

加科思药业2025年中期业绩报告

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核心项目最新进展

1

JAB-23E73 Pan-KRAS抑制剂

- 中、美I期爬坡试验进行中，目前已进入有效剂量范围；
- 临床数据显示**安全可耐受**，未观察到剂量限值毒性（DLT）及3级以上的主要脏器功能毒性，同类药常见的皮肤毒性在本研究中少见（10%），且均为1级；**PK特征良好**，符合临床前结果的预期，已观察到**多个PR**的病例。

2

SHP2抑制剂 + 戈来雷塞

- 戈来雷塞2L NSCLC 在中国获批上市，在2024年首付款2亿元基础上，于2025年5月触发了5000万元人民币里程碑收款；
- 戈来雷塞2L NSCLC 注册性临床数据见刊《自然医学》（*Nature Medicine* IF:50）；
- 一线NSCLC注册三期临床在中国进行中；
- SHP2抑制剂Sitneprotafib转化研究多个联合用药数据发表于《临床肿瘤研究》（*Clinical Cancer Research* IF: 10.2）；
- 联合用药的I/II期临床数据被顶级学术期刊接收，即将在2025 H2发表。

3

JAB-BX600 (tADC) - EGFR抗体偶联的KRAS G12D抑制剂载荷 (First-in-Class)

- 采用超高活性的KRAS G12D抑制剂作为Payload，使用EGFR抗体做递送，发挥抗体的协同作用，抗肿瘤作用更持久；
- JAB-BX600已确定临床候选分子（PCC），细胞活性**皮摩尔（pM）级别**，预计2026 H2 IND。

4

JAB-BX467 (iADC) - HER2抗体偶联的STING激动剂载荷

- STING激动剂使“冷肿瘤”转化为“热肿瘤”，解决70%PD-1无效的冷肿瘤临床未满足需求；
- JAB-BX467 已确定临床候选分子（PCC），IND-enabling阶段，预计2026 H2 IND。

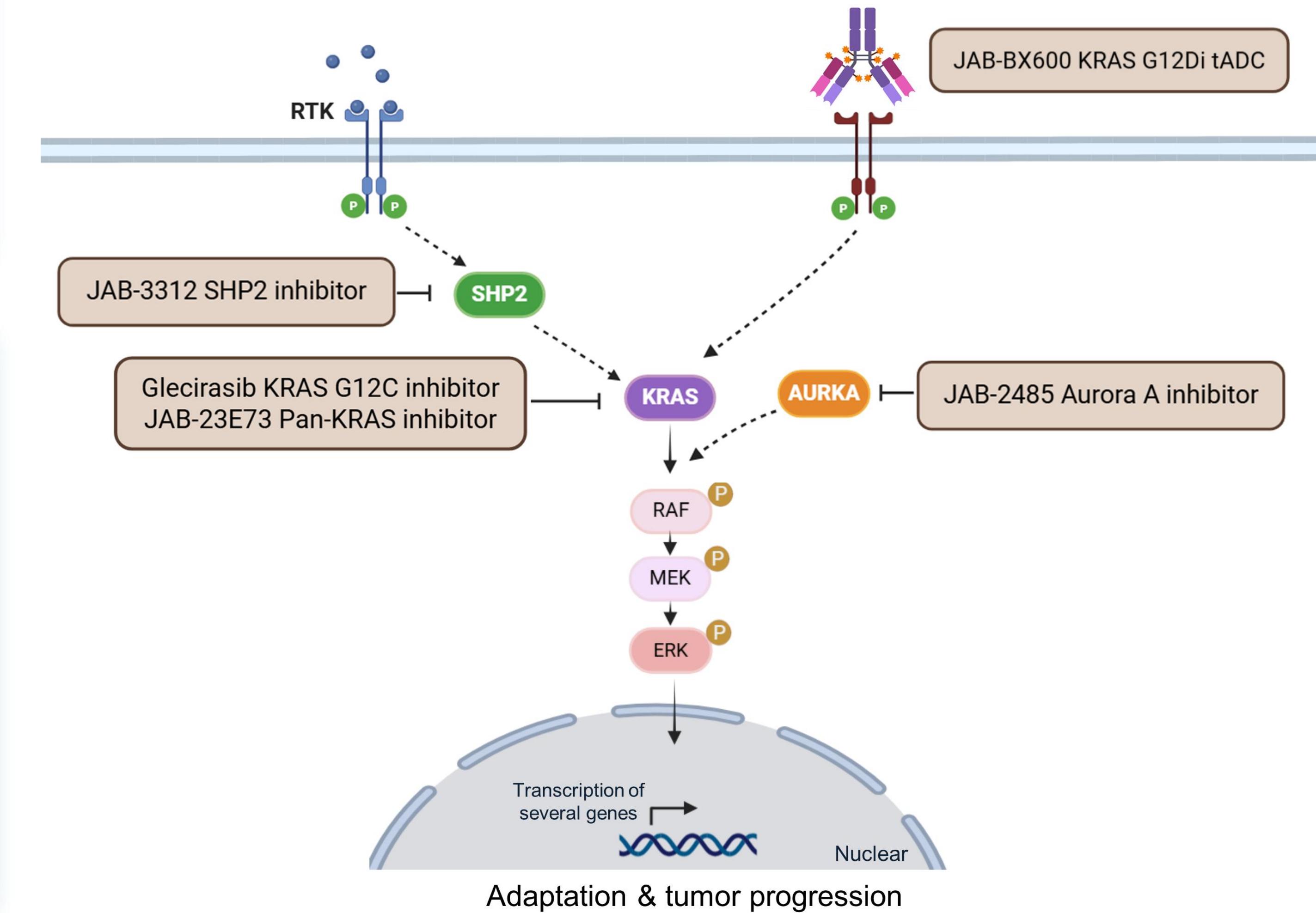
加科思核心产品管线布局（一）：聚焦KRAS信号通路

临床阶段产品 (第一代)

- 戈来雷塞
(JAB-21822 KRAS G12C抑制剂, **NDA获批**)
- JAB-23E73 Pan-KRAS抑制剂, Phase I

临床前研发产品 (第二代) (First-in-Class tADC)

- JAB-BX600 (tADC): 以KRAS G12D抑制剂为载荷, 靶向EGFR的新一代抗体偶联药物
(已确定PCC, 预计2026 H2 IND)
- 其他以KRAS抑制剂为载荷的其他单克隆/双特异性抗体偶联药物

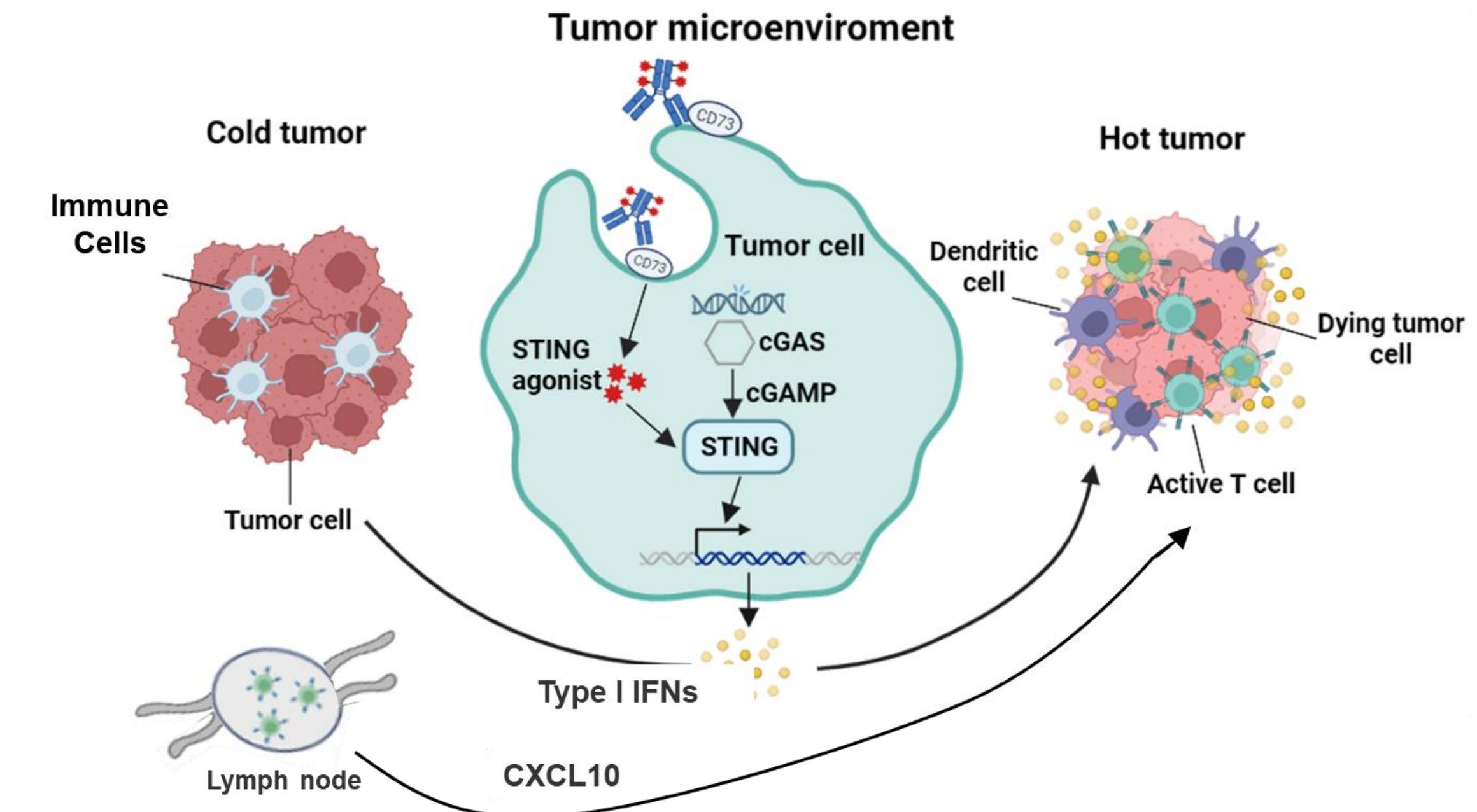


加科思核心产品管线布局（二）：iADC肿瘤免疫2.0

iADC: 肿瘤免疫2.0

- 70%以上的肿瘤患者对PD-1单药无响应（冷肿瘤）
 - 依托小分子药物设计优势，创新性地将特异性STING激动剂作为iADC的载荷（payload），实现肿瘤微环境（TME）免疫细胞浸润，将冷肿瘤转变为热肿瘤，解决冷肿瘤对PD-1单药无响应的治疗困境
 - STING相关研究获2024年拉斯克医学奖（Lasker Medical Research Awards）
-
- iADC: HER2抗体偶联的STING激动剂载荷（Payload） JAB-BX467 IND - enabling阶段，预计2026年H2 IND
 - 其他抗体偶联iADC

iADC促进免疫细胞浸润到TME，激活肿瘤免疫



产品管线布局：核心管线进度全球前三

项目	靶点	适应症	早期研发	IND	临床一期	临床二期	临床三期
JAB-3312*/Glecirasib	SHP2/KRAS G12 C	1L NSCLC					注册临床
Glecirasib*		2L NSCLC					批准上市
		2L 泛瘤种**					注册临床
	KRAS G12C	CRC					注册临床
JAB-23E73		实体瘤			CN/US		
JAB-BX600 (tADC)	pan-KRAS	实体瘤					
JAB-BX700 (tADC)	EGFR/KRAS G12	实体瘤					
JAB-30355	D	实体瘤			CN/US		
JAB-8263	Undisclosed	实体瘤、血液瘤			CN/US		
JAB-2485	ADC	实体瘤			CN/US		
JAB-BX467 (iADC)	P53 Y220C	实体瘤					

