LISATA THERAPEUTICS

# Targeted Therapy *Delivered /* *递送靶向疗法*

David J. Mazzo, Ph.D. / 博士
*President & CEO / 总裁兼首席执行官*

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Nasdaq: LSTA
www.lisata.com

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# Company Overview

# 公司概述

*Lisata at a Glance / Lisata概览*

# Lisata Therapeutics (Nasdaq: LSTA): Summary / 公司概述

***A clinical stage therapeutics development company rapidly advancing a novel solid tumor targeting and penetration technology to improve the efficacy of anti-cancer drugs /***
*一家临床阶段治疗药物开发公司，正在快速推进提高抗癌药物疗效的新型实体肿瘤靶向和穿透技术*

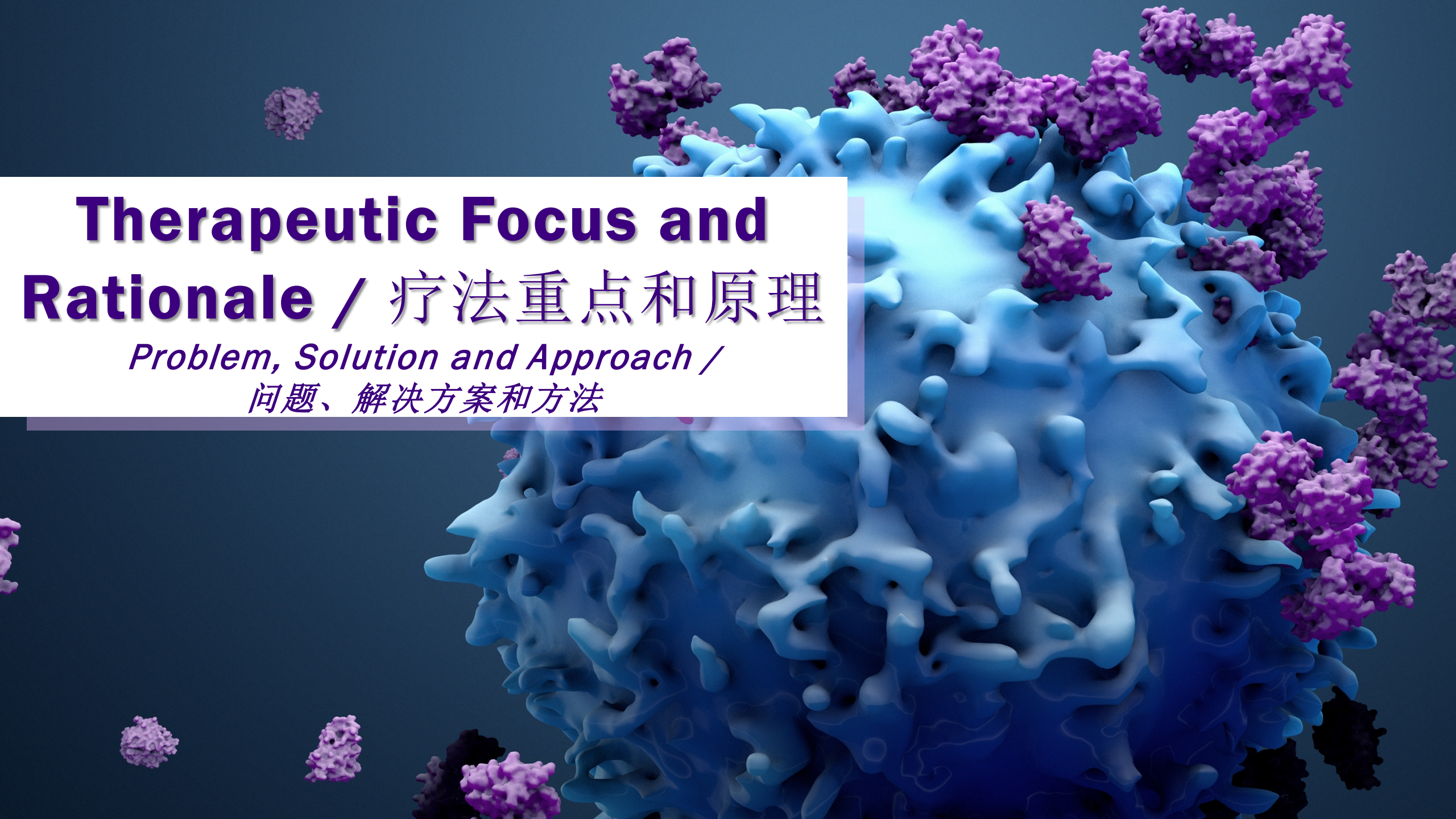
Seasoned management with successful drug development experience and expertise / 经验丰富的管理层具有成功的药物开发经验和专业知识

Proprietary field-leading technology in underserved global indications / 在未得到充分服务的全球适应症方面拥有领域领先的专有技术

Multiple projected product and business milestones over the next 24 months / 在未来24个月内有多个预期的产品和业务里程碑

Platform technology "validated" by existing partnerships with potential for many others / 平台技术通过现有的合作关系得到"验证"，并有望形成许多其他合作关系

***Projected cash runway into 2026, funding all development programs through to data***
*预计现金可用到2026年，可为所有开发项目提供资金，直至获得数据*



# Therapeutic Focus and Rationale / 疗法重点和原理

*Problem, Solution and Approach / 问题、解决方案和方法*

# Improved solid tumor cancer treatment is a vital global need / 改善实体瘤癌症治疗是全球的一项重要需求

Cancer is a leading cause of death worldwide, accounting for nearly 10 million deaths in 2020, or nearly one in six deaths[1] / 癌症是全球的一个主要死因，**2020**年造成近**1000**万例死亡，即近六分之一的死亡人数[1]

**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[2] / 2023**年，仅在美国就诊断出约**200**万的癌症新病例，实体瘤就占了新癌症病例的**90%**以上[2]

Examples of solid tumor cancers include lung, breast, pancreas, liver, bile duct, kidneys, ovaries, brain, colon, prostate, esophagus, and head & neck / 实体瘤癌症的例子包括肺癌、乳腺癌、胰腺癌、肝癌、胆管癌、肾癌、卵巢癌、脑癌、结肠癌、前列腺癌、食道癌和头颈癌

[1] www.who.int/news-room/fact-sheets/detail/cancer
[2] https://seer.cancer.gov/statfacts/html/common.html; As of November 2, 2023 / 截止2023年11月2日

# Current solid tumor treatments are suboptimal / 目前的实体瘤治疗方法不太理想

- **Targeting and penetrating tumors present distinct challenges / 靶向和穿透肿瘤带来了明显的挑战**
  - Tumor stroma acts as a physical barrier, limiting the penetration and distribution of anti-cancer agents into the tumor / 肿瘤基质是一道物理屏障，限制了抗癌药物在肿瘤内的渗透和分布
  - Tumor microenvironment (TME) immunosuppressive cells contribute to tumor resistance and/or metastases / 肿瘤微环境免疫抑制细胞促成了肿瘤的耐药性和/或转移
  - Prolonged or escalated dosing of non-targeted anti-cancer therapy generally leads to intolerable off-target side effects / 延长或加大非靶向抗癌疗法的剂量通常会导致难以忍受的非靶向副作用
  - Translation of animal model results to human safety and efficacy has been inconsistent and challenging / 将动物模型结果转化为人体安全性和有效性的过程并不一致，而且具有挑战性

# *Targeted penetration technology enhances drug delivery to solid tumors*
# *靶向穿透技术增强了对实体瘤的药物递送*

- RGD peptides serve as targeting agents to tumor cells, but do not enhance penetration and delivery of therapeutic agents / RGD 肽可作为肿瘤细胞的靶向药物，但不能增强治疗药物的渗透和递送
- *Internalizing* RGD peptides (iRGDs) combine targeting and penetration enhancement / 内化 RGD 肽（iRGDs）兼具靶向性和穿透性增强功能
- LSTA1 (certepetide) is an iRGD peptide that exploits the C-end Rule (CendR) active transport mechanism to target solid tumors and enhance tumor penetration / LSTA1 (certepetide) 是一种 iRGD 肽，利用 C 端规则 (CendR) 的主动转运机制，靶向实体瘤并增强肿瘤穿透力
- **LSTA1** is in clinical development as a ***tumor targeting and penetration enhancer*** for solid tumor treatment / **LSTA1** 作为一种用于实体瘤治疗的***肿瘤靶向和渗透增强剂***，正在进行临床开发

# LSTA1 promises optimized solid tumor treatment / / Lisata有望优化实体瘤治疗

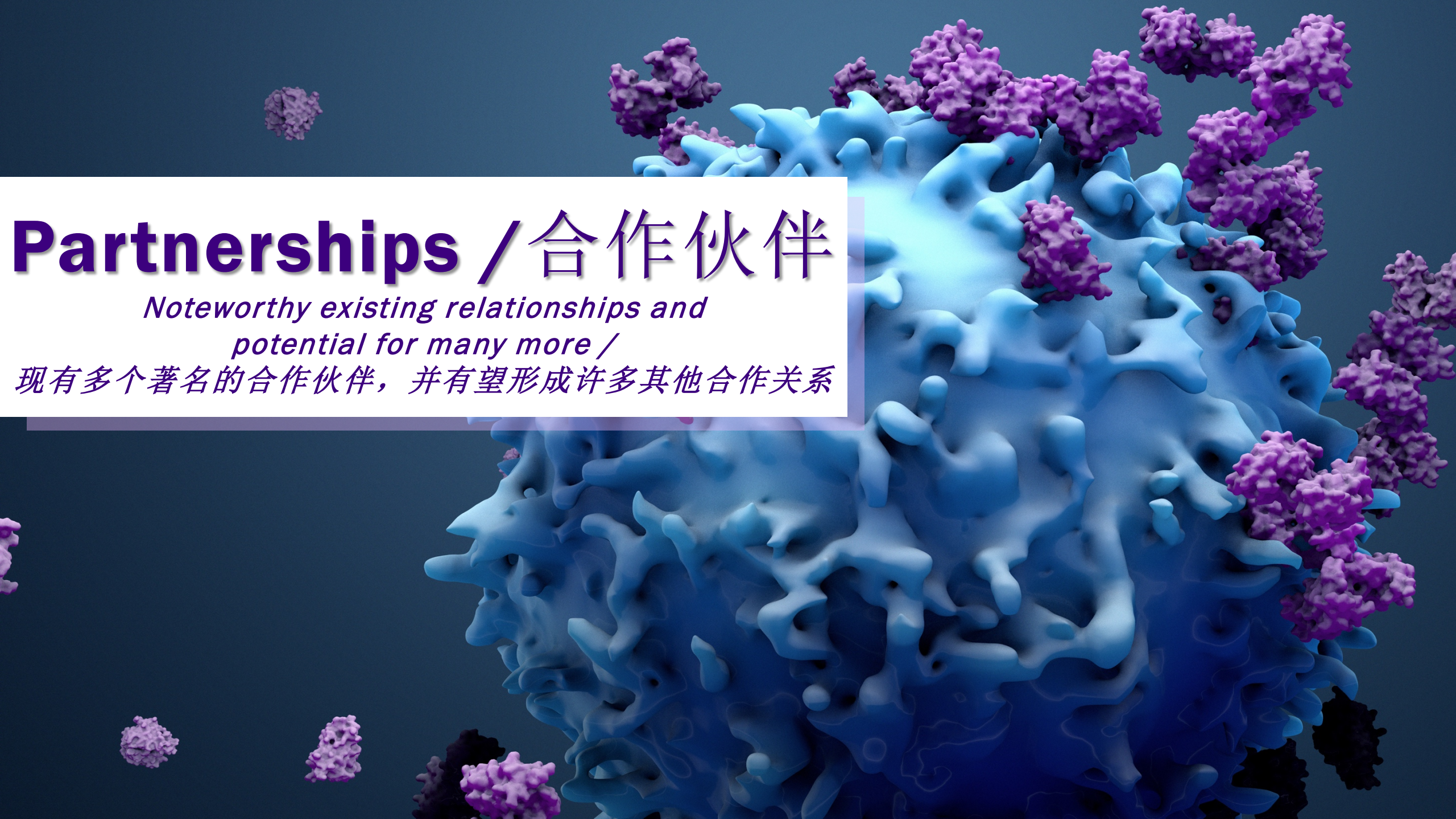
- **LSTA1 converts tumor stroma from a barrier to a conduit for anti-cancer drugs / LSTA1将肿瘤基质从抗癌药的屏障转化为通道**
- **LSTA1 is agnostic to the modality of the companion anti-cancer therapy / LSTA1 与辅助抗癌疗法的模式无关**
  - Mechanism effective with co-administered or molecularly bound (tethered) anti-cancer therapies / 与共用或分子结合（系留）抗癌疗法有效的机制
    - Co-administration presents a streamlined development path to registration / 联合用药为注册提供了简化的开发途径
    - Tethering creates a new chemical entity providing prolonged compound exclusivity /拴系技术创造了一种新的化学实体，可延长化合物的独占期
- **LSTA1 combats resistance and metastases [1] / LSTA1 对抗耐药性和转移[1]**
  - Preclinical data demonstrates that in highly fibrotic tumors, LSTA1 selectively depletes immunosuppressive T cells, enhances cytotoxic T cells and inhibits the metastatic cascade / 临床前数据表明，在高度纤维化的肿瘤中，LSTA1 可选择性地消耗免疫抑制 T 细胞，增强细胞毒性 T 细胞，并抑制转移级联反应

[1]Sugahara, et al. Mol Cancer Ther; 14(1) January 2015 / 2015年1月;
Hamilton, et al., J MolMed. April 2015 / 2015年4月; and
Miyamura, et al., bioRxiv. May 2023 / 2023年5月.

