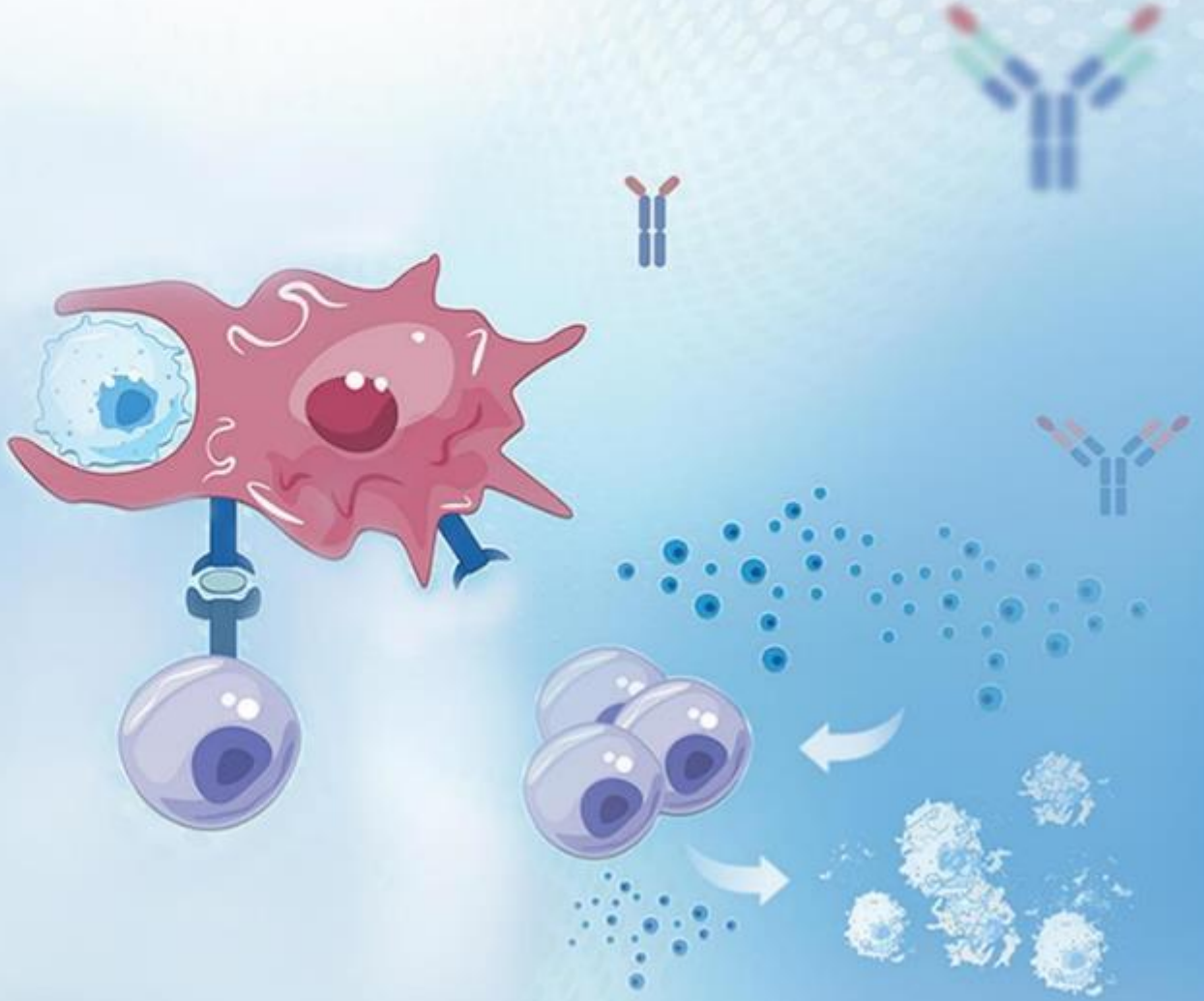
宜明昂科
ImmuneOnco

IMM2510
(珀维拉芙普 α)

2025年5月



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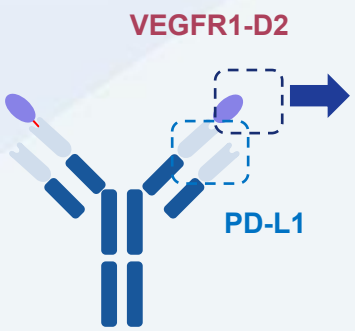
一款靶向VEGF及PD-L1的双特异性分子，采用单克隆抗体-受体重组蛋白结构