• 戈来雷塞及JAB-3312的中国权益于2024年8月30日授权给艾力斯

• **泛瘤种：除NSCLC, CRC以外的其他癌种，如胰腺癌，胆道癌，胃癌，小肠癌，阑尾癌，宫颈癌，头颈癌，卵巢癌，滑膜肉瘤，纵隔肿瘤等

Aurora A

HER2/STING

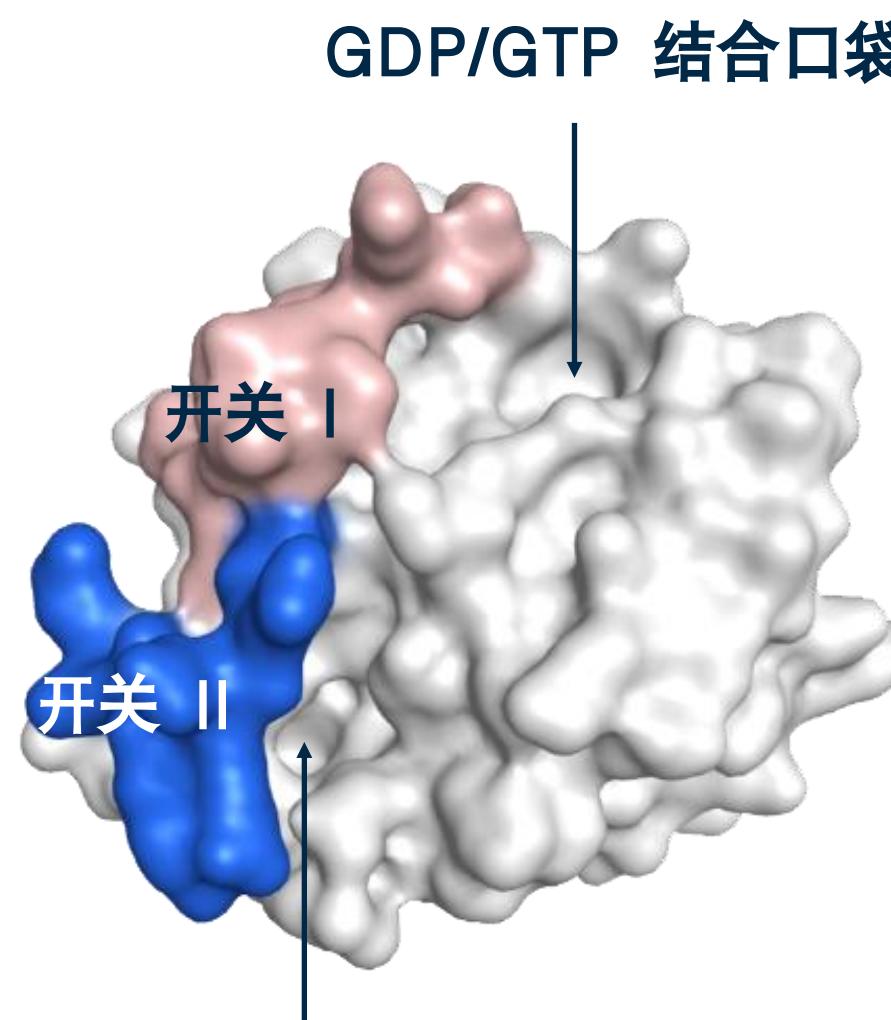
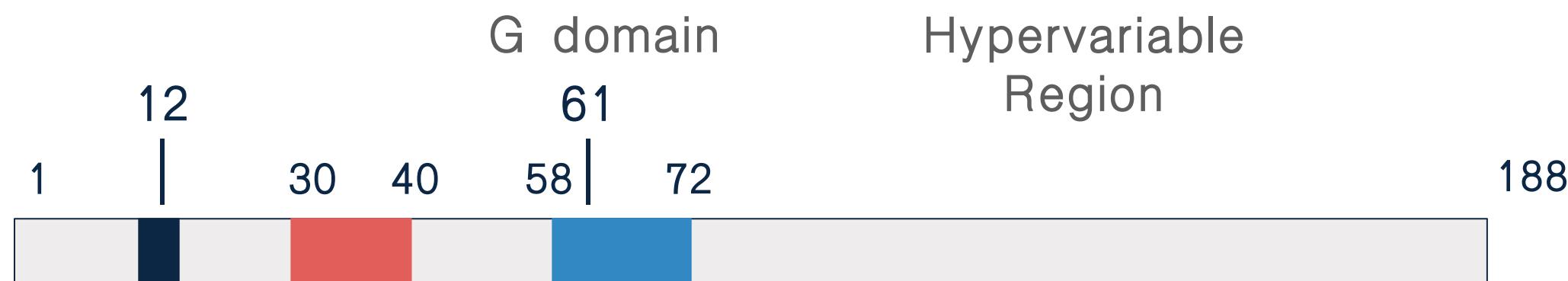
01

我们的管线

泛KRAS抑制剂的开发

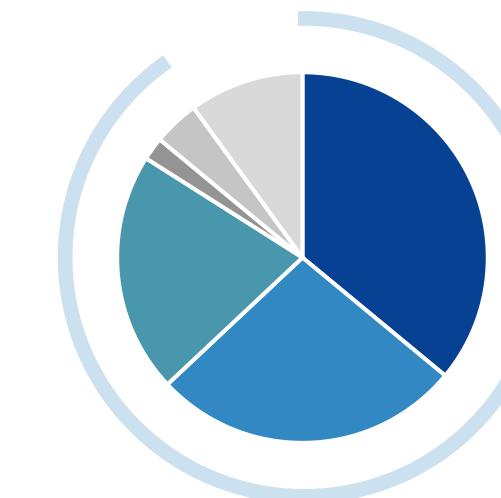
- 25%的人类癌症带有KRAS突变¹
- 每年全球有2,700,000的带有KRAS突变的新增病例²
- 全球销售峰值约200亿美元⁴

KRAS的结构³

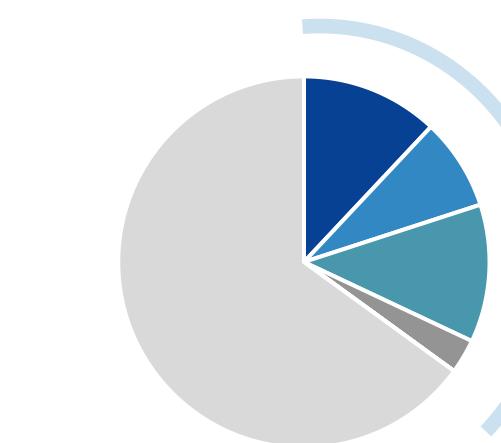


泛KRAS抑制剂结合口袋

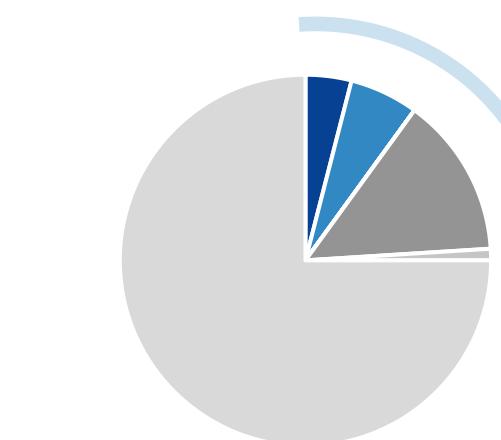
Image prepared by VMD 1.9.3



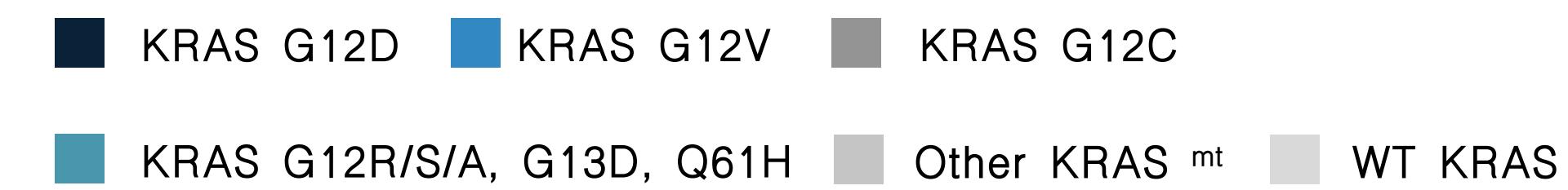
PDAC	
KRAS ^{mt} total	~ 90%
KRAS G12D	~ 36%
KRAS G12R/S/A, G13D, Q61H	~ 36%
KRAS G12V	~ 27%
KRAS G12C	~ 2%



CRC	
KRAS ^{mt} total	~ 35%
KRAS G12D	~ 12%
KRAS G12V	~ 8%
KRAS G12R/S/A, G13D, Q61H	~ 12%
KRAS G12C	~ 3-4%



NSCLC	
KRAS ^{mt} total	~ 10%-25%
KRAS G12D	~4%
KRAS G12V	~6%
KRAS G12C	~14%



1. *npj Precis. Onc.* 6, 91 (2022).

