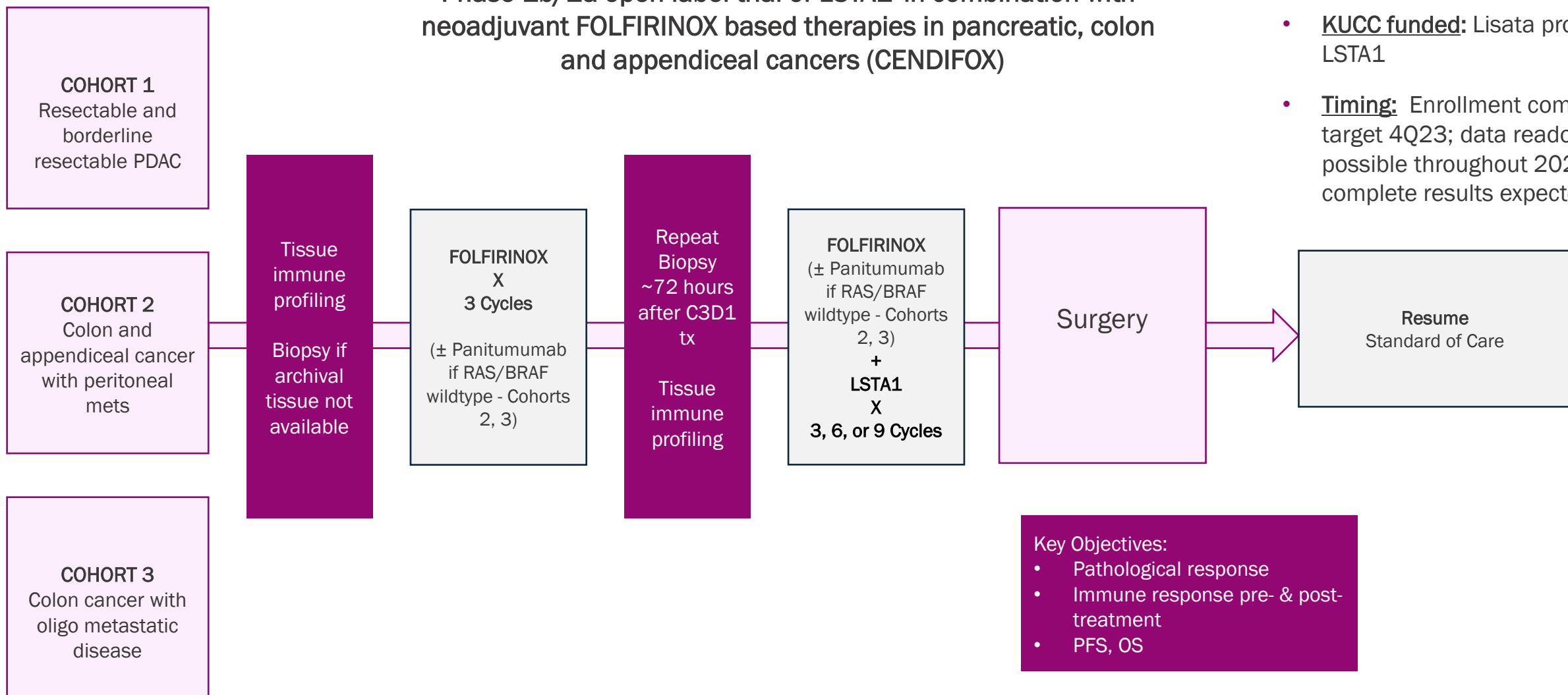
Sponsor/Partner	<ul style="list-style-type: none"><li>University of Kansas Medical Center (Investigator initiated trial in U.S.)</li><li>KUCC funded; Lisata provides LSTA1</li></ul>
Objective	<ul style="list-style-type: none"><li>Evaluate the safety and therapeutic effect of LSTA1 in combination with neoadjuvant FOLFIRINOX-based therapies and an EGFR inhibitor for the treatment of pancreatic, colon and appendiceal cancers and determine immuno-profiling in tumor pre- &amp; post- treatment</li></ul>
Design	<ul style="list-style-type: none"><li>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 LSTA1 ± panitumumab</li></ul>
Study Size	<ul style="list-style-type: none"><li>N=50 (20 PDAC, 15 colon and 15 appendiceal)</li></ul>
Endpoints	<ul style="list-style-type: none"><li>Primary: Drug Safety</li><li>Secondary: Overall Survival, Disease-free Survival, Overall Response Rate, R0 Resection Rate, Pathological Response Rate</li></ul>
Timing	<ul style="list-style-type: none"><li>Enrollment completion target 4Q23</li><li>Data readouts possible throughout 2023 with complete results expected 2024</li></ul>