# LSTA1 development strategy is composed of two main pillars / LSTA1的开发策略是由两个主要的支柱组成

- Pursue rapid global registration in pancreatic ductal adenocarcinoma (mPDAC), initially combined with gemcitabine/nab-paclitaxel standard-of-care (SoC) / 争取在全球范围内迅速注册，最初与gemcitabine/nab-paclitaxel标准疗法联合治疗胰腺癌
  - Phase 2b >95% enrolled / 2b期招募超过了95%

- Demonstrate LSTA1 effectiveness when combined with a variety of SoC regimens (e.g., chemotherapy, immunotherapy, etc.) in a variety of solid tumor cancers / 证明LSTA1与各种标准治疗方案（如化疗、免疫治疗等）联合治疗各种实体肿瘤癌症的有效性
  - Multiple Phase 1b/2a studies underway / 正在进行多个1b/2a期研究



# Partnerships /合作伙伴

*Noteworthy existing relationships and potential for many more /*
*现有多个著名的合作伙伴，并有望形成许多其他合作关系*

# Existing partnerships support LSTA1 promise and broad applicability
# 现有的合作伙伴关系支持LSTA1的前景和广泛的适用性

## *Clinical development alliances exploring combinations with chemo- & immunotherapy /探索与化疗和免疫疗法相结合的临床开发联盟*

- LSTA1/gemcitabine/nab-paclitaxel treatment regimen with ***AGITG (AUS & NZ)*** / LSTA1/gemcitabine/nab-paclitaxel治疗方案，***与AGITG合作（澳大利亚和新西兰）。***
- LSTA1/gemcitabine/nab-paclitaxel treatment regimen ± durvalumab with ***WARPNINE (AUS)*** / LSTA1/gemcitabine/nab-paclitaxel ± durvalumab，与***WARPNINE合作（澳大利亚）***
- LSTA1/FOLFIRINOX treatment regimen ± nivolumab with ***WARPNINE (AUS)*** /LSTA1/FOLFIRINOX治疗方案±nivolumab，与***WARPNINE合作（澳大利亚）***
- LSTA1/gemcitabine/nab-paclitaxel treatment regimen ± atezolizumab with ***ROCHE*** / LSTA1/gemcitabine/nab-paclitaxel ± atezolizumab，与***ROCHE合作***

## *Strategic partnership in China with Qilu Pharmaceutical / 与中国齐鲁制药的战略合作*

- Exclusive rights to LSTA1 in China, Taiwan, Hong Kong and Macau / 在中国大陆、台湾、香港和澳门LSTA1的独家权利
- Qilu assumes all development and commercialization responsibilities/costs in licensed territories / 齐鲁承担许可地区的所有开发和商业化责任/费用
  - Strategy and activities under the auspices of a Joint Steering Committee with Lisata executives /在与Lisata高管组成的联合指导委员会的主持下开展策略执行和活动
- Potential for up to $220 million to Lisata for milestones & tiered double-digit royalties on sales / Lisata有可能获得高达$2.2亿的里程碑付款和阶梯式的两位数销售权利金。

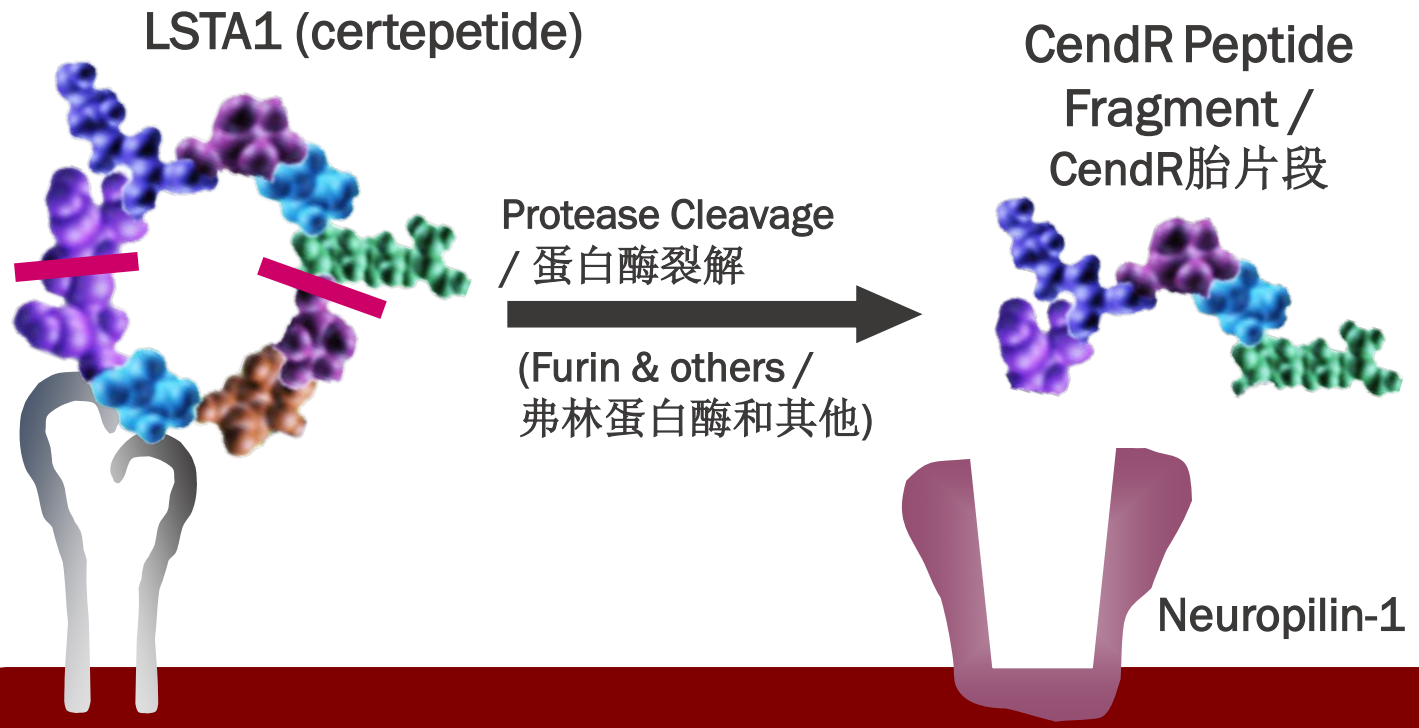
## *Additional partnership opportunities exist for many combinations with LSTA1 in a variety of solid tumor indications / 在各种实体瘤适应症中，与LSTA1组合使用存在更多的合作机会*

# LSTA1

*Strong Scientific Foundation and Rationale*

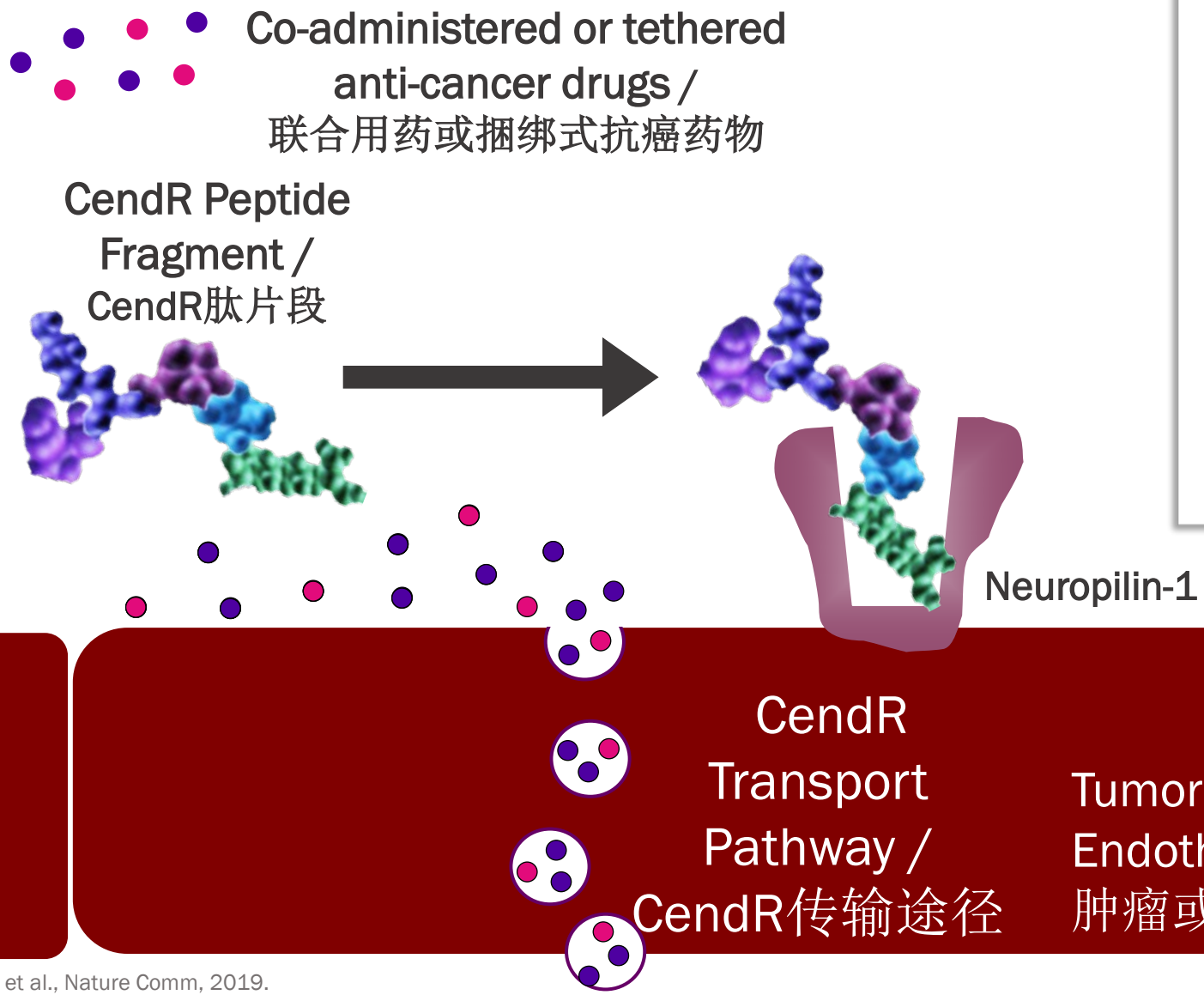
*坚实的科学基础和理论依据*

# LSTA1 Mechanism of Action: Steps 1 & 2 of 3
# LSTA1的作用机制：步骤1和2，共3步




- LSTA1: 9 amino acid cyclic peptide; high binding specificity and affinity to αvβ3/β5 integrins that are upregulated on: /LSTA1：9个氨基酸的环肽；对αvβ3/β5整合蛋白有很高的结合特异性和亲和力，这些整合蛋白上调在：
  - Tumor vascular endothelium /肿瘤血管内皮细胞
  - Tumor cells / 肿瘤细胞
- Once bound to αvβ3/β5 integrins, LSTA1 is cleaved by proteases in the tumor microenvironment, releasing a C-end Rule (CendR) linear peptide fragment / 一旦与αvβ3/β5整合蛋白结合，LSTA1就会被肿瘤微环境中的蛋白酶裂解，释放出一个C端规则（CendR）的线性肽片段

