



Targeted Therapy *Delivered* / 递送 靶向疗法

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公司报告 | 2023年6月15日

Nasdaq: LSTA

www.lisata.com



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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 the long-term success of Lisata’s recently completed merger (the “Merger”) with Cend Therapeutics, Inc. (“Cend”), including the ongoing integration of Cend’s operations; 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 impact of the ongoing COVID-19 pandemic on Lisata’s business, 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; unexpected costs, charges or expenses resulting from the Merger; potential adverse reactions or changes to business relationships resulting from the completion of the Merger; potential underperformance of Lisata’s business following the Merger as compared to management’s initial expectations; 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 March 30, 2023, 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.

A 3D molecular model of a protein complex, rendered in shades of blue and purple. The structure is highly detailed, showing various folds and interactions. The background is a dark blue gradient.

Company Overview

公司概述

**Nasdaq-listed clinical stage
therapeutics development
company with a novel solid
tumor targeting and penetration
technology to improve the
efficacy of anti-cancer drugs /**

一家在纳斯达克上市的临床阶段
治疗药物开发公司，拥有提高抗
癌药物疗效的新型实体肿瘤靶向
和穿透技术



Investment rationale – key company differentiation

投资理由 – 公司关键的差异点



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



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



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



\$61.1 million cash* - no debt; Development funded through critical milestones / \$6110万现金* - 无债务；有足够的开发资金完成关键里程碑

* As of 03/31/2023; includes investments / 截止2023年3月31日；包括投资

Experienced executive leadership team / 经验丰富的高管团队



David J. Mazzo, PhD / 博士
President and Chief Executive Officer
/ 总裁兼首席执行官



Kristen Buck, MD / 医学博士
EVP of R&D and Chief Medical Officer
/ 研发执行副总裁和首席医疗官



Gregory Berkin
VP of IT and Chief Informational Officer /
信息技术副总裁和首席信息官



Tarlq Imam
VP of BD & Operations and Corporate Counsel
/ 业务发展与运营副总裁和公司法律顾问



James Nisco
VP of Finance and Treasury /
财务副总裁



John Menditto
VP of IR and Corporate Communications /
投资者关系与企业公关副总裁

Please visit the management team page on the corporate website for more information: www.lisata.com/
请访问公司网站上的管理团队页面了解更多信息: www.lisata.com。

Lisata holds strong intellectual property portfolio for LSTA1

Lisata拥有LSTA1的强大知识产权组合

Patent extension opportunities could further prolong exclusivity / 专利延期机会可进一步延长独占期

2023 2024 2025 2026 2027 2028 2029 2030 2031 2032 2033 2034 2035 2036 2037 2038 2039 2040 2041

Orphan Drug Market Exclusivity / 孤儿药市场独占期

+ 3 yrs. in EU / 欧盟内三年

Composition of Matter / 物质的成分

Potential Patent Term Extension / 潜在的专利期延长

Composition of Matter / 物质的成分

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Composition of Matter / 物质的成分

Potential Patent Term Extension / 潜在的专利期延长

Method of Use / 使用方法

Method of Use / 使用方法

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 clusters of smaller, more complex structures are attached to the main surface, rendered in a vibrant purple color. The background is a dark, gradient blue. A white rectangular box is overlaid on the left side of the image, containing the title text.

Therapeutic Focus and Rationale / 疗法重点和原理

Improved cancer treatment is a vital global need

改善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 deaths¹ / 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

– *World Health Organization / 世界卫生组织*

¹ www.who.int/news-room/fact-sheets/detail/cancer

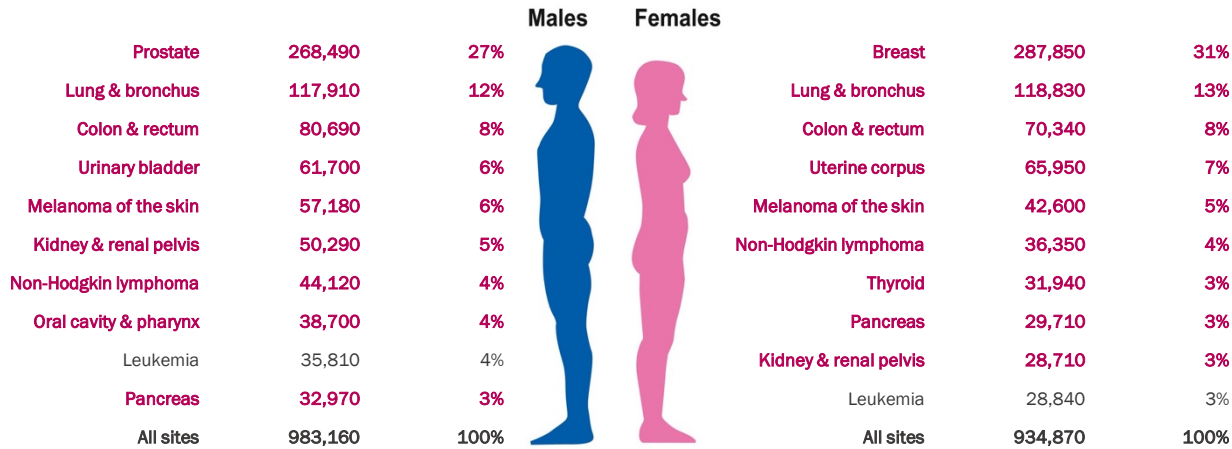
Solid tumor treatment is a large & growing market

实体瘤治疗是一个庞大且不断增长的市场

Estimated New Cancer Cases and Deaths in the United States, 2022¹ /

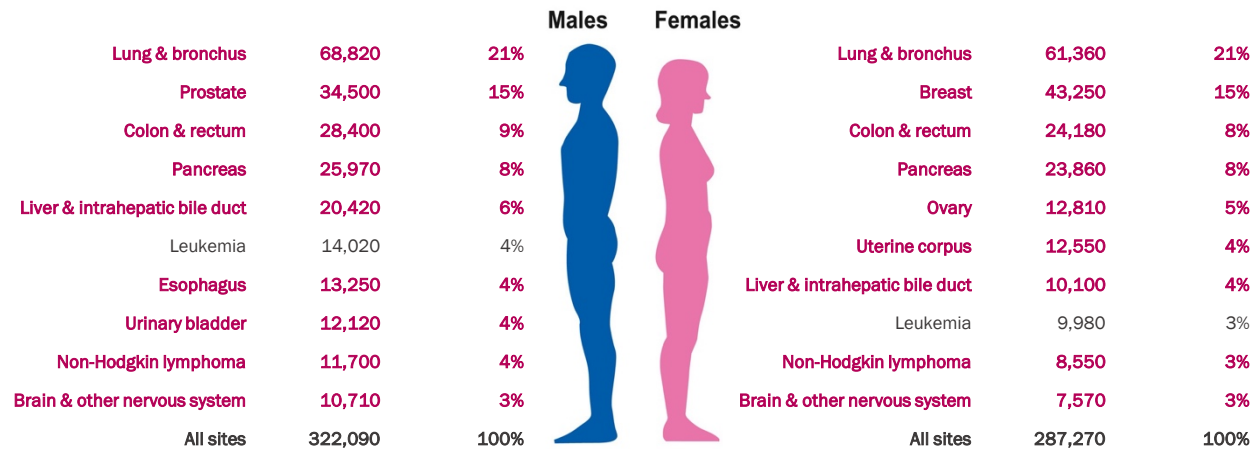
估计美国新的癌症病例和死亡人数，2022¹

Estimated New Cases



>1.9 million new cases of cancer will be diagnosed in 2022 / 2022年将诊断出超过190万的癌症新病例

Estimated Deaths



In the U.S. alone, solid tumors account for >90% of new cancer cases / 仅在美国，实体瘤就占了新癌症病例的90%以上。

¹ CA A Cancer J Clinicians, Volume: 72, Issue: 1, Pages: 7-33, First published: 12 January 2022, DOI: (10.3322/caac.21708)

- **Tumor targeting and intratumoral penetration are suboptimal / 肿瘤靶向性和瘤内穿透性都不太理想**
 - Tumor stroma acts as an effective barrier to anti-cancer agents / 肿瘤基质是抗癌药物的有效屏障
 - Tumor microenvironment 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
 - Continued or escalated dosing of non-targeted anti-cancer therapy can lead to intolerable off-target side effects / 非靶向抗癌治疗的持续或升级剂量可导致无法忍受的非靶向副作用

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

- Converts tumor stroma from ***barrier to conduit*** / 将肿瘤基质从**屏障转化为通道**
 - Combination possible with most anti-cancer drugs / 可与大多数抗癌药物联合使用
 - LSTA1 effectiveness agnostic to co-administered drug modality / LSTA1的有效性跟联合用药的药物模式无关
 - Mechanism effective with co-administered or tethered anti-cancer therapies / 联合用药或捆绑式的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 provides for prolonged compound exclusivity (NCE) / 捆绑用药提供了长期的化合物独占期
- Resistance combated by selective depletion of intratumoral immunosuppressive cells / 通过选择性地耗尽肿瘤内的免疫抑制细胞来对抗阻力

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 cancer, initially in combination with gemcitabine/nab-paclitaxel standard-of-care / 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 underway / 正在进行2b期研究

- Demonstrate LSTA1 effectiveness in combination with a variety of standard-of-care regimens (e.g., chemotherapy, immunotherapy, radiotherapy, 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、放疗等）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

A 3D molecular model of a protein complex, likely a viral capsid, rendered in shades of blue and purple. The structure is highly detailed, showing the intricate surface of the protein subunits. The background is a dark blue gradient.