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

Phase 1b/2a open-label trial of LSTA1 in combination with neoadjuvant FOLFIRINOX based therapies in pancreatic, colon and appendiceal cancers (CENDIFOX)

- **Sponsor/Partner:** University of Kansas Medical Center (ITT)
- **KUCC funded:** Lisata provides LSTA1
- **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 LSTA1 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 LSTA1 or placebo

## Study Size

- N=40 (1:1 SoC + LSTA1 or SoC + placebo)

## Endpoints

- Primary: OS
- Secondary: Safety, ORR, PFS

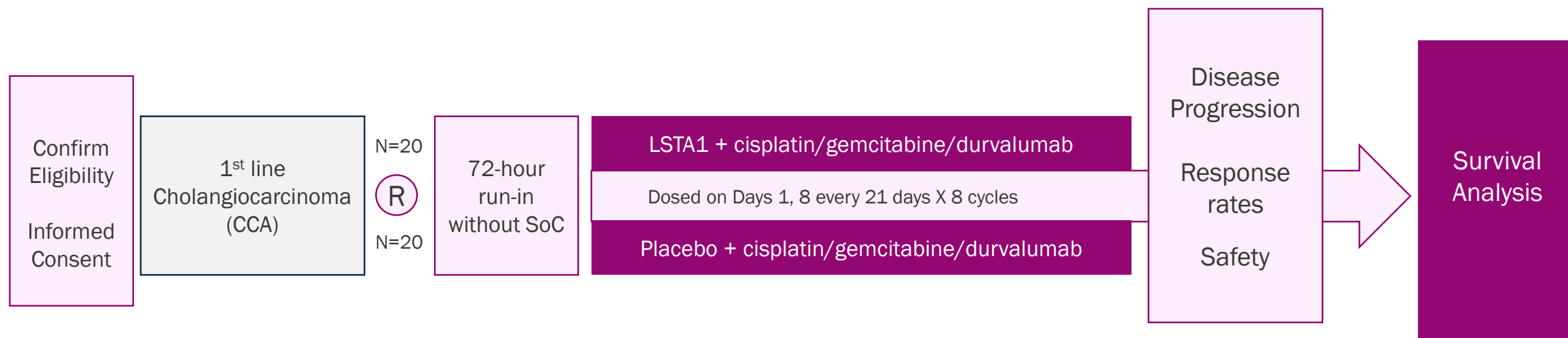
## Timing

- 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 LSTA1 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