# LSTA1 Mechanism of Action: Step 3 of 3
# LSTA1的作用机制：步骤3，共3步



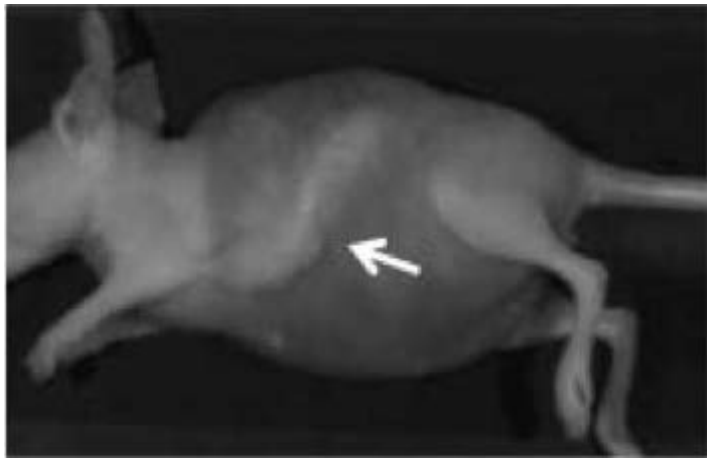

- The CendR fragment then binds with high affinity and selectivity to an adjacent receptor, neuropilin-1, activating the CendR transport pathway[1] / 然后，CendR片段以高亲和力和选择性与邻近的受体-- neuropilin-1结合，激活CendR传输途径。
  - Circulating moieties including unbound LSTA1, unbound CendR peptide fragment and co-administered or tethered drugs penetrate stroma and tumor, providing greater intratumoral access / 循环基团包括未结合的LSTA1、未结合的CendR肽片段和联合使用的或捆绑使用的药物可穿透基质和肿瘤，提供更大的瘤内接触。
  - Activating the CendR pathway has been shown to open intratumoral gap junctions enhancing extravasation of immune cells into tumors / 激活CendR通路已被证明可以打开瘤内缝隙连接，增强免疫细胞向肿瘤的渗透。

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

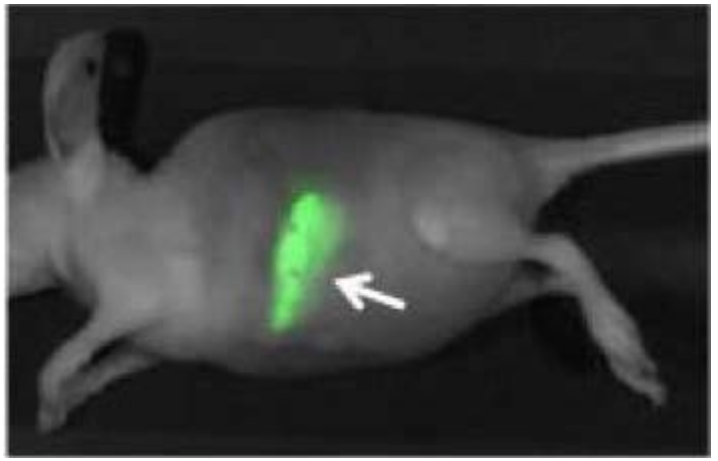
# LSTA1 selectively and efficiently facilitates intratumoral penetration
# LSTA1选择性地、有效地促进瘤内渗透

**Whole body imaging of mice with pancreatic ductal adenocarcinoma (arrow) dosed with Fluorescent Quantum Dots (FQDs) with and without LSTA1 /**患有胰腺导管腺癌的小鼠全身成像（箭头），使用和不使用**LSTA1**的荧光量子点（**FQDs**）

FQD + Etching solution / FQD +蚀刻液



LSTA1 + FQD + Etching solution / LSTA1 + FQD + 蚀刻液



- Etching solution quenches fluorescence in circulation / 蚀刻液在循环中淬灭了荧光
- **LSTA1 provides selective tumor penetration / LSTA1 提供选择性的肿瘤穿透力**

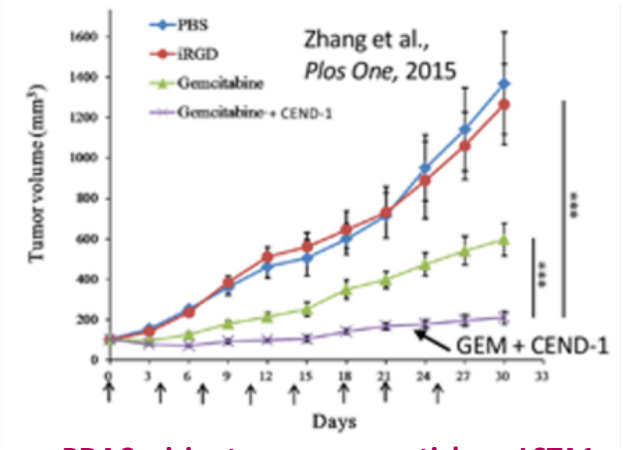
[1] Braun et al., Nature Mater. 2014.
[2] Liu, Braun et al., Nature Comm. 2017.

# Large body of work shows consistent LSTA1 activity/broad applicability
# 大量的工作表明，LSTA1具有一致的活性/广泛的适用性

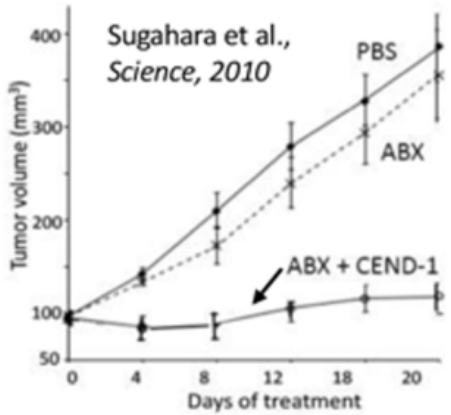
***Sampling of >300 scientific publications showing LSTA1/iRGD augmentation effects /***

*抽样调查了>300份显示**LSTA1/iRGD**增强效果的科学出版物*

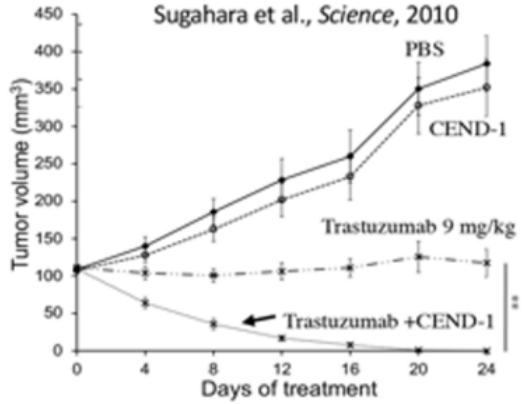
**Lung cancer + gemcitabine + LSTA1**
**肺癌+ gemcitabine + LSTA1**



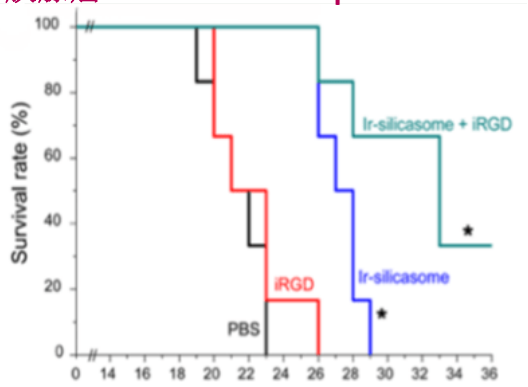

**Breast cancer + nanoparticle Abraxane + LSTA1**
**乳腺癌+ nanoparticle Abraxane + LSTA1**




**Breast cancer + Herceptin® + LSTA1**
**乳腺癌+ Herceptin® + LSTA1**

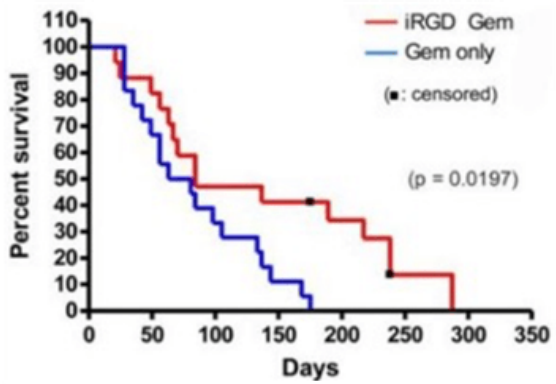



**PDAC + irinotecan nanoparticles + LSTA1**
**胰腺癌+ irinotecan nanoparticles + LSTA1**



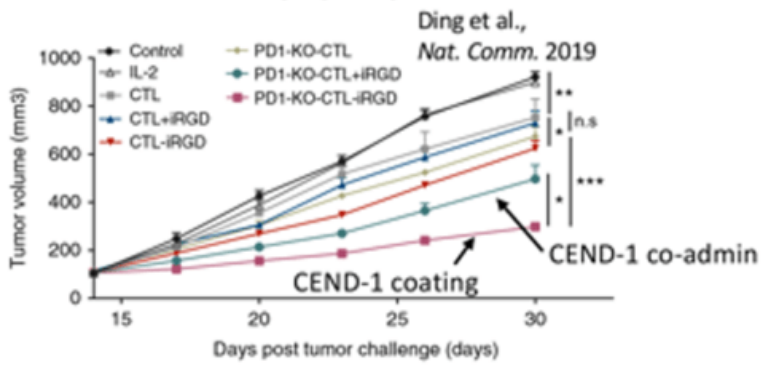

Orthotopically transplanted KPC PDAC tumors CEND-1 + irinotecan nanoparticles (i.v. co-admin) / 原位移植的KPC PDAC肿瘤 CEND-1 + irinotecan nanoparticles （静脉注射联合用药）

**PDAC + gemcitabine + LSTA1**
**胰腺癌+ gemcitabine + LSTA1**




KPC mice genetically engineered to develop PDAC CEND-1 + gemcitabine (i.v. co-admin) / KPC小鼠经遗传工程发展为PDAC CEND-1+ gemcitabine （静脉注射联合用药）

**GI cancer + adoptive cell therapy + LSTA1**
**胃肠道癌 + 细胞疗法 + LSTA1**




[1] Hurtado de Mendoza et al, *Nature Comms*, 2021.
[2] Liu X et al., J Clin Invest, 2017.

# LSTA1 Phase 1b/2a results: Compelling improvement of SoC efficacy
# LSTA1第1b/2a期结果：SoC疗效显著改善

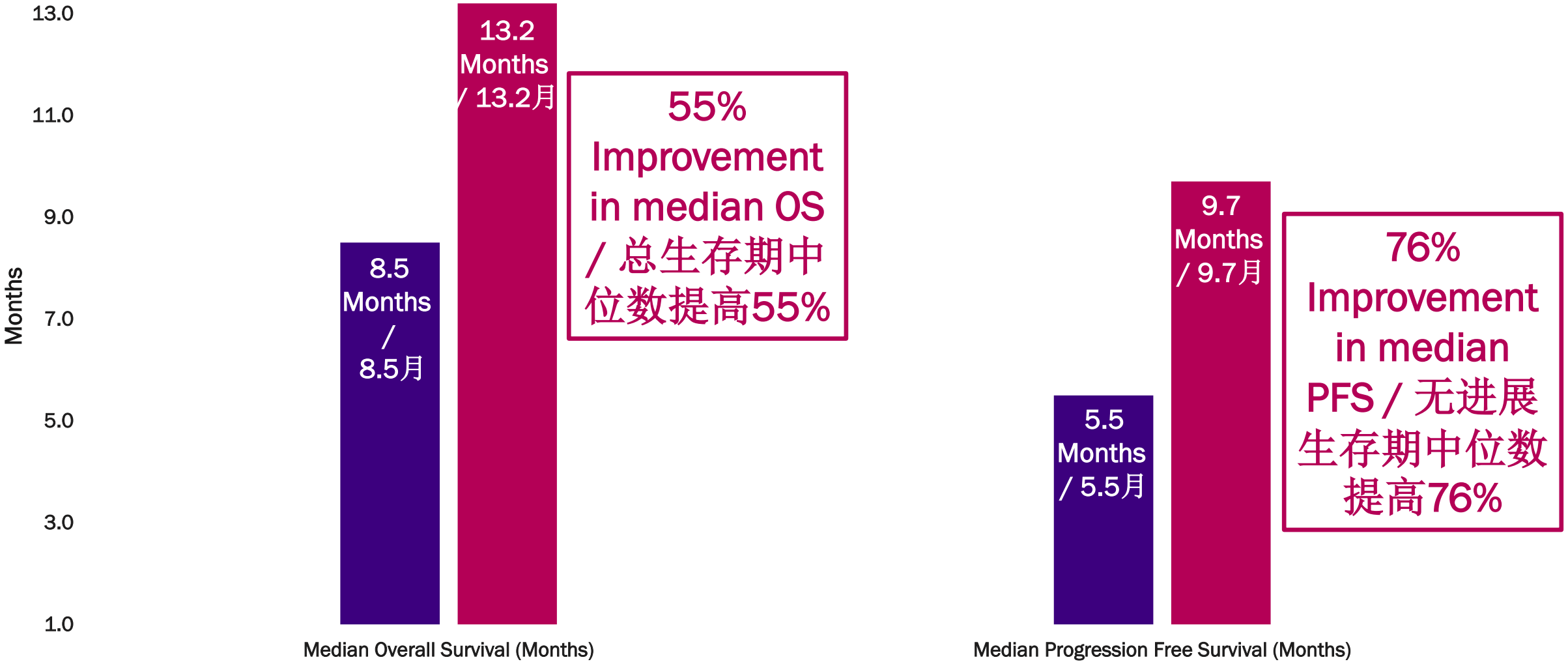
| Endpoints / 终点 | Gemcitabine[1] | Gemcitabine + Nab-paclitaxel[2] | LSTA1 + Gemcitabine + Nab-paclitaxel[3] |
|---|---|---|---|
| N= # of study participants /研究对象数量 | N=171 | N=431 | **N=31** |
| Median Overall Survival /总生存期中位数 | 6.8 mos./ 6.8月 | 8.5 mos. / 8.5月 | **13.2 mos. / 13.2月** |
| Median Progression-Free Survival /无进展生存期中位数 | 3.3 mos. / 3.3月 | 5.5 mos./5.5月 | **9.7 mos./9.7月** |
| Objective Response Rate /客观反应率 | 9.4% (16) | 23% (99) | **59% (17)** |
| Complete Response /完全反应 | 0% (0) | 0.2% (1) | **3.4% (1)** |
| Partial Response / 部分反应 | 9.5% (16) | 23% (98) | **55% (16)** |
| Stable Disease / 疾病稳定 | 41.5% (71) | 27% (118) | **31% (9)** |
| Progressive Disease / 疾病进展 | 34.5% (59) | 20% (86) | **10.3% (3)** |
| Disease Control Rate 16 weeks /疾病控制率16周 | - | 48% | **79%** |
| CA19-9 >20% drop | - | 61% | **96%** |

