LISATA THERAPEUTICS

# Targeted Therapy *Delivered*

# *递送靶向疗法*

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

Corporate Presentation / 公司介绍 | GCFF Bio Investing Conference / GCFF生物科技投资会议

Nasdaq: LSTA

www.lisata.com

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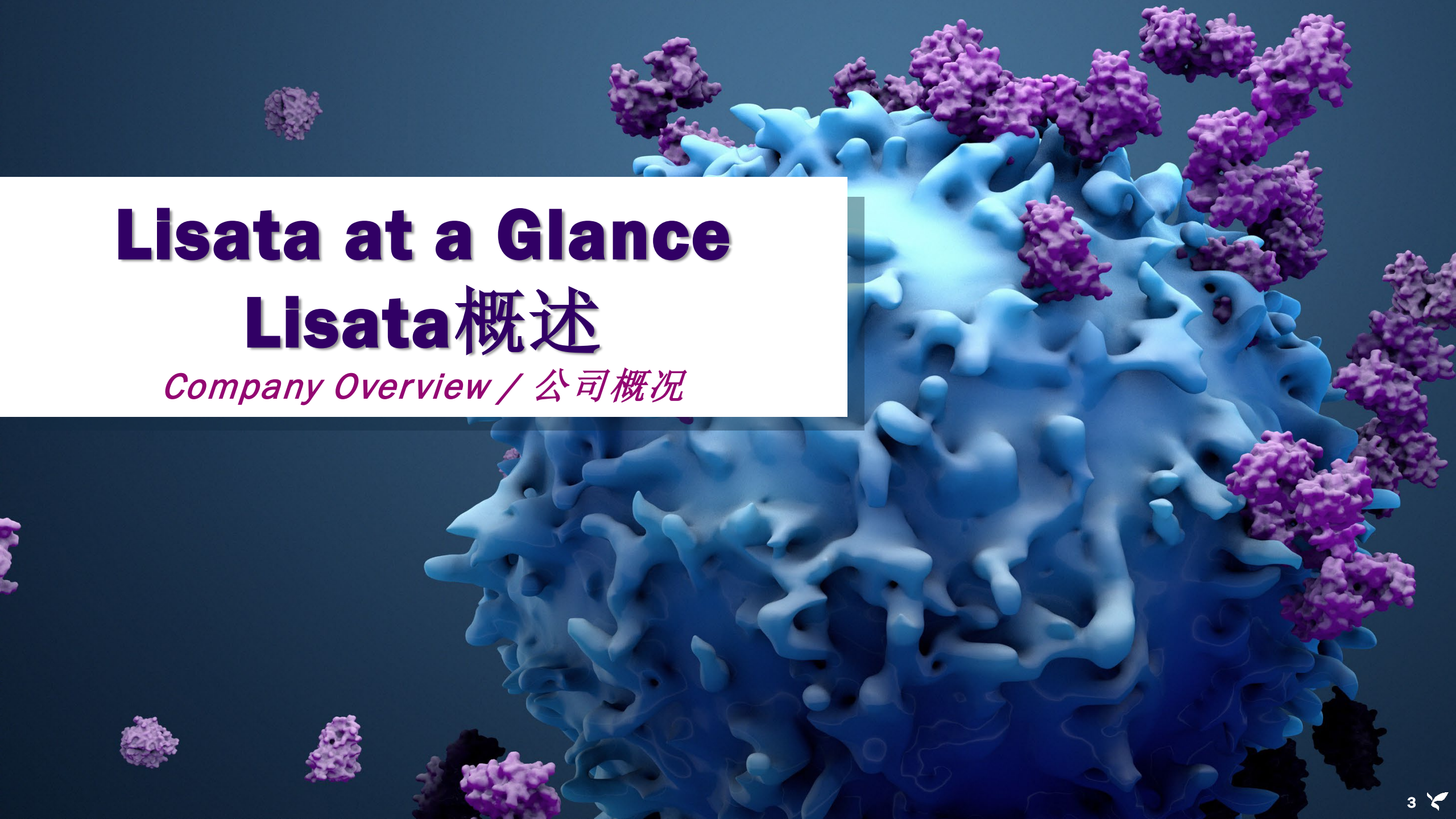


# Lisata at a Glance
# Lisata概述

*Company Overview / 公司概况*

# 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*

*一家处于临床阶段的治疗药物开发公司，正在快速推进一种新型实体瘤靶向和渗透技术，以提高抗癌药物的疗效*

**Seasoned management with successful international drug development experience and expertise** / 经验丰富的管理团队，拥有成功的国际药物开发经验和专业知识

**Proprietary field-leading technology in underserved global indications** / 在服务不足的全球适应症领域拥有专有的领先技术

**Multiple product and business milestones projected over the next 24 months** / 在未来 24 个月内预计将实现多个产品和业务里程碑

**Platform technology "validated" by existing partnerships with potential for many others** / 现有合作关系"验证"了平台技术，并有可能建立许多其他合作关系

***Projected cash runway into 2026, funding all development programs through to data*** / *预计现金资金可以支持到2026年，能够为所有开发计划提供支持，直至数据收集完毕*

# Seasoned leadership with proven track record in drug approvals worldwide
# 经验丰富的领导团队，在全球药品审批方面成绩斐然

## David J. Mazzo, PhD / David J. Mazzo 博士

*President and Chief Executive Officer, Member of the Board of Directors*
*总裁兼首席执行官、董事会成员*

- With >40 years of experience, Dr. Mazzo is a global pharmaceutical executive noted for his strategic prowess and his vast experience developing and launching new products in all therapeutical areas./ Mazzo博士拥有超过40年的经验，是一位全球制药行业高管，以其卓越的战略能力以及在所有治疗领域开发和推出新产品的丰富经验而著称。

RegadoBiosciences, Schering-Plough, Æterna Zentaris, Hoechst Marion Roussel, Chugai, Roche Group, Rhône-Poulenc Rorer

## Kristen K. Buck, MD / 医学博士

*Executive Vice President of R&D and Chief Medical Officer*
*研发执行副总裁兼首席医疗官*

- Dr. Buck is a board certified and licensed physician with >20 years of strategic global drug development, drug/device safety/epidemiology, FDA, and clinical practice experience. / Buck博士是一名经过董事会认证的拥有执照的执业医师，拥有20多年全球战略药物开发、药物/器械安全/流行病学、FDA和临床实践经验。

ICON, IQVIA, FDA, OPTUMInsight, AstraZeneca, B|BRAUN

### Gregory Berkin
*Chief Information Officer and Data Protection Officer*
*首席信息官兼数据保护官*

### James Nisco
*SVP of Finance and Treasury and Chief Accounting Officer*
*财务与资金业务高级副总裁兼首席会计官*

### Tariq Imam
*VP of BD and Operations and Corporate Counsel*
*业务发展和运营副总裁兼公司法律顾问*

### John Menditto
*VP of Investor Relations and Corporate Communications*
*投资者关系与企业传播副总裁*

### Bill Sietsema, PhD
*VP of Global Regulatory Affairs*
*全球监管事务副总裁*

### Ryan Quick
*VP of Chemistry, Manufacturing and Controls*
*化学、制造和控制副总裁*

*Detailed bios can be found at www.lisata.com / 详细履历见www.lisata.com*

# Accomplished, industry veteran, independent board directors
# 富有成就的行业资深独立董事

**Gregory B. Brown, MD**
**医学博士**
*Chairman / 董事会主席*

Biopharma executive with expertise in evaluating scientific, technical, clinical, and medical products as well as in healthcare systems and payor/reimbursement dynamics./ 生物制药高管，擅长评估科学、技术、临床和医疗产品，以及医保系统和付款人/报销动态。

**Steven M. Klosk**
*Director / 董事*

Pharma executive with 25+ years of experience in the pharmaceutical CDMO industry and proven leadership across all stages of product development./ 医药行业高管，在医药CDMO行业拥有25年以上的工作经验，在产品开发的各个阶段拥有出色的领导能力。

**Cynthia L. Flowers**
*Director / 董事*

Biopharma executive with extensive experience in leading and managing companies during transformative years of growth, particularly when it comes to commercialization of products in many therapeutic areas including oncology. / 生物制药领域的高管，在领导和管理公司实现转型增长方面拥有丰富经验，尤其是在包括肿瘤在内的多个治疗领域的产品商业化方面。

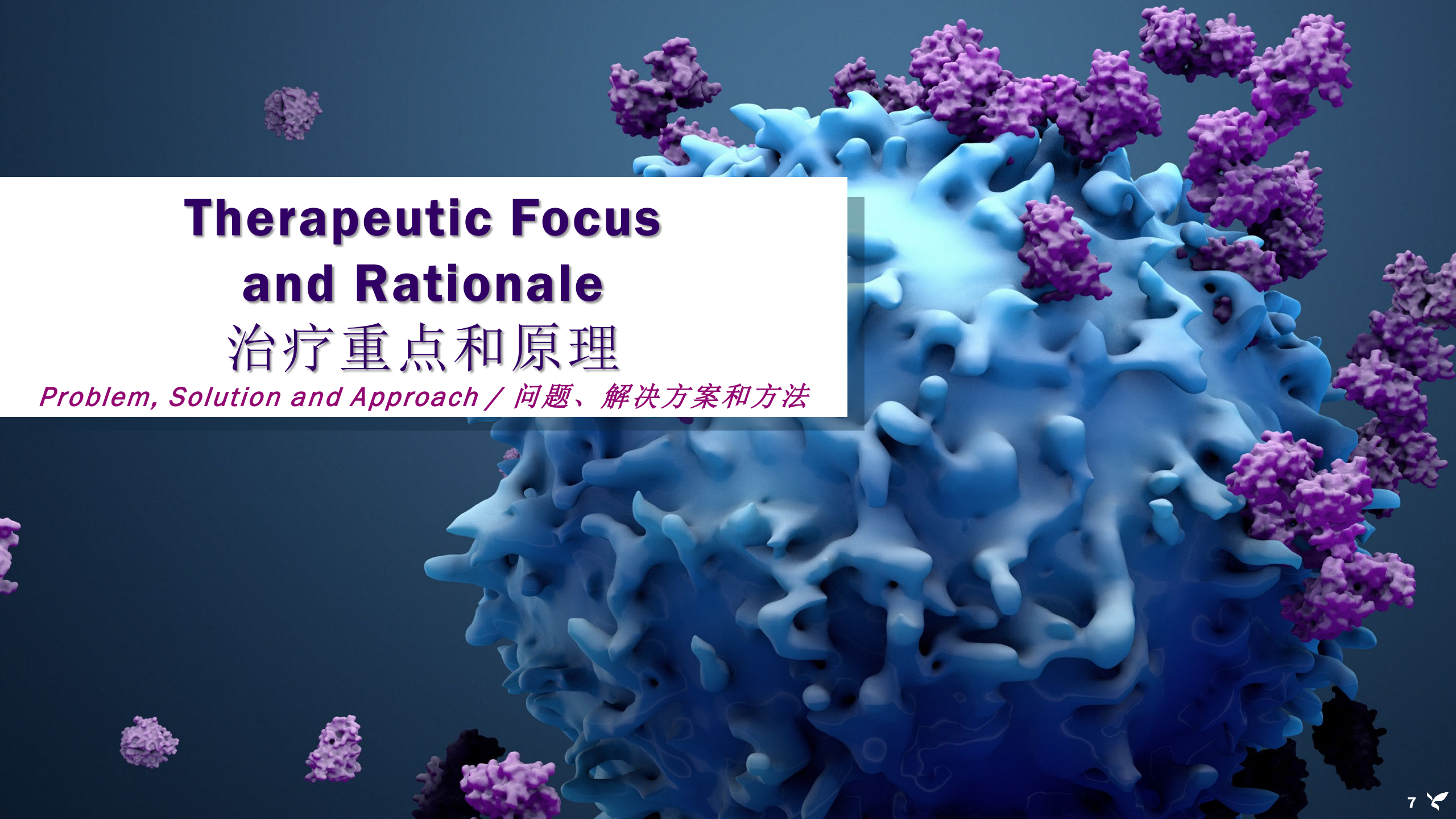
**Mohammad Azab, MD, MSc, MBA / 医学博士、工商管理硕士**
*Director / 董事*

Pharma executive with 30+ years of experience in clinical research, business management, and global development, bringing multiple drugs to market across oncology and other therapeutic areas. / 医药行业高管，在临床研究、业务管理和全球开发方面拥有30多年的经验，曾将多种药物推向市场，涉及肿瘤学和其他治疗领域。

**Heidi Henson**
*Director / 董事*

Senior executive with over two decades of financial operations experience with both public and private companies./ 拥有二十多年上市和私营公司财务运营经验的资深高管。