2. Numbers are estimated using the data from Estimated number of new cases in 2020, International Agency for Research on Cancer, World Health Organization

3. KRAS sequence from *Comput Struct Biotechnol J.* 2019 Dec 26;18:189-198.

4. 据EvaluatePharma预测, 到2030年KRAS抑制剂市场规模将突破200亿美元。

泛KRAS抑制剂竞争格局

进入临床阶段的泛KRAS抑制剂

分子胶 (H/N/KRAS抑制剂)

- RMC-6236: Revolution, ph3

小分子 (KRAS 抑制剂)

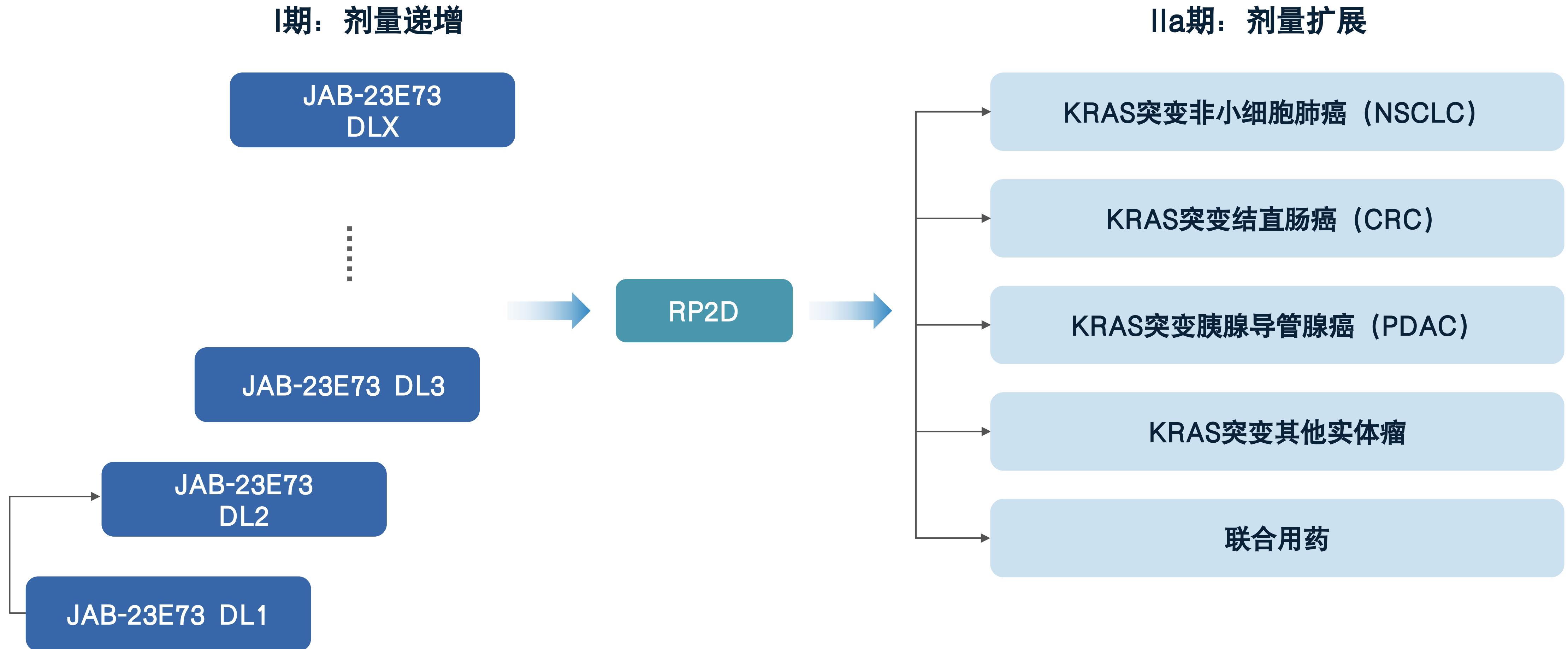
截止2025年6月 Key Players

- JAB-23E73: 加科思, ph1 (2024.9)**
- LY4066434: Eli Lilly, ph1 (2024.10)
- BGB-53038: 百济, ph1 (2024.11)
- ALTA-3263: Alterome, ph1 (2025.3)
- BBO-11818: BridgeBio, ph1 (2025.4)
- PF-07985045: Pfizer, ph1 (2025.6)

Pan-KRAS进临床的专利申请数量及时间对比

申请人	有效优先权数 (件)	最早优先权日	PCT专利申请数
加科思	87	2021-08-18	10
BI	8	2021-12-01	5
BMS (Mirati)	21	2022-02-13	7
Pfizer	15	2022-07-05	4
百济	13	2022-03-04	4
Alterome	11	2023.2.24	3
BridgeBio	5	2022.2.8	5

JAB-23E73在实体瘤中的临床试验



JAB-23E73治疗案例

JAB-23E73首次人体研究（编号：JAB-23E73-1001）在中国和美国进行中

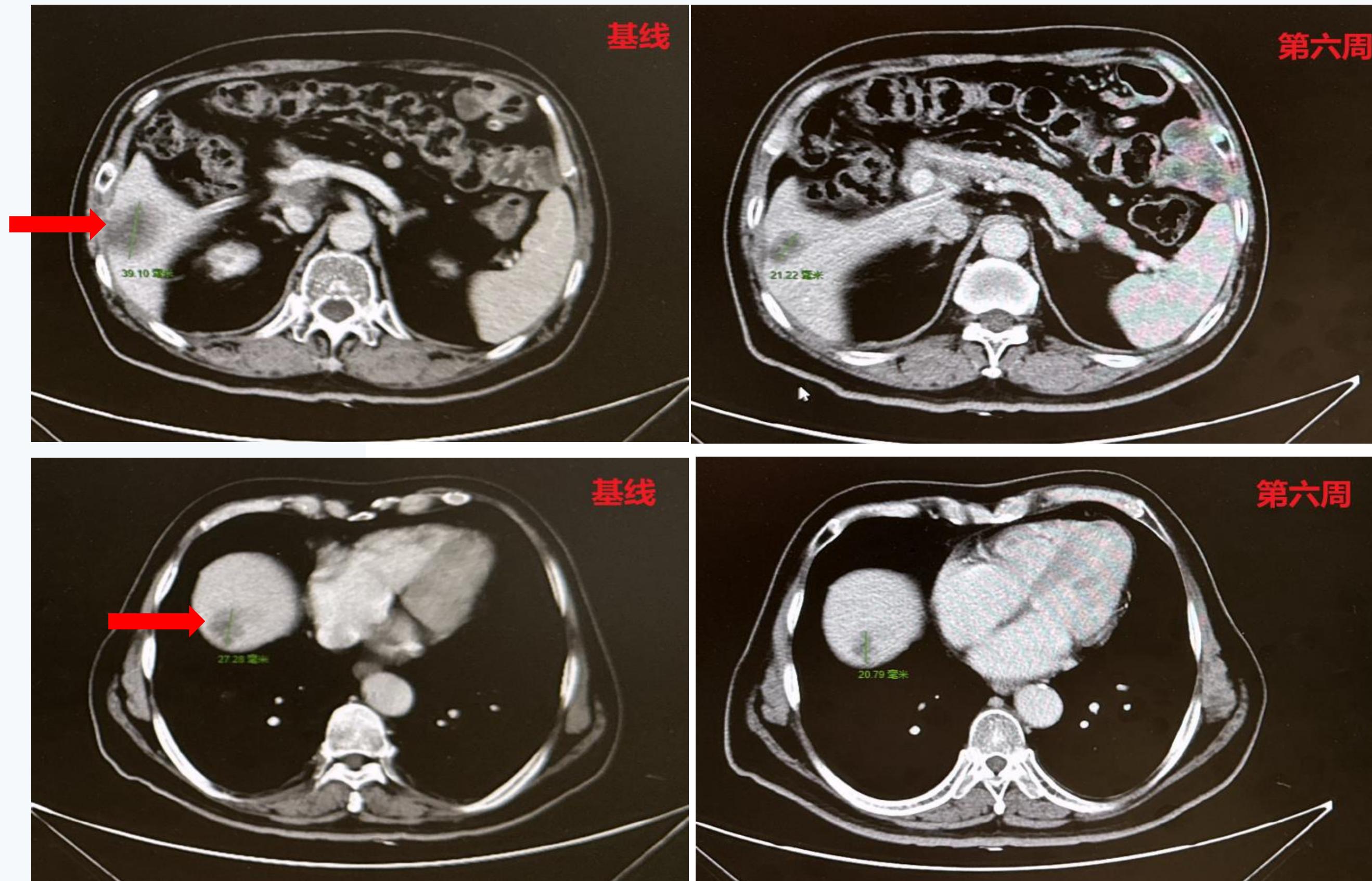
- 2024年11月实现中国首例患者入组(FPI)，目前已进入有效剂量；2025年6月完成美国FPI

- 目前临床数据显示：

安全性良好，爬坡剂量下皮肤毒性发生率10%，均为1级（R M C - 6 2 3 6 90%，3级8%），也没有观察到3级以上的肝脏毒性；

PK符合预期；

已观察到PRs

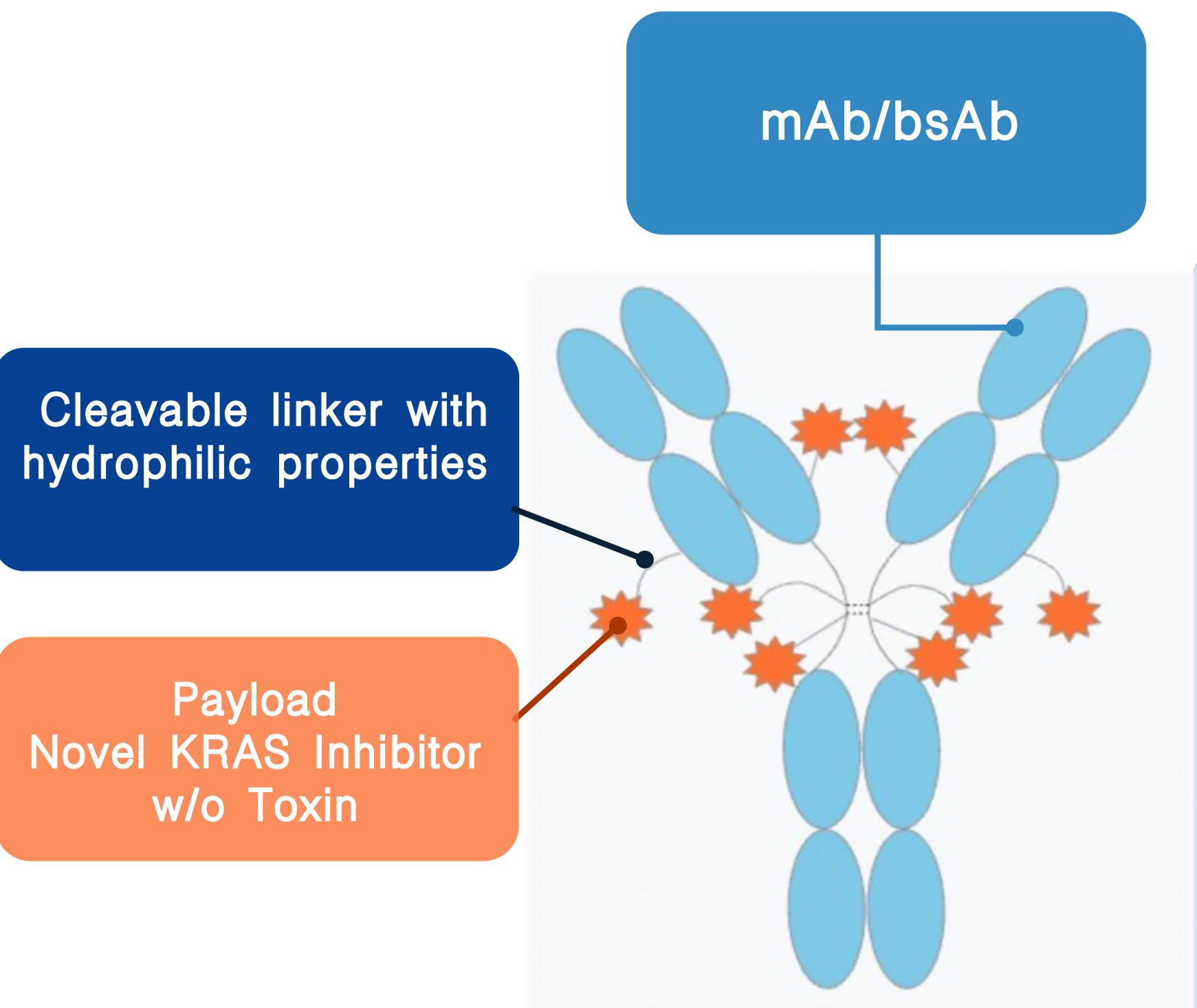


63 y/o PDAC PR (decreased 36% per RECIST)