**First-line, mPDAC patients from 3 sites in Australia / 来自澳大利亚3个地点的一线、mPDAC患者**

**LSTA1 well-tolerated, no dose-limiting toxicities; safety with LSTA1 consistent with SoC alone / LSTA1耐受性良好，没有剂量限制性毒性；LSTA1的安全性与单独使用SoC一致**

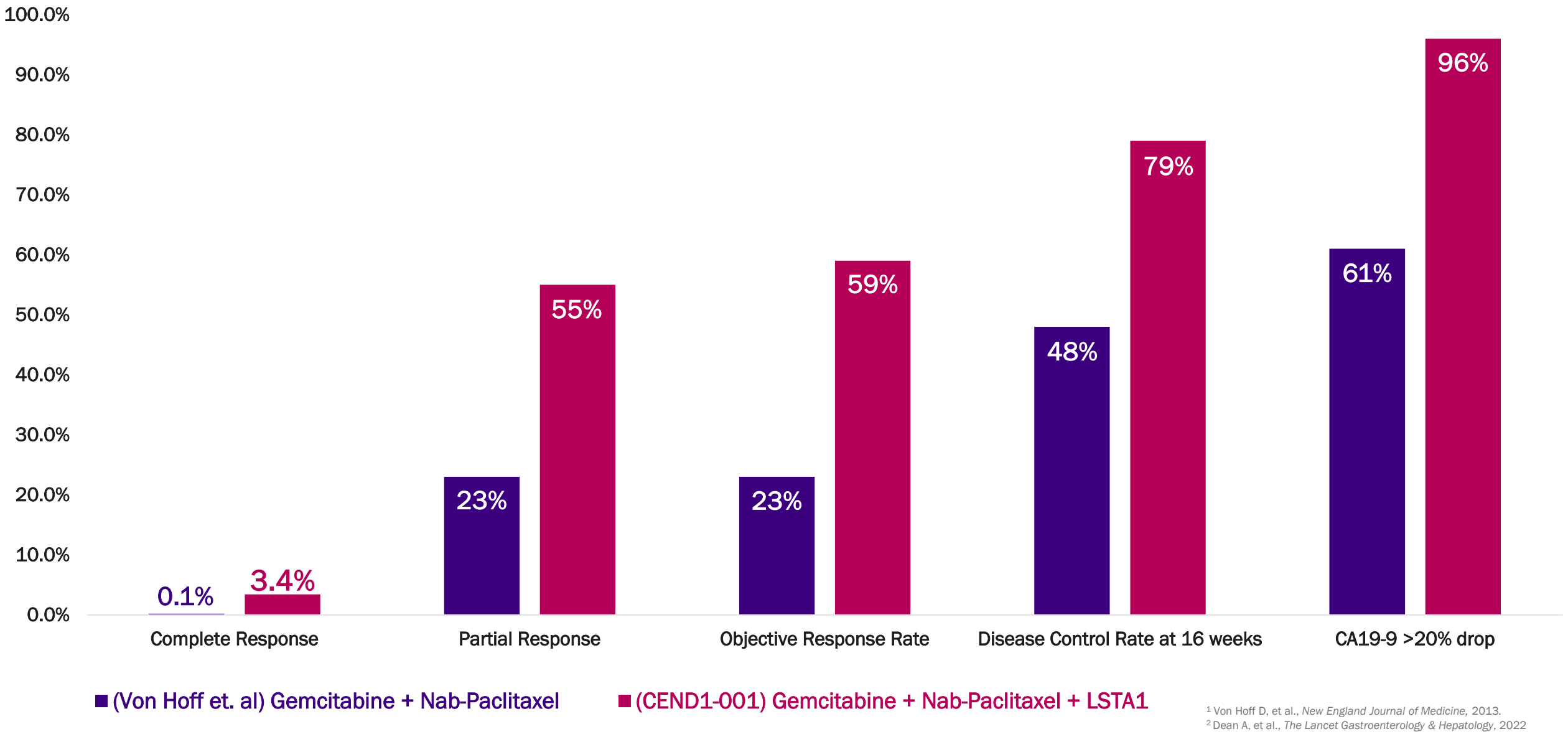
[1] Conroy T, et al., *New England Journal of Medicine*, 2011.
[2] Von Hoff D, et al., *New England Journal of Medicine*, 2013.
[3] Dean A, et al., *The Lancet Gastroenterology & Hepatology*, 2022.

# LSTA1 Phase 1b/2a results: Improved survival vs. SoC alone
# LSTA1第1b/2a期结果：与单用SoC相比生存期提高

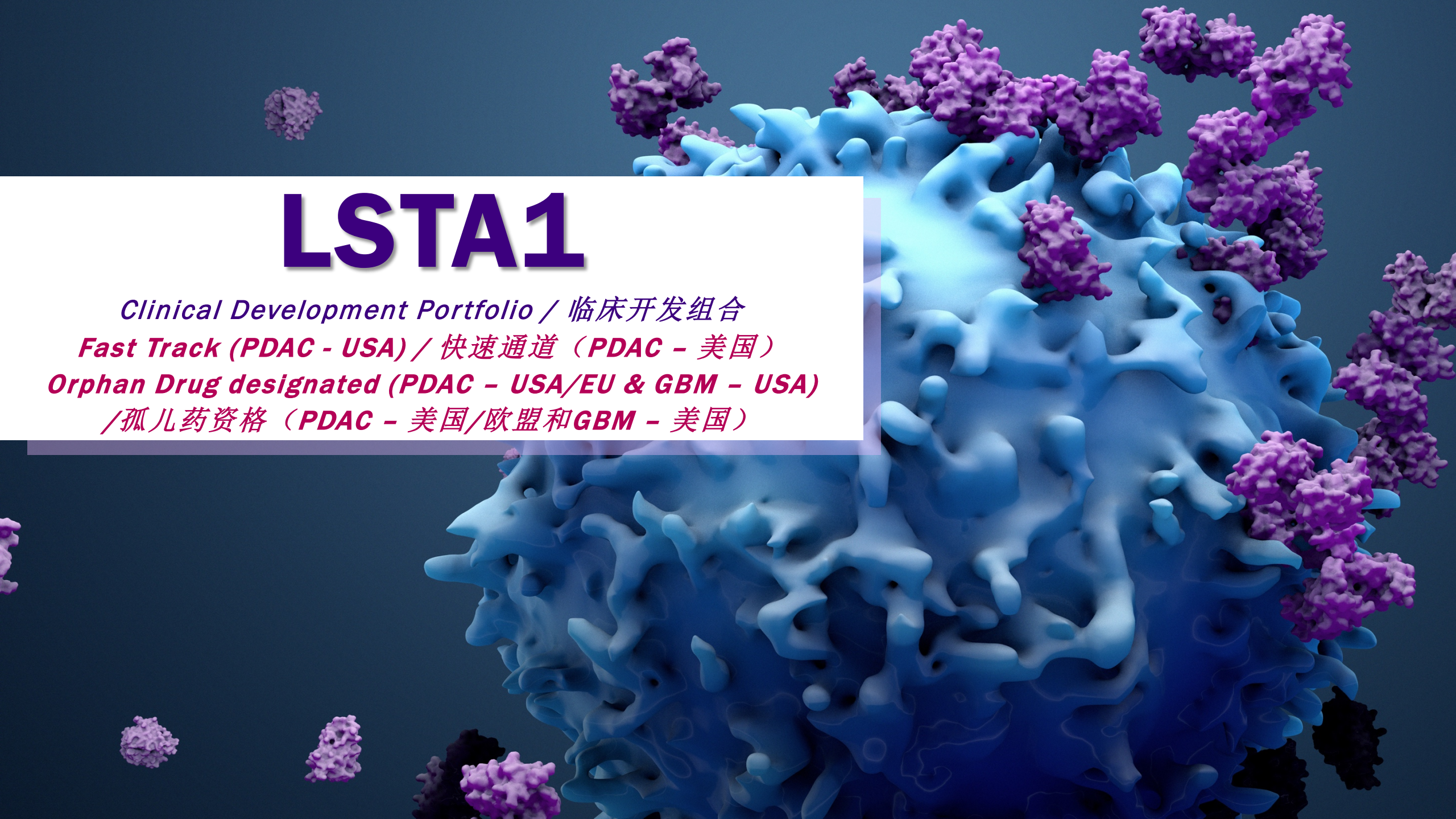



[1] Von Hoff D, et al., *New England Journal of Medicine*, 2013.
[2] Dean A, et al., *The Lancet Gastroenterology & Hepatology*, 2022

# LSTA1 Phase 1b/2a results: Consistent improvement across associated endpoints
# LSTA1第1b/2a期结果：相关终点持续改善




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



# LSTA1

*Clinical Development Portfolio / 临床开发组合*

***Fast Track (PDAC - USA) / 快速通道（PDAC – 美国）***

***Orphan Drug designated (PDAC – USA/EU & GBM – USA)***

***/孤儿药资格（PDAC – 美国/欧盟和GBM – 美国）***

# Implications of Fast Track and Orphan Drug designations
# 快速通道资格和孤儿药资格的作用

- **FDA Fast Track Designation / FDA快速通道资格**
  - More frequent communication with and program-specific guidance from FDA / 与 FDA 进行更频繁的沟通，并从 FDA 获得针对具体项目的指导
  - Eligible for *Accelerated Approval, Priority Review and Rolling Review* / *符合加速审批、优先审查和滚动审查的条件*
- **Orphan Drug Designation / 孤儿药资格**
  - Incentives such as *tax credits, marketing exclusivity, fee waivers* and the opportunity to apply for *grants* to support clinical trials / 税收减免、市场专营权、费用减免等激励措施，以及申请拨款支持临床试验的机会
  - Specialized regulatory assistance from FDA's Office of Orphan Products Development (OOPD) / FDA 的孤儿产品开发办公室 (OOPD) 提供专门的监管援助