*Detailed bios can be found at www.lisata.com / 详细履历见www.lisata.com*



# Therapeutic Focus and Rationale

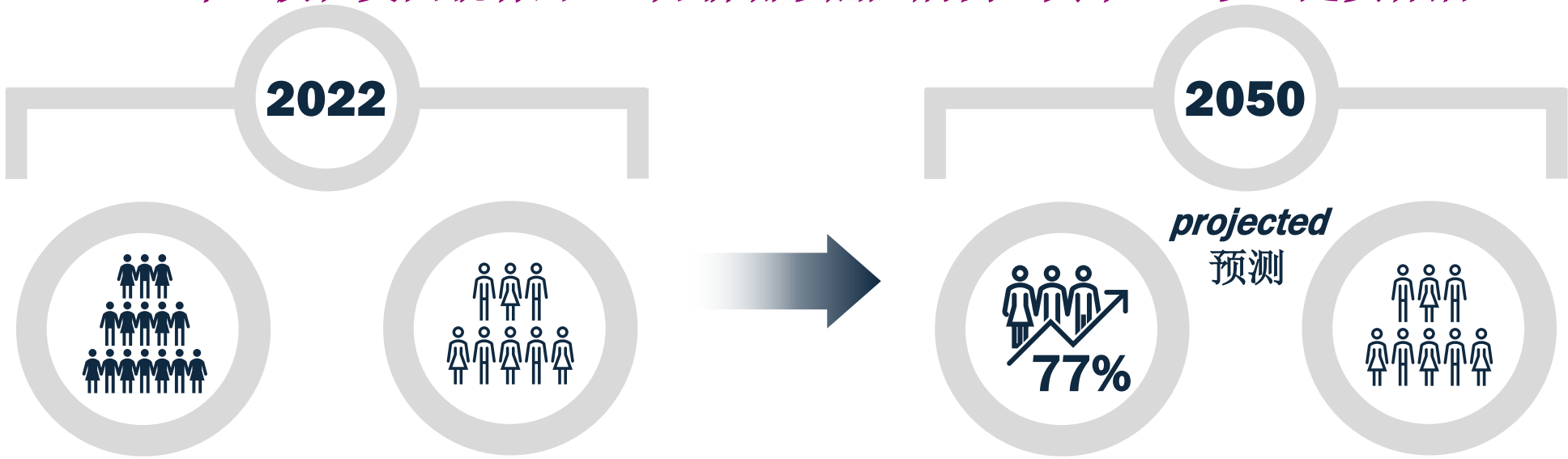
# 治疗重点和原理

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

# Improved solid tumor treatment is a vital global need
# 改善实体肿瘤治疗在全球范围是迫切需求

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

***2023年，仅在美国就有约200万新确诊癌症病例，其中90%以上是实体瘤[1]***




**20 million new cases[2] / 2000 万个新病例[2]**

**9.7 million deaths / 970 万死亡病例**

**35 million new cases[2] / 3500 万新病例[2]**

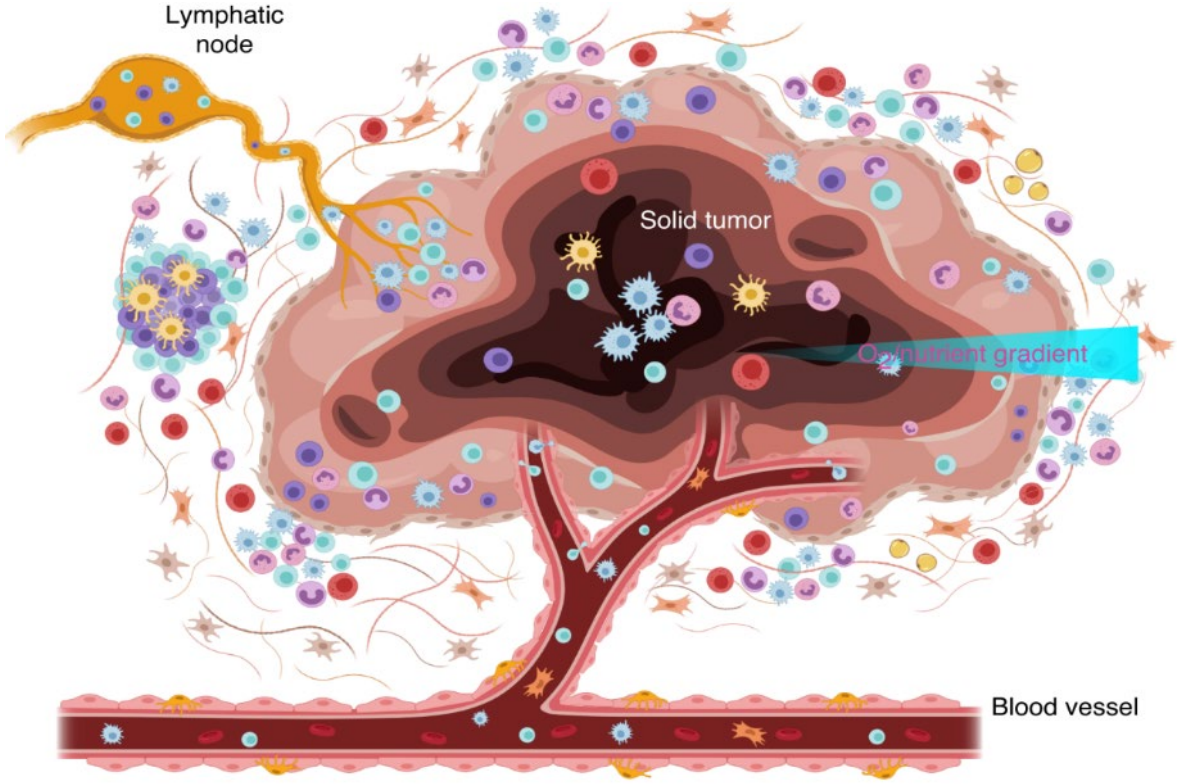
**18.5 million deaths / 1850 万死亡病例**

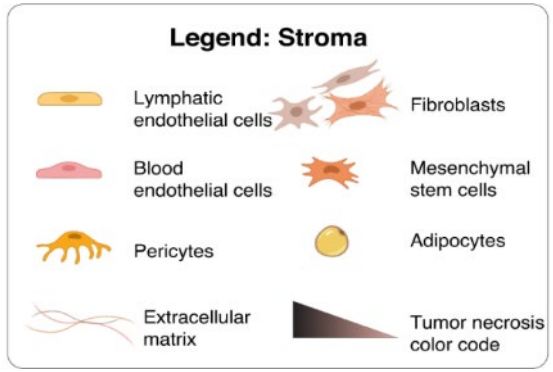
*Examples of solid tumors include cancers of the lung, breast, pancreas, liver, bile duct, kidneys, ovaries, brain, colon, prostate, esophagus, and head & neck / 实体肿瘤包括肺癌、乳腺癌、胰腺癌、肝癌、胆管癌、肾癌、卵巢癌、脑癌、结肠癌、前列腺癌、食道癌和头颈癌*

[1] https://seer.cancer.gov/statfacts/html/common.html; data retrieved November 2, 2023./ 数据检索日期为2023年11月2日

[2] https://gco.iarc.who.int/tomorrow/en/dataviz/tables?mode=population&years=2050&types=1&populations=903_904_905_908_909_935_900; data retrieved Feb 12, 2024./ 数据检索日期为2024年2月12日

# Current solid tumor treatments are suboptimal
# 目前的实体肿瘤治疗效果不理想



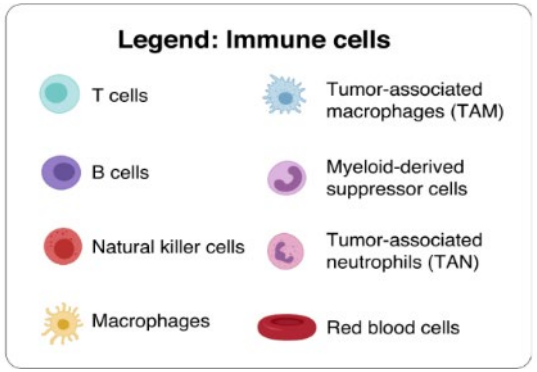




Diagram: Abizanda-Campo, S. et al, *Microsyst Nanoeng* **9**, 154 (2023)

***A challenging tumor microenvironment complicates "targeting" and "penetration" / 有挑战的肿瘤微环境增加了"靶向"和"穿透"的复杂性***

- Tumor stroma acts as a physical barrier to anti-cancer agents / 肿瘤基质是抗癌药物的物理屏障
- An immunosuppressive tumor microenvironment (TME) contributes to tumor resistance and/or metastases / 免疫抑制肿瘤微环境（TME）有助于肿瘤抵抗和/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

# Improving selective solid tumor penetration to maximize treatment effects
# 改善实体肿瘤的选择性渗透，最大限度地提高治疗效果

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

*利用C末端法则（CendR）运输机制促进实体肿瘤渗透*

**RGD peptides target tumor cells, but do not enhance penetration and delivery / RGD肽靶向肿瘤细胞，但不会增强穿透力和输送能力**

***Internalizing* RGD (iRGD) peptides combine targeting and penetration enhancement / 内化RGD（iRGD）肽兼具靶向性和渗透性增强功能**

**Certepetide (LSTA1) is an iRGD peptide that triggers the CendR active transport mechanism to selectively target and deliver anti-cancer drugs to solid tumors / Certepetide (LSTA1) 是一种iRGD肽，可触发CendR活性转运机制，从而选择性地靶向实体瘤并输送抗癌药物**

**Certepetide is in mid- to late-stage clinical development for solid tumor treatment / Certepetide正处于实体瘤治疗的中后期临床开发阶段**

# Certepetide promises optimized solid tumor treatment
# Certepetide有望优化实体瘤治疗

## Certepetide converts tumor stroma from a barrier to a conduit for anti-cancer drugs / Certepetide将肿瘤基质从一个障碍转化为抗癌药物的通道

## Certepetide combats resistance and metastases[1] / Certepetide对抗抗药性和转移[1]

- Selectively depletes immunosuppressive T cells / 选择性耗尽免疫抑制T细胞
- Enhances concentration of cytotoxic T cells / 提高细胞毒性T细胞的浓度
- Inhibits the metastatic cascade / 抑制转移级联反应

## Certepetide is agnostic to the modality of the companion anti-cancer therapy / Certepetide对伴随的抗癌治疗方式不可知

- Effective with co-administered or molecularly bound (tethered) anti-cancer therapies / 与联合用药或分子结合（系留）抗癌疗法一起使用有效
- Co-administration presents an initial streamlined development path to registration / 联合用药提供了一条初步简化的注册开发途径
- Tethering creates a new chemical entity providing new compound patent protection / 系留产生新的化学实体，提供新的化合物专利保护

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

# Certepetide development strategy is composed of two main pillars
# 构成certepetide发展战略的两大支柱

**Focus on Pancreatic & Other Advanced Solid Tumors / 专注于胰腺癌和其他晚期实体肿瘤**

- By 2030, pancreatic cancer is predicted to become the second most common cause of cancer mortality[1] / 预计到2030年，胰腺癌将成为因癌症致死的第二大病因[1]
- Today, only 3% of people diagnosed with pancreatic cancer will survive for 5 years / 目前，只有3%确诊胰腺癌的患者能存活5年
- Current life expectancy at the time of diagnosis is just 4.6 months / 目前确诊时预期平均寿命仅为4.6个月

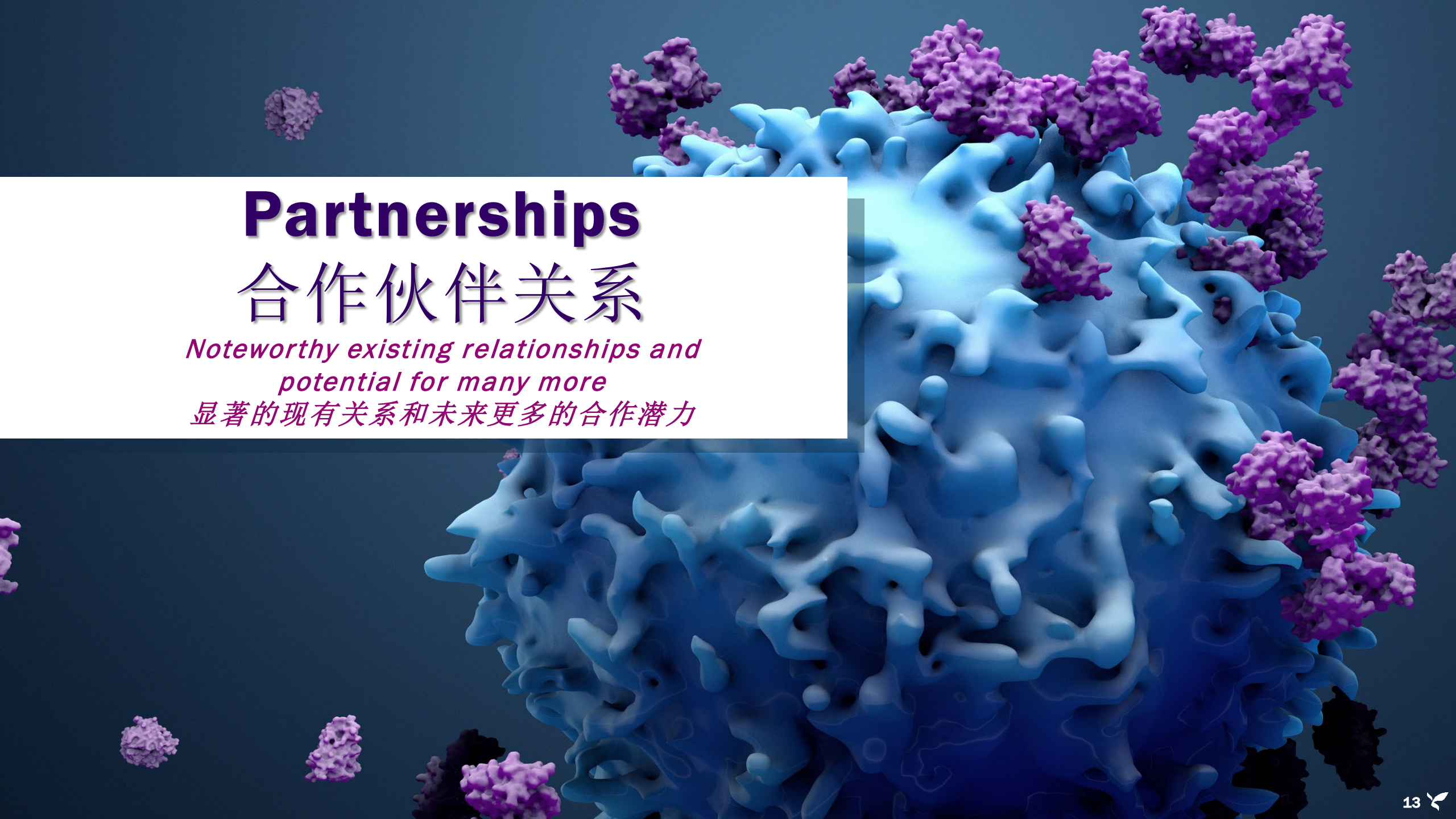
**Pursue rapid global registration in pancreatic ductal adenocarcinoma (mPDAC), initially combined with gemcitabine/nab-paclitaxel standard-of-care (SoC) / 迅速在胰腺导管腺癌（mPDAC）领域开展全球注册，最初与吉西他滨/白蛋白结合紫杉醇标准疗法（SoC）联合使用**

- *Phase 2b 100% enrolled / 第2b阶段100%招募完成*

**Demonstrate certepetide effectiveness when combined with a variety of SoC regimens (e.g., chemotherapy, immunotherapy, etc.) in a variety of solid tumors / 展示certepetide与各种SoC疗法（如化疗、免疫疗法等）联合应用在多种实体肿瘤中的有效性**

- *Multiple Phase 1b/2a studies underway / 多项1b/2a阶段研究正在进行中*

[1] Europe Is Facing a Pancreatic Cancer Emergency - Medscape - January 25, 2024./ 欧洲正面临胰腺癌紧急状况 - Medscape - 2024年1月25 日。



# Partnerships
# 合作伙伴关系

*Noteworthy existing relationships and potential for many more*
*显著的现有关系和未来更多的合作潜力*

# Existing partnerships support certepetide's promise and broad applicability
# 现有的合作伙伴关系支持Certepetide的前景和广泛适用性

## *Development alliances contribute resources without commercial interest in certepetide / 开发联盟在没有商业利益的情况下为certepetide提供资源*