Partnerships / 合作伙伴

Noteworthy existing relationships with the 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

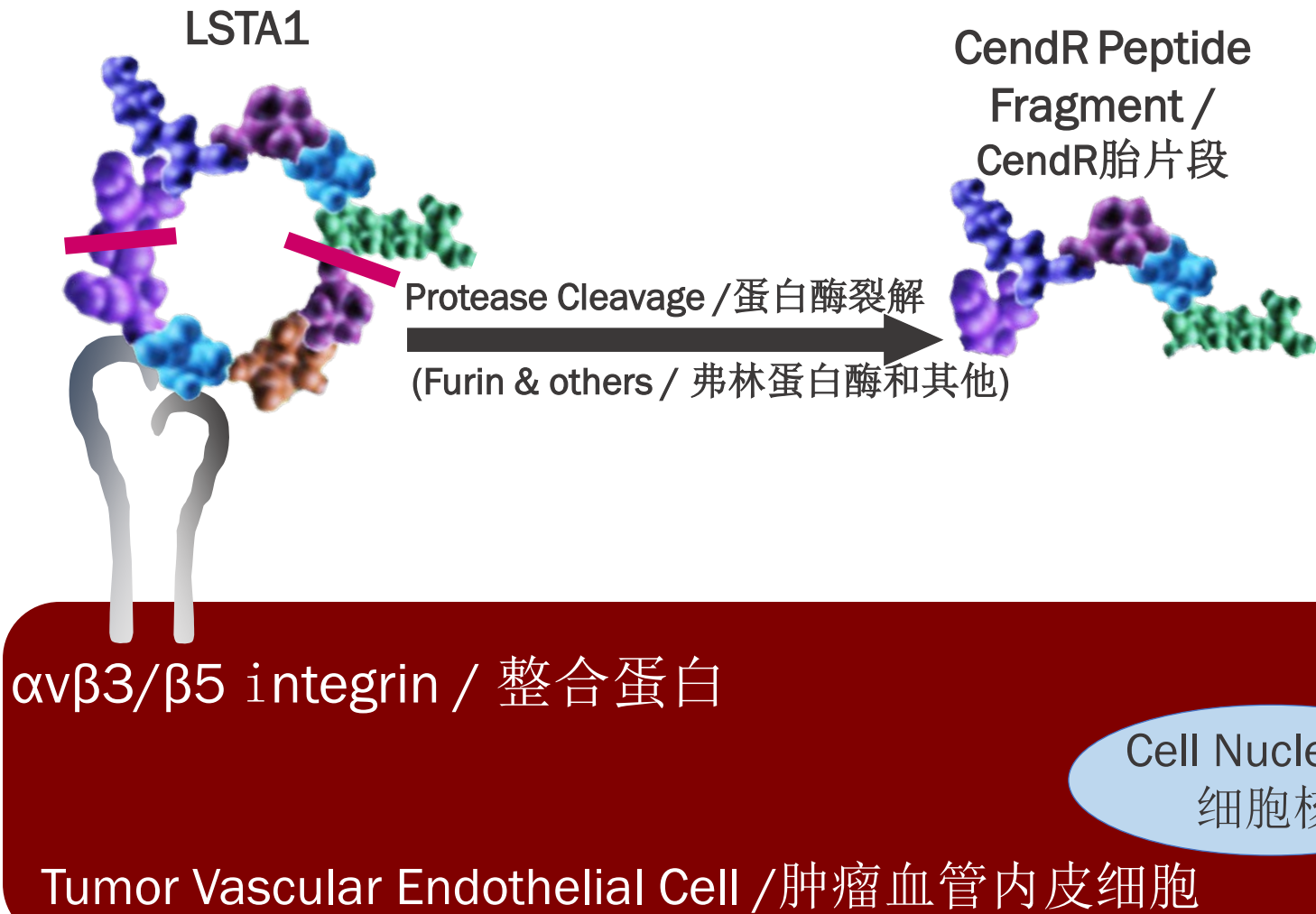
A 3D molecular model of the LSTA1 protein structure. The protein is shown in a light blue color, with a complex, multi-domain structure. Several smaller, purple-colored subunits are attached to the main structure, representing different domains or subunits of the protein. The background is a dark blue gradient.

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

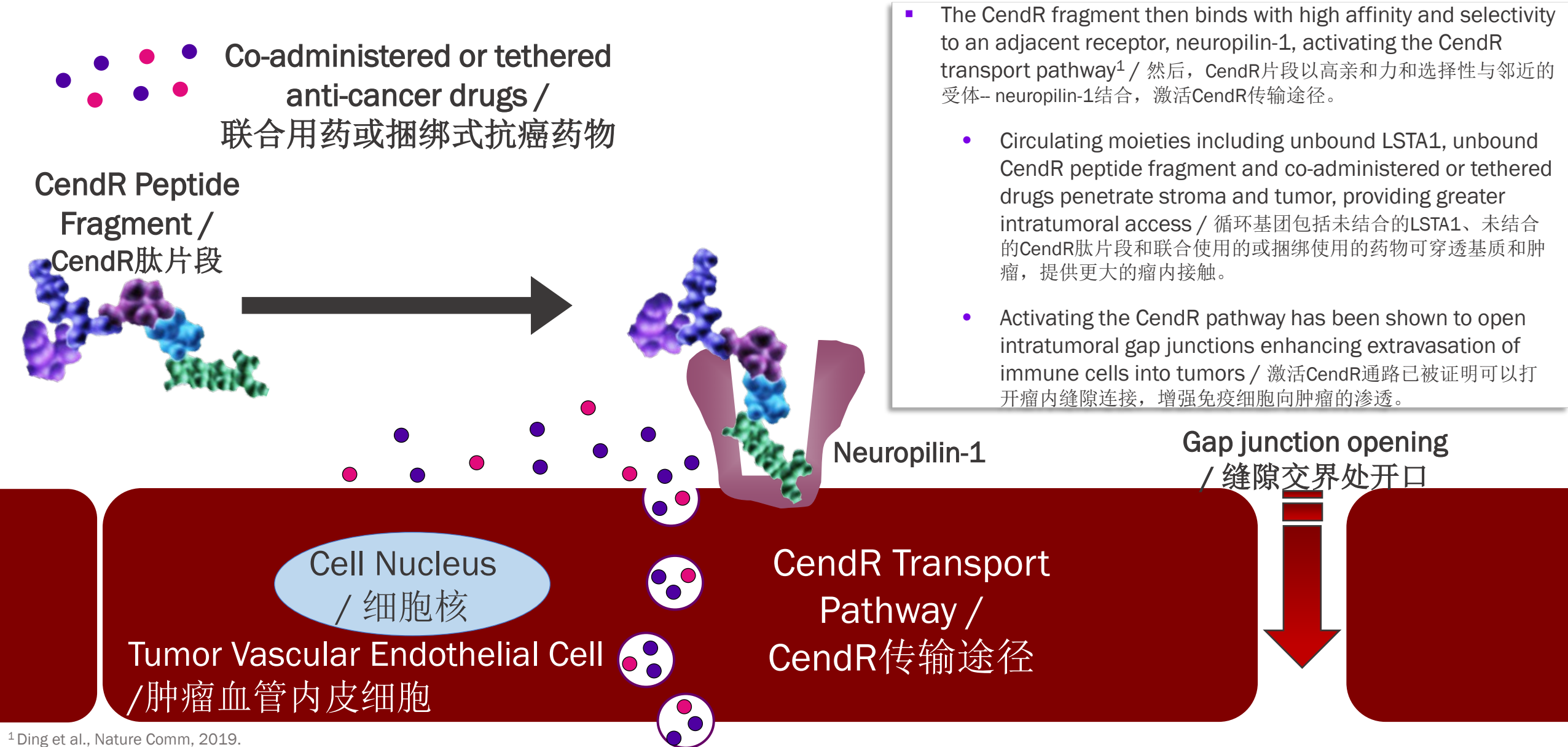
LSTA1的作用机制：步骤1和2，共3步



- LSTA1: 9 amino acid cyclic peptide; high binding specificity and affinity to α v β 3/ β 5 integrins that are upregulated on: /LSTA1: 9个氨基酸的环肽; 对 α v β 3/ β 5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 α v β 3/ β 5 integrins, LSTA1 is cleaved by proteases in the tumor microenvironment, releasing a C-end Rule (CendR) linear peptide fragment / 一旦与 α v β 3/ β 5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



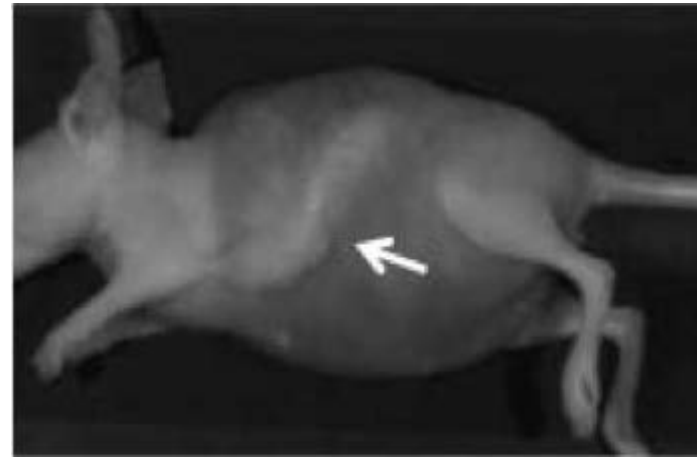
¹Ding et al., Nature Comm, 2019.