# LSTA1 capital efficient development plan; shared costs & selective geography
# LSTA1资本高效开发计划；分担费用和特定区域

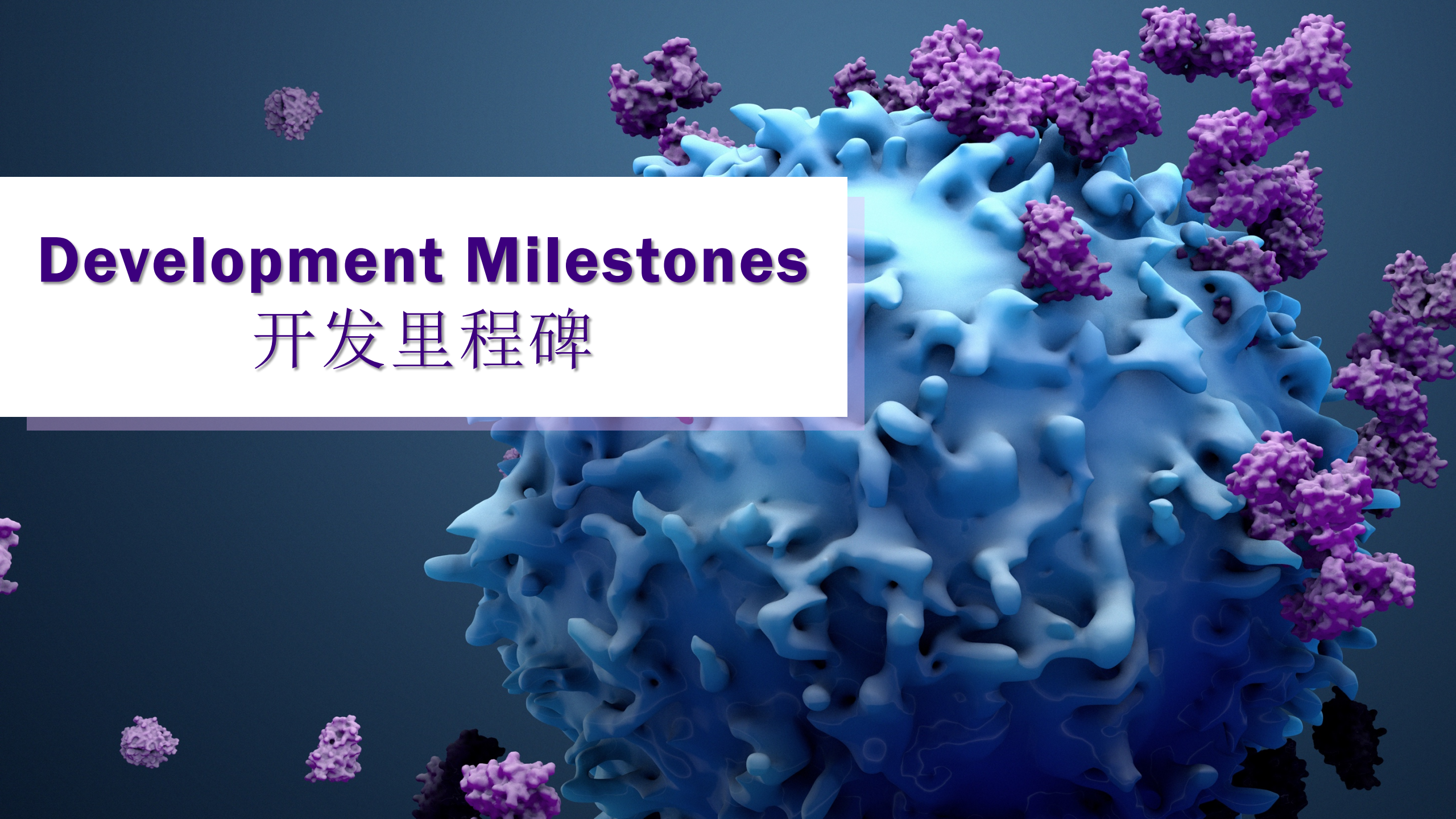
| Partners / 合作伙伴 | Region / 地区 | Indication and Test Articles / 适应症和测试品 | Status / 状态 |
|---|---|---|---|
| AGITG/Lisata | Australia & New Zealand / 澳大利亚和新西兰 | **First-line mPDAC / 一线mPDAC**<br>Gemcitabine/nab-paclitaxel with LSTA1 or placebo / Gemcitabine/nab-paclitaxel与 LSTA1或安慰剂 | Phase 2b (**ASCEND**) / 2b期(**ASCEND**)<br>Placebo-controlled / 安慰剂控制<br>*Enrolling / 正在招募* |
| Lisata | USA, Canada, EU and Asia / 美国、加拿大、欧盟和亚洲 | **Various Solid Tumors / 各种实体瘤**<br>Standard of Care with LSTA1 or placebo/ 用LSTA1或安慰剂标准治疗 | Phase 2a (**BOLSTER**) / 2a期 (**BOLSTER**)<br>Placebo-controlled/ 安慰剂控制<br>*Enrolling / 正在招募* |
| KUCC/Lisata | USA / 美国 | **Pancreatic, Colon, & Appendiceal Cancers / 胰腺癌、结肠癌和阑尾癌**<br>LSTA1 + FOLFIRINOX + panitumumab* | Phase 1b/2a (**CENDIFOX**) / 1b/2a期 (**CENDIFOX**)<br>Open-label / 公开标签<br>*Enrolling / 正在招募* |
| Qilu/Lisata | China / 中国 | **First-line mPDAC / 一线mPDAC**<br>Gemcitabine/nab-paclitaxel + LSTA1 | Phase 1b/2a / 1b/2a期<br>Open-label / 公开标签<br>*Enrolling / 正在招募* |
| WARPNINE/Lisata | Australia / 澳大利亚 | **Locally advanced, non-resectable PDAC / 局部晚期，不可切除的胰腺癌**<br>Durvalumab/gemcitabine/nab-paclitaxel + LSTA1 | Phase 1b/2a (**iLSTA**) / 1b/2a期(**iLSTA**)<br>Open-label / 公开标签<br>*Enrolling / 正在招募* |

**Panitumumab may be added for colorectal or appendiceal patients without Ras mutation / *对于没有Ras突变的结肠癌或阑尾癌患者，可加入Panitumumab*

# LSTA1 capital efficient development plan; shared costs & selective geography
# LSTA1资本高效开发计划；分担费用和特定区域

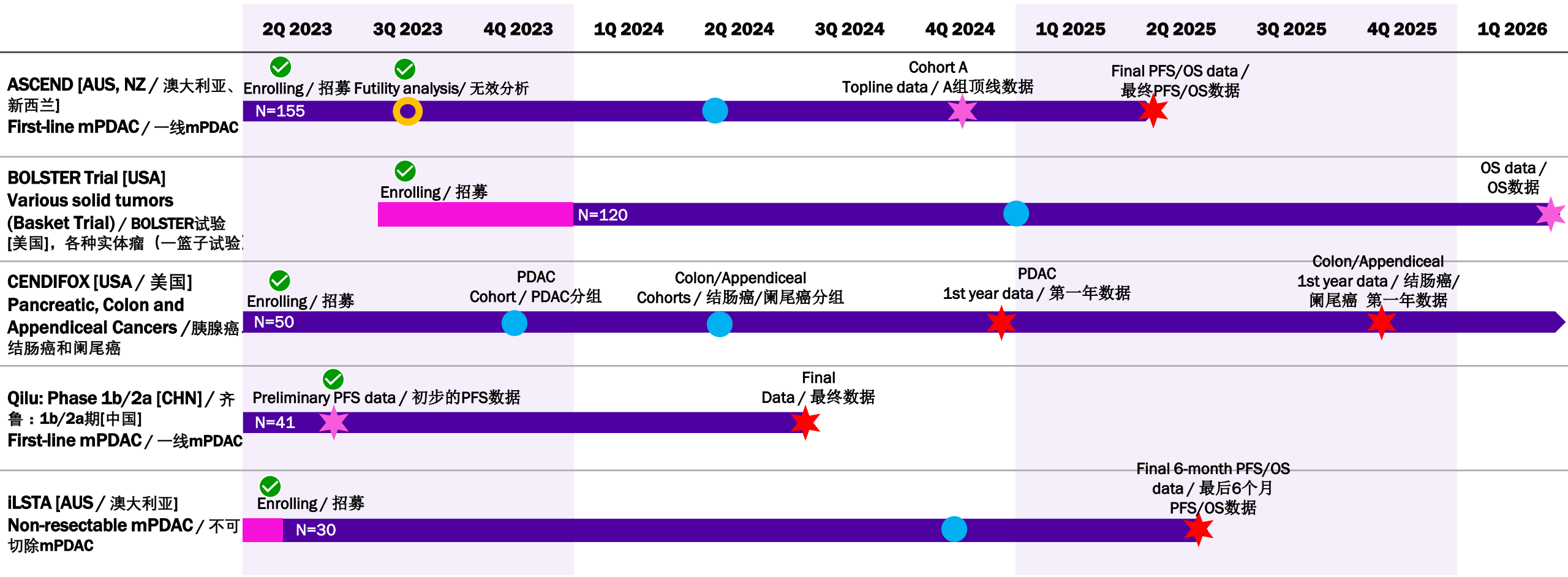
| Partners / 合作伙伴 | Region / 地区 | Indication and Test Articles / 适应症和测试品 | Status / 状态 |
|---|---|---|---|
| UCSD/Columbia University/Lisata | USA / 美国 | **Peritoneal Carcinomatosis (Colon & Ovarian) / 腹膜癌（结肠癌和卵巢癌）**<br>LSTA1 + HIPEC* intraoperative intraperitoneal lavage / LSTA1 + HIPEC *术中腹腔灌洗 | Phase 1b/2a / 1b/2a期<br>Open-label / 开放标签<br>*Pending initiation / 即将启动* |
| Tartu University Lisata | Estonia & Latvia / 爱沙尼亚和拉脱维亚 | **First-line Glioblastoma Multiforme (GBM) / 一线多形性胶质母细胞瘤(GBM)**<br>Temozolomide +/- LSTA1 | Phase 2a / 2a期<br>Placebo-controlled / 安慰剂控制<br>*Pending initiation / 即将启动* |
| Qilu/Lisata | China / 中国 | **First-line mPDAC / 一线mPDAC**<br>Gemcitabine/Nab-paclitaxel + LSTA1 | Phase 2 / 2期<br>Placebo-controlled / 安慰剂控制<br>*Pending initiation / 即将启动* |
| WARPNINE/Lisata | Australia / 澳大利亚 | **Locally advanced, non-resectable Gastroesophageal Adenocarcinoma / 局部晚期，不可切除的胃食管腺癌**<br>Nivolumab/FOLFIRINOX + LSTA1 | Phase 1b/2a (**iGoLSTA**) / 1b/2a期 (**iGoLSTA**)<br>Open-label / 开放标签<br>*Pending initiation / 即将启动* |
| Roche/Lisata | Multi-national / 多国 | **First-line mPDAC / 一线mPDAC**<br>Gemcitabine/nab-paclitaxel/LSTA1 +/- atezolizumab | Phase 1b/2 (**MORPHEUS**) / 1b/2 (**MORPHEUS**)<br>Active-controlled / 主动控制<br>*Pending initiation / 即将启动* |

*Hyperthermic intraperitoneal chemotherapy / 腹腔热灌注化疗



# Development Milestones
# 开发里程碑

# A wealth of anticipated key milestones / 多个预期的主要里程碑




First patient in / 第一个患者入组

Last patient in / 最后一个患者入组

Interim Analysis / 期中分析

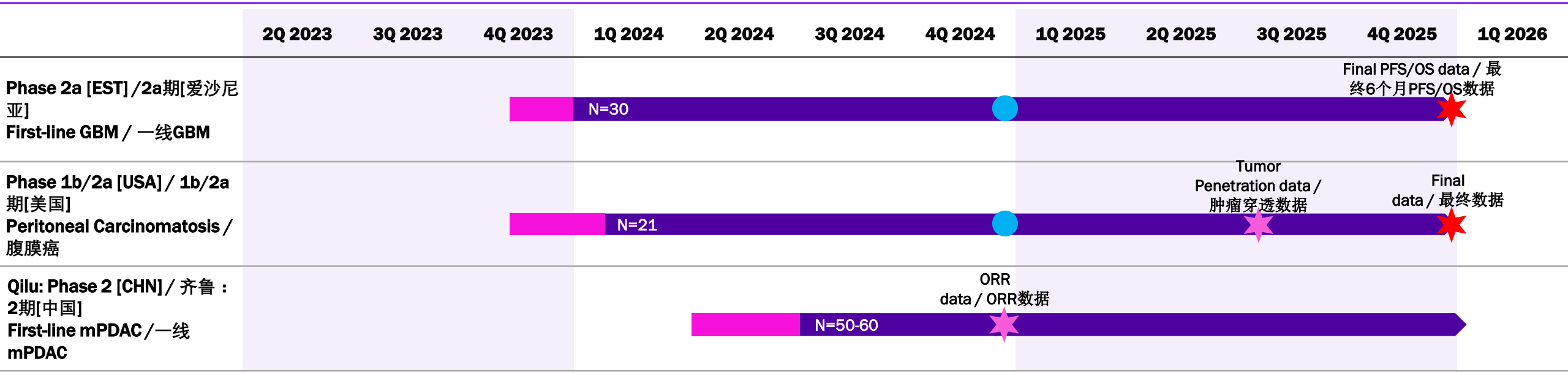
Data / 数据

Final data / 最终数据

Milestone Achieved / 取得里程碑

- PFS: Progression-free Survival /无进展生存期
- OS: Overall Survival / 总生存期
- ORR: Objective Response Rate /客观反应率