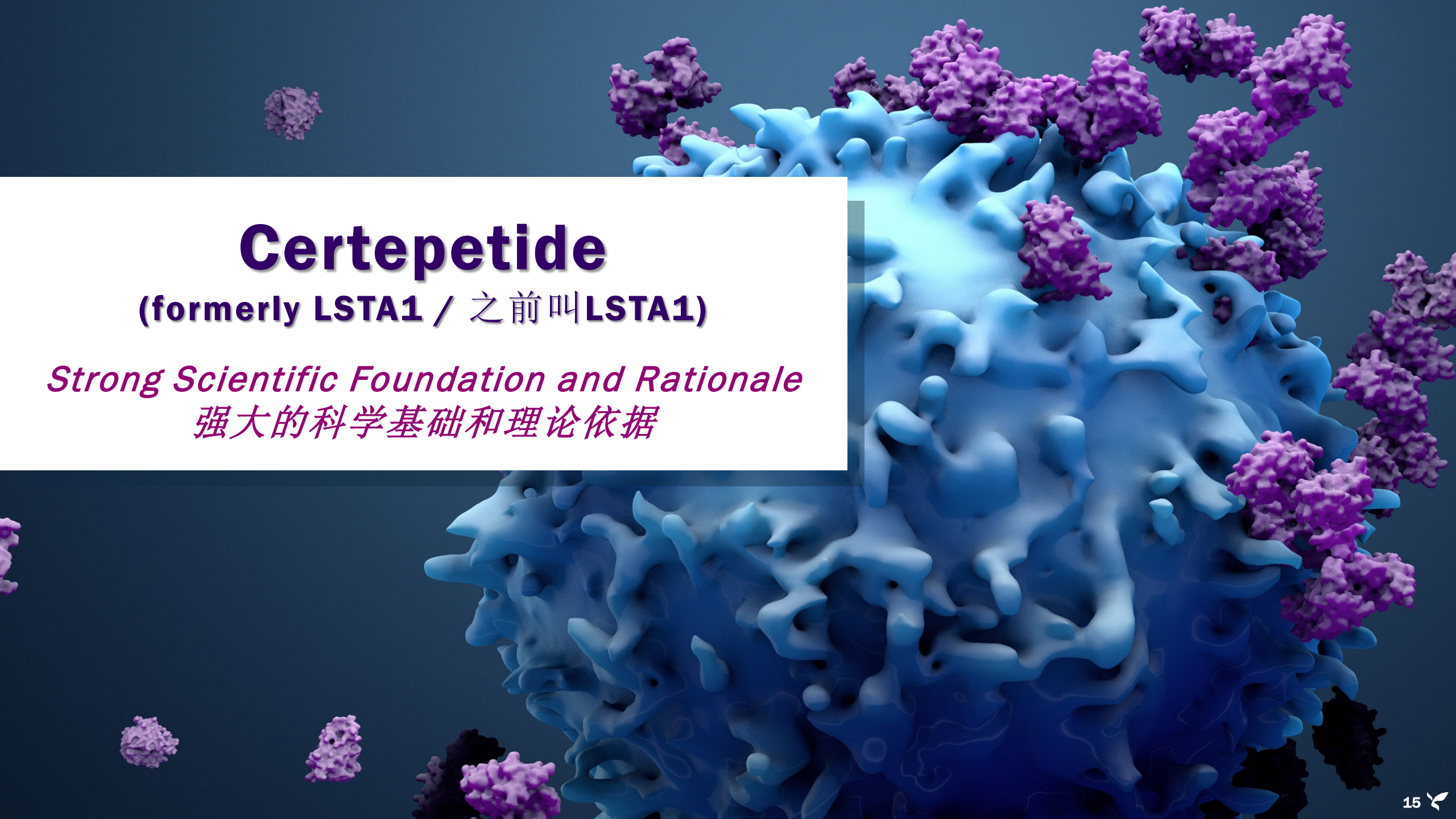
- Australasian Gastro-Intestinal Trials Group - Clinical Trialists Consortium (Australia & New Zealand) / 大拉西亚胃肠道试验小组 - 临床试验者联盟（澳大利亚和新西兰）
- WARPNINE - Foundation (Australia) / **WARPNINE** - 基金会（澳大利亚）

## *Strategic commercial partnership in China with **Qilu Pharmaceutical** / 与齐鲁制药在中国建立战略商业合作伙伴关系*

- Exclusive rights to certepetide in China, Taiwan, Hong Kong and Macau / 在中国大陆、台湾省、香港和澳门地区独家销售 **certepetide**
- Qilu assumes all development and commercialization responsibilities/costs in licensed territories / 齐鲁制药承担许可区域内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**管理人员组成的联合指导委员会的主持下制定战略和开展活动
- Collected $15 million in milestones to date / 迄今已收取**$1500**万里程碑款项
- Potential for additional $221 million in milestones plus royalties on sales / 有可能额外获得**$2.21**亿的里程碑款项和销售特许权使用费

## *Additional partnership opportunities exist for many combinations with certepetide / 在certepetide身上存在许多与其他药物结合的额外合作机会*

- By indication, modality of co-administered drug(s), and/or geography / 按适应症、联合用药方式和/或地域分类



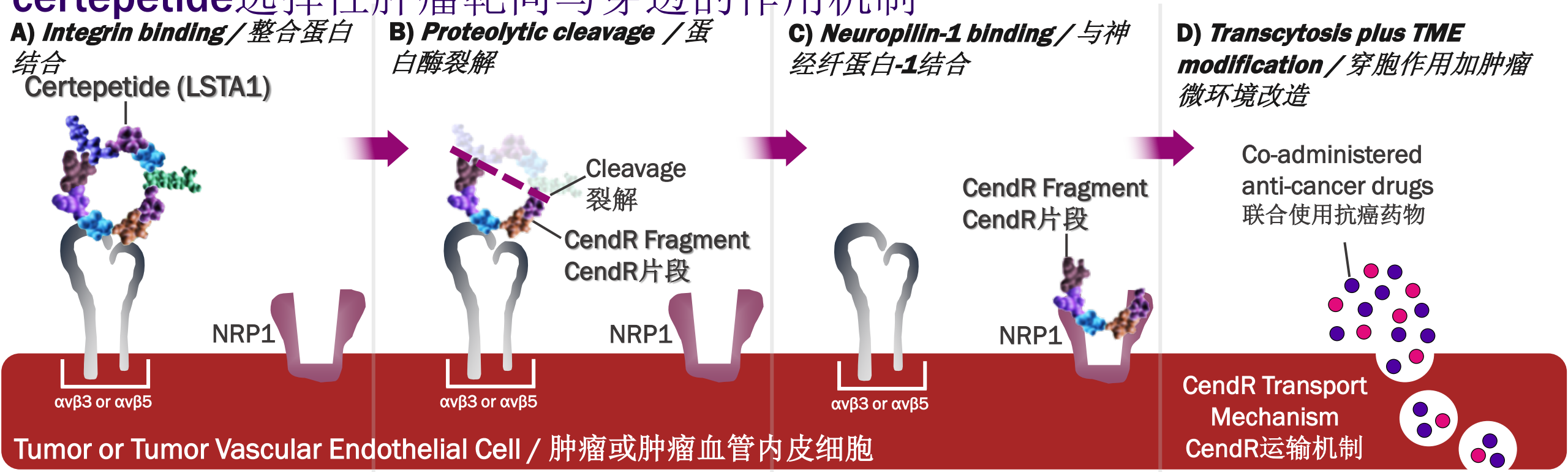
# Certepetide

## (formerly LSTA1 / 之前叫LSTA1)

*Strong Scientific Foundation and Rationale*

*强大的科学基础和理论依据*

# Certepetide selective tumor targeting & penetration mechanism of action
# certepetide选择性肿瘤靶向与穿透的作用机制




Certepetide is a 9 amino acid cyclic peptide with high binding affinity and specificity to αvβ3/β5 integrins that are upregulated on tumor cells and tumor endothelial cells (i.e., components of tumor stroma) / Certepetide是一种由9个氨基酸构成的环肽，与肿瘤细胞和肿瘤内皮细胞（即肿瘤基质的组成部分）上调的αvβ3/β5整合素具有高结合亲和力和特异性。

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

一旦与αvβ3或β5整合素结合，certepetide会在肿瘤微环境（TME）中被蛋白酶裂解，释放出一个C端法则（CendR）线性肽片段。

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

CendR片段与同一细胞或邻近细胞上的邻近受体神经纤蛋白-1 (NRP1) 具有高亲和力和特异性结合，激活CendR运输途径并触发肿瘤穿透

- CendR pathway actuation triggers tumor penetration of circulating co-administered anti-cancer drugs / CendR通路的激活触发了循环共用抗癌药物对肿瘤的渗透
- Certepetide-induced TME modification provokes reduction of immunosuppressive T cells, augmentation of cytotoxic T cells, and inhibition of metastases / certepetide诱导的肿瘤微环境调整引发了免疫抑制T细胞的减少，细胞毒T细胞的增加以及转移的抑制

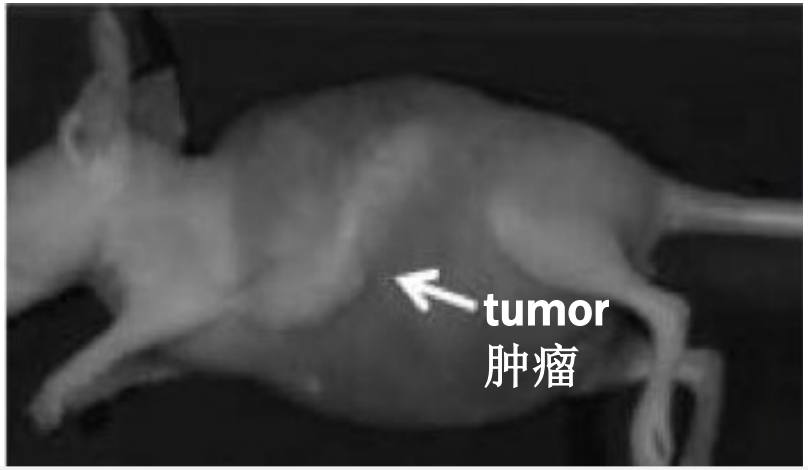
[1] Ding et al., Nature Comm, 2019./ Ding等人，《自然-通讯》，2019年

# Certepetide selectively and efficiently facilitates intratumoral penetration
# Certepetide可选择性地有效促进瘤内渗透

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

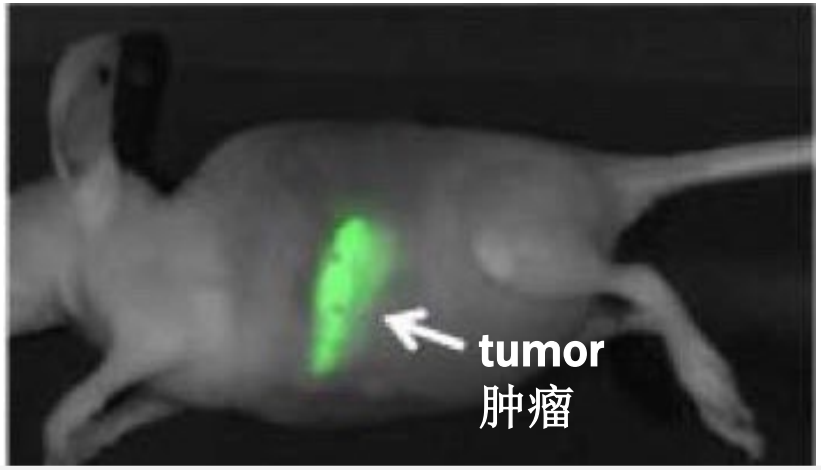
**胰腺导管腺癌小鼠全身成像（箭头），注射荧光量子点（FQDs）时与/不与certepetide一同使用**

- Circulating FQDs result in whole body fluorescence / 循环中的FQDs导致全身发出荧光
- Etching solution quenches fluorescence in circulation / 蚀刻溶液熄灭循环中的荧光




**FQDs + Etching solution / FQDs+蚀刻溶液**

*All FQDs in circulation / 循环中的所有FQDs*




**Certepetide + FQDs + Etching solution / Certepetide+FQDs+蚀刻溶液**

*All FQDs in tumor / 肿瘤中的所有FQDs*

***Certepetide provides targeted tumor penetration***
***Certepetide具有靶向穿透肿瘤的能力***

[1] Braun et al., Nature Mater. 2014./ Braun等人，Nature Mater，2014年。
[2] Liu, Braun et al., Nature Comm. 2017. / Liu、Braun等人，《自然通讯》，2017年。

# Certepetide/iRGD activity & broad applicability consistently demonstrated

# 继续显示Certepetide/iRGD活性和广泛适用性

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

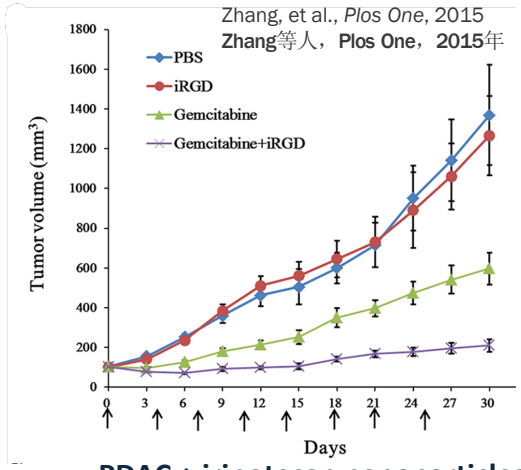
***超过350篇科学出版物的抽样显示，使用Certepetide/iRGD可以改善存活率***

**Lung cancer + gemcitabine**

**肺癌+吉西他滨**

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

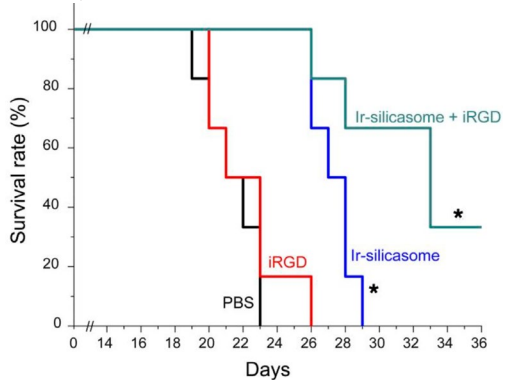
**Zhang**等人，**Plos One**，**2015**年




**PDAC + irinotecan nanoparticles**

**PDAC+伊立替康纳米颗粒**

Liu X et al., J Clin Invest, 2017 / **Liu X**等，**J Clin Invest**，**2017**年




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

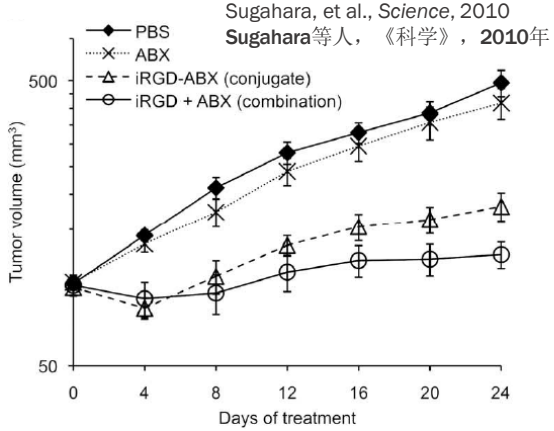
原位移植的**KPC PDAC**肿瘤**iRGD**+伊立替康纳米粒子（静脉联合给药）

**Breast cancer + nanoparticle Abraxane**

**乳腺癌+纳米粒子白蛋白紫杉醇**

Sugahara, et al., *Science*, 2010

**Sugahara**等人，《科学》，**2010**年

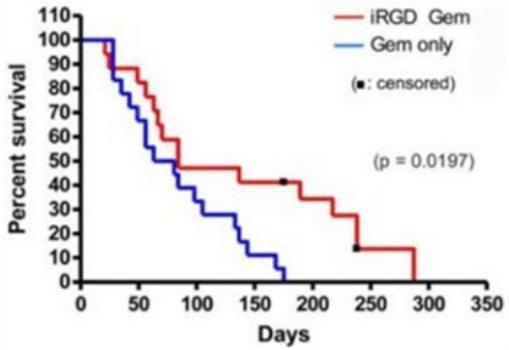



**PDAC + gemcitabine**

**PDAC+吉西他滨**

Hurtado de Mendoza et al, Nature Comms, 2021

Hurtado de Mendoza等人，《自然通讯》，2021年




KPC mice genetically engineered to develop PDAC

iRGD + gemcitabine (i.v. co-admin)