LSTA1 selectively and efficiently facilitates intratumoral penetration

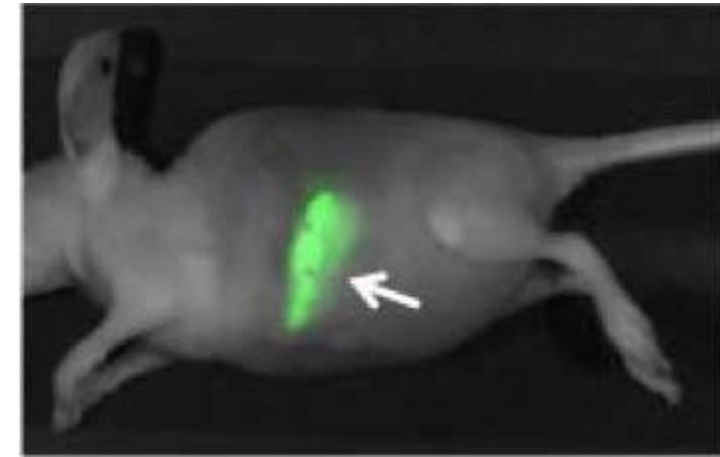
LSTA1选择性地、有效地促进瘤内渗透

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.

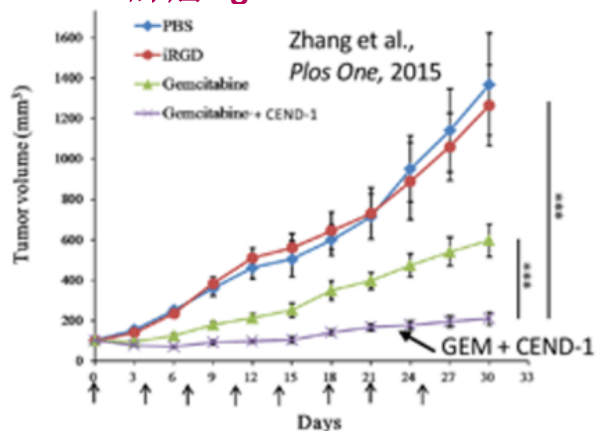
Large body of work shows consistent LSTA1 activity/broad applicability

大量的工作表明LSTA1具有一致的活性/广泛的适用性

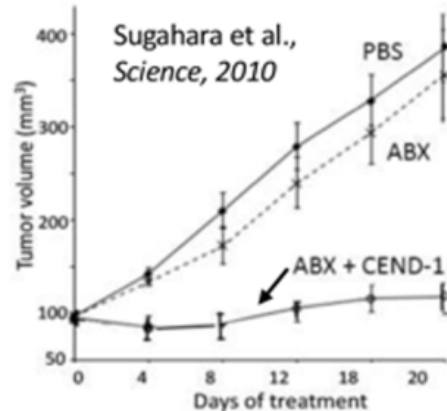
Sampling of >225 scientific publication showing LSTA1 augmentation effects /

抽样调查了>225份显示LSTA1增强效果的科学出版物

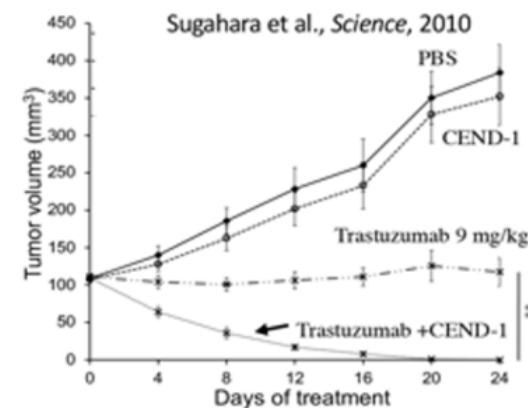
Lung cancer + gemcitabine + LSTA1
肺癌+ gemcitabine + LSTA1



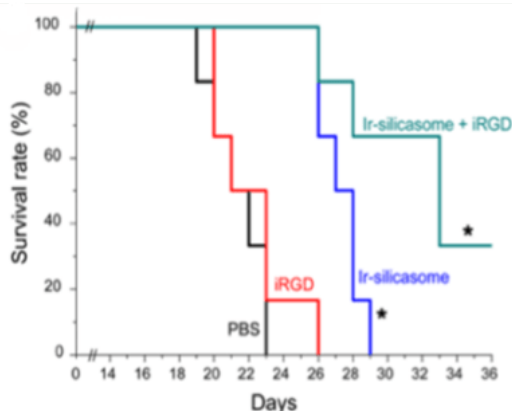
Breast cancer + nanoparticle Abraxane + LSTA1
乳腺癌+ nanoparticle Abraxane + LSTA1



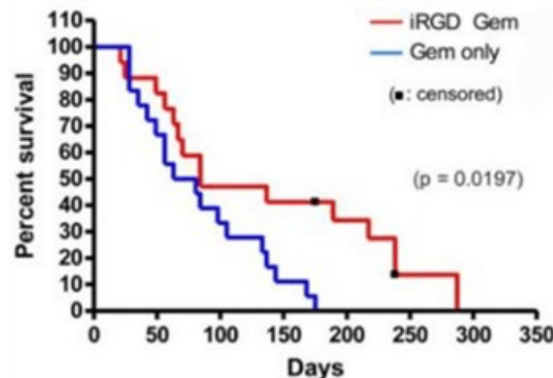
Breast cancer + Herceptin® + LSTA1
乳腺癌+ Herceptin® + LSTA1



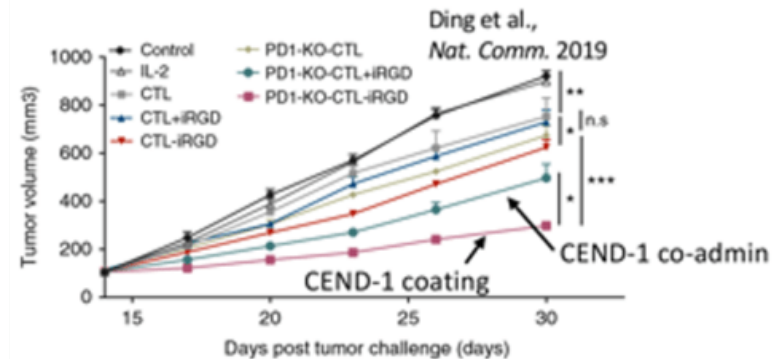
PDAC + irinotecan nanoparticles + LSTA1



PDAC + gemcitabine + LSTA1



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

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)


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

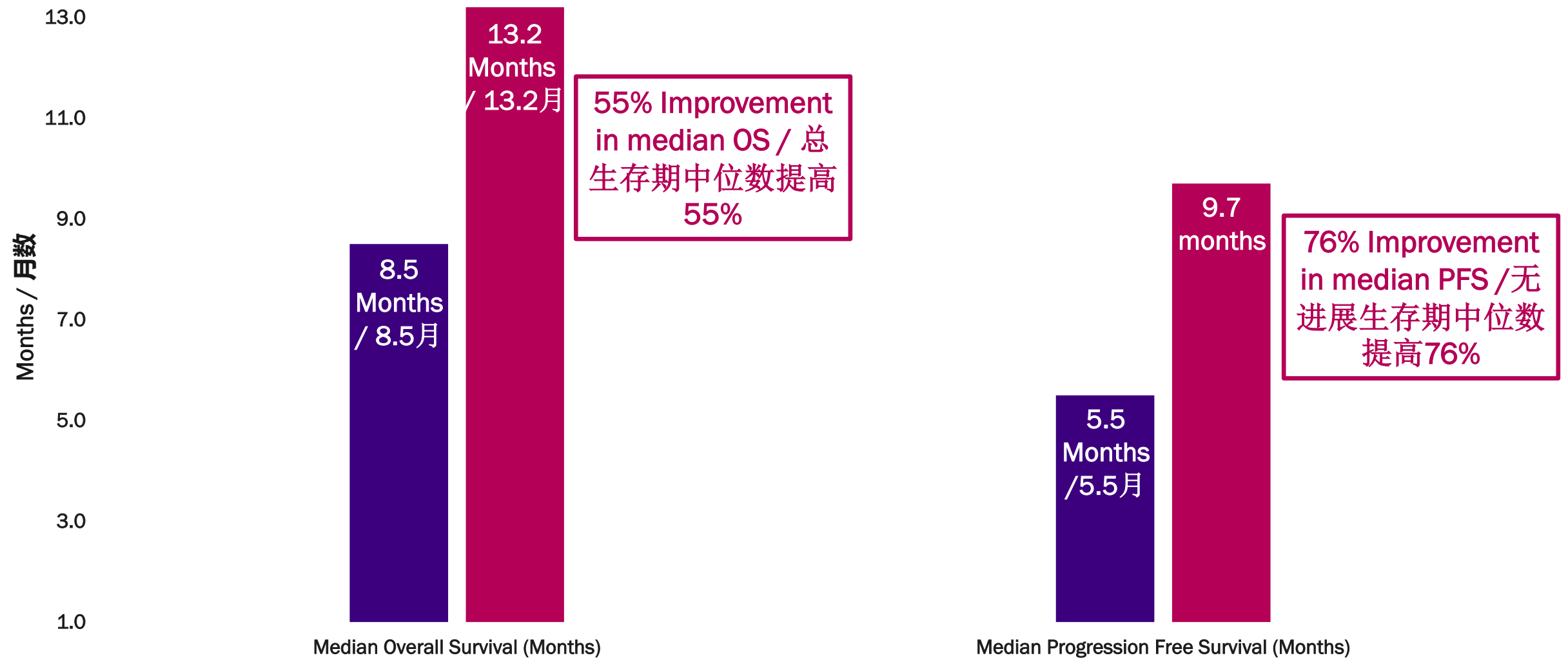
¹ Conroy T, et al., *New England Journal of Medicine*, 2011.