02

First-in-Class KRAS tADC

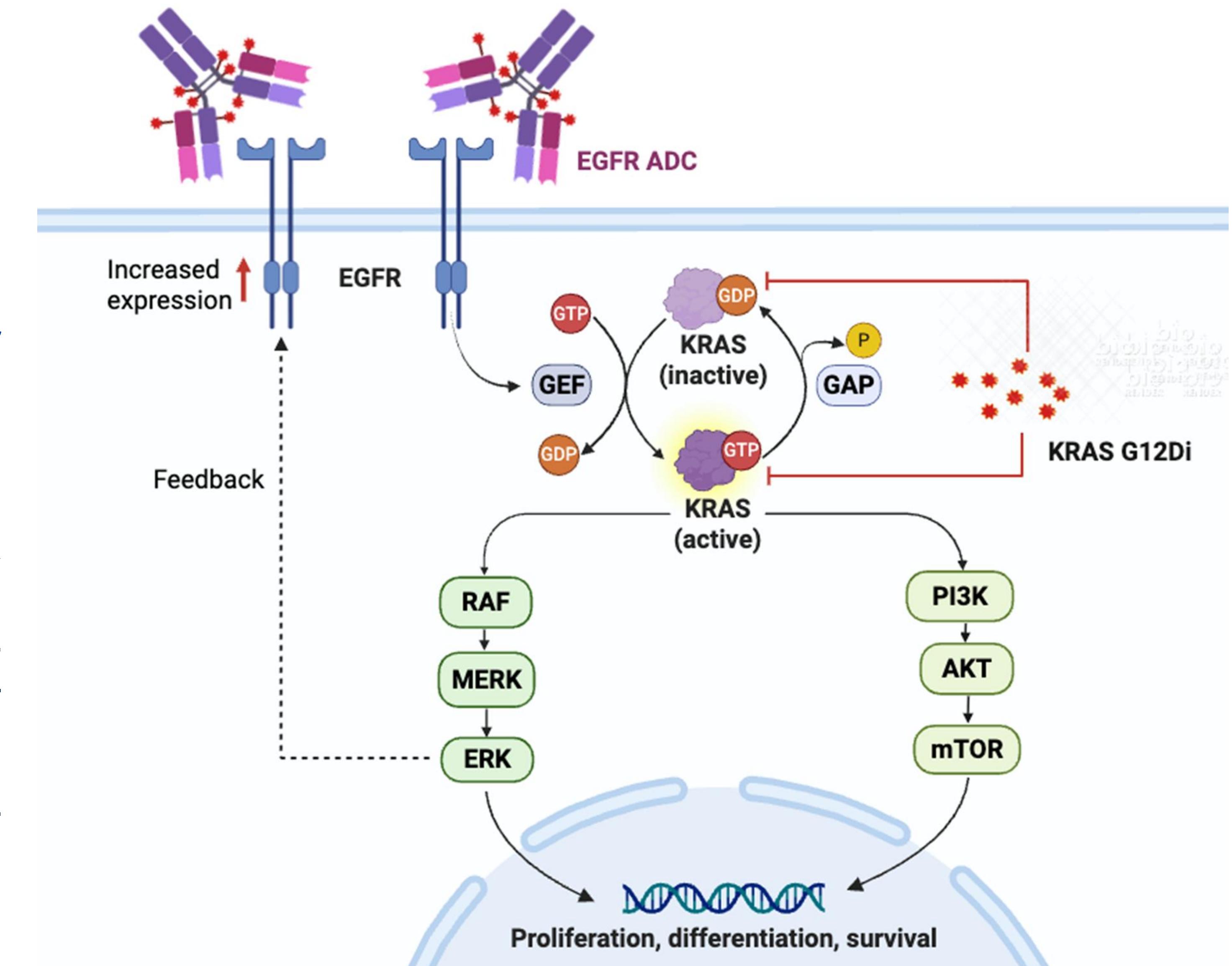
KRAS Inhibitor tADC



- 小分子口服KRAS G12D抑制剂：已经有数家进入临床，部分项目已经停止开发，只有一个项目进入临床二期，进入临床的分子基本都是**纳摩尔(nM)级别的细胞活性**
- KRAS G12Di tADC
 - 1) 以高活性的小分子KRAS G12D抑制剂作为Payload的tADC，具有**皮摩尔(pM)级别的细胞活性**
 - 2) 一般的口服小分子在肿瘤的浓度是血浆浓度的**1-10倍**
tADC释放的G12D抑制剂在肿瘤的浓度是血浆浓度的**1000倍**，安全窗更宽
 - 3) 小分子抑制剂和抗体可以发挥协同作用，疗效更持久
- 加科思KRAS G12D ADC产品的优势：payload专利申请早（2020年11月），专利保护范围最广（34件有效优先权），有空间选择高活性的小分子作为payload
- 其他以KRAS抑制剂为载荷的单克隆/双特异性抗体偶联药物

EGFR-KRAS G12Di tADC

- 采用高活性的KRAS G12D抑制剂作为Payload
Payload细胞活性在KRAS G12D抑制剂项目中是目前最高的；
tADC细胞活性高达皮摩尔 (pM) 级别，其他临床项目均为纳摩尔 (nM) 级别
- 一般的口服小分子在肿瘤的浓度是血浆浓度的**1-10倍**
tADC释放的G12D抑制剂在肿瘤的浓度是血浆浓度的**1000倍**，安全窗更宽
- 以EGFR抗体做递送，同时发挥抗体的协同作用，并且可以有效阻断KRAS抑制剂单药治疗诱导的EGFR反馈激活，克服代偿性耐药
- 与口服小分子抑制剂相比，精准靶向，增强安全性和治疗窗口，疗效更持久