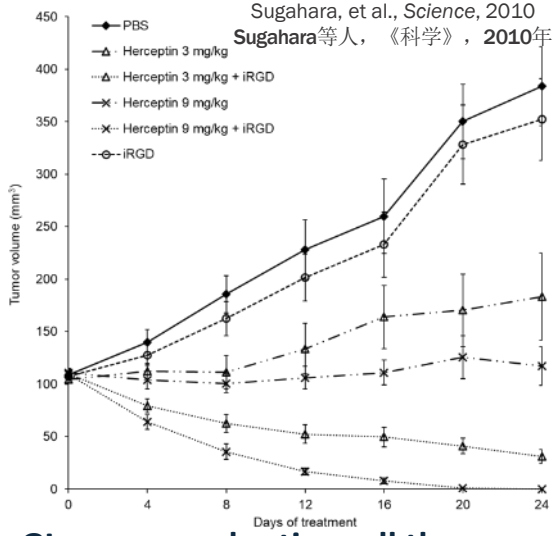
经过基因改造的**KPC**小鼠患上**PDAC iRGD**+吉西他滨（静脉联合给药）

**Breast cancer + Herceptin®**

**乳腺癌+赫赛汀®**

Sugahara, et al., *Science*, 2010

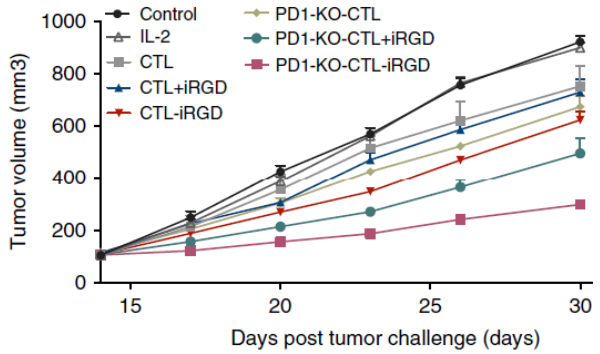
**Sugahara**等人，《科学》，**2010**年




**GI cancer + adoptive cell therapy**

**消化道癌+过继细胞疗法**

Ding, et al., *Nature*, 2019 / **Ding**等人，《自然》杂志，**2019**年



# Certepetide Ph 1b/2a results: Compelling improvement of SoC efficacy
# Certepetide 1b/2a阶段结果：最佳疗法疗效显著改善

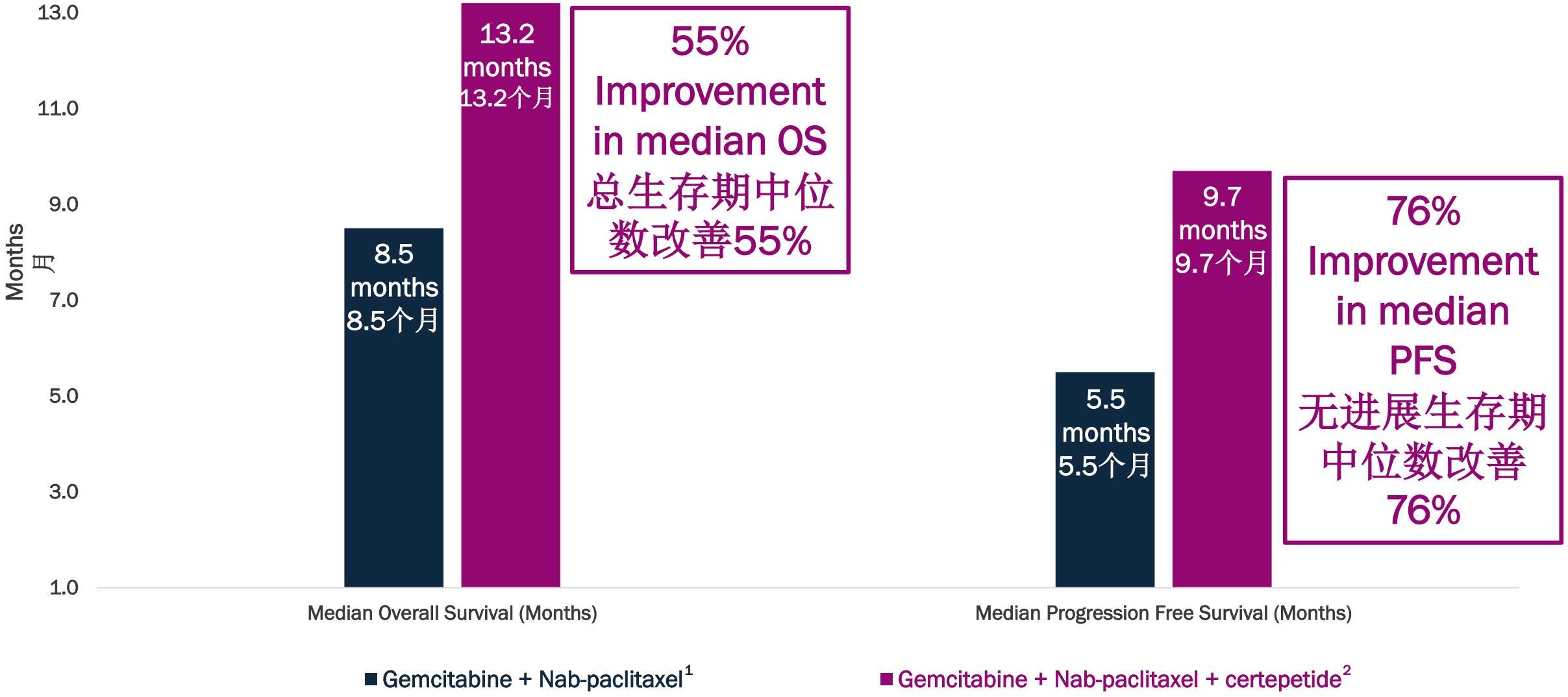
| Endpoints 终点 | Gemcitabine + Nab-paclitaxel 吉西他滨+纳米白蛋白紫杉醇[1] | Certepetide + Gemcitabine + Nab-paclitaxel / Certepetide+吉西他滨+纳米白蛋白紫杉醇[2] |
|---|---|---|
| N= # of study participants / 研究参与人数 | N=431 | N=31 |
| Median Overall Survival / 总生存期中位数 | 8.5 mos./ 8.5个月 | 13.2 mos. / 13.2个月 |
| Median Progression-Free Survival / 无进展生存期中位数 | 5.5 mos./ 5.5个月 | 9.7 mos. / 9.7个月 |
| Objective Response Rate / 客观缓解率 | 23% (99) | 59% (17) |
| Complete Response / 完全缓解 | 0.2% (1) | 3.4% (1) |
| Partial Response / 部分缓解 | 23% (98) | 55% (16) |
| Stable Disease / 病情稳定 | 27% (118) | 31% (9) |
| Progressive Disease / 病情进展 | 20% (86) | 10.3% (3) |
| Disease Control Rate 16 weeks / 16周病情控制率 | 48% | 79% |
| CA19-9 >20% drop / CA19-9下降超过20% | 61% | 96% |

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

- Certepetide well-tolerated with no dose-limiting toxicities / Certepetide耐受良好，没有剂量限制的毒性反应
- Safety of certepetide + SoC consistent with SoC alone / certepetide＋最佳疗法与单独使用最佳疗法的安全性一致

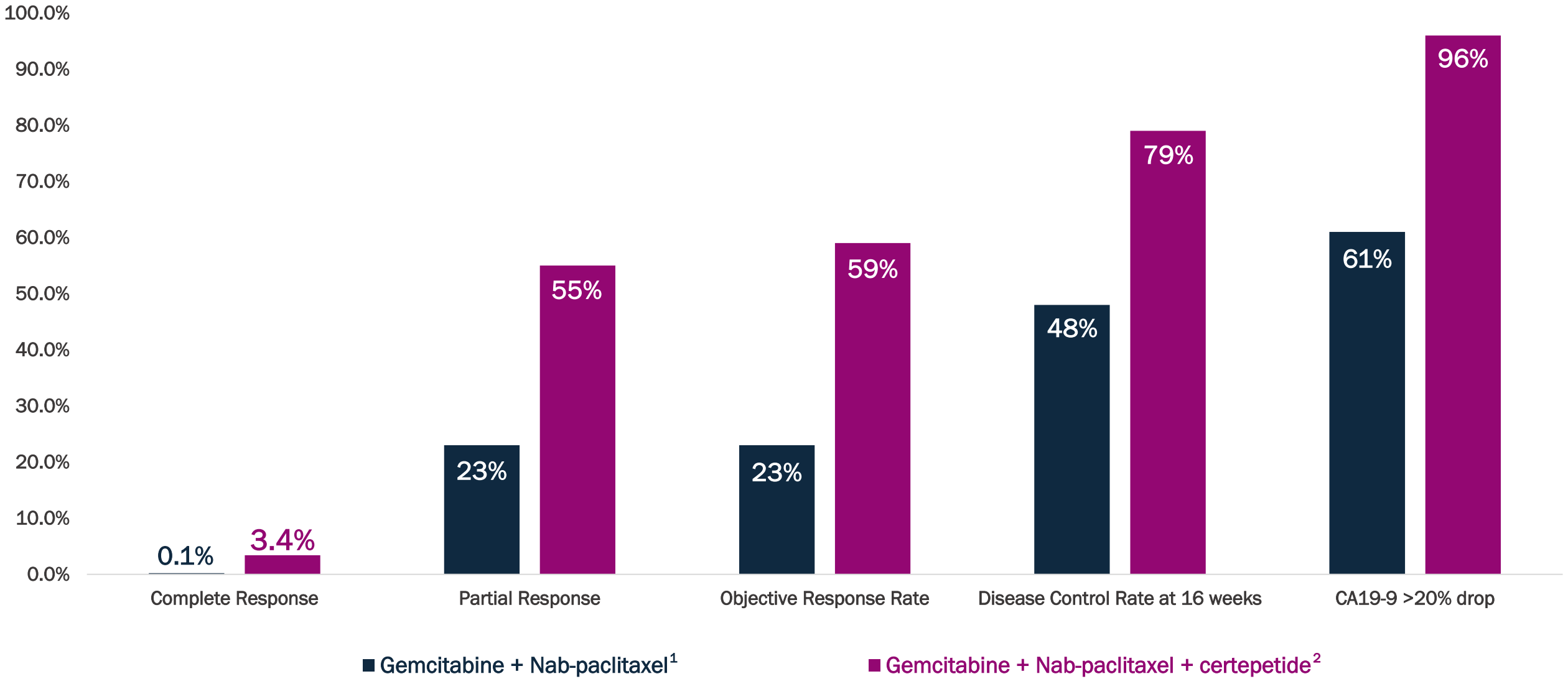
[1] Von Hoff D, et al., *New England Journal of Medicine*, 2013./ Von Hoff D等人，《新英格兰医学杂志》，2013年。
[2] Dean A, et al., *The Lancet Gastroenterology & Hepatology*, 2022./ Dean A等人，《柳叶刀胃肠病学与肝病学》，2022年。

# Certepetide Ph 1b/2a results: Improved survival vs. SoC alone
# certepetide 1b/2a阶段结果： 与单独使用最佳疗法相比，生存率有所提高




[1] Von Hoff D, et al., *New England Journal of Medicine*, 2013./ *Von Hoff D等人，《新英格兰医学杂志》，2013年。*
[2] Dean A, et al., *The Lancet Gastroenterology & Hepatology*, 2022./ Dean A等人，《柳叶刀胃肠病学与肝病学》，2022年。

# Certepetide Ph 1b/2a results: Consistent improvement across associated endpoints
# certepetide 1b/2a期结果：相关终点持续改善



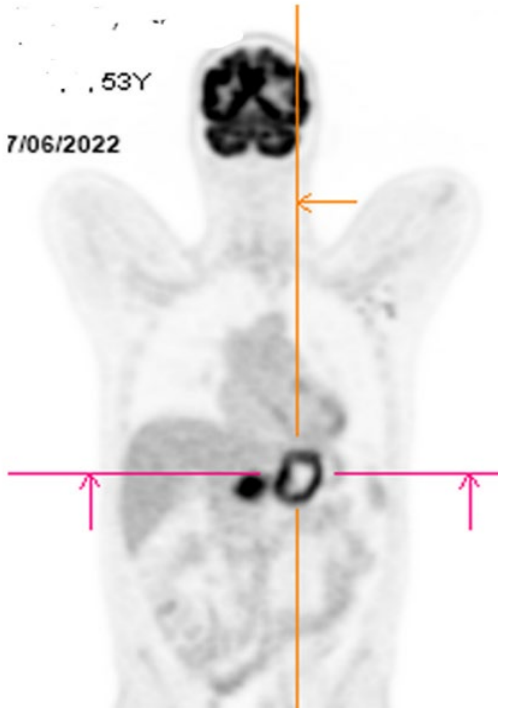

[1] Von Hoff D, et al., *New England Journal of Medicine*, 2013./ *Von Hoff D等人，《新英格兰医学杂志》，2013年。*
[2] Dean A, et al., *The Lancet Gastroenterology & Hepatology*, 2022./ Dean A等人，《柳叶刀胃肠病学与肝病学》，2022年。

# Clinical evidence of certepetide activity in other solid tumors
# 在其他实体瘤中应用certepetide的临床证据

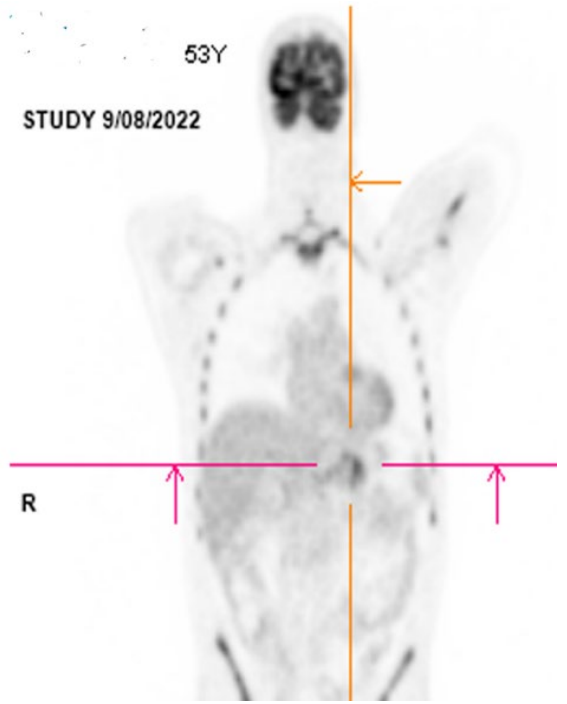
***Certepetide potentiated a complete response in metastatic gastroesophageal adenocarcinoma (mGEAC)***
***certepetide能增强转移性胃食管腺癌（mGEAC）的完全缓解能力***

- 53-year-old male with mGEAC with significant (> 5cm) nodal metastases (June 2022) / 53岁男性，胃食管腺癌患者，有明显（>5厘米）结节转移（2022年6月）
- SoC combination radiotherapy and chemo-therapy (FOLFIRINOX), with immunotherapy (pembrolizumab) later added resulting in partial response / 最佳疗法联合放化疗（FOLFIRINOX），随后加入免疫疗法（派姆单抗），得到部分缓解
- Certepetide added to above regimen at cycle 7 and exploratory laparoscopy after cycle 18 (September 2022) showed no discernable disease – **complete response** / 在第7个周期将certepetide加入上述治疗方案，第18个周期（2022年9月）后的腹腔镜检查显示无明显疾病–完全缓解