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



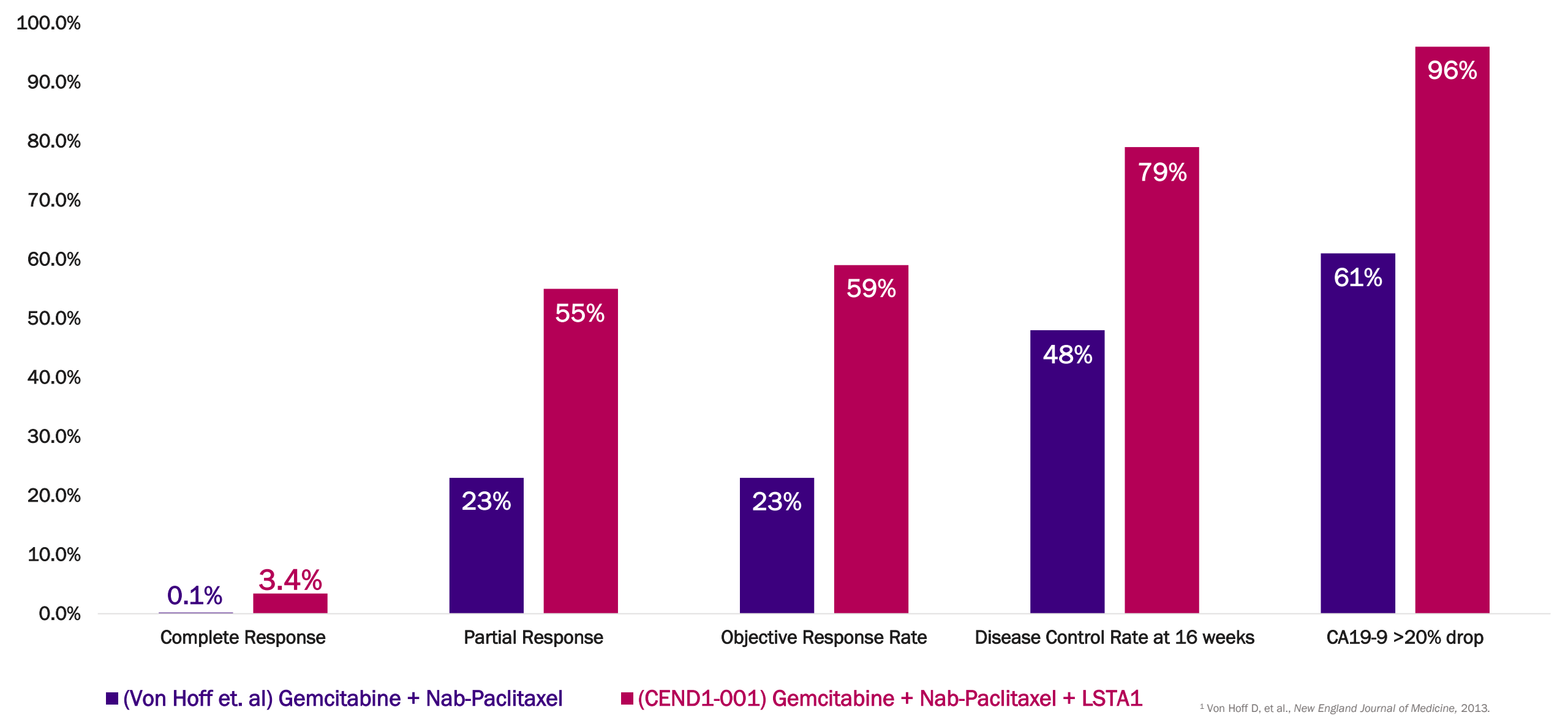
■ (Von Hoff et. al) Gemcitabine + Nab-Paclitaxel

■ (CEND1-001) Gemcitabine + Nab-Paclitaxel + LSTA1

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 and Orphan Drug designated (PDAC) - USA
快速通道和孤儿药资格(PDAC) - 美国

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

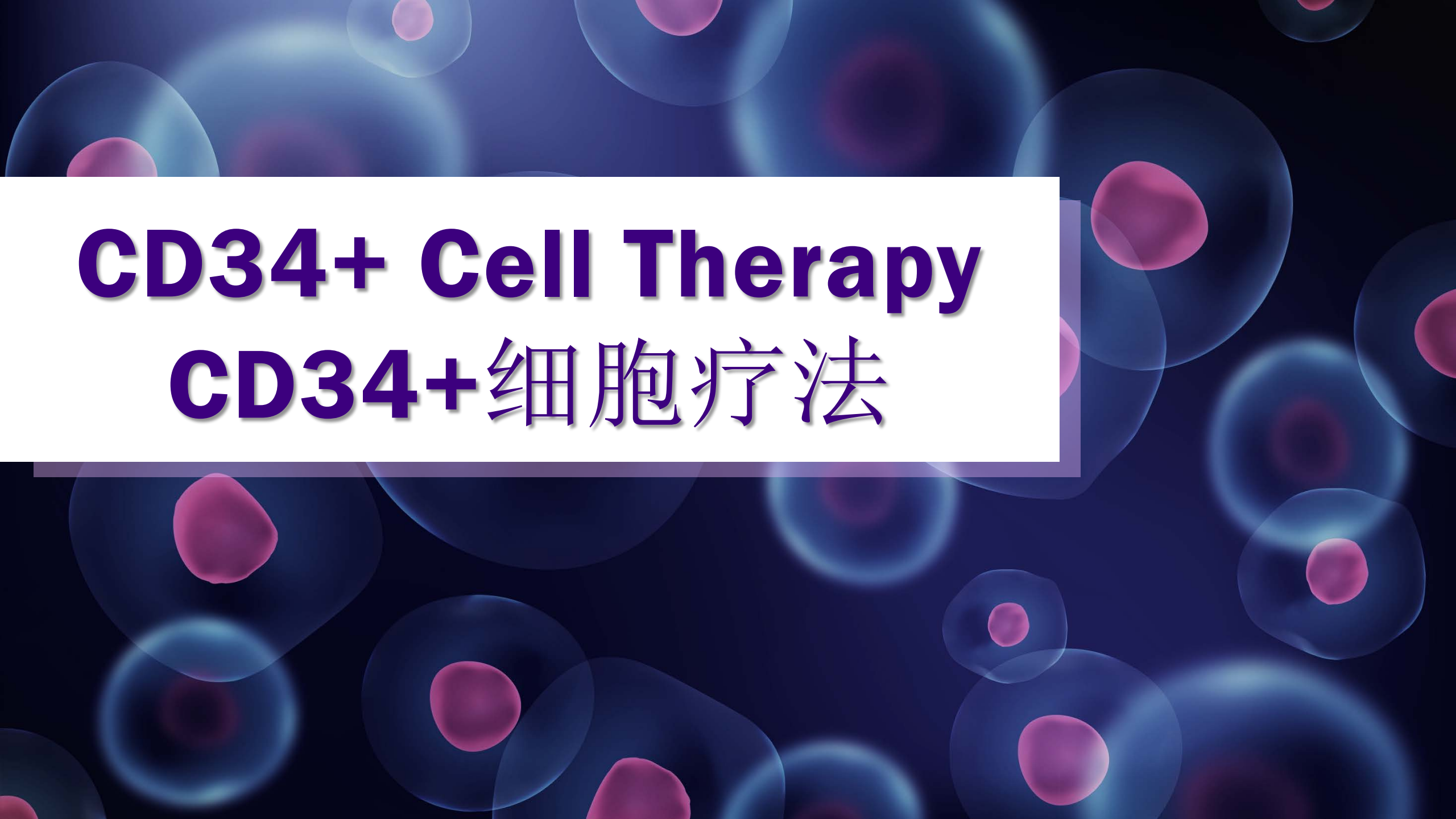
Partners / 合作伙伴	Region / 地区	Indication and Test Articles / 适应症和测试品	Status / 状态
AGITG/Lisata	Australia & New Zealand / 澳大利亚和新西兰	First-line mPDAC / 一线mPDAC Gemcitabine/nab-paclitaxel with LSTA1 or placebo / Gemcitabine/nab-paclitaxel与LSTA1或安慰剂	Phase 2b (ASCEND) / 2b期(ASCEND) Placebo-controlled / 安慰剂控制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

*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
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) Temozolomide +/- LSTA1	Phase 2a / 2a期 Placebo-controlled / 安慰剂控制 <i>Pending initiation / 即将启动</i>
UCSD/Columbia University/Lisata	USA / 美国	Peritoneal Carcinomatosis (Colon & Ovarian) / 腹膜癌 (结肠癌和卵巢癌) LSTA1 + HIPEC intraoperative intraperitoneal lavage / LSTA1+HIPEC术中腹腔灌洗术	Phase 1b/2a / 1b/2a期 Open-label / 开放标签 <i>Pending initiation / 即将启动</i>
QILU/Lisata	China / 中国	First-line mPDAC / 一线mPDAC Gemcitabine/Nab-paclitaxel + LSTA1	Phase 2 / 2期 Placebo-controlled / 安慰剂控制 <i>Pending initiation / 即将启动</i>
Roche/Lisata	Multi-national / 多国	First-line mPDAC / 一线mPDAC Gemcitabine/nab-paclitaxel/LSTA1 +/- atezolizumab	Phase 1b/2 (MORPHEUS) / 1b/2 (MORPHEUS) Active-controlled / 主动控制 <i>Pending initiation / 即将启动</i>