IMM2510 – 靶点介绍 和 分子结构

IMM2510 分子结构



VEGF

VEGF受体trap **结合包括VEGF-A在内的更广泛的VEGF 受体配体**，因而有更广泛的抗血管生成活性

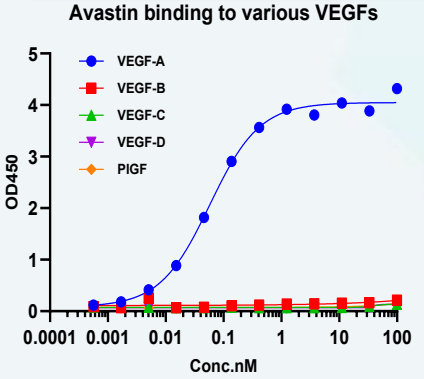
PD-L1

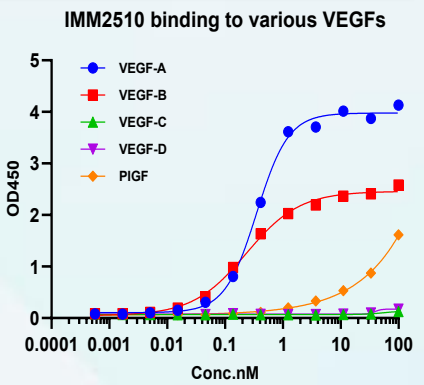
表达PD-L1的肿瘤细胞可通过**与T细胞表面的PD-1结合**来逃避T细胞的攻击