# A wealth of anticipated key milestones (contd.) /多个预期的主要里程碑（续）




First patient in / 第一个患者入组

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Interim Analysis / 期中分析

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Milestone Achieved / 取得里程碑

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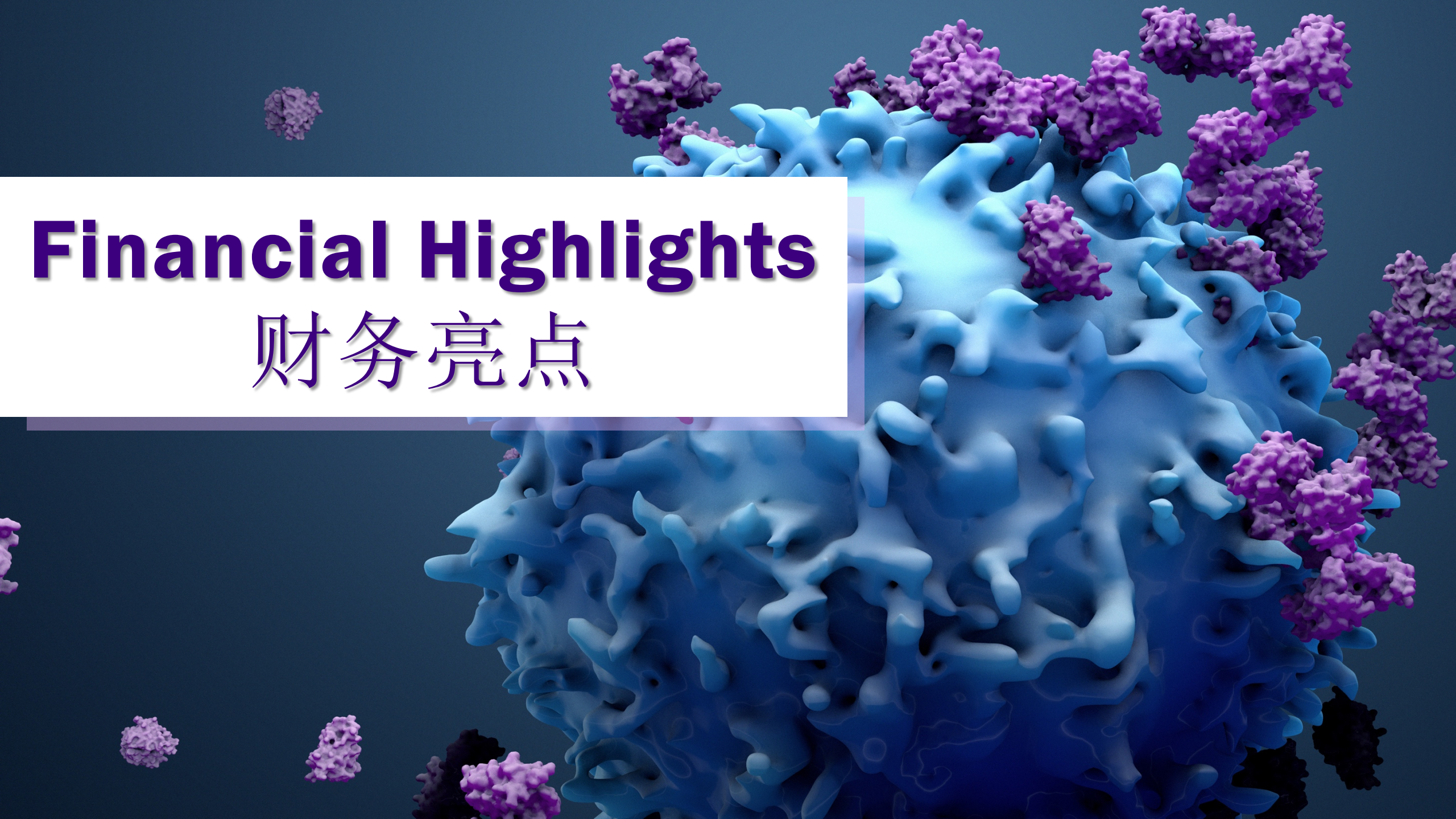


# Financial Highlights
# 财务亮点

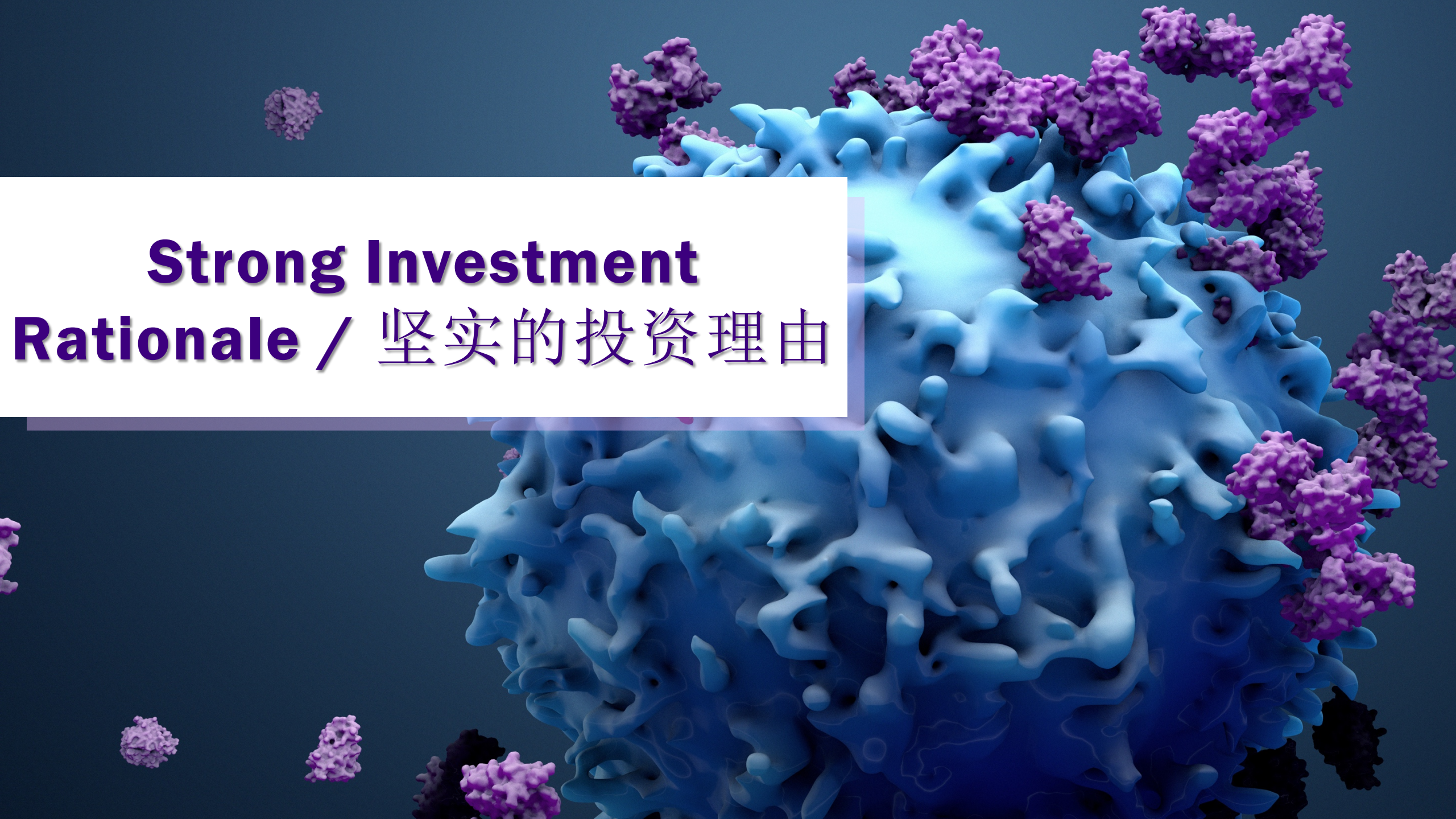
# Capital projected to fund all clinical programs to data / 预计所持资金足以推进所有临床项目直至获得数据

**Cash & Investments / 现金与投资**
*As of 9/30/2023 / 截止2023年9月30日*
**$54.4M / $5440万**

**Debt / 债务**
**$0**

**Projected Cash Runway Into / 预期现金可用到**
**1Q2026 / 2026年第一季度**

| | |
|---|---|
| Common Shares Outstanding (9/30/2023):/ 发行在外普通股（2023年9月30日） | 8.1 million shares / 810万股 |
| Options Outstanding (9/30/2023): / 发行在外期权（2023年9月30日）<br>Exercise Price/ 行权价: $0.02 - $4.22 = 1,082,000 shares / 108.2**万股**<br>Exercise Price/ 行权价: > $4.22 = 239,000 shares / 23.9**万股** | 1.3 million shares / 130万股 |
| Warrants Outstanding (9/30/2023): / 发行在外认股权证（2023年9月30日）<br>Weighted Average Exercise Price: $42.51 / 加权平均行权价：$42.57 | 1.4 million shares / 140万股 |



# Strong Investment Rationale / 坚实的投资理由

# Key factors supporting investment in Lisata Therapeutics
# 支持投资Lisata Therapeutics的关键因素

## PEOPLE / 人才

**Seasoned management with successful international development experience and expertise** / 经验丰富的管理层具有成功的国际开发经验和专业知识

## TECHNOLOGY / 技术

**Proprietary field-leading technology in underserved global indications** / / 在未得到充分服务的全球适应症方面拥有领域领先的专有技术

## MILESTONES / 里程碑

**Multiple projected product and business milestones over the next 24 months** / 在未来24个月内有多个预期的产品和业务里程碑

## CAPITAL / 资金

**$54.4 million cash*- no debt; Development funded through critical data milestones** / **$5440**万现金*- 无债务；有足够的开发资金完成关键数据里程碑

## PARTNERING / 合作

**Platform technology "validated" by existing partnerships with potential for many others** / 平台技术通过现有的合作关系得到"验证"，并有望形成许多其他合作关系

* As of 9/30/2023; includes investments / 截止2023年9月30日；包括投资

LISATA THERAPEUTICS

# Targeted Therapy

## *Delivered /*

## *递送*靶向疗法


**Investor Relations Contact:/ 投资者关系联系人：**

John D. Menditto

VP, IR & Corporate Communications /

投资者关系与企业公关副总裁

o: (908) 842-0084 | e: jmenditto@lisata.com


Nasdaq: LSTA | *www.lisata.com*

# Appendix

# 附录

# 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] | **Various Solid Tumors;** SoC with LSTA1 or placebo | **Phase 2a (BOLSTER)** | Assess LSTA1 safety and effectiveness in several tumor types 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