CD34+ Cell Therapy

CD34+细胞疗法

HONEDRA®

Critical Limb Ischemia / 严重肢体缺血
(Japan / 日本)

SAKIGAKE designated - Japan / SAKIGAKE 资格 - 日本

Orphan Drug designated (Buerger's disease) - USA / 孤儿药资格 (柏格氏症) - 美国

*Advanced Therapeutic Medicinal Product (ATMP) designated - EU / 先进的治疗药物
产品(ATMP) 资格 - 欧盟*

HONEDRA[®]: autologous CD34+ cell therapy / 自体的CD34 +细胞疗法

Arteriosclerosis Obliterans (ASO); Critical Limb Ischemia (CLI) / 动脉硬化闭塞症(ASO); 严重肢体缺血(CLI)

- CLI: arterial obstruction impeding blood flow in the lower extremities with severe rest pain and non-healing ulcers / CLI: 动脉阻塞阻碍了下肢的血流，并伴有严重的休息疼痛和不愈合的溃疡。
- Buerger's disease (BD) (a subset of ASO); is inflammation in small and medium arteries (orphan population) / 柏格氏症 (BD) (ASO的一个亚型); 是中小动脉的炎症 (孤儿症群体)。
- Current surgical intervention, angioplasty, stenting and pharmacotherapy) do not adequately treat CLI and BD / 目前的手术干预、血管成形术、支架和药物治疗) 并不能充分治疗CLI和BD
- Multi-million-dollar opportunity with an increasing prevalence of CLI in Japan / 随着日本CLI发病率的上升，出现了价值数百万美元的机会
- Positive previously published Phase 2 results in Japan^{1,2} / 以前在日本发表的2期结果是积极的^{1,2}

Development Status / 开发状态

- **Clinical trial completed / 完成的临床试验**
 - HONEDRA[®] was generally safe and well tolerated / HONEDRA[®]总体上是安全的，而且耐受性良好。
 - HONEDRA[®] group reached CLI-free status faster than SoC group (primary endpoint) / HONEDRA[®]组比SoC组更快达到无CLI状态 (主要端点)
- PMDA has offered guidance toward a confirmatory study to support a JNDA / PMDA已经为支持JNDA的确认性研究提供了指导。
- Advisory firm specializing in Japan partnerships engaged to assist out-licensing of product / 专门从事日本合作关系的咨询公司参与协助产品的对外授权

Provides potential value upside with no further capital outlay / 在没有进一步资本支出的情况下提供潜在的价值上升空间

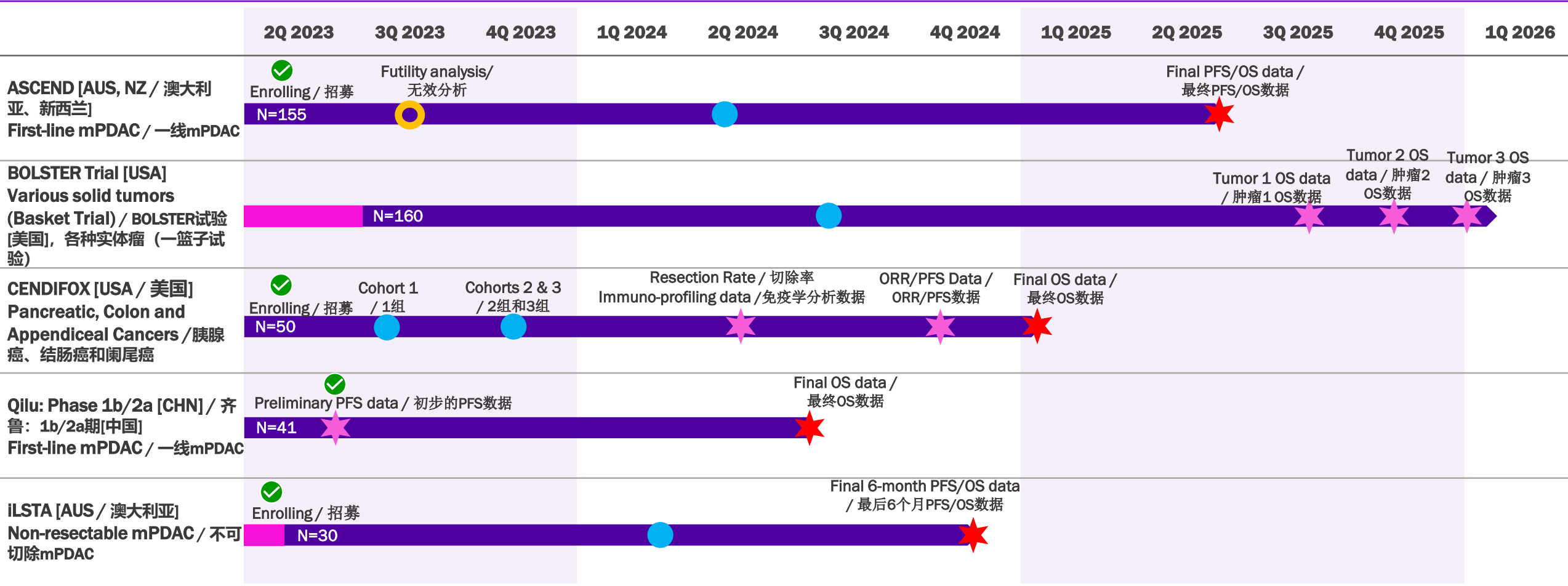
¹ Reinecke H., European Heart Journal, 2015 Apr 14;36(15):932-8.

² Kinoshita et al, Atherosclerosis 224 (2012) 440-445

A 3D molecular model of a protein complex, likely a virus capsid, rendered in light blue and purple. The structure is highly detailed, showing the intricate surface of the protein. The background is a dark blue gradient. The text is overlaid on a white rectangular box on the left side of the image.

Development Milestones / 开发里程碑

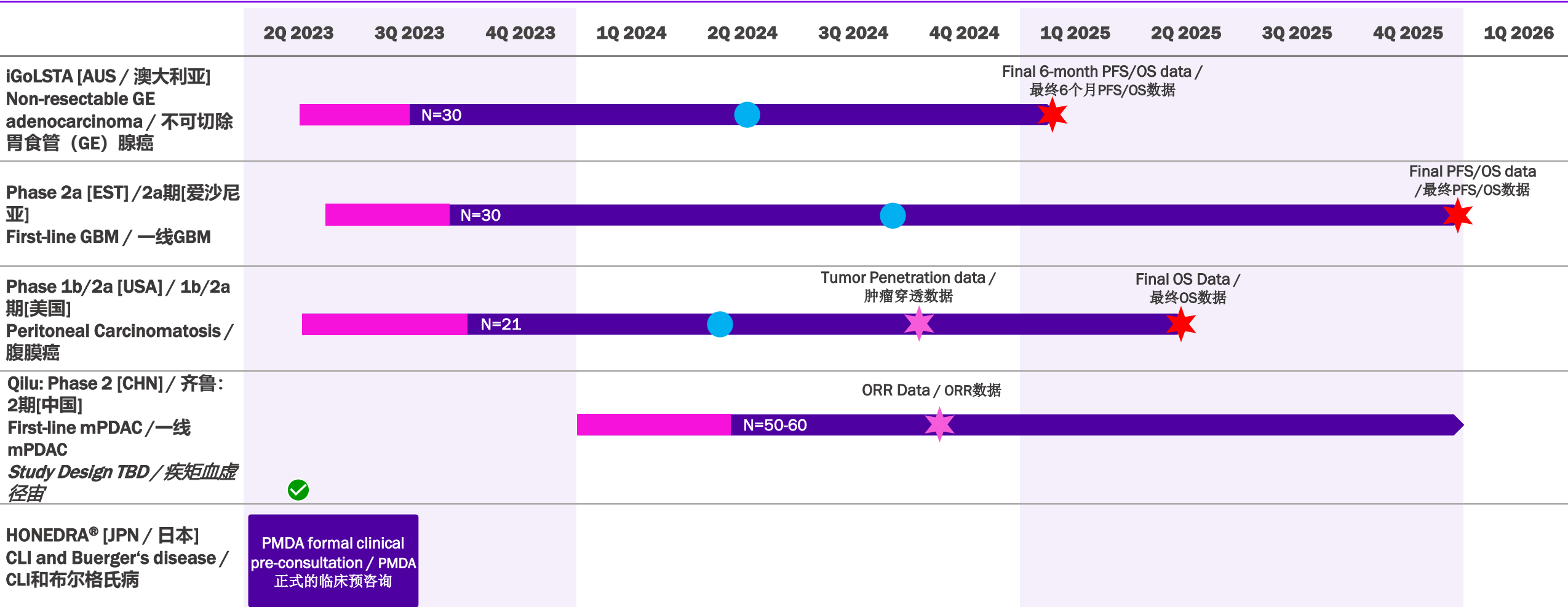
A wealth of anticipated key milestones / 多个预期的主要里程碑



- 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)



Final 6-month PFS/OS data /
最终6个月PFS/OS数据

Final PFS/OS data /
最终PFS/OS数据

Tumor Penetration data /
肿瘤穿透数据

Final OS Data /
最终OS数据

ORR Data / ORR数据

PMDA formal clinical
pre-consultation / PMDA
正式的临床预咨询

- 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 3D molecular model of a protein or enzyme, rendered in shades of blue and purple. The structure is highly detailed, showing various folds, loops, and clusters of atoms. The background is a dark blue gradient.