FDG-PET* scan June 2022
FDG-PET扫描，2022年6月




FDG-PET scan Sept. 2022
FDG-PET扫描2022年9月




Reduction in FDG activity demonstrate[1]
FDG活性减少得到证实[1]

**Fluorodeoxyglucose (FDG)-positron emission tomography (PET) / 氟脱氧葡萄糖（FDG）-正电子发射断层扫描（PET）*

[1] Buck, K.K, Dean, A., McSweeney, T. LSTA1 Potentiates Complete Response in Metastatic Gastroesophageal Adenocarcinoma. Oncol Cancer Case Rep. 2023, 9(6), 001-003
Buck, K.K, Dean, A., McSweeney, T. LSTA1增强转移性胃食管腺癌的完全缓解，Oncol Cancer Case Rep. 2023, 9(6), 001-003

# Certepetide

*Clinical/Regulatory Development Portfolio*
*临床/监管开发组合*

# Certepetide regulatory designations and implications certepetide的监管指定和影响

## FDA Fast Track Designation FDA快速通道认定

- More frequent communication with and program-specific guidance from FDA / 与**FDA**更加频繁的沟通，并获得针对具体项目的指导
- Eligible for ***Accelerated Approval, Priority Review and Rolling Review*** /符合*加速批准、优先审评和滚动审评*条件
- ***Certepetide received Fast Track Designation from FDA for pancreatic cancer / Certepetide获得FDA针对胰腺癌的快速通道认定***

## FDA Rare Pediatric Disease Designation FDA罕见儿科疾病认定

- 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 / 有资格获得*优先审评凭单*，可用于获取后续营销申请的优先审查，也可出售或转让
- Historically, vouchers have sold for $350 million USD and, more recently, have sold for $75-$100 million USD / 过去，优先审评凭单的售价为**3.5**亿美元，近期则为**$7500**万美元至**$1**亿美元
- ***Certepetide received Rare Pediatric Disease Designation from FDA for osteosarcoma / certepetide获得了FDA对于骨肉瘤的罕见儿科疾病认定***

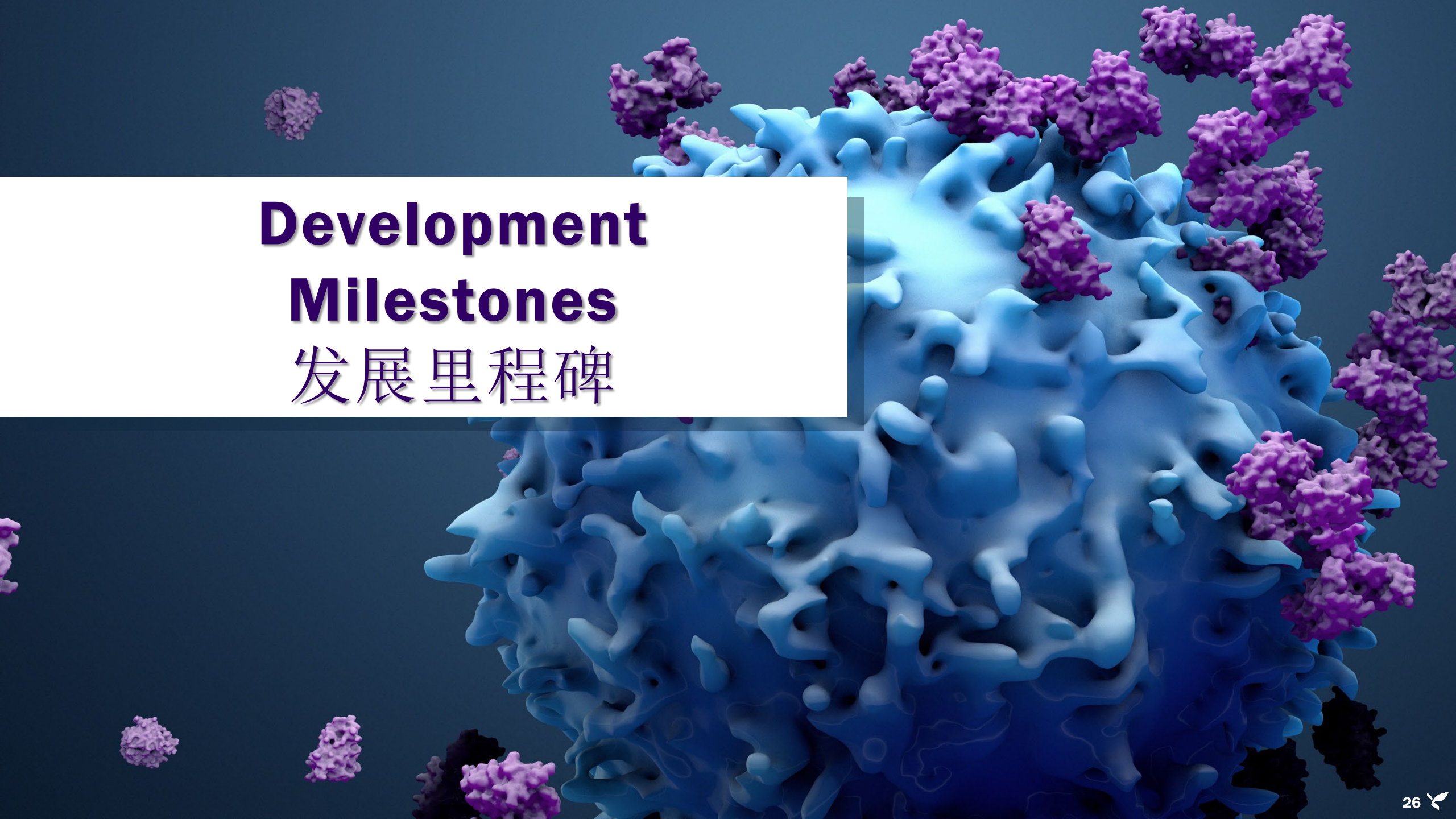
## Orphan Drug Designation 孤儿药认定

- Incentives such as ***tax credits, marketing exclusivity, fee waivers and grant eligibility*** to support clinical trials / 通过*税收减免、市场专营权、费用减免和资助资格*等激励措施，以支持临床试验
- Specialized regulatory assistance from FDA's Office of Orphan Products Development / 得到**FDA**孤儿药发展办公室提供的专业监管协助
- ***Certepetide received Orphan Drug Designations from FDA and EMA for pancreatic cancer, from FDA for malignant glioma, and from FDA for osteosarcoma / Certepetide获得了FDA和EMA对胰腺癌、FDA对恶性胶质瘤，以及FDA对骨肉瘤的孤儿药认定***

# Certepetide capital efficient development plan / certepetide资本高效发展计划

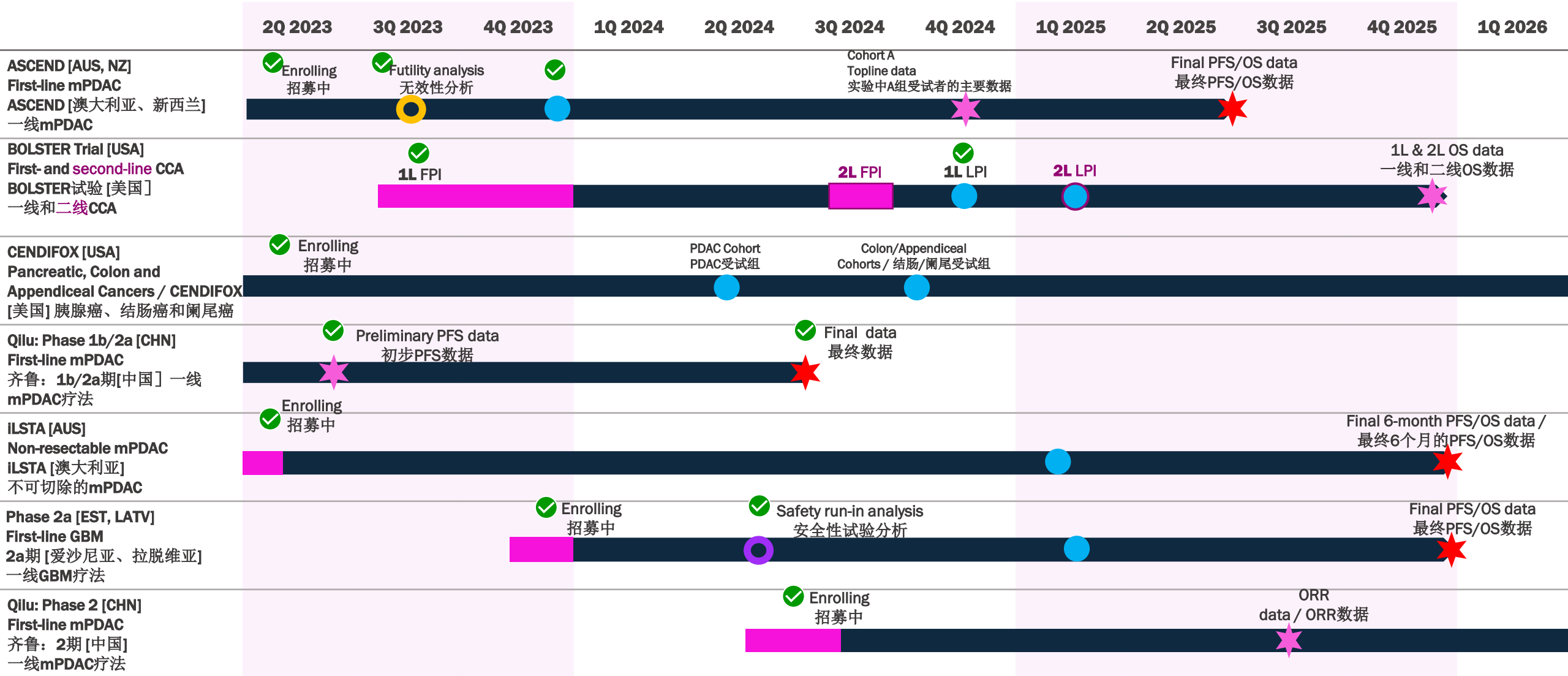
| Sponsor(s)<br>赞助商 | Indication<br>指征 | Description<br>说明 | Current Phase / 当前阶段 |
|---|---|---|---|
| AGITG/Lisata | *First-line mPDAC*<br>*一线mPDAC* | ▪ **ASCEND:** Phase 2b, placebo-controlled trial (N=158) / **ASCEND**：2b期安慰剂对照试验（N=158）<br>▪ *Gemcitabine/nab-paclitaxel + certepetide or placebo / 吉西他滨/白蛋白结合型紫杉醇+certepetide或安慰剂*<br>▪ Australia/New Zealand / 澳大利亚/新西兰 | Enrollment complete<br>完成招募 |
| Lisata | *First- and Second-line Cholangiocarcinoma (CCA)*<br>*一线和二线胆管癌 (CCA)* | ▪ **BOLSTER:** Phase 2a, placebo-controlled trial (N=80) / **BOLSTER**：2a期、安慰剂对照试验（N=80）<br>▪ *1L CCA: Gemcitabine/cisplatin/durvalumab with certepetide or placebo / 一线胆管细胞癌：吉西他滨/顺铂/杜瓦霉素联合certepetide或安慰剂*<br>▪ *2L CCA: FOLFOX with certepetide or placebo / 二线胆管细胞癌：FOLFOX联合certepetide或安慰剂*<br>▪ United States / 美国 | 1L CCA Enrollment complete<br>1线CCA招募完成<br>2L CCA Enrolling soon<br>2线CCA即将招募 |
| KUCC/Lisata<br>*Investigator-initiated trial*<br>*研究者发起的试验* | *Pancreatic, Colon, and Appendiceal Cancers*<br>*胰腺癌、结肠癌和阑尾癌* | ▪ **CENDIFOX:** Phase 1b/2a, open-label trial (N=51) / **CENDIFOX**：1b/2a期，开放标签试验（N=51）<br>▪ *FOLFIRINOX + panitumumab* + certepetide / FOLFIRINOX + 帕尼单抗*+certepetide*<br>▪ United States / 美国 | Enrolling / 招募中 |
| Qilu/Lisata | *First-line mPDAC*<br>*一线mPDAC* | ▪ Phase 1b/2a, open-label trial (N=41) / 1b/2a期、开放标签试验（N=41）<br>▪ *Gemcitabine/nab-paclitaxel + certepetide / 吉西他滨/白蛋白结合型紫杉醇+certepetide*<br>▪ China / 中国 | Enrollment complete<br>完成招募 |
| WARPNINE/Lisata | *Locally advanced, non-resectable PDAC*<br>*局部晚期、不可切除的PDAC* | ▪ **iLSTA:** Phase 1b/2a, open-label trial (N=30) / **iLSTA**：1b/2a期开放标签试验（N=30）<br>▪ *Gemcitabine/nab-paclitaxel/durvalumab + certepetide / 吉西他滨/白蛋白结合型紫杉醇/德瓦鲁单抗+certepetide*<br>▪ Australia / 澳大利亚 | Enrolling / 招募中 |
| Tartu University/Lisata<br>*Investigator-initiated trial /*<br>*研究者发起的试验* | *First-line Glioblastoma Multiforme (GBM)*<br>*一线多形性胶质母细胞瘤（GBM）* | ▪ Phase 2a, placebo-controlled trial (N=30) / 2a期安慰剂对照试验（N=30）<br>▪ *Temozolomide +/- certepetide / 替莫唑胺+/-certepetide*<br>▪ Estonia/Latvia / 爱沙尼亚/拉脱维亚 | Enrolling / 招募中 |
| Qilu/Lisata | *First-line mPDAC*<br>*一线mPDAC* | ▪ Phase 2, placebo-controlled trial (N=120) / 2期安慰剂对照试验（N=120）<br>▪ *Gemcitabine/nab-paclitaxel + certepetide / 吉西他滨/白蛋白结合型紫杉醇+certepetide*<br>▪ China / 中国 | Enrolling / 招募中 |

**Panitumumab may be added for colorectal or appendiceal patients without Ras mutation. / 对于没有Ras突变的结直肠或阑尾癌患者，可以添加帕尼单抗。*



# Development Milestones
# 发展里程碑

# A wealth of anticipated key milestones / 一系列预期中的重要里程碑




First patient in 第一位患者加入 | Last patient in 最后一位患者 | Interim analysis 中期分析 | Safety run-in analysis 安全性试验分析 | Data 数据 | Final data 最终数据 | Milestone achieved 实现的里程碑

- PFS: Progression-free Survival / 无进展生存期
- OS: Overall Survival / 总生存期
- ORR: Objective Response Rate / 客观缓解率

**Several of these studies are investigator-initiated trials. Lisata has limited control and thus, timelines and expectations may be subject to change.*