ADCC

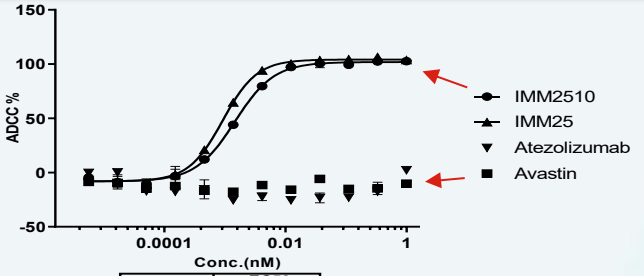
ADCC 增强型抗体旨在诱导免疫抑制的PD-L1+肿瘤细胞的直接杀伤

IMM2510结合各种 VEGF受体配体，Avastin仅结合VEGF-A





IMM2510 有ADCC增强活性

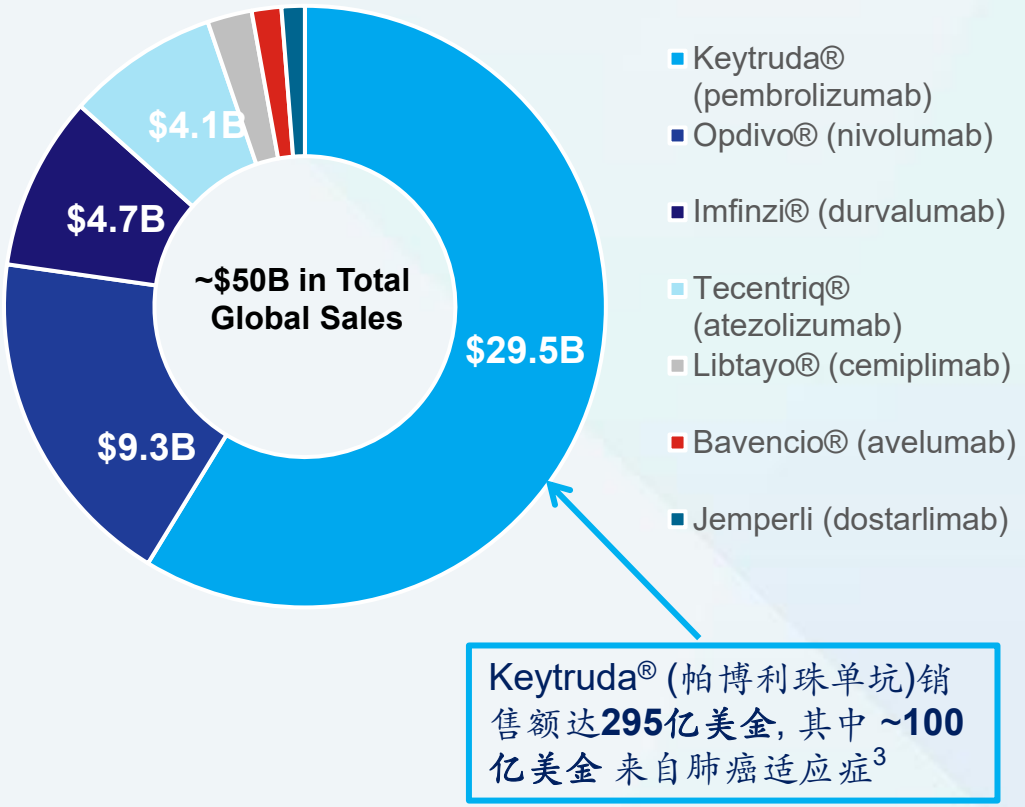


	EC50
IMM2510	0.001461
IMM25	0.0009247

IMM2510剑指最大肿瘤适应症：非小细胞肺癌

- **非小细胞肺癌是Keytruda最大的市场，**占销售额1/3
- **PD-(L)1** 抑制剂预计在2028年将达到约900亿美元全球销售[1]
  - 4个PD-(L)1抑制剂2024年销售均达40亿以上[2]
- **VEGF** 抑制剂市场还有额外空间值得扩展

2024 PD-(L)1 抑制剂销售额[2]

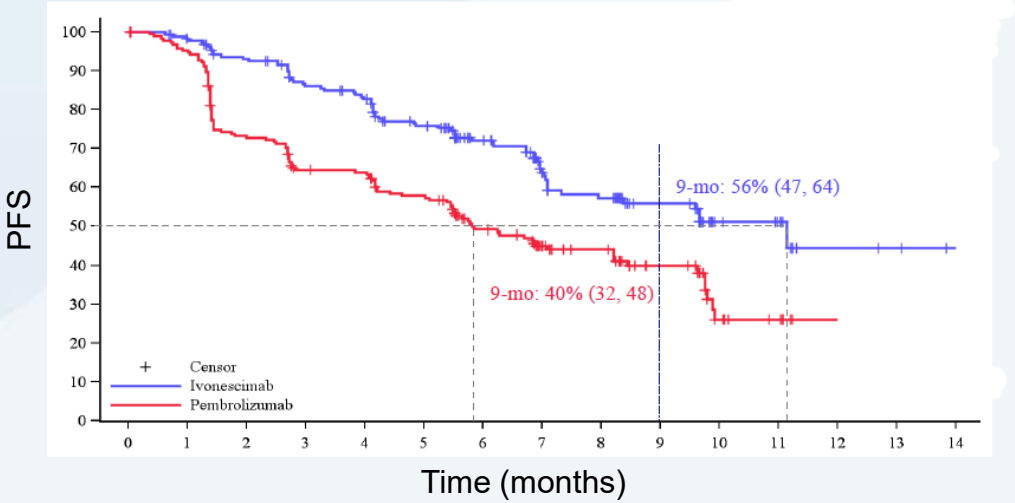


Keytruda® (帕博利珠单抗)销售额达**295亿美金**，其中 **~100亿美金** 来自肺癌适应症[3]

[1] IQVIA 人类科学数据研究所，“Global Oncology Trends 2024: Outlook to 2028”
[2] 公司盈利新闻稿
[3] Stifel于 2024年3月25日发表的研究报告

PD-(L)1xVEGF 双抗以下临床表现优于帕博利珠单抗

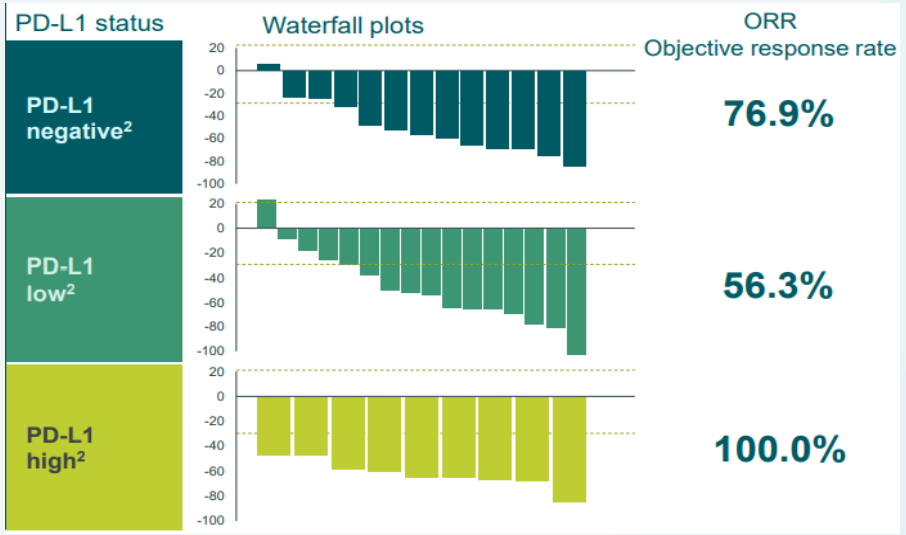
依沃西单抗: HARMONi-2 试验[1]