Financial Highlights

财务亮点

Lisata projects available capital to fund all clinical data milestones /

Lisata有足够的资金用于完成临床数据里程碑

Cash & Investments /

现金与投资

As of 3/31/2023 / 截止2023
年3月31日

\$61.1M /
6110万

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 (3/31/2023): / 发行在外普通股 (2023年3月31日)

8.0 million shares / 800万股

Options Outstanding (3/31/2023): / 发行在外期权 (2023年3月31日)

Exercise Price / 行权价: \$0.02 - \$4.22 = 1,231,000 shares / 123.1万股

Exercise Price: / 行权价 > \$4.22 = 262,000 shares / 26.2万股

1.5 million shares¹ / 150万股¹

Warrants Outstanding (3/31/2023): / 发行在外认股权证 (2023年3月31日)

Weighted Average Exercise Price: \$42.57 / 加权平均行权价: \$42.57

1.4 million shares / 140万股

¹Includes 1.2 million options assumed through the merger at a weighted average exercise price of \$3.77 / 包括通过合并承担的120万份期权, 加权平均行使价为\$3.77。

A 3D molecular model of a protein-ligand complex. The protein is shown as a large, light blue, textured surface with various indentations and protrusions. Several smaller, purple, textured clusters are bound to the protein's surface. The background is a dark blue gradient.

Strong Investment Rationale / 坚实的投资理由

Investment rationale – key company differentiation

投资理由 - 公司关键的差异点



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



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



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



\$61.1 million cash* - no debt; Development funded through critical milestones / \$6110万现金* - 无债务；有足够的开发资金完成关键里程碑

* As of 03/31/2023; includes investments / 截止2023年3月31日；包括投资



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

A 3D molecular model of a protein surface, rendered in light blue and purple. The surface is highly textured and irregular, with many protrusions and indentations. The background is a dark blue gradient. The text 'Appendix / 附录' is overlaid on a white rectangular background in the center-left.

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 (Basket Trial)	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)

CD34+ cell therapy current clinical trials

Legacy development programs provide potential value upside with no further capital outlay

Sponsor [Development Venue]	Indication and Trial Product/Comparator	Stage of Development	Strategic Rationale
Lisata [Japan]	Critical Limb Ischemia & Buerger's Disease; HONEDRA® (LSTA12)	Registration Eligible	Assess safety and efficacy of LSTA12 in a controlled trial vs. SoC alone in the context of qualifying for approval in Japan under the accelerated regulatory pathway applicable to regenerative medicines

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 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

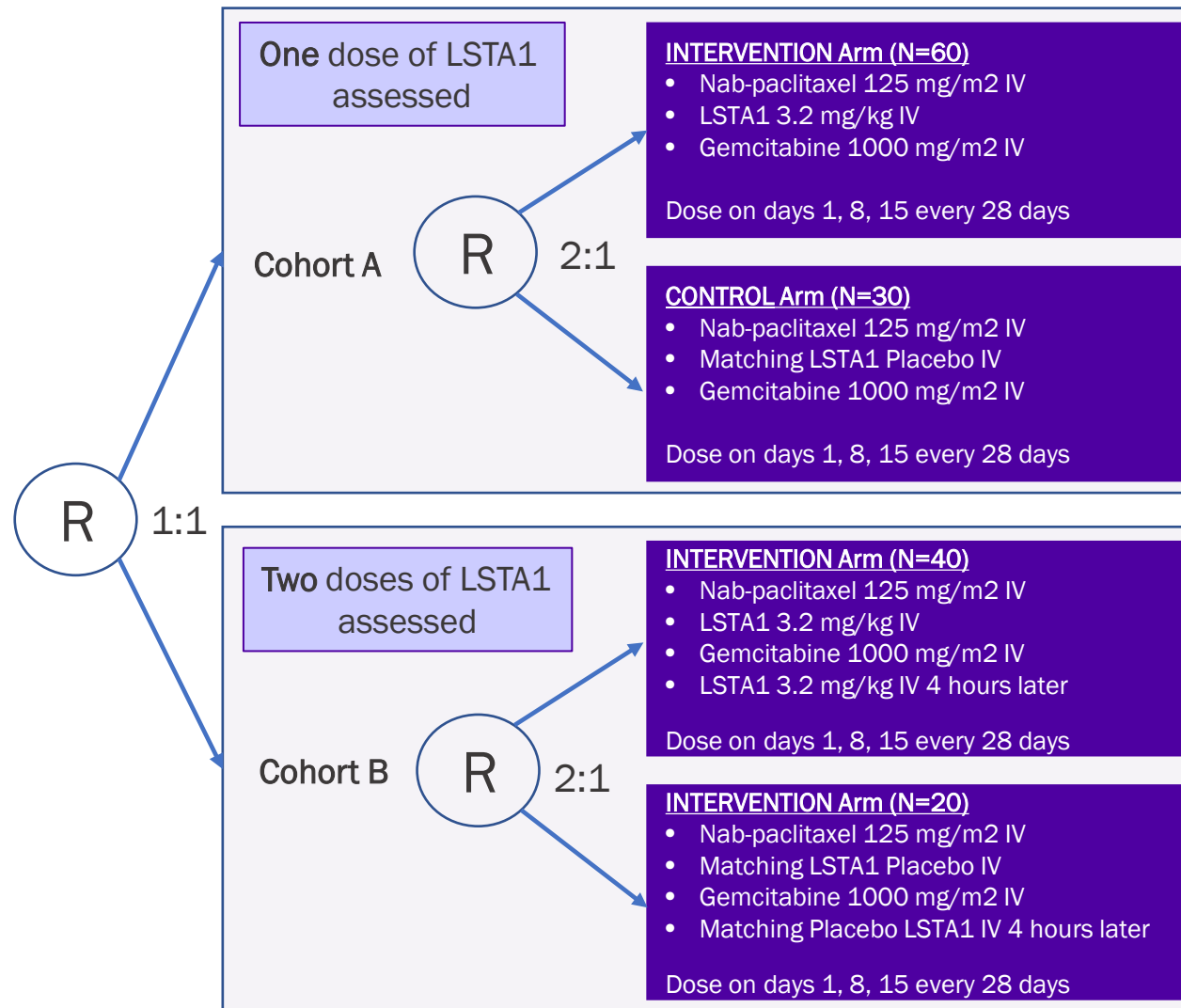
- Primary: Progression Free Survival
- Secondary: AEs, SAEs, Overall Survival, Objective Tumor Response Rate

Timing

- Enrollment completion target late 2Q24
- 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

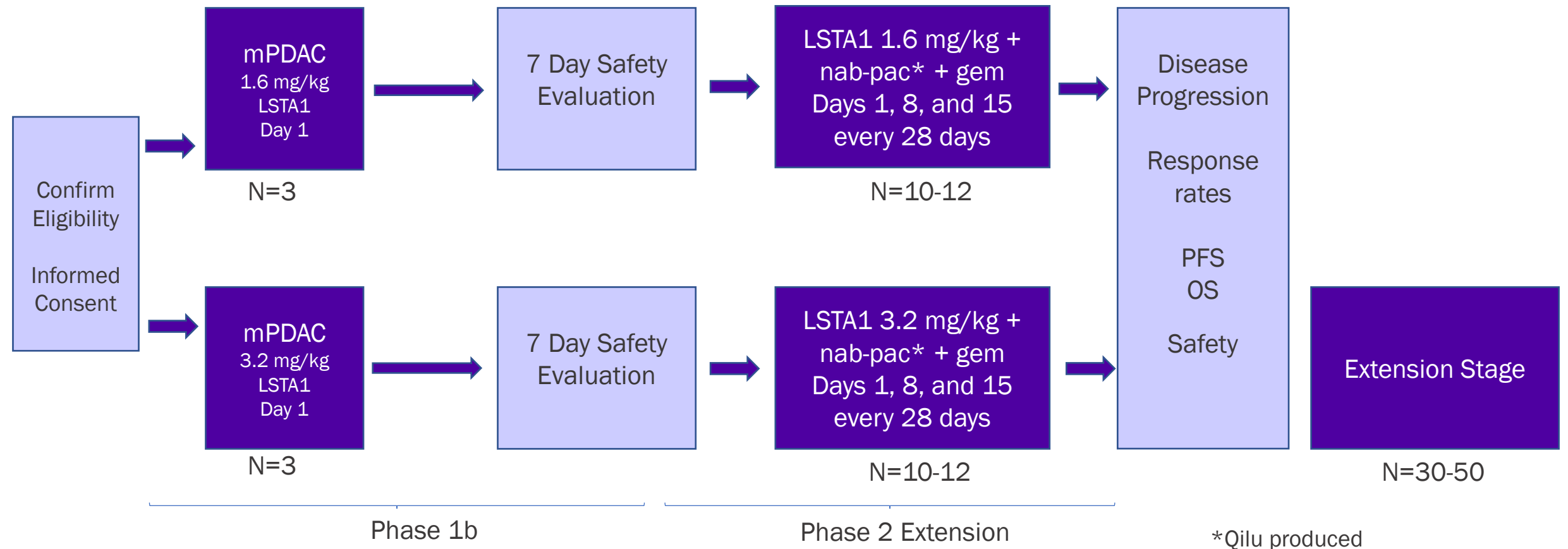
Phase 1b/2a open-label trial in mPDAC in China