**其中几项研究是研究者发起的试验。Lisata的控制能力有限，因此时间安排和预期可能会发生变化。*

# Financial Highlights
# 财务亮点

# Capital projected to fund all clinical programs to data
# 现有资金预计能够为所有临床计划提供支持，一直到获得最终数据

## Cash & Investments
现金与投资

*As of 3/31/2024*
*截止2024年3月31日*

**$43.3M**

**$4330万**

## Debt
债务

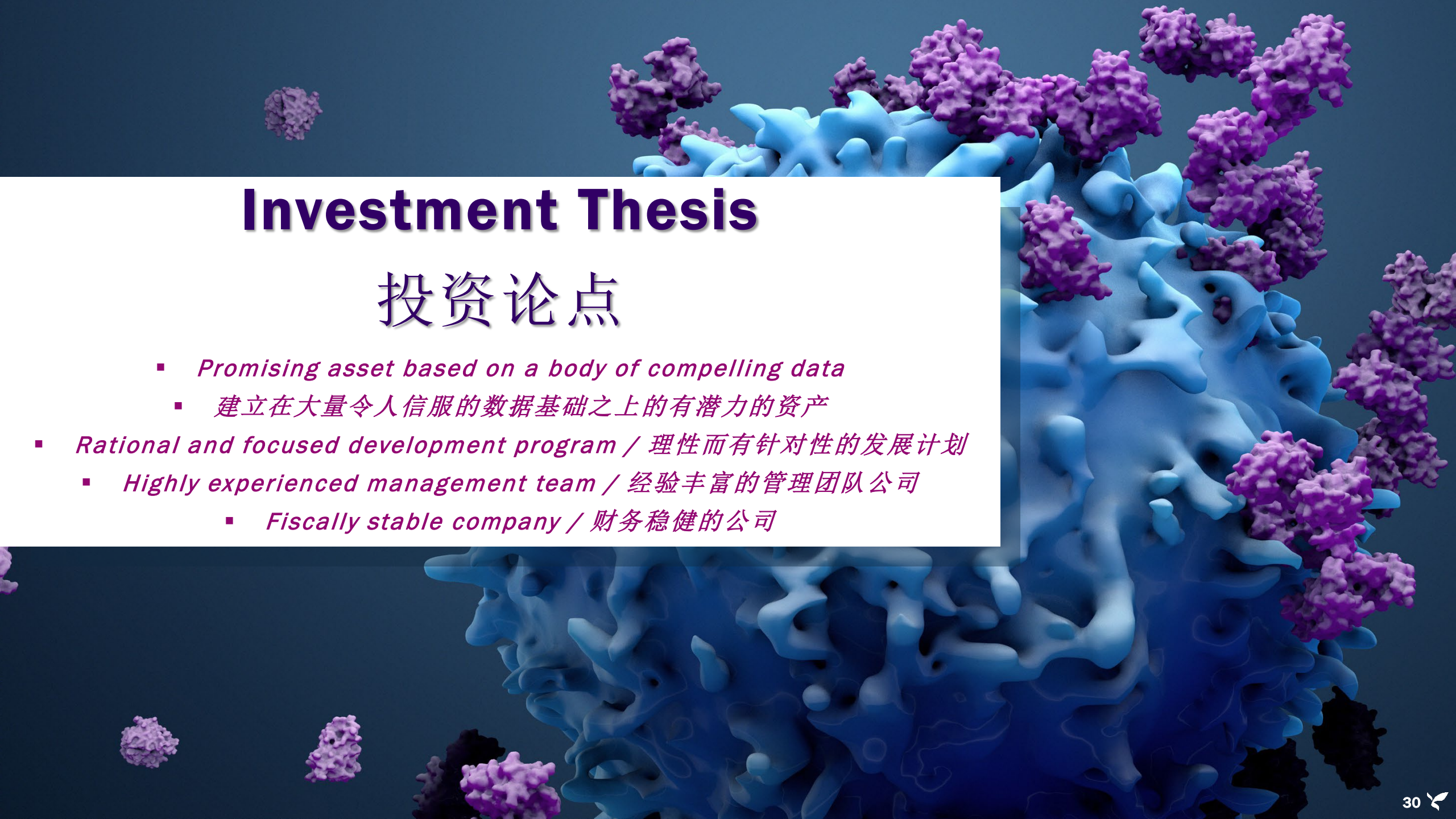
**$0**

## Projected Cash Runway Into
预计现金储备可支持至

**1Q2026**

**2026年第一季度**

| | |
|---|---|
| Common Shares Outstanding (3/31/2024) / 流通的普通股数量 (截止2024年3月31日): | 8.3 million shares<br>830万股 |
| Options Outstanding (3/31/2024)/ 未行权的期权 (截止2024年3月31日):<br>Exercise Price / 行权价格: $0.02 - $4.22 = 1,216,100 shares / 股<br>Exercise Price / 行权价格: > $4.22 = 237,800 shares / 股 | 1.5 million shares<br>150万股 |
| Warrants Outstanding (3/31/2024)/ 未行权的认股权证 (截止2024年3月31日):<br>Weighted Average Exercise Price / 加权平均行使价格: $42.51 | 1.4 million shares<br>140万股 |



# Investment Thesis

# 投资论点

- *Promising asset based on a body of compelling data*
- *建立在大量令人信服的数据基础之上的有潜力的资产*
- *Rational and focused development program / 理性而有针对性的发展计划*
- *Highly experienced management team / 经验丰富的管理团队公司*
- *Fiscally stable company / 财务稳健的公司*

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

## PEOPLE / 团队

Seasoned management with successful international development experience and expertise

经验丰富的管理团队，拥有成功的国际发展经验和专业知识

## INTELLECTUAL PROPERTY 知识产权

Proprietary field-leading technology in underserved global indications

在全球未得到充分服务的适应领域拥有领先的专有技术

## MILESTONES 里程碑

Multiple projected product and business milestones over the next 24 months

预计在未来 24 个月内实现多个产品和业务里程碑

## CAPITAL 资本

$43.3 million cash*- no debt; Development funded through critical data milestones

$4330万现金* - 无债务；通过关键数据里程碑获得开发资金

## PARTNERING 伙伴关系

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

现有合作关系 “验证 ”了平台技术，并有可能建立许多其他合作关系

* As of 3/31/2024; includes investments / 截至2024年3月31日；包括投资

LISATA THERAPEUTICS

# Targeted Therapy *Delivered*

# *递送*靶向疗法


**Investor Relations Contact:**
**投资者关系请联系：**
John D. Menditto
VP, IR & Corporate Communications
投资者关系与企业传播副总裁
o: (908) 842-0084 | e: jmenditto@lisata.com


Nasdaq: LSTA | *www.lisata.com*

# Appendix

# 附录

# Certepetide capital efficient development plan / certepetide资本高效的发展计划

| Development Partner(s) [Development Venue] 开发伙伴[开发地] | Indication and Trial Product/Comparator 适应症和临床试验产品/参照 | Stage of Development 开发阶段 | Strategic Rationale 战略依据 |
|---|---|---|---|
| Lisata/AGITG [Australia/New Zealand] [澳大利亚/新西兰] | **First-line mPDAC / 一线mPDAC;** Gemcitabine/nab-paclitaxel with certepetide or placebo 吉西他滨/白蛋白结合型紫杉醇联合certepetide或安慰剂 | **Phase 2b / 2b阶段 (ASCEND)** | Corroborate Phase 1b results in a placebo-controlled trial and evaluate 2 dose regimens of certepetide for dose optimization 在安慰剂对照试验中证实1b阶段的结果，并评估2种用于优化计量的certepetide剂量方案 |
| Lisata [United States] [美国] | **First- and Second-line Cholangiocarcinoma (CCA) / 一线和二线胆管癌 (CCA);** 1L CCA: Gemcitabine/cisplatin/durvalumab with certepetide or placebo / 一线;吉西他滨/顺铂/德瓦鲁单抗联合certepetide或安慰剂 2L CCA: FOLFOX with certepetide or placebo / 二线：FOLFOX联合certepetide或安慰剂 | **Phase 2a / 2a阶段 (BOLSTER)** | Assess certepetide safety and effectiveness in cholangiocarcinoma in a placebo-controlled trial (Proof-of-Concept) 在安慰剂对照试验中评估certepetide对胆管癌的安全性和有效性（概念验证） |
| KUCC/Lisata* [United States] [美国] | **Pancreatic, Colon & Appendiceal Cancers / 胰腺癌、结肠癌和阑尾癌;** FOLFIRINOX + panitumumab** with certepetide / FOLFIRINOX + 帕尼单抗**，联合certepetide | **Phase 1b/2a / 1b/2a阶段 (CENDIFOX)** | Tumor immuno-profiling pre- & post- treatment and certepetide effectiveness assessment in combination with chemo and an EGFR inhibitor (open label) / 结合化疗和表皮生长因子受体（EGFR）抑制剂进行治疗前和治疗后的肿瘤免疫分析以及Certepetide 疗效评估（开放标签） |
| Qilu [China] 齐鲁制药[中国] | **First-line mPDAC / 一线mPDAC;** Gemcitabine/nab-paclitaxel + certepetide / 吉西他滨/白蛋白结合型紫杉醇联合certepetide | **Phase 1b/2a 1b/2a阶段** | Assess safety, PK and therapeutic effect of certepetide in Chinese patients (open label) / 评估certepetide在中国患者中的安全性、药代动力学和治疗效果（开放标签） |
| WARPNINE/Lisata [Australia] / [澳大利亚] | **Locally Advanced Non-Resectable PDAC / 局部晚期无法切除的PDAC;** Gemcitabine/nab-paclitaxel/durvalumab + certepetide / 吉西他滨/白蛋白结合型紫杉醇/德瓦单抗+certepetide | **Phase 1b/2a / 1b/2a阶段 (ILSTA)** | Assess certepetide safety and effectiveness in combination with IO & Chemo in locally advanced PDAC; determine if inoperable tumors can become operable (open label) / 评估certepetide与免疫疗法和化疗联合应用在局部晚期胰腺导管腺癌（PDAC）中的安全性和有效性；确定是否可以对无法手术的肿瘤进行开刀（开放标签） |
| Tartu University/Lisata* [Estonia/Latvia] [爱沙尼亚/拉脱维亚] | **First-line Glioblastoma Multiforme / 一线多形性胶质母细胞瘤;** Temozolomide +/- certepetide / 替莫唑胺+/-certepetide | **Phase 2a 2a阶段** | Assess certepetide safety and effectiveness in additional tumor type (GBM) in a placebo-controlled trial / 在一项安慰剂对照试验中，评估certepetide对其他肿瘤类型（GBM）的安全性和有效性 |
| Qilu [China] 齐鲁制药 [中国] | **First-line mPDAC / 一线mPDAC;** Gemcitabine/Nab-paclitaxel + certepetide 吉西他滨/白蛋白结合型紫杉醇 +certepetide | **Phase 2b 2a阶段** | Continue development of certepetide in China (placebo controlled) 在中国继续进行certepetide的开发（安慰剂对照） |

**Investigator-initiated trial / 研究者发起的试验*

***Panitumumab may be added for colorectal or appendiceal patients without Ras mutation / 无Ras基因突变的结直肠或阑尾患者可加用帕尼单抗*

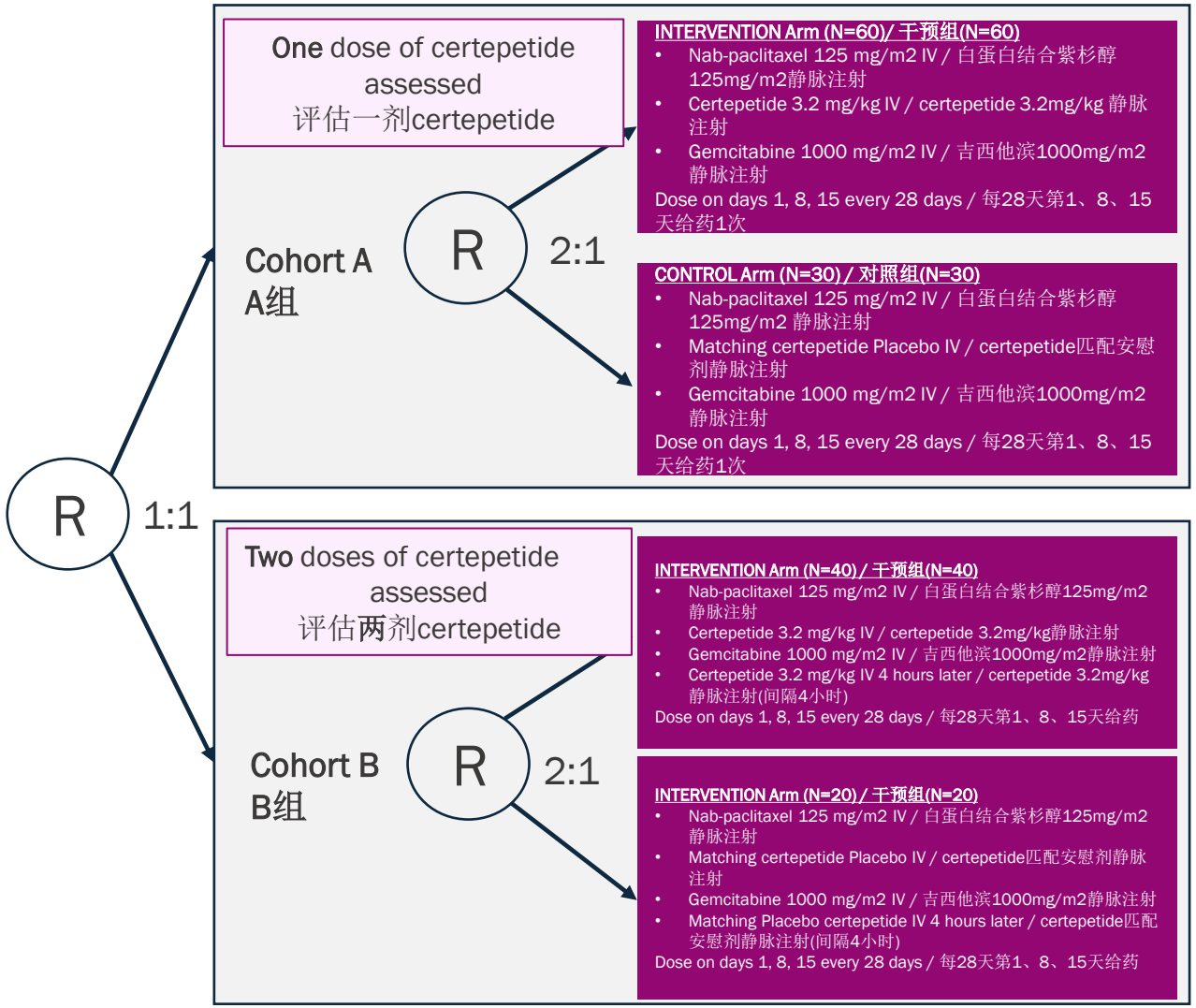
# ASCEND: Phase 2b, blinded, randomized trial in mPDAC
# ASCEND：在mPDAC中进行2b阶段盲法随机分组试验

| | |
|---|---|
| Sponsor/Partner<br>赞助商/合作伙伴 | ▪ Australasian Gastro-Intestinal Trials Group (AGITG) in collaboration with the NHMRC Clinical Trials Centre at the University of Sydney / 澳大利亚胃肠道试验小组与悉尼大学国家健康与医疗研究委员会（NHMRC）临床试验中心合作<br>▪ Lisata funded (LSTA eligible for ~43% rebate on all qualified R&D expenses in AUS)/ Lisata资助（LSTA有资格获得澳大利亚所有合格研发费用~43%的回扣） |
| Objective<br>目标 | ▪ Corroborate Phase 1b results in a placebo-controlled study / 在安慰剂对照研究中验证1b阶段结果<br>▪ Determine if a second dose of certepetide further improves patient outcomes / 确定第二剂量的certepetide是否能进一步改善患者预后 |
| Design<br>设计 | ▪ Phase 2b randomized, double-blind study in mPDAC testing gemcitabine + nab-paclitaxel SoC with one of two certepetide dose regimens or placebo / 在mPDAC中进行的2b期随机双盲研究，测试吉西他滨 +白蛋白结合紫杉醇标准治疗方案与与两种不同剂量的certepetide或安慰剂搭配的结果 |
| Study Size<br>研究规模 | ▪ N=158 (~30 sites in Australia and New Zealand) / 受试者人数为158（澳大利亚和新西兰约30个试验点） |
| Endpoints<br>终点 | ▪ Primary: Progression Free Survival / 主要终点：无进展生存期<br>▪ Secondary: AEs, SAEs, Overall Survival, Objective Tumor Response Rate / 次要终点：不良事件、严重不良事件、总生存期、客观肿瘤缓解率 |
| Timing<br>时间点 | ▪ Enrollment completed December 2023 / 2023年12月完成入组<br>▪ Earliest possible data 4Q24 / 最早可能在 24 年第四季度获得数据 |