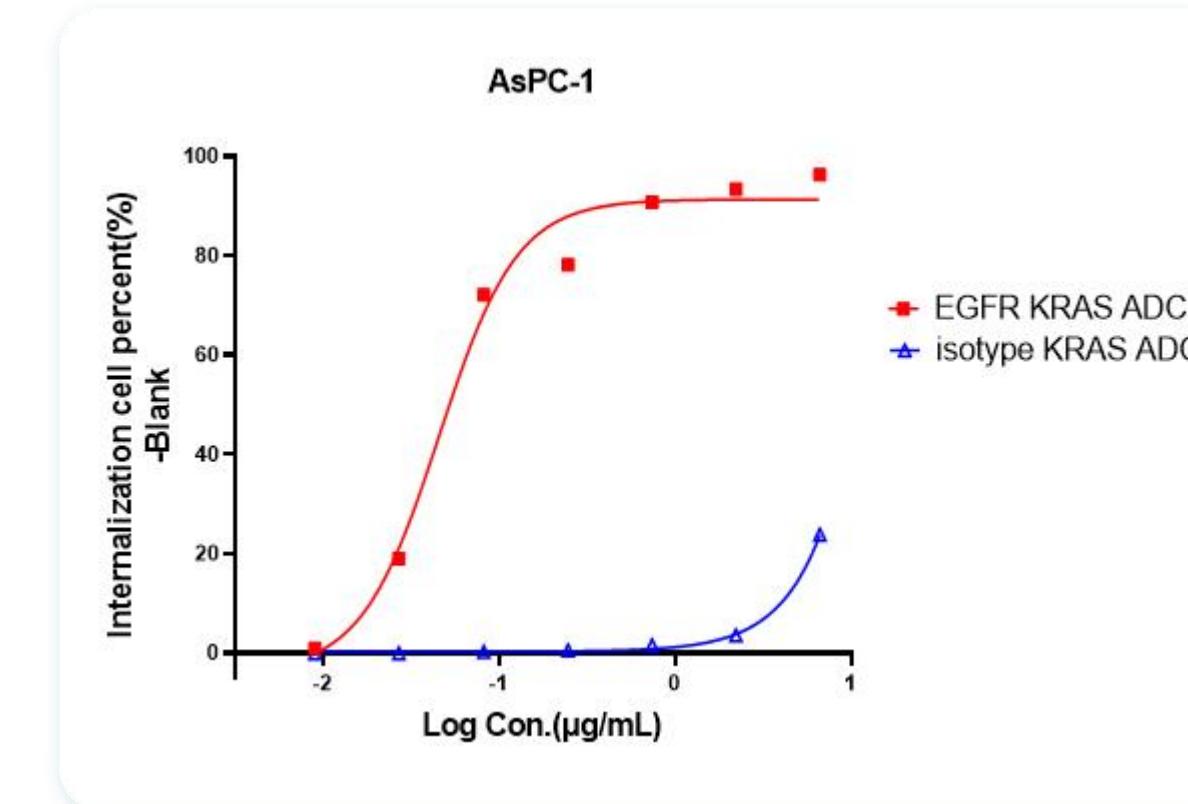


EGFR-KRAS G12Di tADC

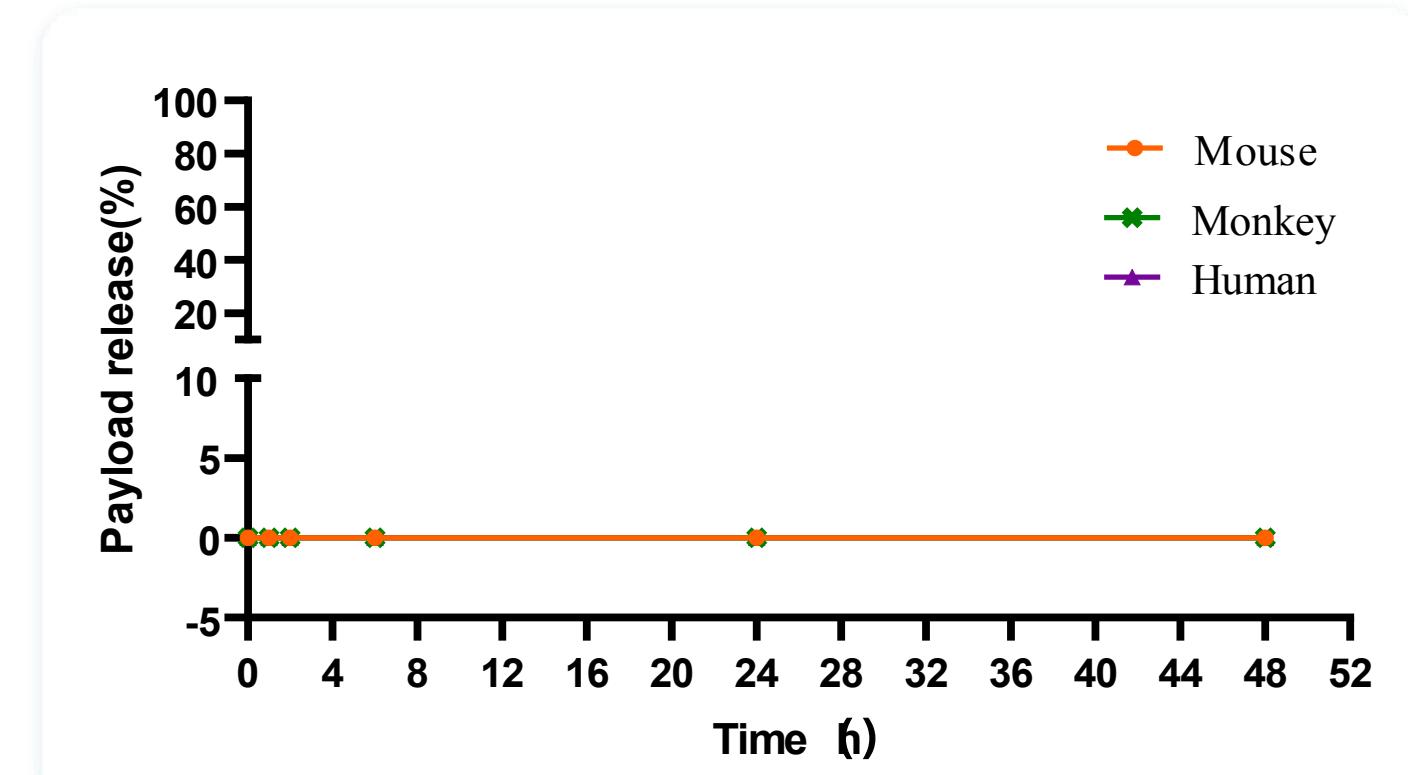
JAB-BX600 细胞活性

Cell Line	Tissue of Origin	Cell Viability, IC ₅₀ , (nM)
AsPC-1	Pancreas	0.008
PK59	Pancreas	0.022
LS513	Colon	0.016
Gp2d	Colon	0.011

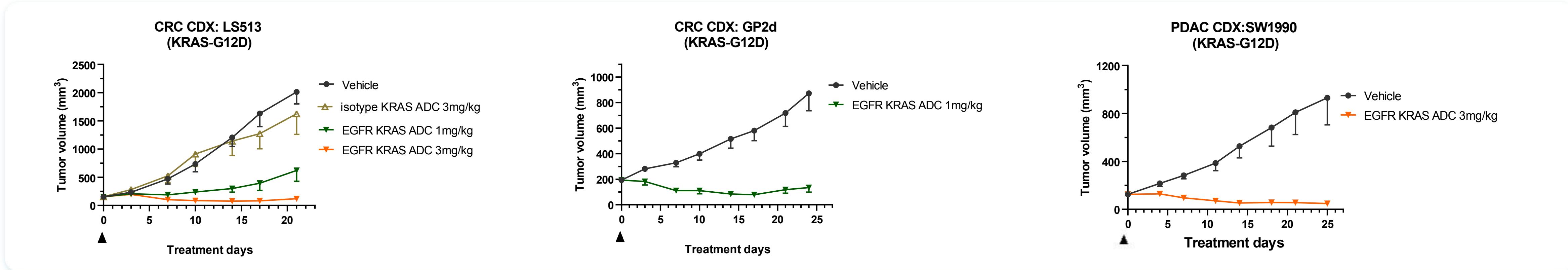
JAB-BX600的内吞率



JAB-BX600的血浆稳定性



JAB-BX600小鼠体内药效



- JAB-BX600在体外细胞实验中表现出优异的活性，在肿瘤中富集，并且在血浆中几乎不释放
- JAB-BX600单次给药对CRC和PDAC模型均具有优异的抗肿瘤效果
- 目前已经确定PCC，预计2026 H2 IND

戈来雷塞及SHP2抑制剂

中国权益



首付款及里程碑付款约9亿人民币+两位数比例的净销售分级提成
其中JAB-3312净销售额提成最高为20%

2L NSCLC

新药生产上市申请 (NDA) 于2025年5月在中国获批上市

- cORR 49.6%
- mPFS 8.2m
- DOR 14.5m
- OS 17.5m
- 消化道毒性(所有级别)<10%

中国销售峰值10-20亿人民币

1L NSCLC

戈来雷塞口服+SHP2抑制剂JAB-3312口服 (N=119)

- cORR 77.1%
- mPFS 12.2m

对比标准疗法:

PD-1抗体注射+含铂化疗注射+培美曲塞注射

KRAS G12C突变, 且PD-L1<1%

- cORR 33.1%
- mPFS 6.2m

注册性3期临床研究在中国进行中
联合用药的I/II期临床数据被顶级学术期刊接收, 即将在2025 H2发表

2L 泛瘤种

戈来雷塞 单药 (N=50)

- PDAC: cORR 41.9% (14/31), mPFS 5.6 m, mOS 10.7 m
- 泛瘤种: cORR 57.9 (11/19), DCR 84.2% (16/19)
- 单药治疗相关性不良事件 (TRAE) 主要为1-2级。

泛瘤种: 除NSCLC, PADC, CRC以外的其他癌种, 如胆道癌, 胃癌, 小肠癌, 阑尾癌, 宫颈癌, 头颈癌, 卵巢癌, 滑膜肉瘤, 纵隔肿瘤等

胰腺癌及泛瘤种单臂2期注册性临床研究在中国进行中
临床数据被顶级学术期刊接收

3L CRC

戈来雷塞+西妥昔单抗 (N=46)

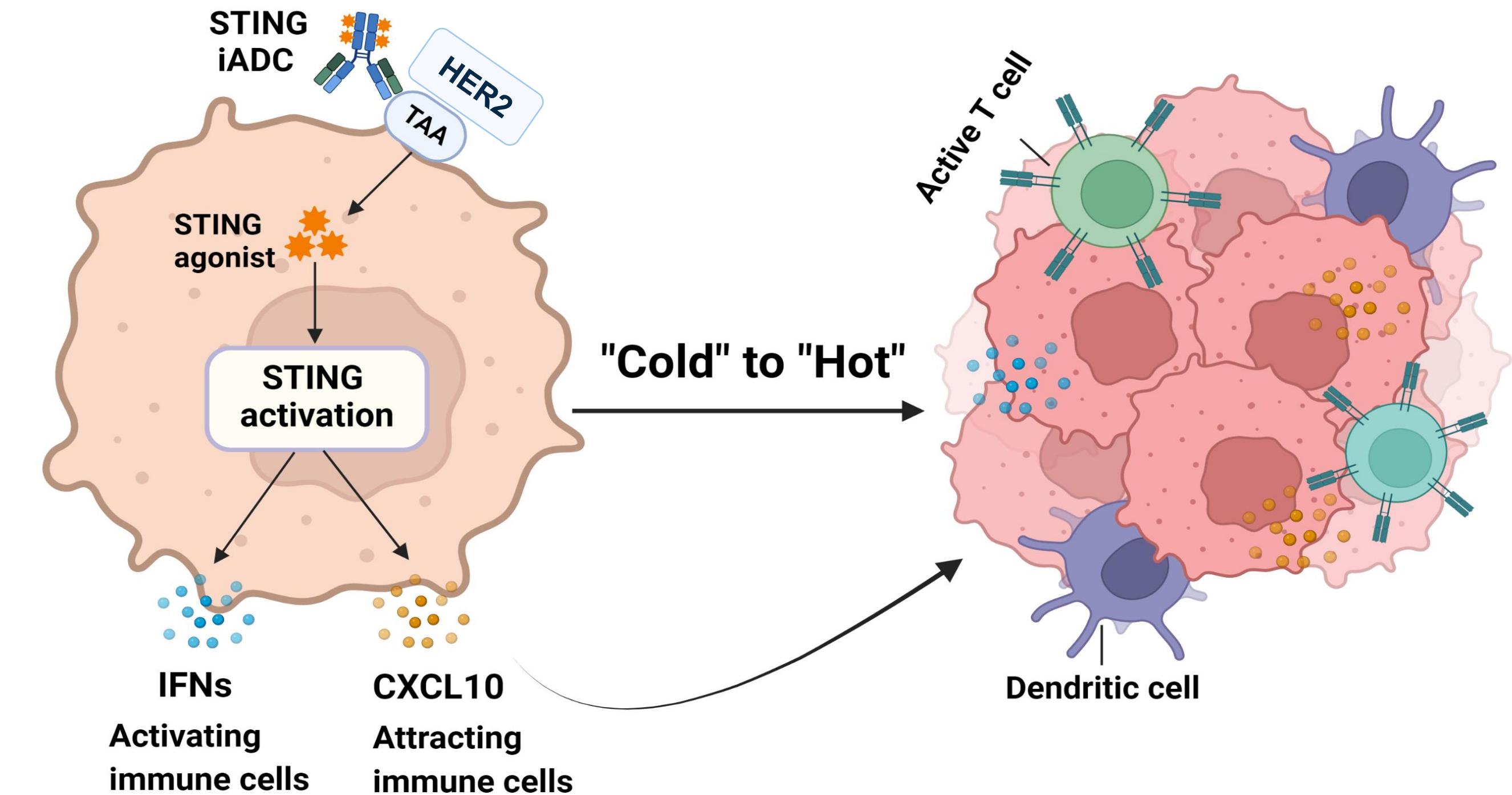
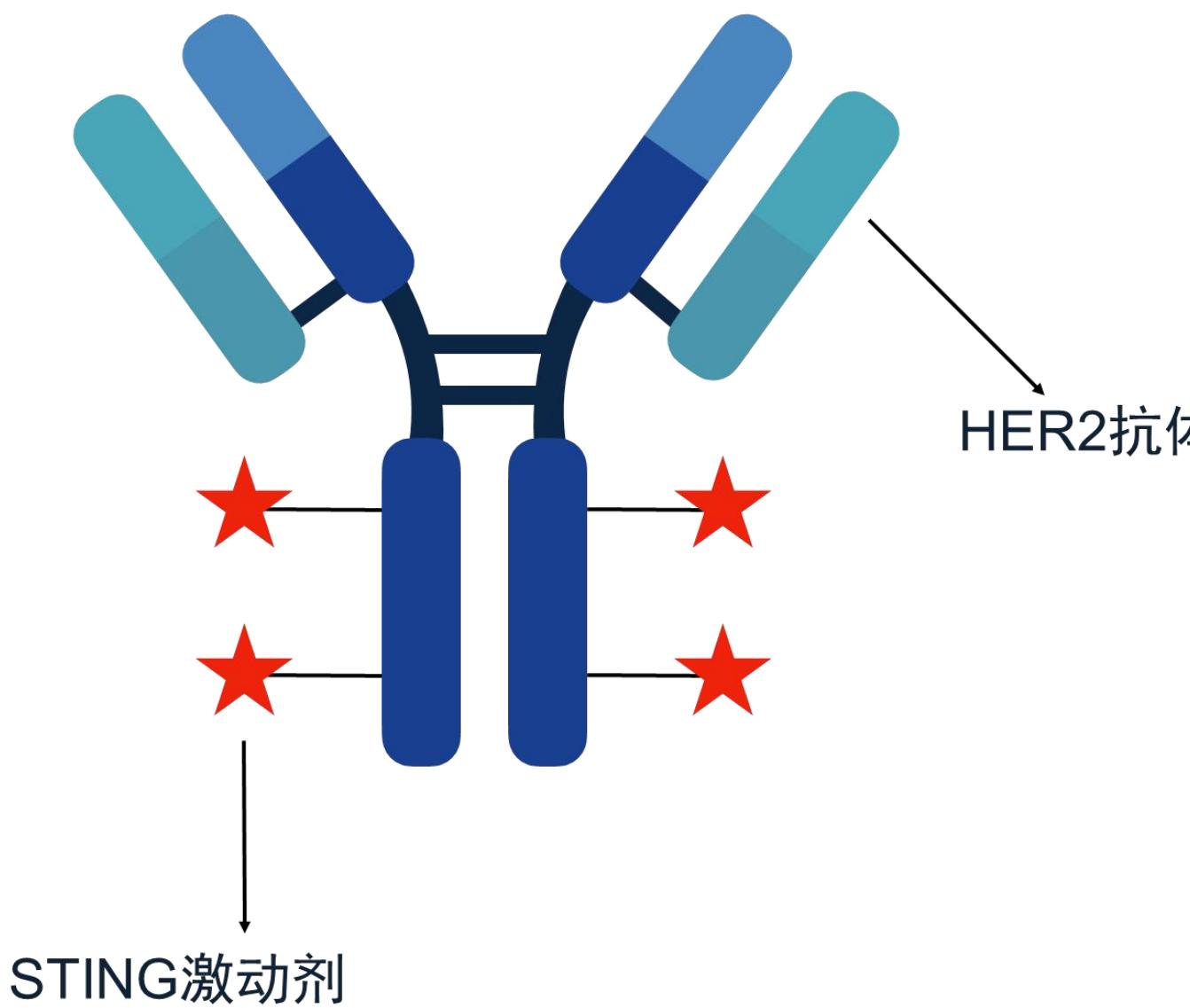
- ORR 50% (23/46)
- DCR 87.0%(40/46)
- mPFS 6.9m
- mOS 19.3m