在 III 期 HARMONi-2 试验中，依沃西单抗在 PD-L1 阳性 NSCLC 患者中的 PFS （HR： 0.51， p<0.0001） 和 OS （HR： 0.777， p=NS） 方面显示出比帕博利珠单抗具有临床意义的改善。

PD-(L)1xVEGF双特异性抗体在很大程度上避免了显著的 VEGF相关毒性，包括严重出血事件.

BNT327: TNBC试验[2]

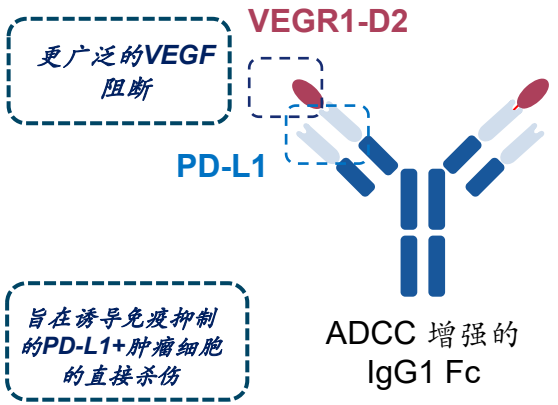


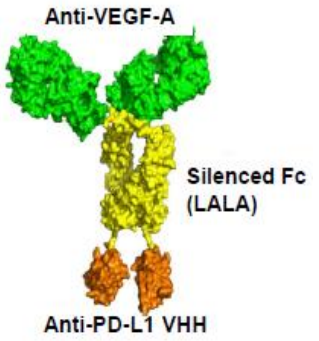
BNT327 在TNBC 患者联合化疗中，无论 PD-L1 表达如何，都取得了临床获益，表明 **PD-（L）1xVEGF 双特异性药物有可能治疗现有 PD-（L）1 疗法目前未满足的患者群体**

[1] Zhou et al. Presented at WCLC 2024.
[2] Y. Meng et al. Presented at ESMO 2024.
NS =不具有统计显著性; TNBC: 三阴乳腺癌

竞争格局

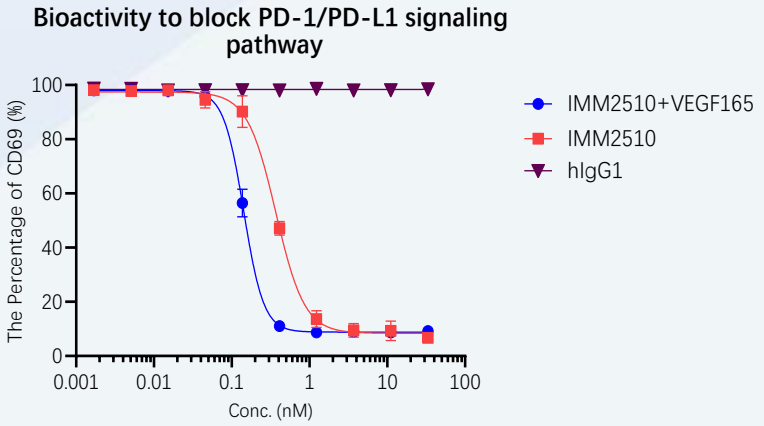
	IMM2510 (宜明昂科 / Instil Bio)	PM8002 (BioNTech)	AK112 (康方生物/ Summit)
VEGF 结合	VEGF-A, VEGF-B, PlGF	VEGF-A	VEGF-A
PD-1 or PD-L1	PD-L1	PD-L1	PD-1
ADCC	增强的 ADCC	无	无