Sponsor/Partner	<ul style="list-style-type: none">▪ Qilu Pharmaceutical (funds all development in China)
Objective	<ul style="list-style-type: none">▪ Evaluate safety, pharmacokinetics and preliminary efficacy of LSTA1 added to SoC in Chinese patients with mPDAC
Design	<ul style="list-style-type: none">▪ 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	<ul style="list-style-type: none">▪ 50 subjects (~15 sites)
Endpoints	<ul style="list-style-type: none">▪ Primary: AEs, SAEs, Objective Response Rate, Duration of Response, Disease Control Rate, Overall Survival, and Progression Free Survival▪ Secondary: Pharmacokinetic parameters
Timing	<ul style="list-style-type: none">▪ 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



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 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
- Secondary: Overall Survival, Disease-free Survival, Overall Response Rate, RO Resection Rate, Pathological Response Rate

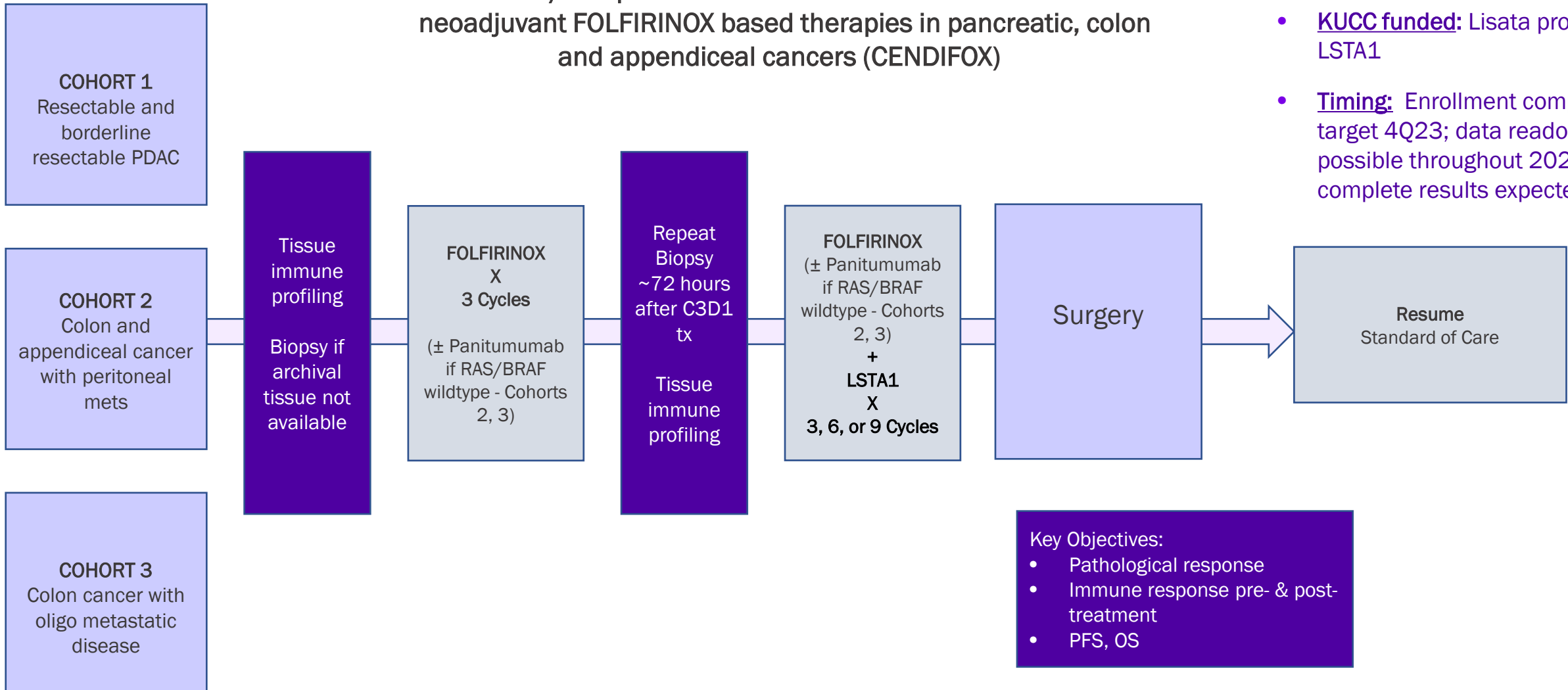
Timing

- 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

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 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
- 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

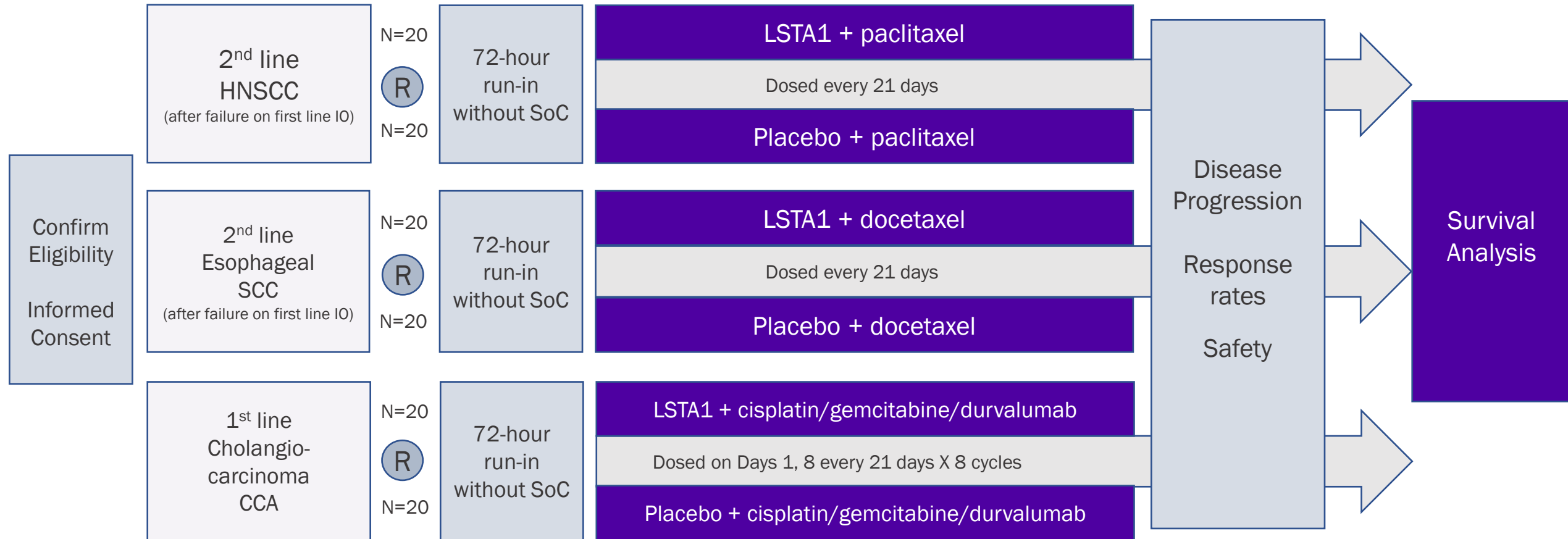
Timing

- Trial initiation target: 2Q23

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:** Trial initiation target 2Q23



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
- Safety

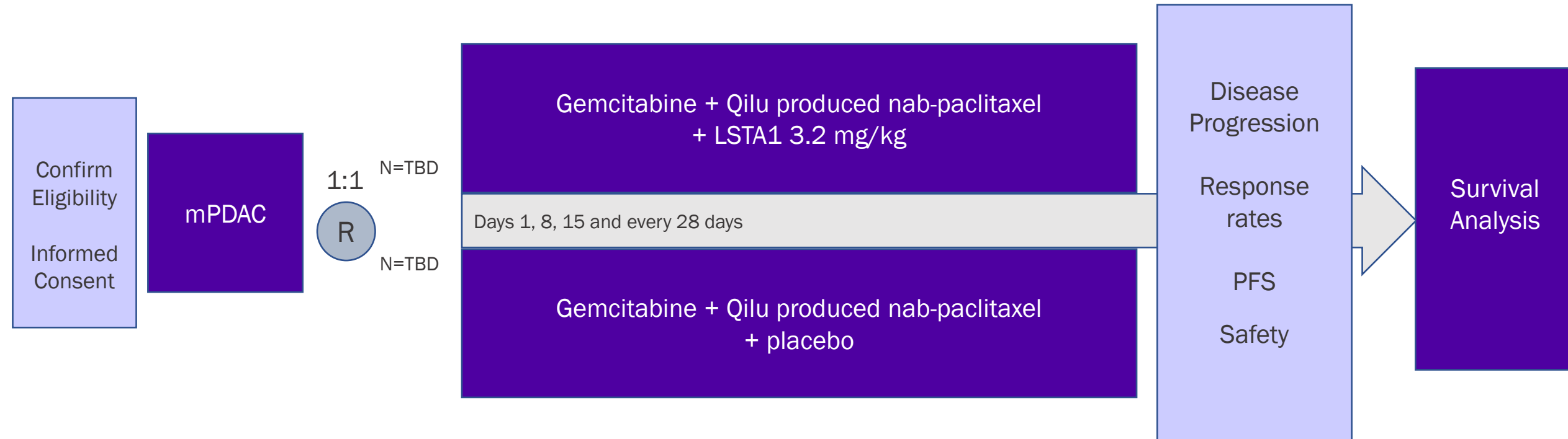
Timing

- 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
- Lisata providing study drug