Glecirasib联合西妥昔单抗治疗晚期KRAS G12C突变晚期结直肠癌的疗效优于Glecirasib单药治疗, 同时保持良好的安全性。

注册性3期临床研究方案于2024年5月获CDE批准
临床数据被顶级学术期刊接收

以STING激动剂为payload的iADC

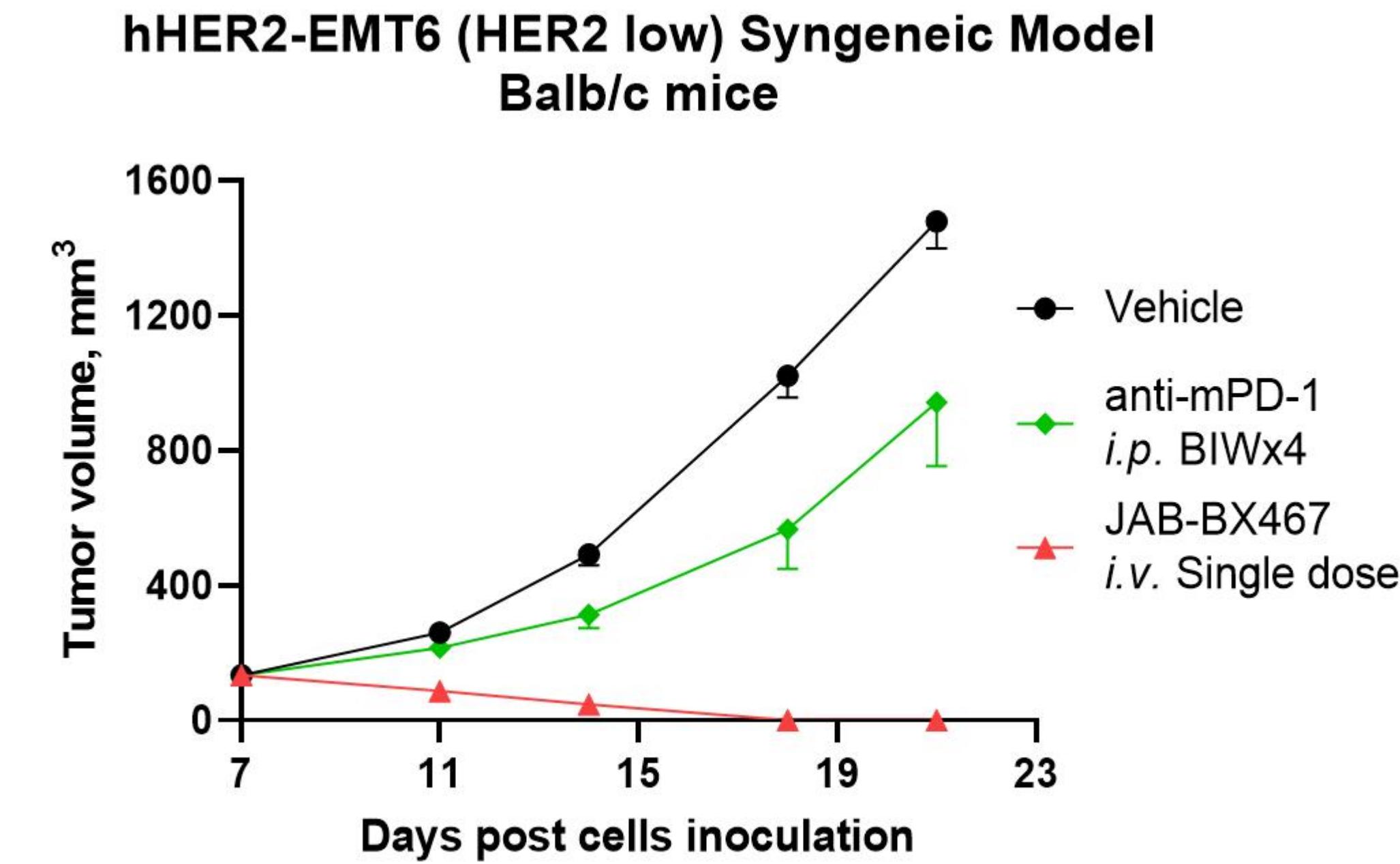
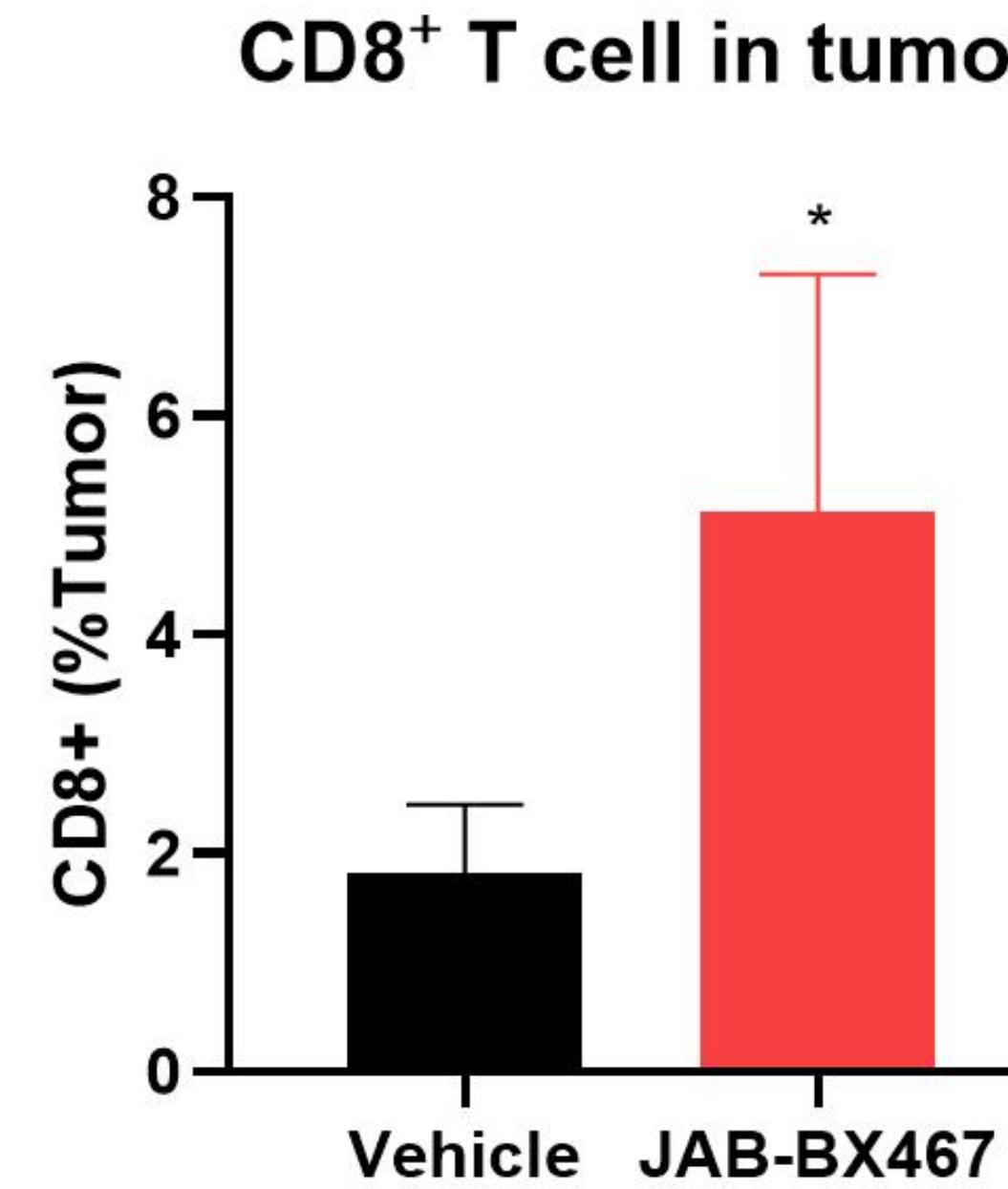
JAB-BX467: HER2-STING iADC