# ASCEND: Phase 2b, blinded, randomized trial in mPDAC
# ASCEND：在mPDAC中进行2b阶段盲法随机分组试验

Phase 2b randomized, double-blind study in mPDAC testing gemcitabine + nab-paclitaxel (SoC) with two certepetide dose regimens or placebo

2b期随机、双盲研究，在转移性胰腺导管腺癌(mPDAC)患者中评估吉西他滨+白蛋白结合紫杉醇(标准治疗)联合两种剂量的certepetide或安慰剂的疗效




- Sponsor/Partner: AGITG in collaboration with the NHMRC Clinical Trial Centre at the University of Sydney / 赞助商/合作伙伴：AGITG与悉尼大学NHMRC临床试验中心合作
- LSTA funded / LSTA资助
- Timing: Enrollment completed December 2023; Earliest possible data 4Q24 / 时间安排：2023年12月完成人员招募；最早可能在24年第4季度获得数据

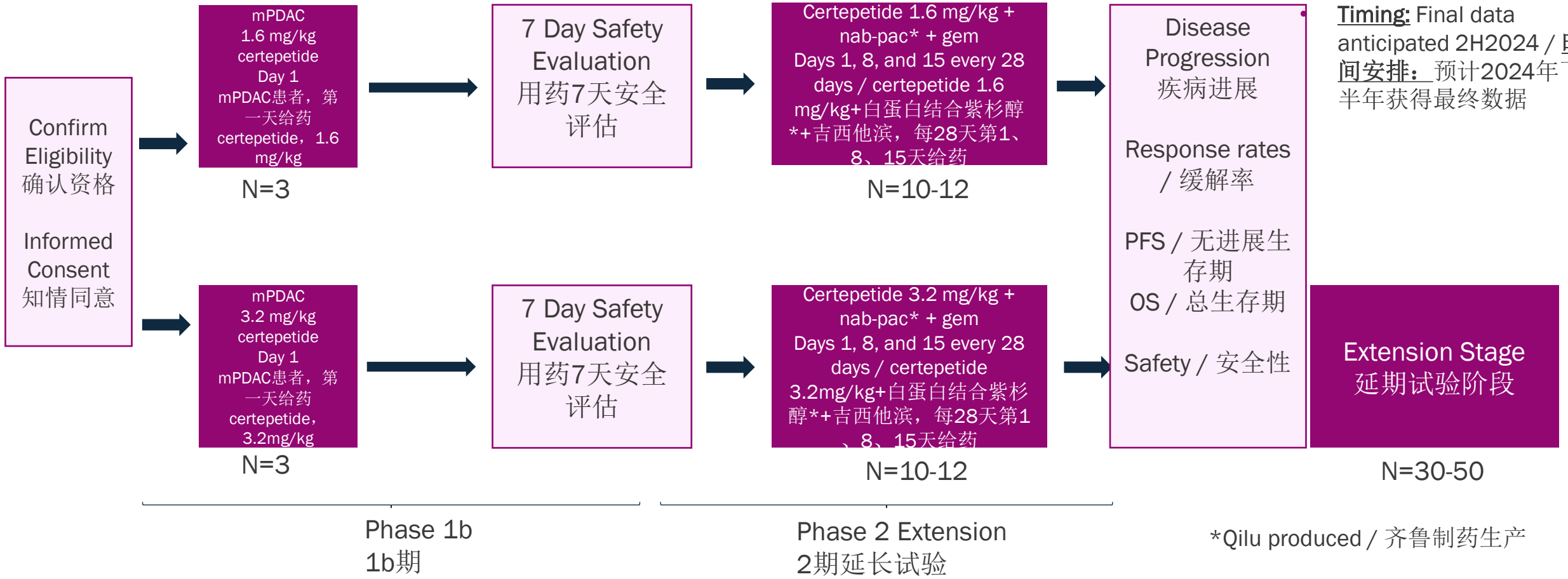
Endpoints / 终点
- Progression Free Survival (PFS) / 无进展生存期（PFS）
- ORR / 客观缓解率
- OS / 总生存期
- Safety / 安全性
- QoL / 生活质量
- Exploratory Endpoints / 探索性终点

# Phase 1b/2a open-label trial in mPDAC in China
# 在中国mPDAC患者中进行的1b/2a期开放标签试验

| | |
|---|---|
| **Sponsor/Partner**<br>**赞助商/合作伙伴** | ▪ Qilu Pharmaceutical (funds all development in China) / 齐鲁制药（资助在中国的所有开发项目） |
| **Objective**<br>**目标** | ▪ Evaluate safety, pharmacokinetics and preliminary efficacy of certepetide added to SoC in Chinese patients with mPDAC / 评估certepetide联合标准治疗方案在中国转移性胰腺导管腺癌(mPDAC)患者中的安全性、药代动力学和初步疗效 |
| **Design**<br>**设计** | ▪ Phase 1b/2a open-label study in advanced mPDAC patients of Chinese ethnicity testing SoC chemotherapy (gemcitabine + Qilu-produced nab-paclitaxel) in combination with certepetide / 1b/2a期开放标签研究，评估在中国晚期转移性胰腺导管腺癌(mPDAC)患者中标准化疗(吉西他滨+齐鲁制药生产的白蛋白结合紫杉醇)联合certepetide的安全性和疗效 |
| **Study Size**<br>**研究规模** | ▪ N=50 (~15 sites) / 人数为50人（约15个试验点） |
| **Endpoints**<br>**终点** | ▪ Primary: AEs, SAEs, Objective Response Rate, Duration of Response, Disease Control Rate, Overall Survival, and Progression Free Survival / 主要终点：不良事件、严重不良事件、客观缓解率、缓解持续时间、疾病控制率、总生存期和无进展生存期<br>▪ Secondary: Pharmacokinetic parameters / 次要终点：药代动力学参数 |
| **Timing**<br>**时间点** | ▪ Final data anticipated 2H2024 / 预计在2024年下半年得到最终数据 |

# Phase 1b/2a open-label trial in mPDAC in China
# 在中国mPDAC患者中进行的1b/2a期开放标签试验

**Phase 1b/2a study evaluating the safety, pharmacokinetics, and preliminary efficacy of certepetide for injection in Chinese patients with advanced metastatic pancreatic ductal adenocarcinoma / 1b/2a期研究，评估注射certepetide在中国晚期转移性胰腺导管腺癌患者中的安全性、药代动力学和初步疗效**




- **Sponsor/Partner:** Qilu Pharmaceutical (funds all development in China) / **赞助商/合作伙伴**：齐鲁制药（资助在中国的所有开发项目）
- **Timing:** Final data anticipated 2H2024 / **时间安排：** 预计2024年下半年获得最终数据

*Qilu produced / 齐鲁制药生产

# CENDIFOX: Phase 1b/2a open-label trial in PDAC and other cancers
# CENDIFOX：1b/2a期开放标签试验，评估在PDAC及其他癌症中的疗效

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|---|---|
| **Sponsor/Partner**<br>**赞助商/合作伙伴** | ▪ University of Kansas Medical Center (Investigator initiated trial in U.S.) / 堪萨斯大学医学中心（研究者在美国发起的试验）<br>▪ KUCC funded; Lisata provides certepetide / 试验由堪萨斯大学癌症中心资助，Lisata提供certepetide |
| **Objective**<br>**目标** | ▪ Evaluate the safety and therapeutic effect of certepetide in combination with neoadjuvant FOLFIRINOX-based therapies and an EGFR inhibitor for the treatment of pancreatic, colon and appendiceal cancers and determine immuno-profiling in tumor pre- & post- treatment / 评估certepetide与新辅助FOLFIRINOX为基础的疗法及EGFR抑制剂联合用于治疗胰腺癌、结肠癌和阑尾癌的安全性和疗效，并确定治疗前后肿瘤免疫状况的变化 |
| **Design**<br>**设计** | ▪ Phase 1b/2a open-label study in resectable pancreatic, colon with oligo metastases and appendiceal with peritoneal metastases cancers testing SoC chemotherapy (neoadjuvant FOLFIRINOX-based therapies) with certepetide ± panitumumab / 1b/2a期开放标签研究，评估可切除胰腺癌、少数转移灶结肠癌和腹膜转移阑尾癌患者接受标准化疗(新辅助FOLFIRINOX为基础的疗法)联合certepetide±帕尼单抗的疗效和安全性 |
| **Study Size**<br>**研究规模** | ▪ N=51 (21 PDAC, 15 colon and 15 appendiceal) / 人数为51人（其中胰腺癌21例、结肠癌15例、阑尾癌15例） |
| **Endpoints**<br>**终点** | ▪ Primary: Drug Safety / 主要终点：药物安全性<br>▪ Secondary: Overall Survival, Disease-free Survival, Overall Response Rate, RO Resection Rate, Pathological Response Rate / 次要终点：总生存期、无病生存期、总缓解率、R0切除率、病理缓解率 |
| **Timing**<br>**时间点** | ▪ Enrollment completion target 4Q24 / 目标是在2024年第4季度完成入组工作 |

# CENDIFOX: Phase 1b/2a open-label trial in PDAC and other cancers
# CENDIFOX：1b/2a期开放标签试验，评估在PDAC及其他癌症中的疗效

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

1b/2a期开放标签试验，评估certepetide联合新辅助FOLFIRINOX为基础的疗法在胰腺癌、结肠癌和阑尾癌患者中的疗效和安全性(CENDIFOX)

- **COHORT 1 / 第一组**
  Resectable and borderline resectable PDAC
  可切除和边缘可切除的PDAC
- **COHORT 2 / 第二组**
  Colon and appendiceal cancer with peritoneal mets
  结肠癌和阑尾癌伴腹膜转移
- **COHORT 3 / 第三组**
  Colon cancer with oligo metastatic disease / 少数转移灶的结肠癌

Tissue immune profiling 组织免疫分析

Biopsy if archival tissue not available 如果没有档案组织，则需要进行活检

**FOLFIRINOX X 3 Cycles FOLFIRINOX连用3个疗程**

(± Panitumumab if RAS/BRAF wildtype - Cohorts 2, 3 / 如果是RAS/BRAF野生型，则±帕尼单抗 - 第二组、第三组)

Repeat Biopsy ~72 hours after C3D1 tx 重复活检 在第3个疗程第1天给药约72小时后

Tissue immune profiling 组织免疫分析

**FOLFIRINOX**
(± Panitumumab if RAS/BRAF wildtype - Cohorts 2, 3)
**+ Certepetide X 3, 6, or 9 Cycles**
（如果是RAS/BRAF野生型，则±帕尼单抗–第2、3组）
**+certepetide 3、6或9个周期**

Surgery 手术治疗

**Resume**
Standard of Care
**恢复**
标准疗法

- **Sponsor/Partner:** University of Kansas Medical Center (ITT) / **赞助商/合作伙伴**：堪萨斯大学医学中心（ITT）
- **KUCC funded:** Lisata provides certepetide / **KUCC 资助**： Lisata提供certepetide
- **Timing:** Enrollment completion target 4Q24 / **时间安排**：目标是24年第4季度完成入组

Key Objectives: / 主要目标：
- Pathological response / 病理反应
- Immune response pre- & post-treatment / 治疗前后的免疫反应
- PFS, OS / 无进展生存期、总生存期

# BOLSTER: Phase 2 blinded, randomized trial in Cholangiocarcinoma
# BOLSTER：在胆管癌患者中的2期盲法随机试验

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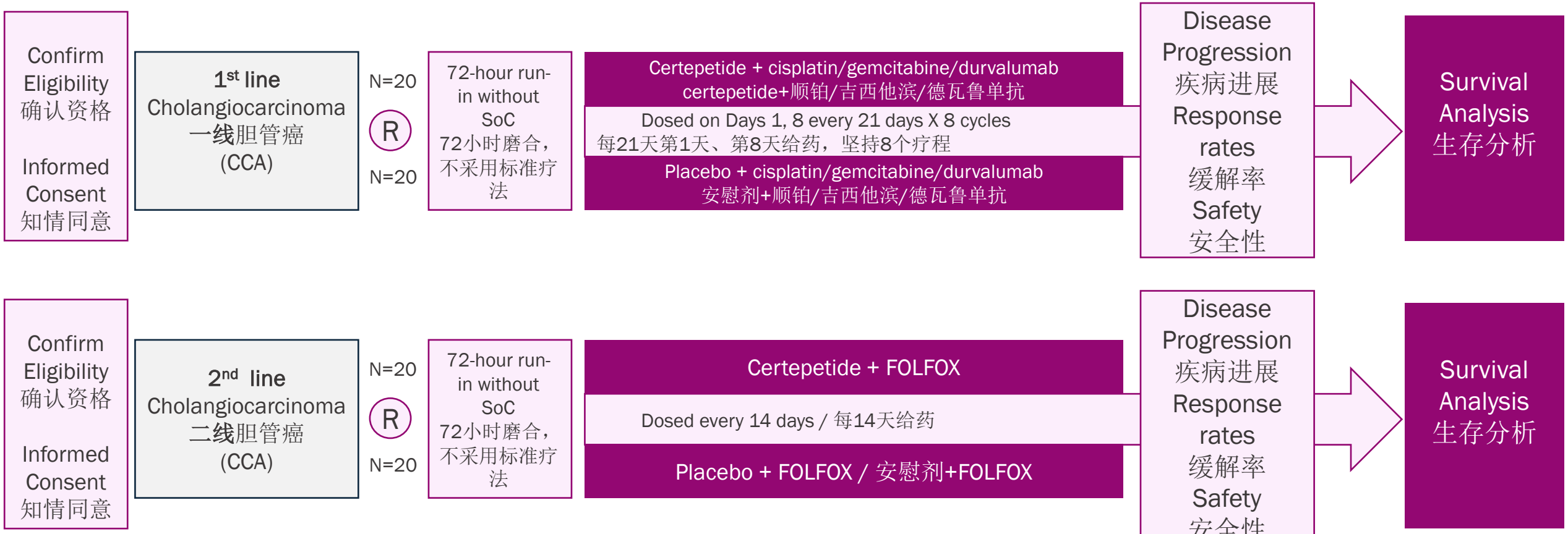
| **Sponsor/Partner**<br>**赞助商/合作伙伴** | ▪ Lisata (U.S./ 美国) |
| **Objective**<br>**目标** | ▪ Evaluate the preliminary efficacy, safety and tolerability of certepetide in combination with standards of care in subjects with first- and second-line cholangiocarcinoma / 评估certepetide联合标准治疗在一线和二线胆管癌患者中的初步疗效、安全性和耐受性 |
| **Design**<br>**设计** | ▪ Phase 2 randomized, double-blind, placebo-controlled, proof-of-concept trial in first- and second-line cholangiocarcinoma testing corresponding SoC with certepetide or placebo / 2期随机、双盲、安慰剂对照的概念验证性试验，在一线和二线胆管癌患者中评估certepetide联合相应标准治疗方案与安慰剂联合标准治疗方案的疗效 |
| **Study Size**<br>**研究规模** | ▪ N=80 (N=40 per tumor type) / 人数为80(每种肿瘤类型各40例)<br>▪ 1:1 SoC + certepetide or SoC + placebo / 人数为80(每种肿瘤类型各40例) 1:1随机分配到标准疗法+certepetide组或标准疗法+安慰剂组 |
| **Endpoints**<br>**终点** | ▪ Primary: OS / 主要终点：总生存期（OS）<br>▪ Secondary: Safety, ORR, PFS / 次要终点：安全性、客观缓解率(ORR)、无进展生存期(PFS) |
| **Timing**<br>**时间点** | ▪ Enrollment completed for 1L CCA / 一线胆管细胞癌(CCA)的入组工作已经完成<br>▪ Enrollment anticipated July 2024 for 2L CCA / 二线胆管细胞癌(CCA)的入组预计将于2024年7月开始 |