Objective

- Evaluate safety and therapeutic effect of LSTA1 in combination with IO & Chemo in locally advanced non-resectable pancreatic ductal adenocarcinoma (PDAC); determine if inoperable tumors can become operable

Design

- Phase 1b/2a proof-of-concept safety and early efficacy study of LSTA1 in combination with durvalumab, gemcitabine and nab-paclitaxel, as first-line treatment in *locally advanced* non-resectable pancreatic adenocarcinoma

Study Size

- N=30

Endpoints

- Safety and tolerability; 28-day DLTs
- Objective response rate, PFS, OS, duration of response, immune cell infiltration

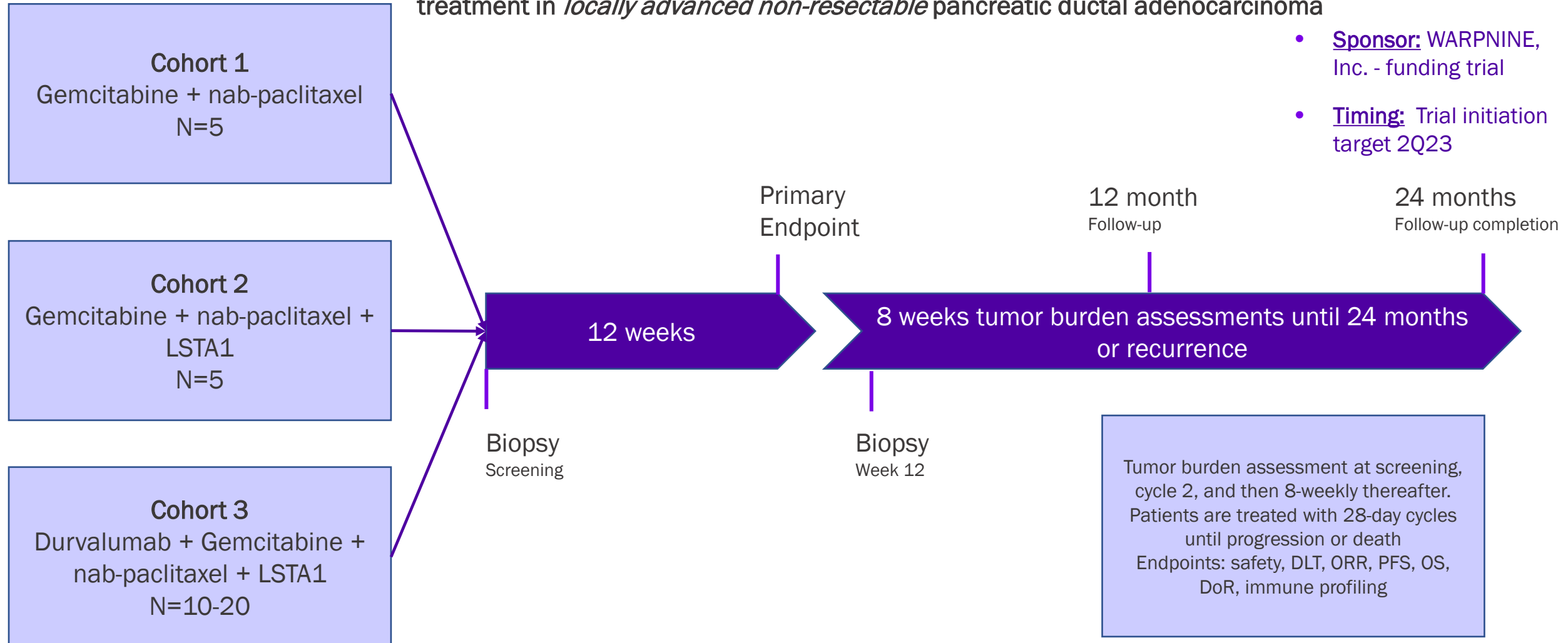
Timing

- Trial initiation target 2Q23

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:** WARPINE, Inc. - funding trial
- **Timing:** Trial initiation target 2023



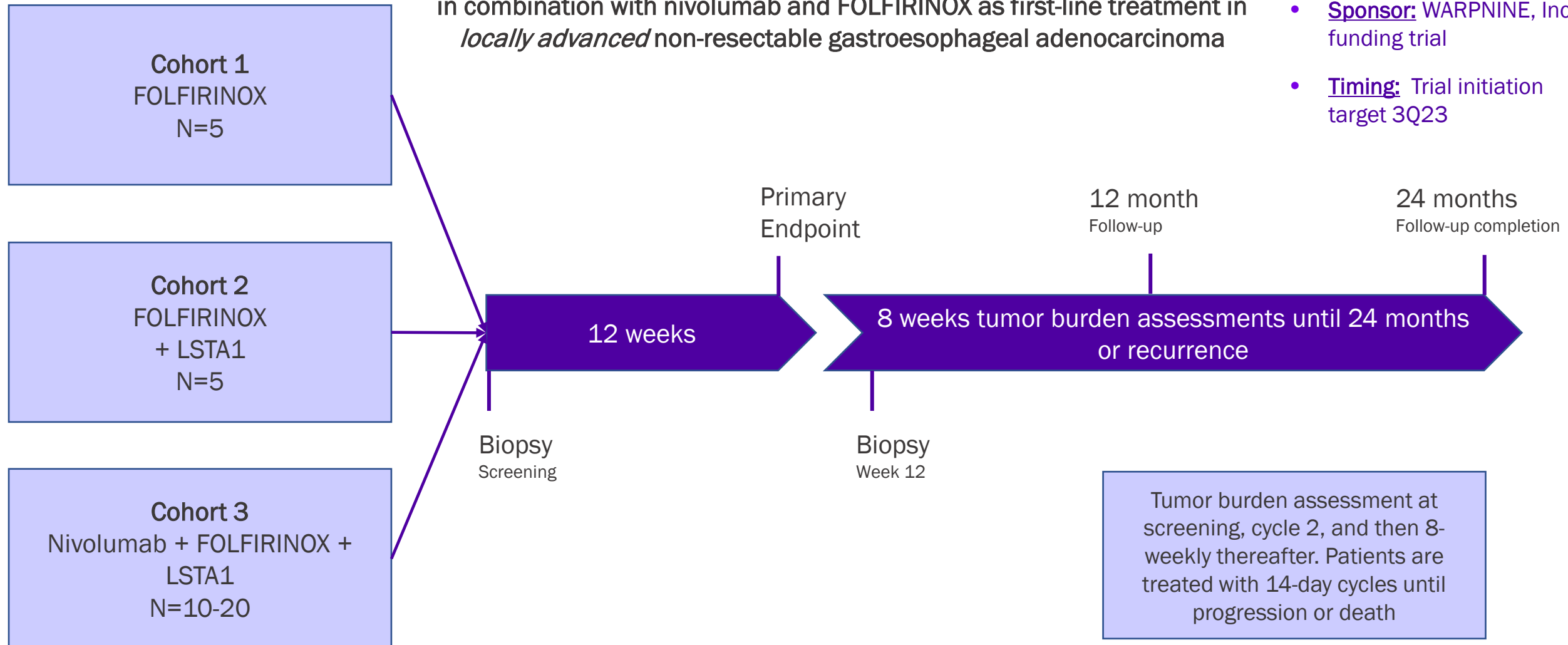
iGoLSTA: Phase 1b/2a trial in locally advanced GEAC with chemo & IO

Sponsor/Partner	<ul style="list-style-type: none">■ WARPNINE, Inc. (registered charity in Australia) is funding trial■ Lisata providing study drug
Objective	<ul style="list-style-type: none">■ Evaluate LSTA1 safety & therapeutic effect in combination with IO & Chemo in locally advanced non-resectable gastroesophageal adenocarcinoma (GEAC); determine if inoperable tumors can become operable
Design	<ul style="list-style-type: none">■ Phase 1b/2a proof-of-concept, safety and early efficacy study of LSTA1 in combination with nivolumab and FOLFIRINOX, as first-line treatment in <i>locally advanced</i> non-resectable gastroesophageal adenocarcinoma
Study Size	<ul style="list-style-type: none">■ N=30
Endpoints	<ul style="list-style-type: none">■ Safety and tolerability; 28-day DLTs■ Objective response rate, PFS, OS, duration of response, immune cell infiltration
Timing	<ul style="list-style-type: none">■ Trial initiation 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:** Trial initiation target 3Q23



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

Sponsor/Partner	<ul style="list-style-type: none">■ Tartu University Hospital (Investigator initiated trial in Estonia)■ Lisata providing study drug and funding trial
Objective	<ul style="list-style-type: none">■ Evaluate safety, tolerability, and therapeutic effect of LSTA1 in combination with standard-of-care (temozolomide) in patients with previously untreated Glioblastoma Multiforme
Design	<ul style="list-style-type: none">■ 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)
Study Size	<ul style="list-style-type: none">■ N=40
Endpoints	<ul style="list-style-type: none">■ Safety, tolerability■ ORR, PFS, OS, disease control rate
Timing	<ul style="list-style-type: none">■ Trial initiation target 3Q23

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