IMM2510体外研究显示出与 PD-L1 的协同结合

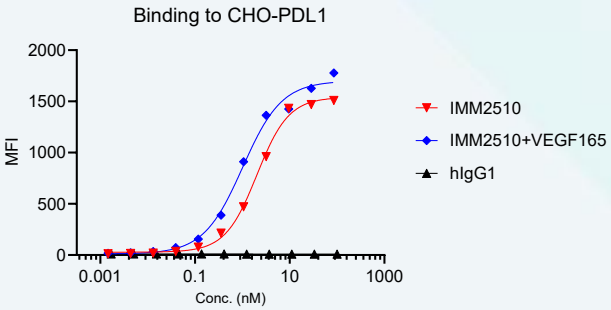
VEGF 的存在增强了IMM2510的 PD-1 信号抑制



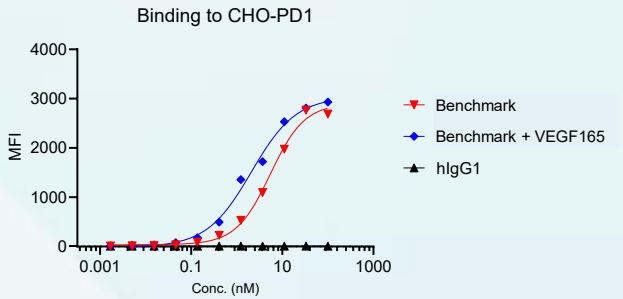
	IMM2510	IMM2510+VEGF165
IC50	0.3697	0.1429

- IMM2510 表明在 VEGF 存在下对 PD-1/PD-L1 信号传导的阻断增强（协同效应）

IMM2510和可比抗体分别与CHO-PDL1 和CHO-PD1细胞的结合能力，均被VEGF增强



	IC50
IMM2510	2.035
IMM2510+VEGF165	1.013



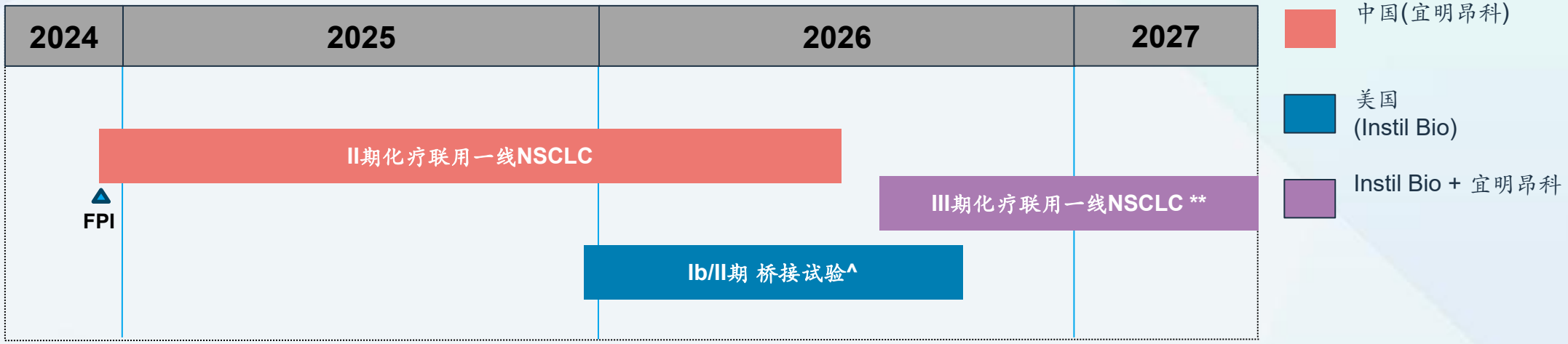
	IC50
Benchmark	5.464
Benchmark +VEGF165	2.094