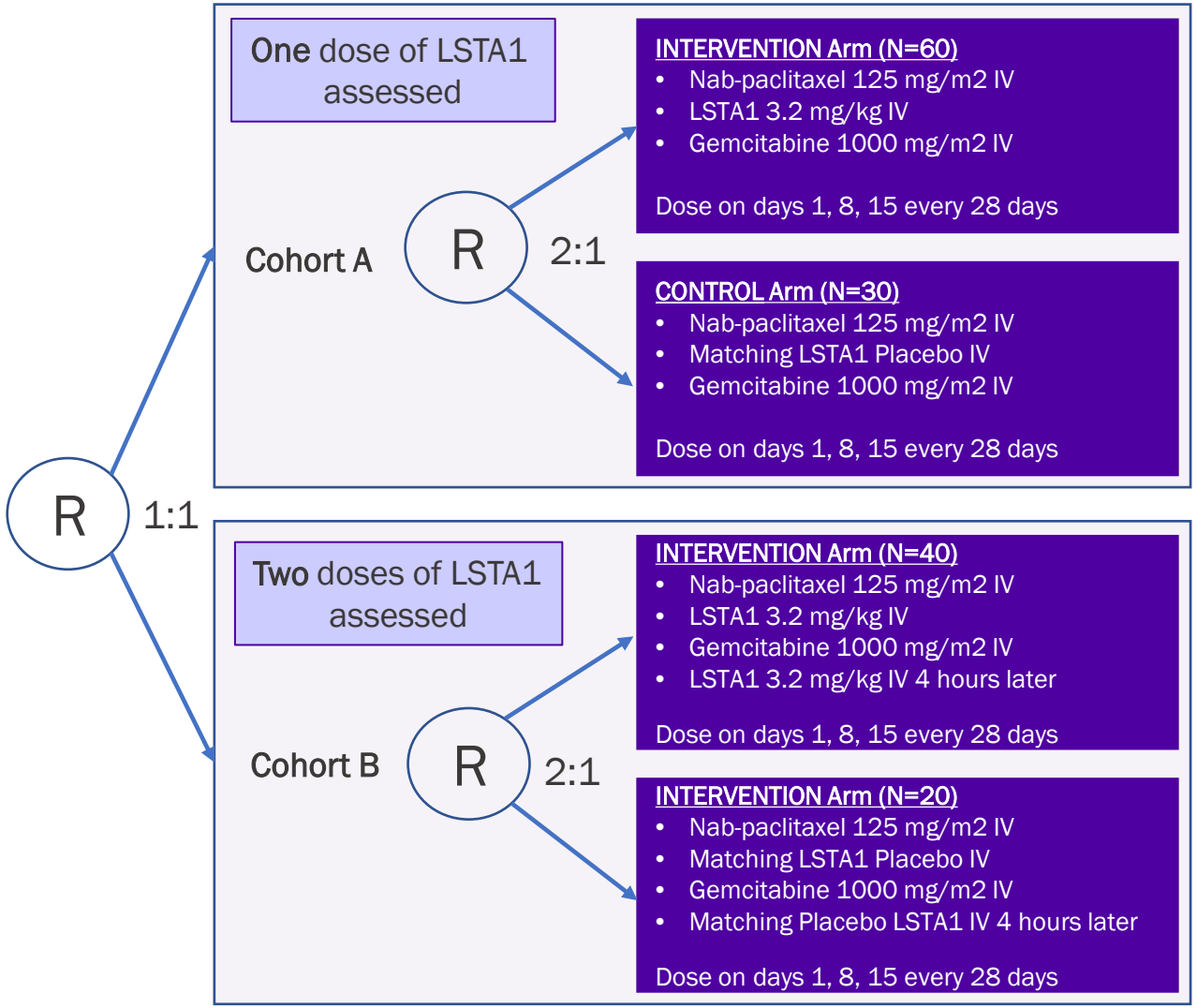
| Development Partner(s) [Development Venue] | Indication and Trial Product/Comparator | Stage of Development | Strategic Rationale |
|---|---|---|---|
| Tartu University/Lisata [Estonia] | **First-line Glioblastoma Multiforme;** Temozolomide ± LSTA1 | **Phase 2a** | Assess LSTA1 safety and effectiveness in additional tumor type (GBM) a in placebo-controlled trial |
| UCSD/Columbia University/Lisata [United States] | **Peritoneal Carcinomatosis** LSTA+HIPEC intraoperatively | **Phase 1b/2a** | 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) |
| Roche/Lisata [Multi-national] | **First-line mPDAC;** Gemcitabine/nab-paclitaxel/LSTA1 ± atezolizumab | **Phase 1b/2 (MORPHEUS)** | Assess LSTA1 safety and effectiveness in combination with SoC chemotherapy & immunotherapy (controlled trial) |

# 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<br>▪ 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<br>▪ Determine if a second dose of LSTA1 further improves patient outcomes |
| **Design** | ▪ Phase 2b randomized, double-blind study in mPDAC testing gemcitabine + nab-paclitaxel SoC with one of two LSTA1 dose regimens or placebo |
| **Study Size** | ▪ ~150 subjects (~40 sites planned in Australia and New Zealand) |
| **Endpoints** | ▪ Primary: Progression Free Survival<br>▪ Secondary: AEs, SAEs, Overall Survival, Objective Tumor Response Rate |
| **Timing** | ▪ Enrollment completion target late 2Q24<br>▪ 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 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 completion target late 2Q24; Earliest possible data 2024

**Endpoints**

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

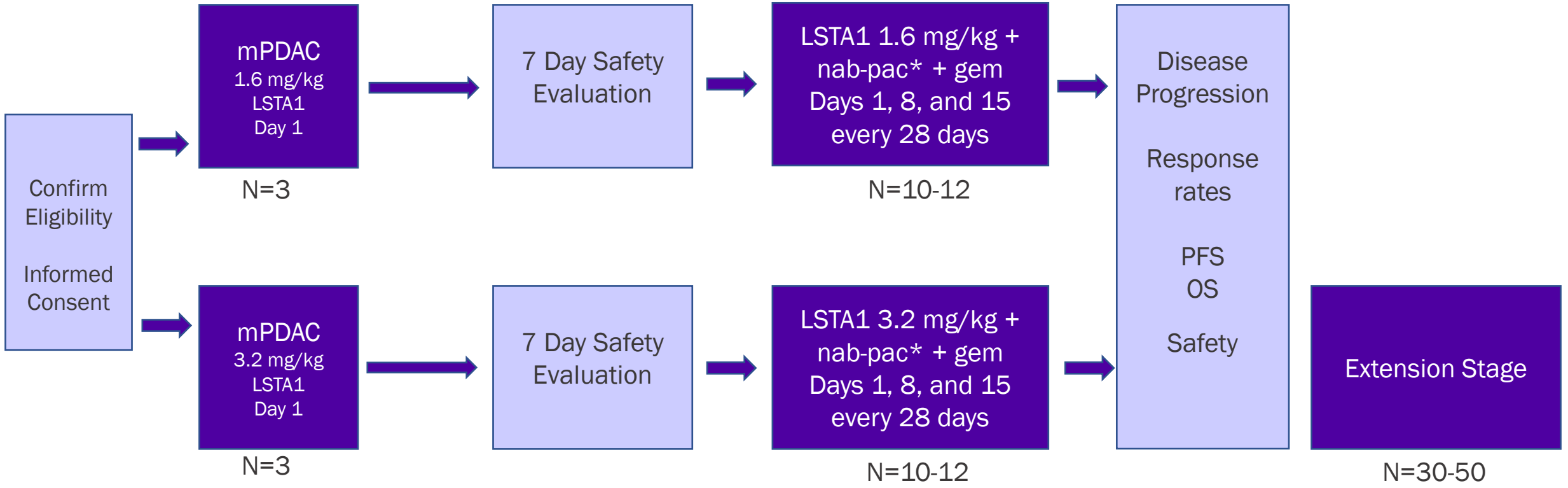
# Phase 1b/2a open-label trial in mPDAC in China

| | |
|---|---|
| **Sponsor/Partner** | ▪ Qilu Pharmaceutical (funds all development in China) |
| **Objective** | ▪ Evaluate safety, pharmacokinetics and preliminary efficacy of LSTA1 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 LSTA1 |
| **Study Size** | ▪ 50 subjects (~15 sites) |
| **Endpoints** | ▪ Primary: AEs, SAEs, Objective Response Rate, Duration of Response, Disease Control Rate, Overall Survival, and Progression Free Survival<br>▪ 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 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




*Qilu produced

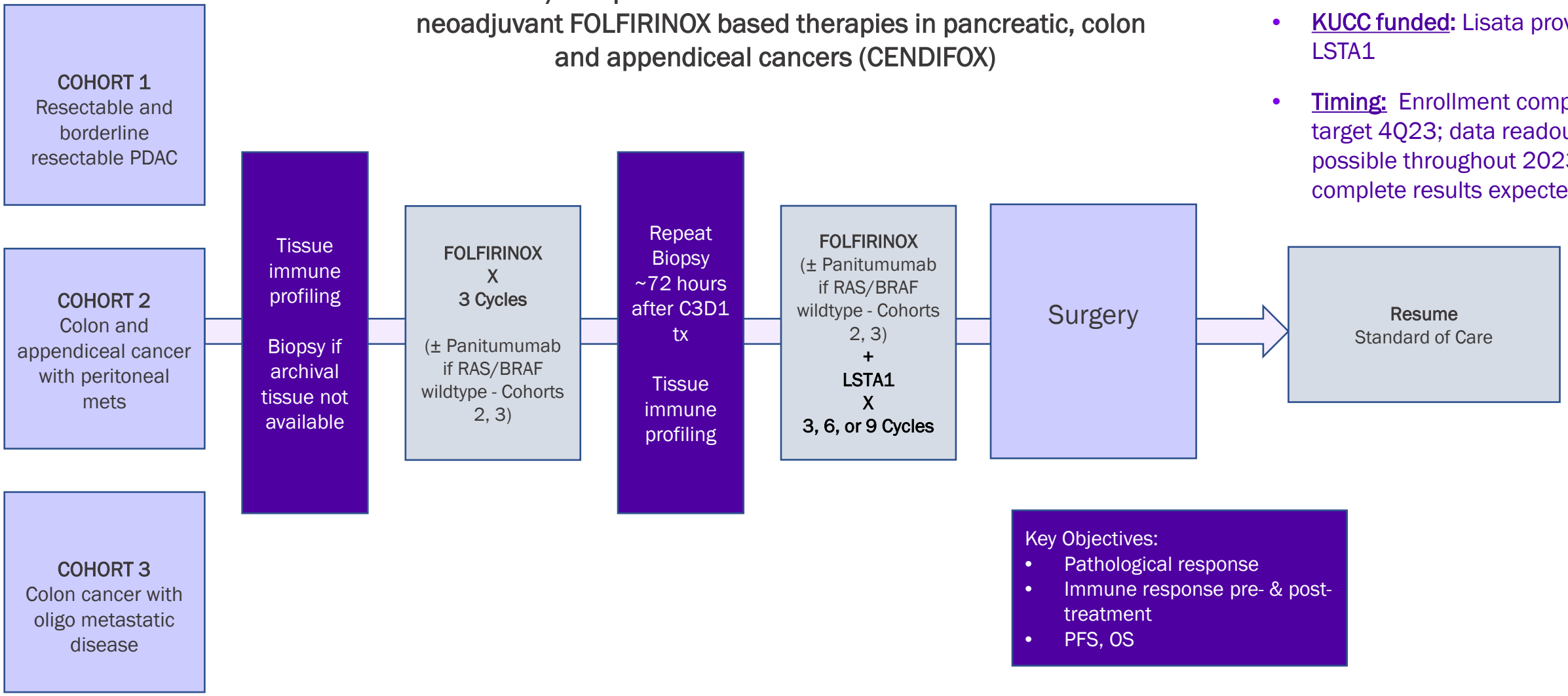
# CENDIFOX: Phase 1b/2a open-label trial in PDAC and other cancers

| | |
|---|---|
| **Sponsor/Partner** | ▪ University of Kansas Medical Center (Investigator initiated trial in U.S.)<br>▪ KUCC funded; Lisata provides LSTA1 |
| **Objective** | ▪ 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- & 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 LSTA1 ± panitumumab |
| **Study Size** | ▪ 50 subjects (20 PDAC, 15 colon and 15 appendiceal) |
| **Endpoints** | ▪ Primary: Drug Safety<br>▪ Secondary: Overall Survival, Disease-free Survival, Overall Response Rate, RO Resection Rate, Pathological Response Rate |
| **Timing** | ▪ Enrollment completion target 4Q23<br>▪ 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 LSTA1
- **Timing:** Enrollment completion target 4Q23; data readouts possible throughout 2023; complete results expected 2024