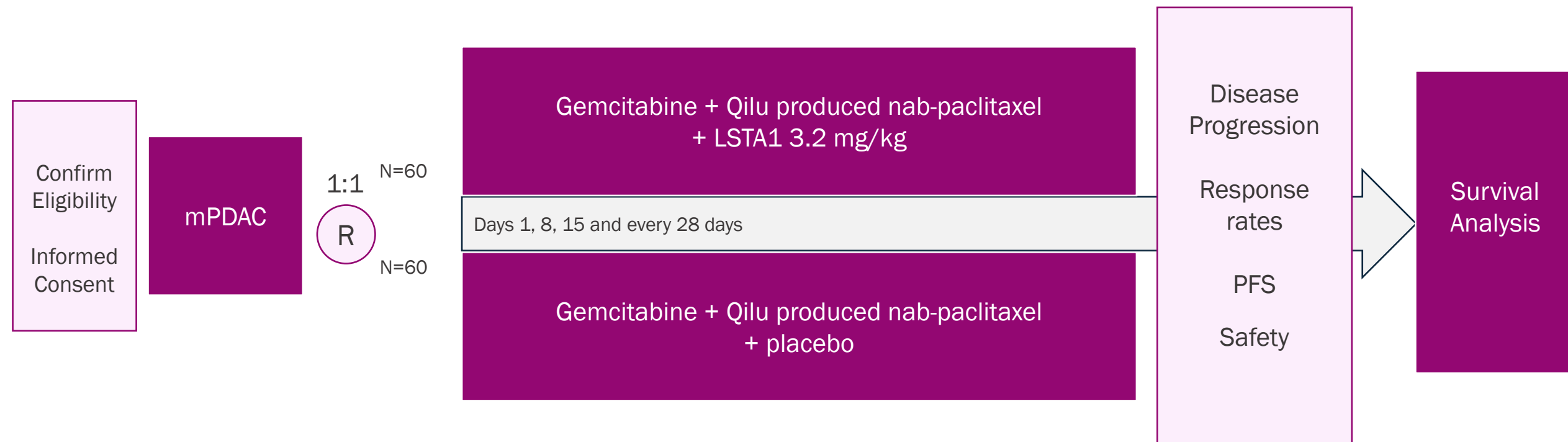
Sponsor/Partner	<ul style="list-style-type: none"><li>▪ Qilu Pharmaceutical (funds all development in China)</li></ul>
Objective	<ul style="list-style-type: none"><li>▪ Further evaluate safety and therapeutic efficacy of LSTA1 when added to SoC in Chinese patients with locally advanced unresectable mPDAC</li></ul>
Design	<ul style="list-style-type: none"><li>▪ Phase 2b, double-blind, placebo-controlled, randomized study evaluating LSTA1 + SoC (Qilu-produced nab-paclitaxel and gemcitabine) vs. placebo + SoC</li></ul>
Study Size	<ul style="list-style-type: none"><li>▪ N=120 (1:1 SoC + LSTA1 or SoC + placebo)</li></ul>
Endpoints	<ul style="list-style-type: none"><li>▪ Objective response rate, progression free survival, duration of response, disease control rate, overall survival</li><li>▪ Safety</li></ul>
Timing	<ul style="list-style-type: none"><li>▪ Trial initiation target 2Q24</li></ul>