# BOLSTER: Phase 2 blinded, randomized PoC trial in various cancers
# BOLSTER：在各种癌症中进行2期盲法、随机PoC试验

- Sponsor / 赞助商: Lisata
- Timing / 时间安排:
  - Enrollment completed for 1L CCA / 一线胆管癌招募已完成
  - Enrollment anticipated July 2024 for 2L CCA / 预计2024年7月进行二线胆管癌招募

**Phase 2a, double-blind, placebo-controlled, multi-center, randomized study evaluating certepetide when added to standard of care (SoC) versus standard of care alone in subjects with first- and second-line cholangiocarcinoma**
**2a期、双盲、安慰剂对照、多中心、随机研究，评估将certepetide添加到标准疗法（SoC）与仅采用标准疗法相比，在一线和二线胆管癌患者中的疗效**



# Phase 2 double-blind, placebo-controlled trial in mPDAC in China
# 在中国mPDAC患者中进行2期双盲安慰剂对照试验

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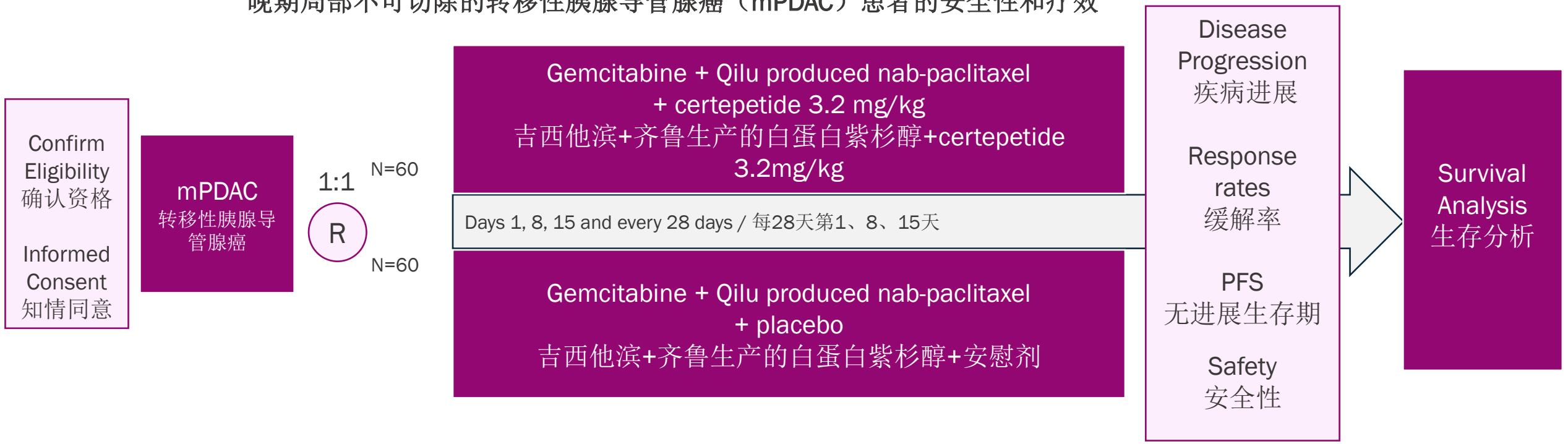
| **Sponsor/Partner**<br>**赞助商/合作伙伴** | ▪ Qilu Pharmaceutical (funds all development in China) / 齐鲁制药（资助在中国的所有开发项目） |
| **Objective**<br>**目标** | ▪ Further evaluate safety and therapeutic efficacy of certepetide when added to SoC in Chinese patients with locally advanced unresectable mPDAC / 在中国的局部晚期不可切除mPDAC患者中进一步评估certepetide联合标准治疗方案的安全性和治疗有效性 |
| **Design**<br>**设计** | ▪ Phase 2b, double-blind, placebo-controlled, randomized study evaluating certepetide + SoC (Qilu-produced nab-paclitaxel and gemcitabine) vs. placebo + SoC / 2b期、双盲、安慰剂对照、随机研究，评估certepetide联合标准治疗方案(齐鲁制药生产的白蛋白结合紫杉醇和吉西他滨)与安慰剂联合标准治疗方案的疗效 |
| **Study Size**<br>**研究规模** | ▪ N=120 (1:1 SoC + certepetide or SoC + placebo) / 人数为120人(1:1随机分配到标准疗法+certepetide组或标准疗法+安慰剂组) |
| **Endpoints**<br>**终点** | ▪ Objective response rate, progression free survival, duration of response, disease control rate, overall survival / 客观反应率、无进展生存期、反应持续时间、疾病控制率、总生存期<br>▪ Safety / 安全性 |
| **Timing**<br>**时间点** | ▪ Trial initiated 2Q24 / 2024年第二季度启动试验 |

# Phase 2 blinded, placebo-controlled trial in mPDAC in China
# 在中国mPDAC患者中进行2期双盲安慰剂对照试验

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

2b期，双盲，安慰剂对照，随机，多中心研究，评估certepetide与标准疗法（白蛋白型紫杉醇和吉西他滨）结合，对比单独采用标准疗法和安慰剂，对中国晚期局部不可切除的转移性胰腺导管腺癌（mPDAC）患者的安全性和疗效

- **Sponsor/Partner:** Qilu Pharmaceutical (funds all development in China) / **赞助商/合作伙伴：** 齐鲁制药（资助在中国的所有开发项目）
- **Timing:** Trial initiated 2Q24 / **时间安排：** 24年第二季度启动临床试验



# iLSTA: Phase 1b/2a trial in locally advanced PDAC with chemo & IO
# iLSTA：在局部晚期胰腺导管腺癌(PDAC)中的化疗和免疫治疗1b/2a期试验

| | |
|---|---|
| **Sponsor/Partner**<br>**赞助商/合作伙伴** | ▪ WARPNINE, Inc. (registered charity in Australia) is funding trial / WARPNINE, Inc.（澳大利亚注册慈善机构）在资助试验<br>▪ Lisata providing study drug / Lisata提供研究药物 |
| **Objective**<br>**目标** | ▪ 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 / 评估LSTA1联合免疫治疗和化疗在局部晚期不可切除胰腺导管腺癌(PDAC)中的安全性和治疗效果;确定是否可以对不可切除的肿瘤开刀 |
| **Design**<br>**设计** | ▪ 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 / 1b/2a期概念验证性研究,旨在评估LSTA1联合德瓦鲁单抗、吉西他滨和白蛋白结合紫杉醇作为局部晚期不可切除胰腺腺癌一线治疗的安全性和初步疗效 |
| **Study Size**<br>**研究规模** | ▪ N=30 / 人数为30人 |
| **Endpoints**<br>**终点** | ▪ Safety and tolerability; 28-day DLTs / 安全性和耐受性;28天剂量限制性毒性<br>▪ Objective response rate, PFS, OS, duration of response, immune cell infiltration / 客观缓解率、无进展生存期、总生存期、缓解持续时间、免疫细胞浸润 |
| **Timing**<br>**时间点** | ▪ Enrollment commenced April 2023 / 2023年4月开始招募 |

# iLSTA: Phase 1b/2a trial in locally advanced PDAC with chemo & IO
# iLSTA：在局部晚期胰腺导管腺癌(PDAC)中的化疗和免疫治疗1b/2a期试验

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 / LSTA1与德瓦鲁单抗、吉西他滨和白蛋白紫杉醇联合治疗局部晚期不可切除胰腺导管腺癌的1b/2a期临床安全性和早期疗效验证研究

Randomize / 随机进行

**Cohort 1 / 第一组**
Gemcitabine + nab-paclitaxel + Placebo LSTA1 + Placebo durvalumab
N=5 / 吉西他滨+白蛋白结合紫杉醇+安慰剂 LSTA1+安慰剂德瓦鲁单抗
人数为5

**Cohort 2 / 第二组**
Gemcitabine + nab-paclitaxel + LSTA1 + Placebo durvalumab
N=5 / 吉西他滨+白蛋白结合紫杉醇+LSTA1+安慰剂德瓦鲁单抗
人数为5

**Cohort 3 / 第三组**
Gemcitabine + nab-paclitaxel + LSTA1 + durvalumab
N=up to 20 / 吉西他滨+白蛋白结合紫杉醇 +LSTA1+德瓦鲁单抗
人数最多可达20

Primary Endpoint 主要终点

12 weeks / 12周

EUS Biopsy
Screening
胃肠道超声活检筛查

12 month
Follow-up
12个月随访

24 months
Follow-up completion
24 个月完成随访

8 weeks tumor burden assessments until 24 months or recurrence / 8周肿瘤负荷评估，一直至24个月或复发

EUS & Biopsy
At weeks 12-16
第12-16周进行内镜超声和活检

Tumor burden assessment at screening, cycle 2, and then 8-weekly thereafter.
Patients are treated with 28-day cycles until surgery, definitive radiotherapy, unacceptable toxicity, progression or death
Endpoints: safety, DLT, ORR, PFS, OS, DoR, immune profiling
肿瘤负荷评估在第二个疗程筛查时进行，然后每8周进行一次。 患者接受28天为一周期的治疗，直至手术、明确放疗、无法接受的毒性、疾病进展或死亡。 终点：安全性、最大耐受剂量（DLT）、总体缓解率（ORR）、无进展生存期（PFS）、总生存期（OS）、持续缓解时间（DoR）、免疫特征分析

- Sponsor / 赞助商: WARPNINE, Inc. - funding trial / 为试验提供资金
- Timing / 时间安排: Enrollment commenced April 2023 / 2023年4月开始人员入组

# Phase 2a trial of certepetide with SoC in first-line GBM
# 2a期试验评估certepetide联合标准疗法在一线胶质母细胞瘤(GBM)中的疗效

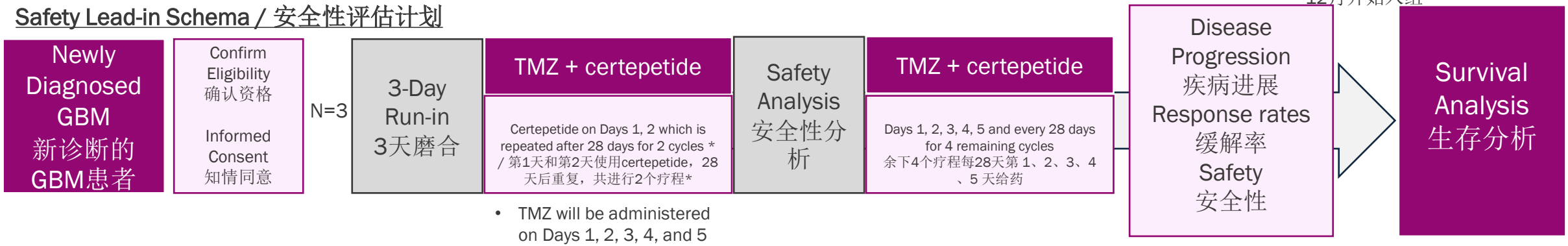
| | |
|---|---|
| **Sponsor/Partner**<br>**赞助商/合作伙伴** | ▪ Tartu University Hospital (Investigator initiated trial in Estonia)/ 塔图大学医院（研究者在爱沙尼亚发起的试验）<br>▪ Lisata providing study drug and funding trial / Lisata提供研究药物并资助试验 |
| **Objective**<br>**目标** | ▪ Evaluate safety, tolerability, and therapeutic effect of certepetide in combination with standard-of-care (temozolomide) in patients with previously untreated Glioblastoma Multiforme / 评估certepetide联合标准疗法（替莫唑胺）在初次治疗胶质母细胞瘤患者中的安全性、耐受性和治疗效果 |
| **Design**<br>**设计** | ▪ Phase 2a proof-of-concept, double-blind, placebo-controlled, randomized study evaluating certepetide when added to standard of care (temozolomide) versus SoC and placebo in subjects with newly diagnosed Glioblastoma Multiforme (GBM)/ 2a期概念验证、双盲、安慰剂对照、随机研究，评估在新诊断的胶质母细胞瘤(GBM)患者中，certepetide联合标准治疗(替莫唑胺)与标准治疗加安慰剂相比的疗效 |
| **Study Size**<br>**研究规模** | ▪ N=30 total (N=3 safety run-in, N=18 in main study schema)<br>▪ 总共30例受试者(其中3例为安全性试验阶段,18例为主研究方案阶段) |
| **Endpoints**<br>**终点** | ▪ Safety, tolerability / 安全性、耐受性<br>▪ ORR, PFS, OS, disease control rate / 客观缓解率、无进展生存期、总生存期、疾病控制率 |
| **Timing**<br>**时间点** | ▪ Enrollment commenced December 2023 / 2023年12月开始招募 |

# Phase 2a trial of certepetide with SoC in first-line GBM
# 2a期试验评估certepetide联合标准疗法在一线胶质母细胞瘤(GBM)中的疗效

Phase 2a proof-of-concept double-blind, placebo-controlled, randomized, proof-of-concept study evaluating certepetide when added to standard of care (temozolomide) versus temozolomide and matching certepetide placebo in subjects with newly diagnosed GBM / 2a期概念验证双盲、安慰剂对照、随机的概念验证研究，评估将certepetide加入标准疗法（替莫唑胺）与替莫唑胺和相匹配的certepetide安慰剂对比，在新诊断的胶质母细胞瘤（GBM）患者中的疗效

- Sponsor / 赞助商: Tartu University Hospital; Estonia / 塔尔图大学医院 爱沙尼亚
- Funding / 资金支持: Lisata
- Timing / 时间安排: Enrollment commenced December 2023 / 2023年12月开始入组

## Safety Lead-in Schema / 安全性评估计划




- TMZ will be administered on Days 1, 2, 3, 4, and 5 of each cycle / 每个疗程的第1、2、3、4和5天使用替莫唑胺

## Main Study Schema / 主要研究计划