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




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

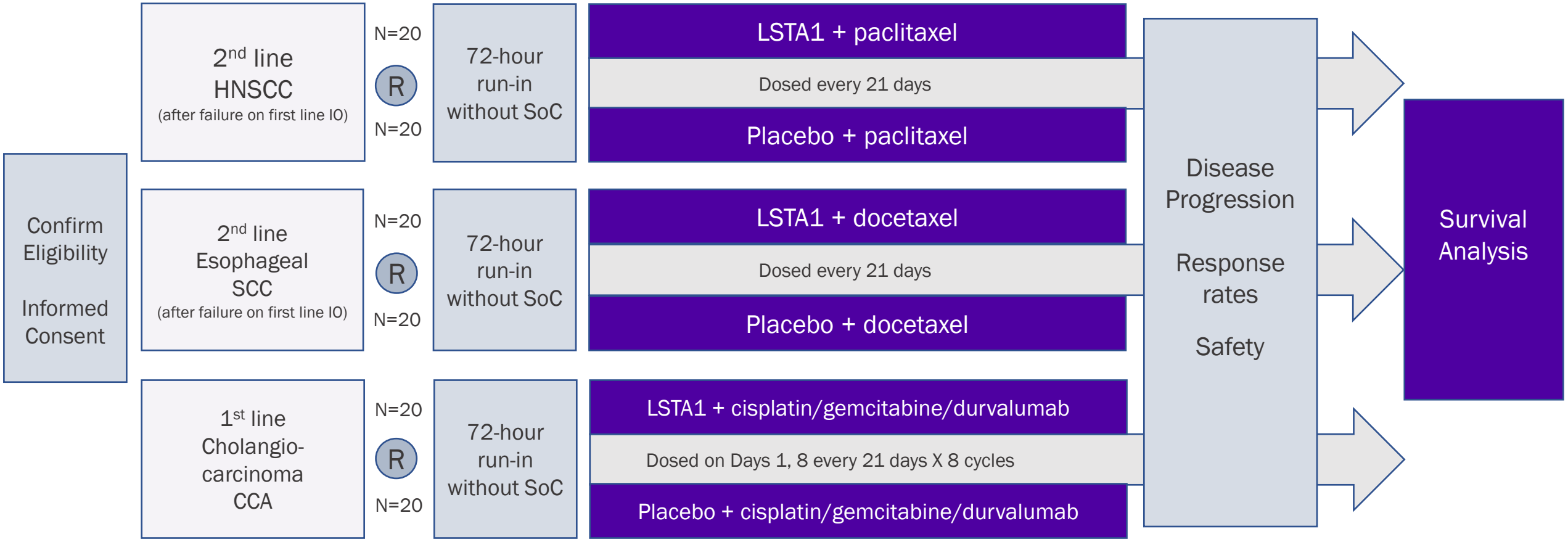
# BOLSTER: Phase 2 blinded, randomized PoC trial in various cancers

| | |
|---|---|
| **Sponsor/Partner** | ▪ Lisata (U.S.) |
| **Objective** | ▪ Evaluate the preliminary efficacy, safety and tolerability of LSTA1 in combination with standards of care in subjects with advanced solid tumors |
| **Design** | ▪ Phase 2 randomized, double-blind, placebo-controlled, proof-of-concept trial in 2nd line head and neck SCC, 2nd line esophageal SCC and 1st line cholangiocarcinoma testing corresponding SoC with LSTA1 or placebo |
| **Study Size** | ▪ 120 (40 per tumor type split 1:1 SoC + LSTA1 or SoC + placebo) |
| **Endpoints** | ▪ Primary: OS<br>▪ Secondary: Safety, ORR, PFS |
| **Objective** | ▪ Evaluate the preliminary efficacy, safety and tolerability of LSTA1 in combination with standards of care in subjects with advanced solid tumors |
| **Timing** | ▪ First patient in target 3Q23 |

# 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 advanced solid tumors**

- **Sponsor:** Lisata
- **Timing:** First patient in target 3Q23



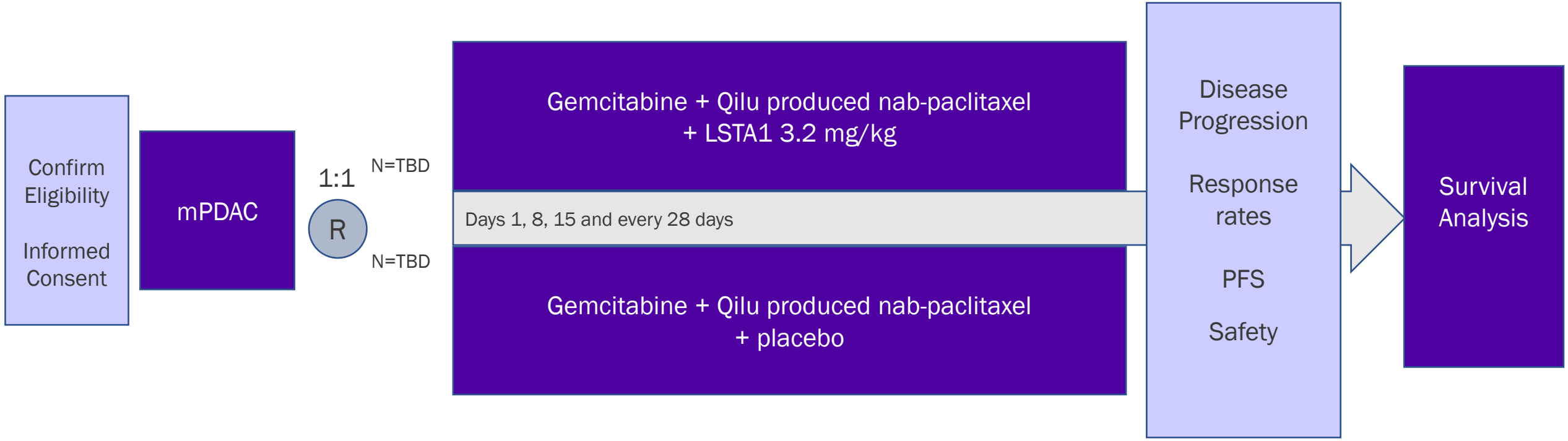
# Phase 2 blinded, placebo-controlled trial in mPDAC in China

| | |
|---|---|
| **Sponsor/Partner** | ▪ Qilu Pharmaceutical (funds all development in China) |
| **Objective** | ▪ Further evaluate safety and therapeutic efficacy of LSTA1 when added to SoC in Chinese patients with mPDAC |
| **Design** | ▪ Phase 2b, double-blind, placebo-controlled, randomized study evaluating LSTA1 + SoC (Qilu-produced nab-paclitaxel and gemcitabine) vs. placebo + SoC |
| **Study Size** | ▪ TBD |
| **Endpoints** | ▪ Objective response rate, progression free survival, overall survival<br>▪ Safety |
| **Timing** | ▪ Trial initiation target 1Q24 |

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

Phase 2b, double-blind, placebo-controlled, randomized, study evaluating LSTA1 when added to standard of care (nab-paclitaxel and gemcitabine) vs. standard of care alone and placebo in Chinese subjects with mPDAC

- **Sponsor/Partner:** Qilu Pharmaceutical (funds all development in China)
- **Timing:** Trial initiation target 4Q23



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

| | |
|---|---|
| **Sponsor/Partner** | ▪ WARPNINE, Inc. (registered charity in Australia) is funding trial<br>▪ 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<br>▪ Objective response rate, PFS, OS, duration of response, immune cell infiltration |
| **Timing** | ▪ Enrollment completion target 2Q24 |

# 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

- **Sponsor:** WARPNINE, Inc. - funding trial
- **Timing:** Enrollment completion target 2Q24

**Cohort 1**
Gemcitabine + nab-paclitaxel
N=5

**Cohort 2**
Gemcitabine + nab-paclitaxel + LSTA1
N=5

**Cohort 3**
Durvalumab + Gemcitabine + nab-paclitaxel + LSTA1
N=10-20

Biopsy
Screening

12 weeks

Primary Endpoint

Biopsy
Week 12

8 weeks tumor burden assessments until 24 months or recurrence

12 month
Follow-up

24 months
Follow-up completion

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

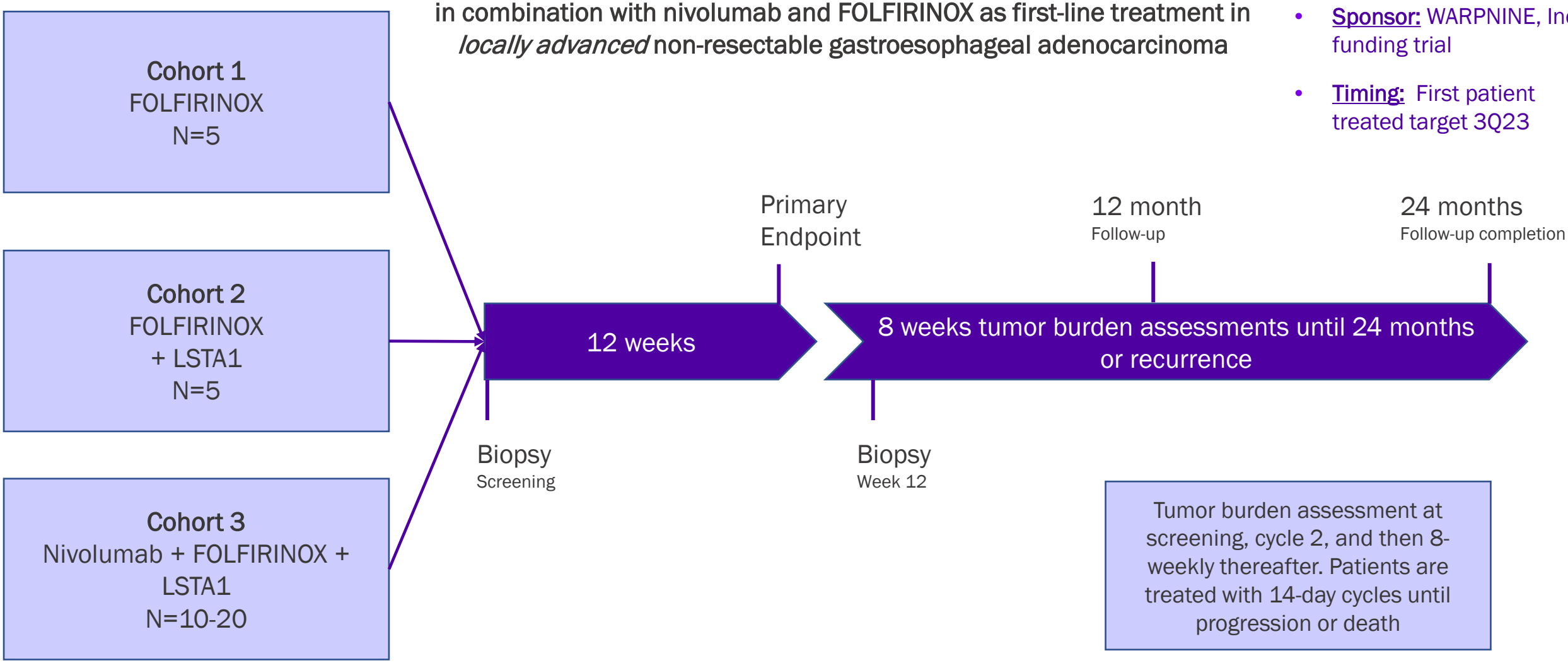
# iGoLSTA: Phase 1b/2a trial in locally advanced GEAC with chemo & IO

| | |
|---|---|
| **Sponsor/Partner** | ▪ WARPNINE, Inc. (registered charity in Australia) is funding trial<br>▪ Lisata providing study drug |
| **Objective** | ▪ Evaluate LSTA1 safety & therapeutic effect in combination with IO & Chemo in locally advanced non-resectable gastroesophogeal adenocarcinoma (GEAC); determine if inoperable tumors can become operable |
| **Design** | ▪ Phase 1b/2a proof-of-concept, safety and early efficacy study of LSTA1 in combination with nivolumab and FOLFIRINOX, as first-line treatment in *locally advanced* non-resectable gastroesophageal adenocarcinoma |
| **Study Size** | ▪ N=30 |
| **Endpoints** | ▪ Safety and tolerability; 28-day DLTs<br>▪ Objective response rate, PFS, OS, duration of response, immune cell infiltration |
| **Timing** | ▪ First patient treated target 3Q23 |

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

Phase 1b/2a proof-of-concept safety and early efficacy study of LSTA1 in combination with nivolumab and FOLFIRINOX as first-line treatment in *locally advanced* non-resectable gastroesophageal adenocarcinoma

- **Sponsor:** WARPNINE, Inc. funding trial
- **Timing:** First patient treated target 3Q23



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

| | |
|---|---|
| **Sponsor/Partner** | ▪ Tartu University Hospital (Investigator initiated trial in Estonia)<br>▪ Lisata providing study drug and funding trial |
| **Objective** | ▪ Evaluate safety, tolerability, and therapeutic effect of LSTA1 in combination with standard-of-care (temozolomide) in patients with previously untreated Glioblastoma Multiforme |
| **Design** | ▪ Phase 2a 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) |
| **Study Size** | ▪ N=30 |
| **Endpoints** | ▪ Safety, tolerability<br>▪ ORR, PFS, OS, disease control rate |
| **Timing** | ▪ First patient treated target 4Q23 |

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

Phase 2a 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:** First patient treated target 4Q23