# 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 LSTA1 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

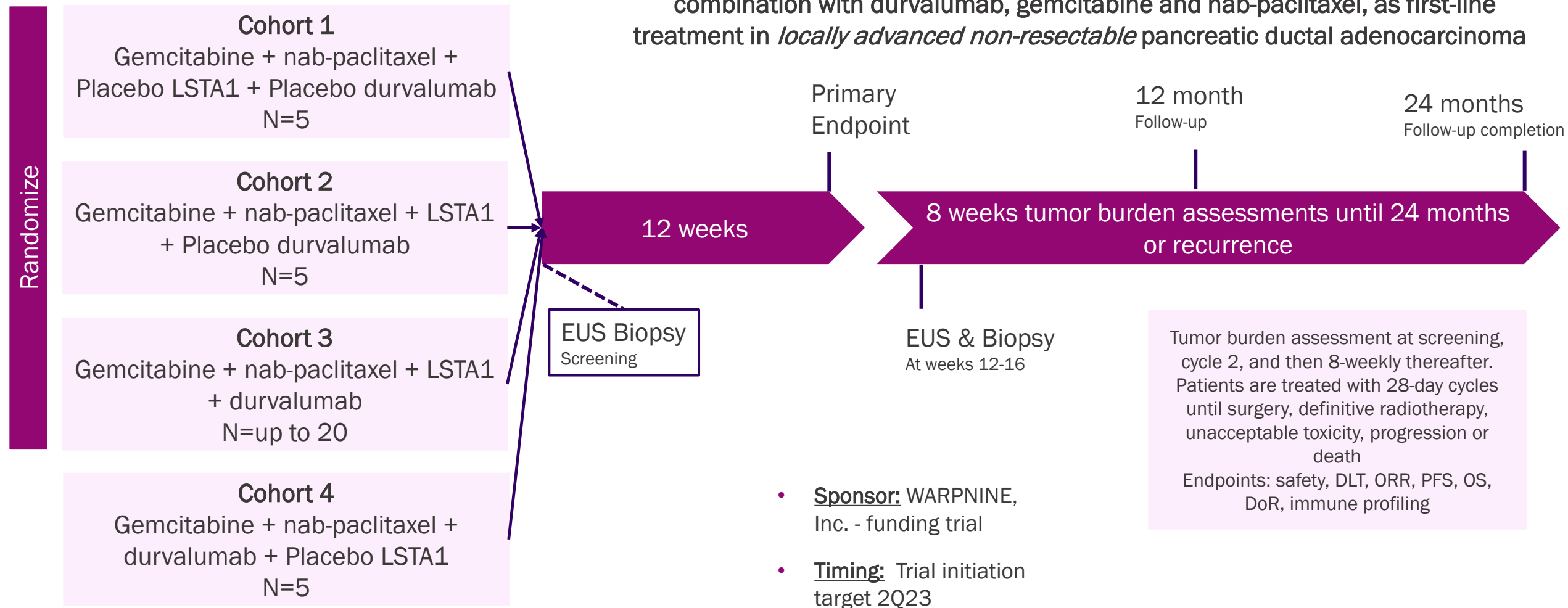


# iLSTA: Phase 1b/2a trial in locally advanced PDAC with chemo & IO

Sponsor/Partner	<ul style="list-style-type: none"><li>WARPNINE, Inc. (registered charity in Australia) is funding trial</li><li>Lisata providing study drug</li></ul>
Objective	<ul style="list-style-type: none"><li>Evaluate safety and therapeutic effect of LSTA1 in combination with IO &amp; Chemo in locally advanced non-resectable pancreatic ductal adenocarcinoma (PDAC); determine if inoperable tumors can become operable</li></ul>
Design	<ul style="list-style-type: none"><li>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</li></ul>
Study Size	<ul style="list-style-type: none"><li>N=30</li></ul>
Endpoints	<ul style="list-style-type: none"><li>Safety and tolerability; 28-day DLTs</li><li>Objective response rate, PFS, OS, duration of response, immune cell infiltration</li></ul>
Timing	<ul style="list-style-type: none"><li>Trial initiation target 2Q23</li><li>Enrollment commenced April 2023</li></ul>