JAB-BX467 (HER2-STING iADC)

- HER2在多种癌症表达, JAB-BX467利用靶向递送能力将STING激动剂在肿瘤部位富集
- STING激动剂促进干扰素和趋化因子的分泌, 活化肿瘤部位免疫细胞, 并增加肿瘤部位免疫细胞的募集, 使“冷肿瘤”转化为“热肿瘤”, 解决70%PD-1无效的冷肿瘤临床未满足需求

JAB-BX467 (HER2-STING) 促进T细胞浸润，对冷肿瘤有效

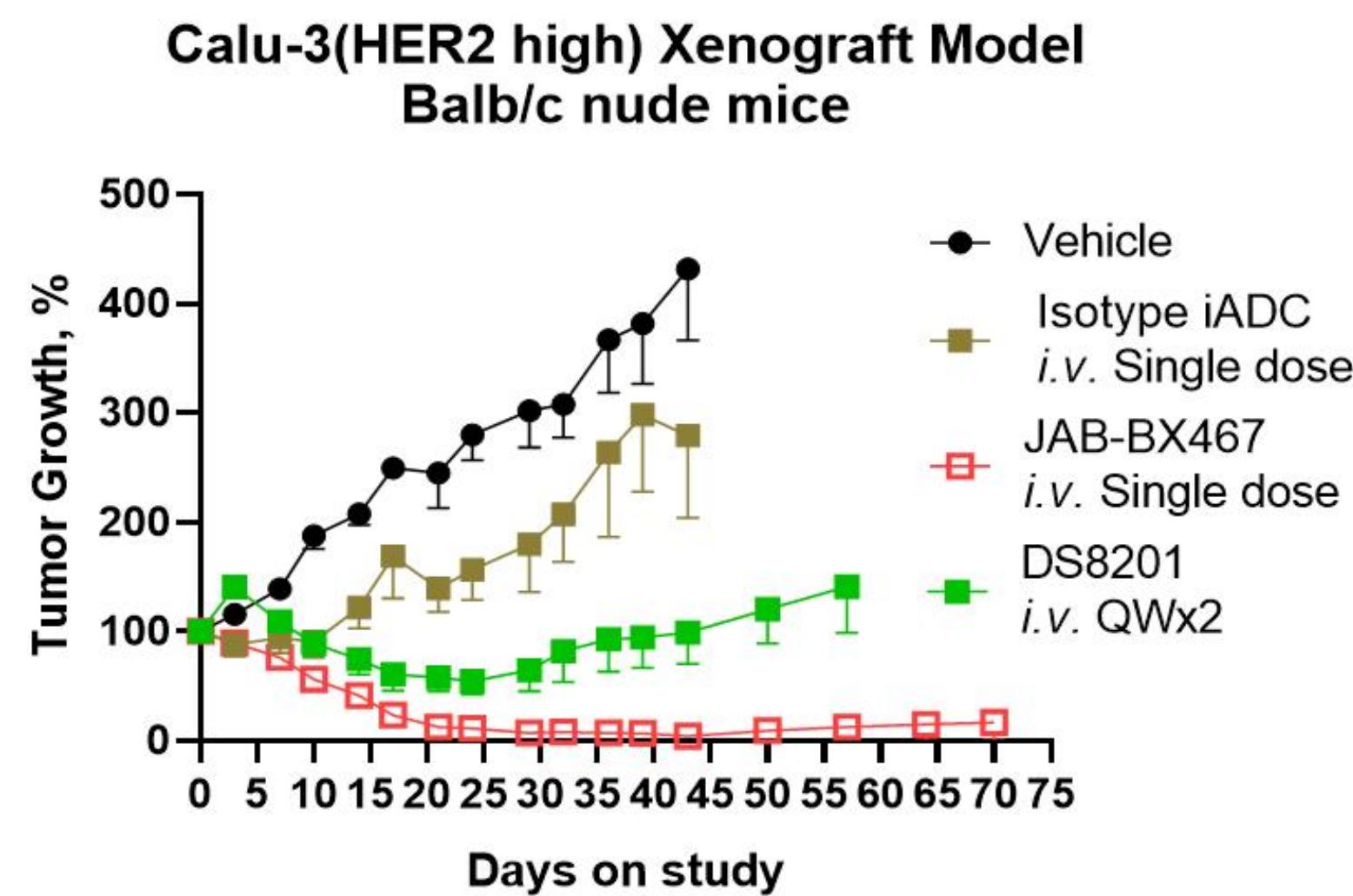


低表达人HER2的EMT6模型（免疫健全小鼠，冷肿瘤）：

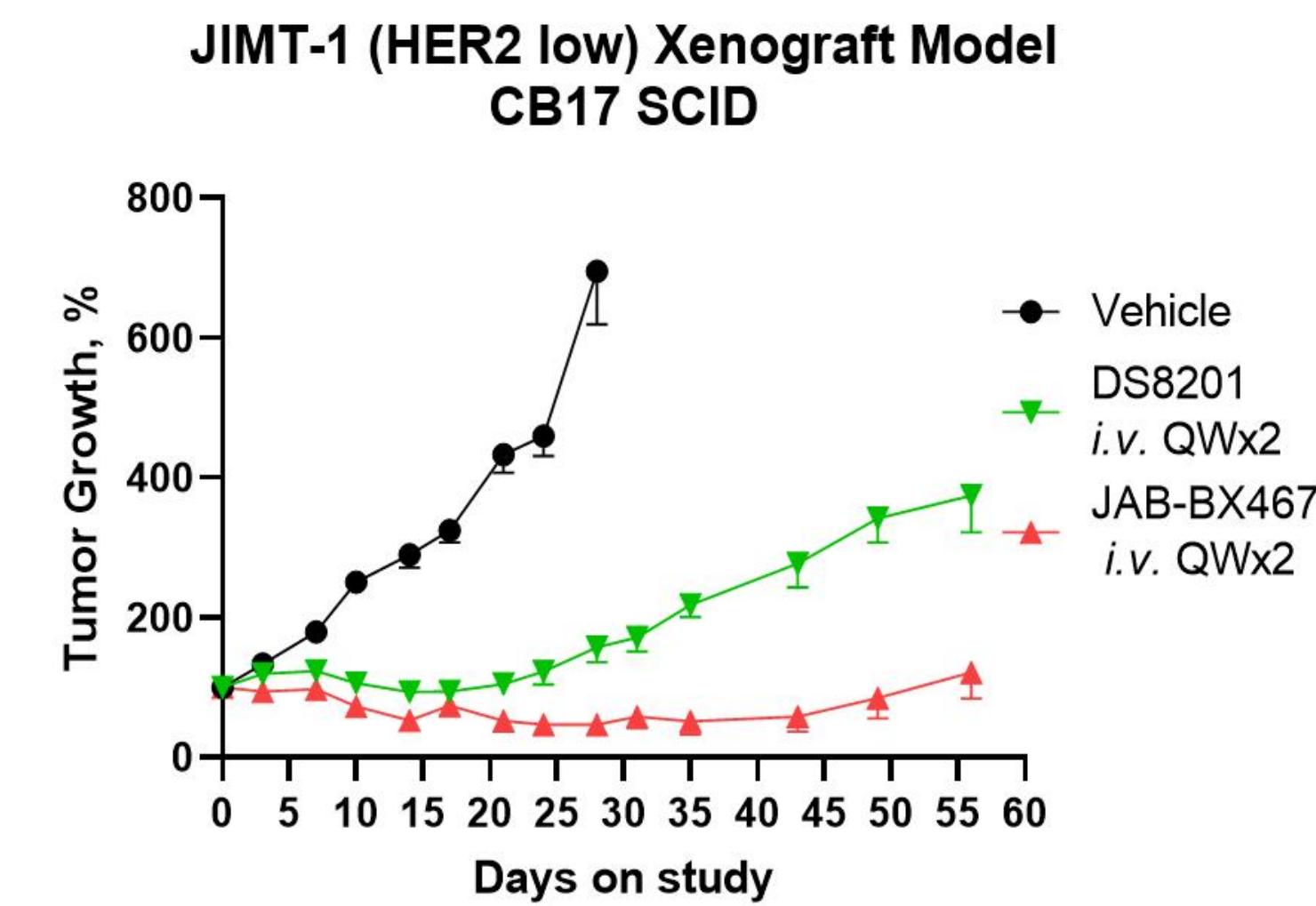
- JAB-BX467促进肿瘤组织中T细胞的浸润
- PD-1单药对冷肿瘤无效

JAB-BX467 (HER2-STING) 对HER2高/低表达的人肿瘤细胞具有明显且持久的杀伤作用

HER2高表达的肿瘤



HER2低表达的肿瘤



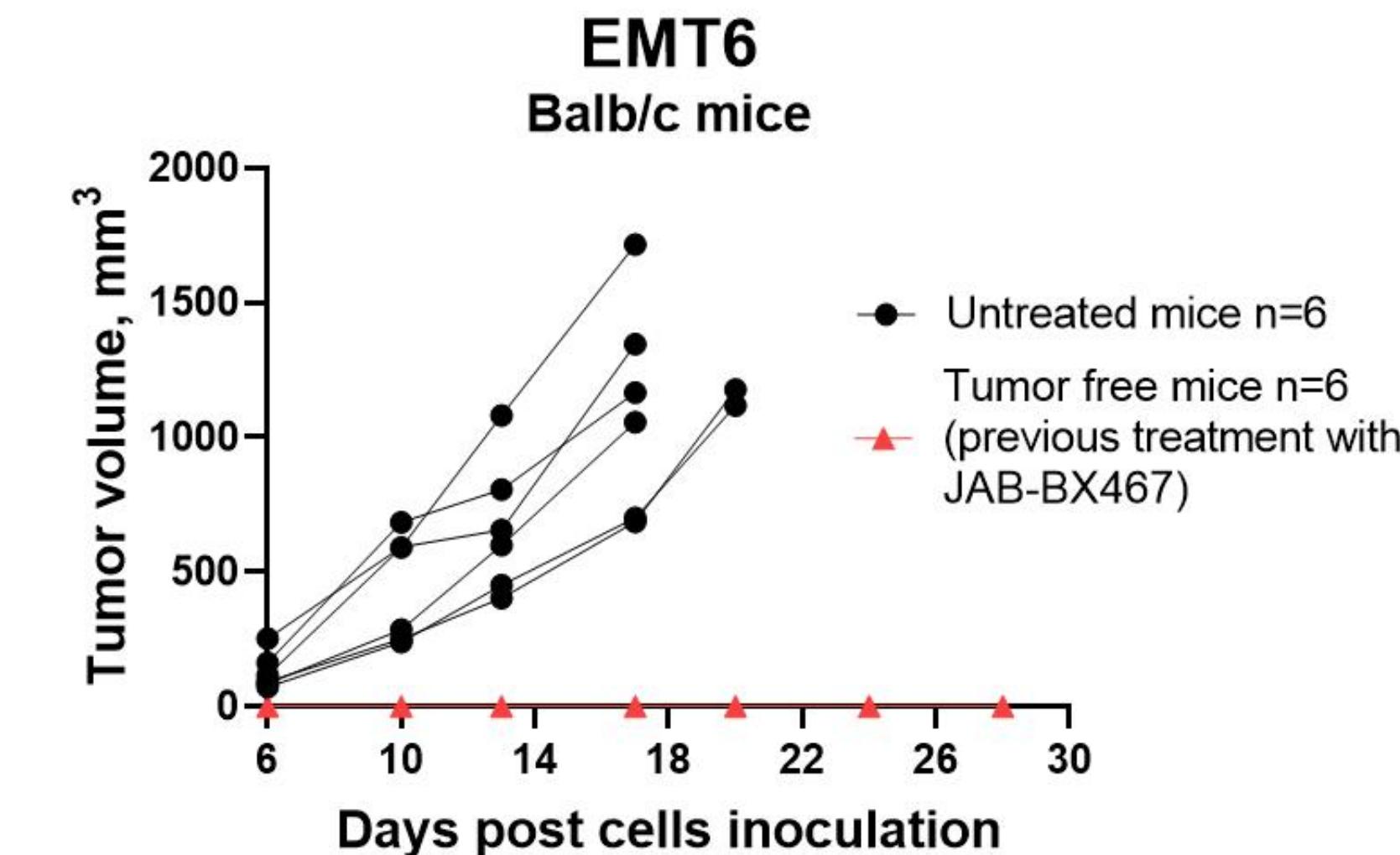
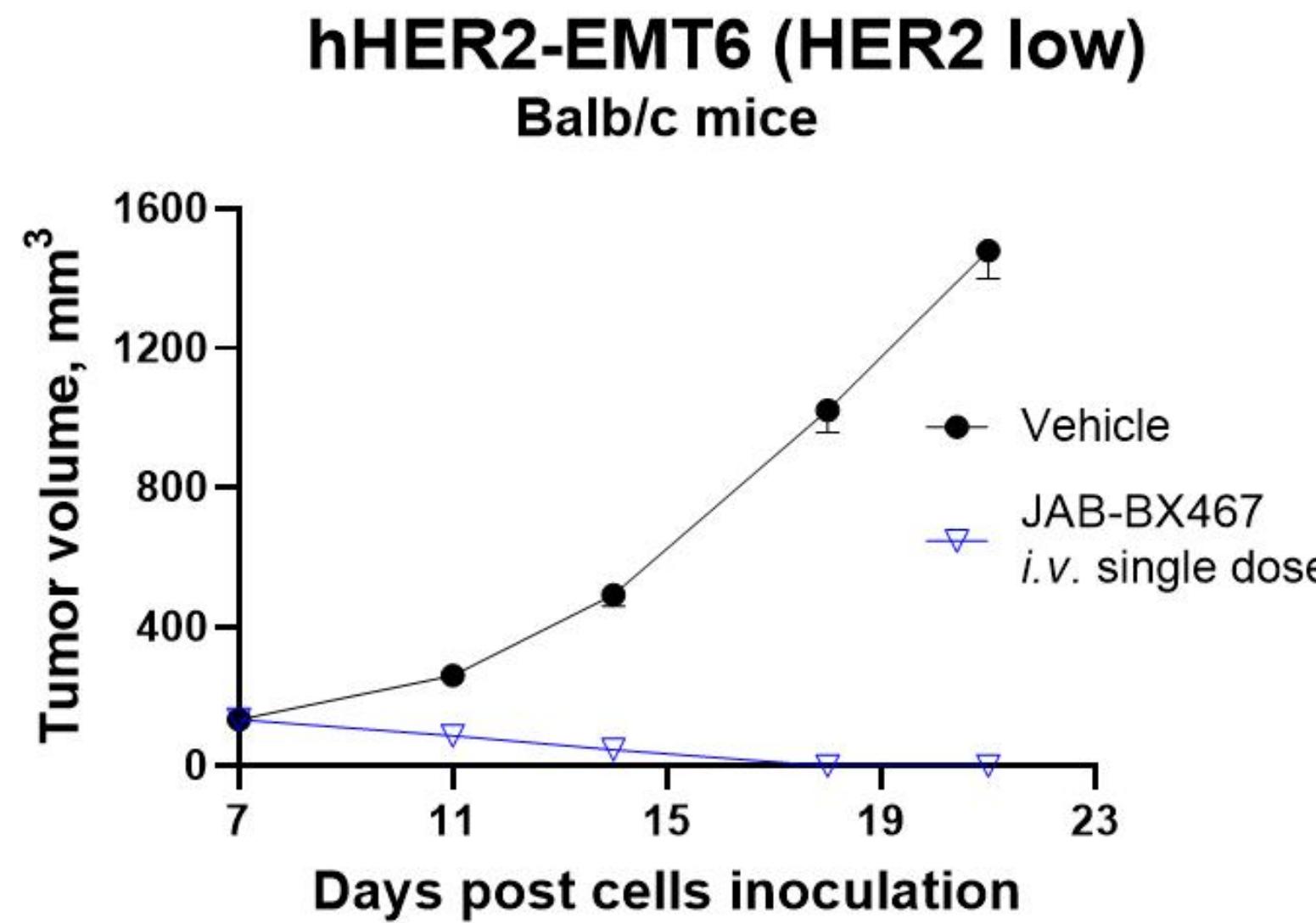
JAB-BX467在HER2高表达的肺癌模型（免疫缺陷鼠，缺失T）中，单次给药可导致肿瘤完全消退，活性强于DS8201。

JAB-BX467两次注射给药在HER2低表达模型中（免疫缺陷鼠，缺失T），可以持久抑制肿瘤生长，停药后肿瘤反弹较慢，活性强于DS8201。

JAB-BX467 介导长期免疫记忆

JAB-BX467 0.1mg/kg给药
后肿瘤完全消失(n=6)

二次接种
EMT6细胞(n=6)



- 药效研究中，肿瘤完全消失的动物，二次接种EMT6（红色），采用相同周岁的动物接种EMT6（黑色）作为对照，具有JAB-BX467给药史的动物再接种后，肿瘤在体内不能生长，而对照组生长正常。因此JAB-BX467具有强大且持久的介导免疫记忆的作用。

STING iADC竞争格局

药物	公司	载荷	抗体	开发阶段	适应症
XMT-2056	Mersana Therapeutics	Non-CDN STING agonist	Anti-HER2	Phase I	晚期或复发实体瘤单药治疗
JAB-BX467	加科思	Non-CDN STING agonist	Anti-HER2	临床前已确定PCC 预计2026 H2 IND	实体瘤
DS3610	第一三共 (Daiichi Sankyo)	CDN STING agonist	未知	临床前 预计2025 H2进入临床	--

- 关于XMT-2056:

2022年8月FDA批准进入临床，2023年3月由于5级严重毒性，FDA暂停其临床实验，2023年10月FDA解除对XMT-2056的临床实验控制，Mersana降低了XMT-2056的第一阶段剂量递增起始剂量。
- 关于DS3610:

第一三共开发的新型STING ADC药物，预计2025年下半年进入临床。

其他项目进展

01

JAB - 30355 P53

Y220C

✓ 中、美I期临床入组中

02

JAB - 8263 BET抑制剂

- ✓ 已完成中、美一期临床爬坡，确定RP2D剂量为0.3mg;
- ✓ 二期临床启动计划中。

03

JAB - 2485 Aurora A抑制

剂

✓ 中、美I期临床RP2D剂量优化中

03

迈向全球市场

2025年中期财务概况

2025上半年主要财务数据

- 2025年上半年研发费用约**9300万元**。
- 2025年上半年主要经营及融资资金流入**6180万元**，期后收到艾力斯合作款约**4500万**
 - 截止报告日，2025年收到艾力斯合作款约**5300万元**。其中2025年1-6约收款约**800万**。
 - 2025年1月获得亦庄国投第三笔**4500万元**投资，已收到全部1.5亿元融资
 - 净利息收款约880万。
- 董事会7月批准股份回购方案，根据联交所规定适时回购股票
 - 回购价格不得高于前五日收盘均价的105%

资金余额稳定，可支撑未来约4年的支出



现金、银行余额和银行授信**13.4亿元**
大部分银行授信期限为中长期

未来里程碑预期

项目	里程碑	预期时间
KRAS G12C抑制剂戈来雷塞	二线NSCLC在中国的商业化许可销售分成	2026 Q1
JAB-23E73	Pan-KRAS抑制剂完成临床I期剂量爬坡并确定II期临床推荐剂量 (RP2D)	2025 H2
JAB-23E73	临床一期数据披露	2026 H1
JAB-30355	完成剂量爬坡	2025 H2
JAB-2485	Aurora A抑制剂完成中美临床I期剂量爬坡并确定II期临床推荐剂量	2025 H2
JAB-BX467 HER2-STING iADC	IND	2026 H2
JABX600 EGFR-KRAS G12Di tADC	IND	2026 H2

未来收入来源



戈来雷塞及JAB-3312中国权益授权合作 里程碑及销售分成

- 戈来雷塞和JAB-3312中国权益License-out里程碑收款
- 戈来雷塞单药：肺癌II线中国销售分成（2025年开始）
- 戈来雷塞单药：泛瘤种II线中国销售分成
- 戈来雷塞和JAB-3312联用：肺癌I线中国销售分成

管线项目中潜在的BD授权收入

公司战略



核心项目全球前三



自主研发
变构抑制剂
和iADC平台



全球市场



谢谢！