# 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



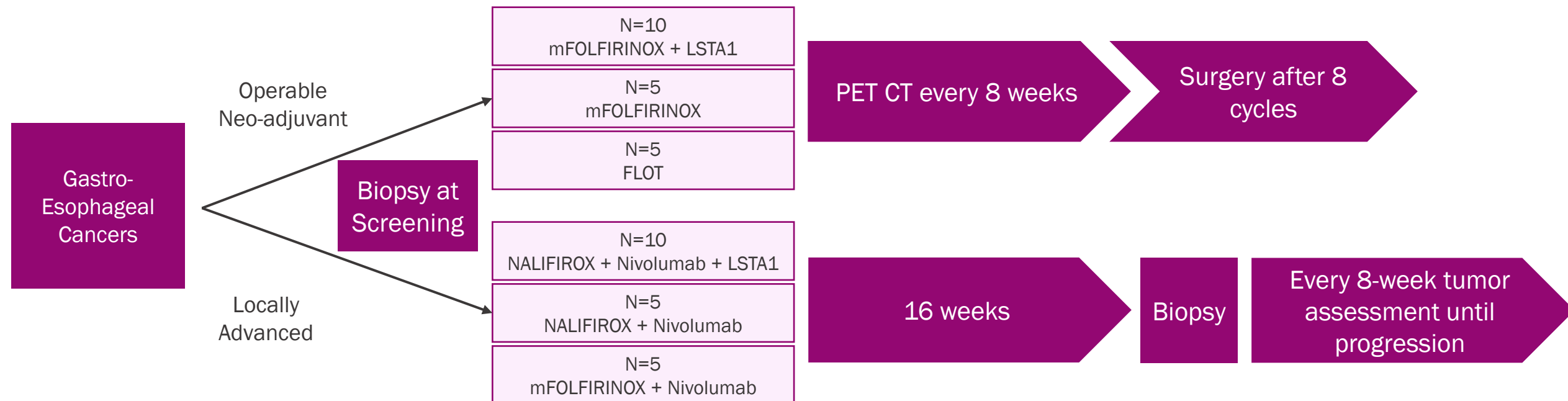
# iGoLSTA: Phase 1b/2a trial in operable/inoperable GEC with chemo & IO

Sponsor/Partner	<ul style="list-style-type: none"><li>■ WARPNINE, Inc. (registered charity in Australia) is funding trial</li><li>■ Lisata providing study drug</li></ul>
Objective	<ul style="list-style-type: none"><li>■ Evaluate LSTA1 safety &amp; therapeutic effect in combination neoadjuvant chemo in operable gastroesophageal (GE) cancers.</li><li>■ Evaluate LSTA1 safety and therapeutic effect in combination with immunotherapy and chemotherapy for advanced non-resectable GE cancers</li></ul>
Design	<ul style="list-style-type: none"><li>■ Phase 1b/2a proof-of-concept, two cohort, 6 arm safety and early efficacy study of LSTA1 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</li></ul>
Study Size	<ul style="list-style-type: none"><li>■ N=40 (20 per cohort)</li></ul>
Endpoints	<ul style="list-style-type: none"><li>■ Safety and tolerability</li><li>■ Objective response rate, PFS, OS, duration of response, immune cell infiltration</li></ul>
Timing	<ul style="list-style-type: none"><li>■ Trial initiation target 3Q23</li></ul>



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

Phase 1b/2a proof-of-concept safety and early efficacy study of LSTA1 in combination with chemotherapy and immunotherapy in *resectable* and *locally advanced non-resectable* gastroesophageal cancers



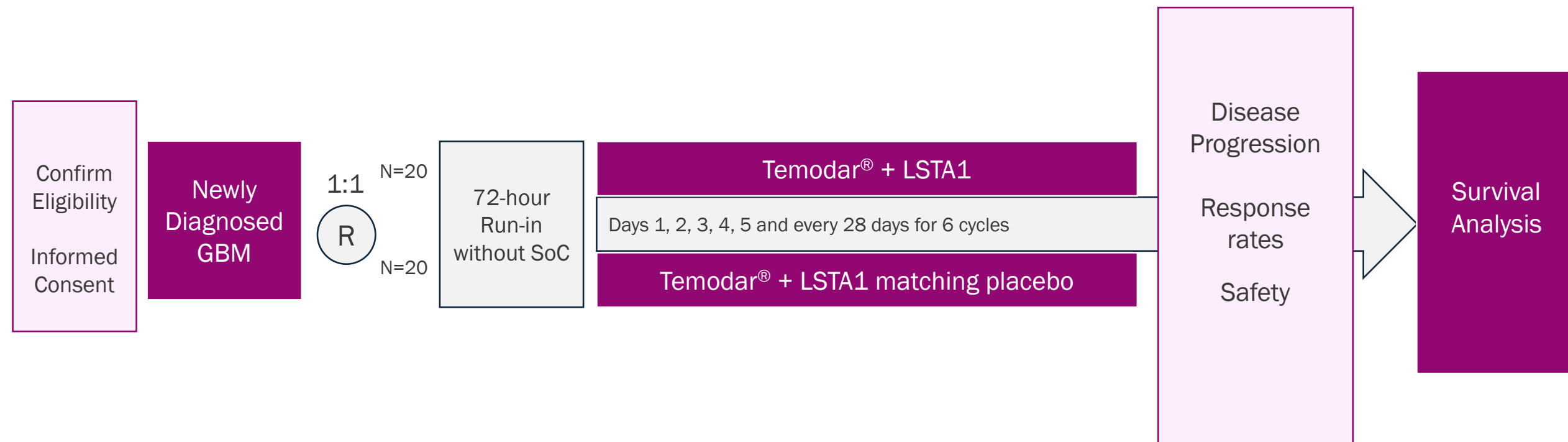
# Phase 2a trial of LSTA1 with SoC in first-line GBM

Sponsor/Partner	<ul style="list-style-type: none"><li>▪ Tartu University Hospital (Investigator initiated trial in Estonia)</li><li>▪ Lisata providing study drug and funding trial</li></ul>
Objective	<ul style="list-style-type: none"><li>▪ Evaluate safety, tolerability, and therapeutic effect of LSTA1 in combination with standard-of-care (temozolomide) in patients with previously untreated Glioblastoma Multiforme</li></ul>
Design	<ul style="list-style-type: none"><li>▪ Phase 2a proof-of-concept, double-blind, placebo-controlled, randomized study evaluating LSTA1 when added to standard of care (temozolomide) versus SoC and placebo in subjects with newly diagnosed Glioblastoma Multiforme (GBM)</li></ul>
Study Size	<ul style="list-style-type: none"><li>▪ N=40</li></ul>
Endpoints	<ul style="list-style-type: none"><li>▪ Safety, tolerability</li><li>▪ ORR, PFS, OS, disease control rate</li></ul>
Timing	<ul style="list-style-type: none"><li>▪ Trial initiation target 3Q23</li><li>▪ Enrollment commenced December 2023</li></ul>

# Phase 2a trial of LSTA1 with SoC in first-line in GBM

Phase 2a proof-of-concept double-blind, placebo-controlled, randomized, proof-of-concept study evaluating LSTA1 when added to standard of care (temozolomide) versus temozolomide and matching LSTA1 placebo in subjects with newly diagnosed GBM

- **Sponsor:** Tartu University Hospital; Estonia
- **Funding:** Lisata
- **Timing:** Trial initiation target 3Q23



# Phase 1 trial of LSTA+HIPEC in Peritoneal Carcinomatosis

Sponsor/Partner	<ul style="list-style-type: none"><li>University of California, San Diego (Investigator initiated trial)</li></ul>
Objective	<ul style="list-style-type: none"><li>Evaluate safety of LSTA1 in combination with hyperthermic intraperitoneal chemotherapy (HIPEC) or HIPEC alone (without LSTA1) in patients with peritoneal metastases</li></ul>
Design	<ul style="list-style-type: none"><li>Phase 1 single-center, unblinded, randomized trial to determine the safety and tolerability of LSTA1 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 LSTA1 with HIPEC versus HIPEC alone after CRS.</li></ul>
Study Size	<ul style="list-style-type: none"><li>N=21</li></ul>
Endpoints	<ul style="list-style-type: none"><li>Safety and tolerability</li><li>PFS, OS</li></ul>
Timing	<ul style="list-style-type: none"><li>First patient treated target 4Q23</li></ul>



# Phase 1 trial of LSTA+HIPEC in Peritoneal Carcinomatosis

A Phase I, single center, unblinded, randomized controlled trial of Intraperitoneal LSTA1 in Patients Undergoing Cytoreductive Surgery and HIPEC for Peritoneal Surface Malignancy

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