- 在 VEGF 存在下，可比抗体* 和 IMM2510 分别表现出与 PD-1 和 PD-L1 的结合亲和力发生类似的变化

*可比抗体为临床最先进的 PD1xVEGF 双特异性抗体

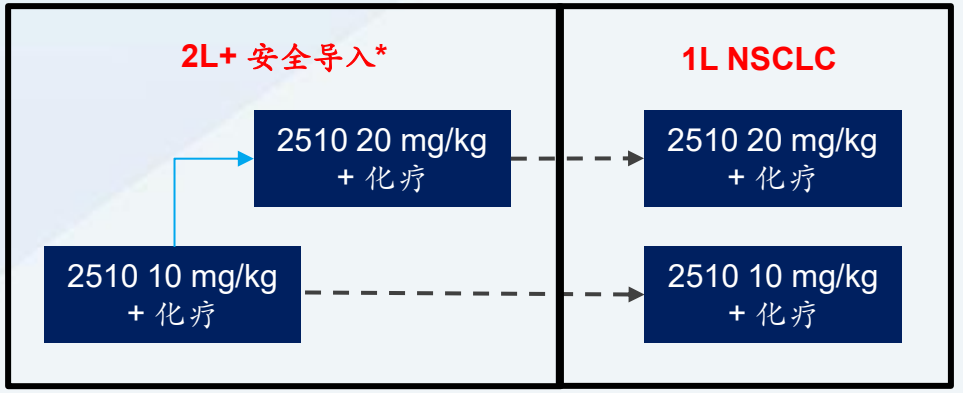
IMM2510 的临床策略优先推一线 NSCLC

- 有机会成为具有差异化分子结构的同类最佳产品：VEGF trap 和 ADCC增强
- **IMM2510 + 化疗一线NSCLC II期临床在中国加速入组中**
- 美国Ib/II期桥接试验计划2025年底启动，基于获得所需的监管审批
- 中国目前各类实体瘤已入组超过190例*



* 截至2025年5月21
**取决于与监管的沟通
^预期开展联用或不联用化疗的实体瘤（NSCLC患者较多）剂量优化单药试验

IMM2510+化疗NSCLC Ib/II期试验

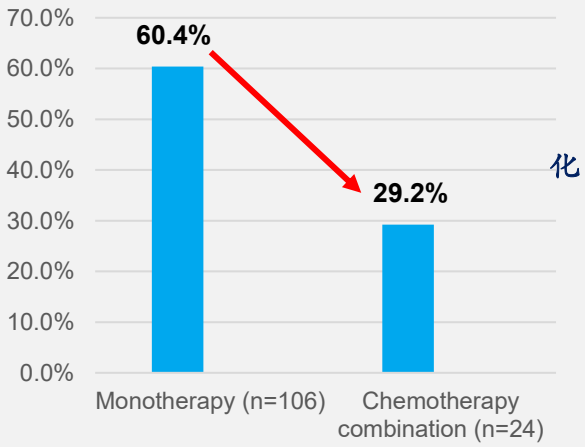


*安全导入期针对复发难治的NSCLC
**截至2025年5月21日
*** 截至2025年5月9日的初步数据
基于铂类双药化疗;化疗使用了 4 个周期；IMM2510 使用周期为 Q3W

入组进展**

- **1L NSCLC:** >20 患者入组
- **2L+ NSCLC 安全导入:** 12 患者入组
- 预期在 2025 年下半年发布 >60人 1L 患者的初步安全性和有效性结果

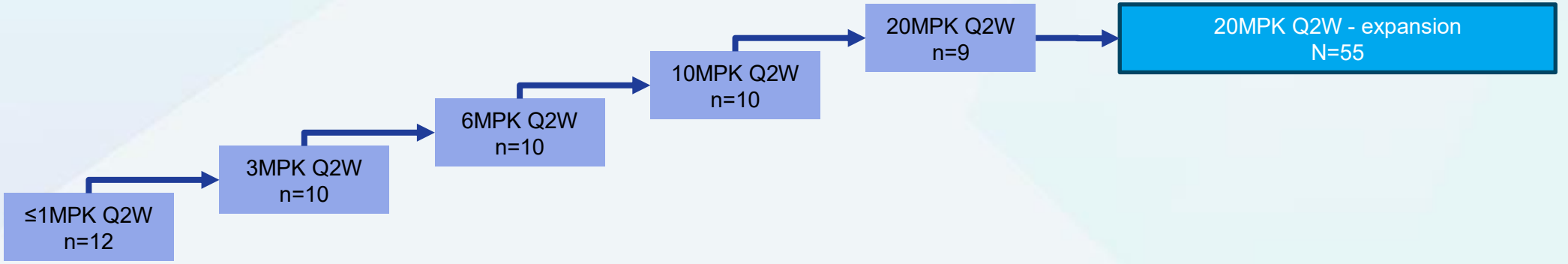
安全性更新***



化疗联合研究中 IRR 的频率和严重程度降低

I/II期单药试验的患者基线

106 例患者入组并给药治疗:



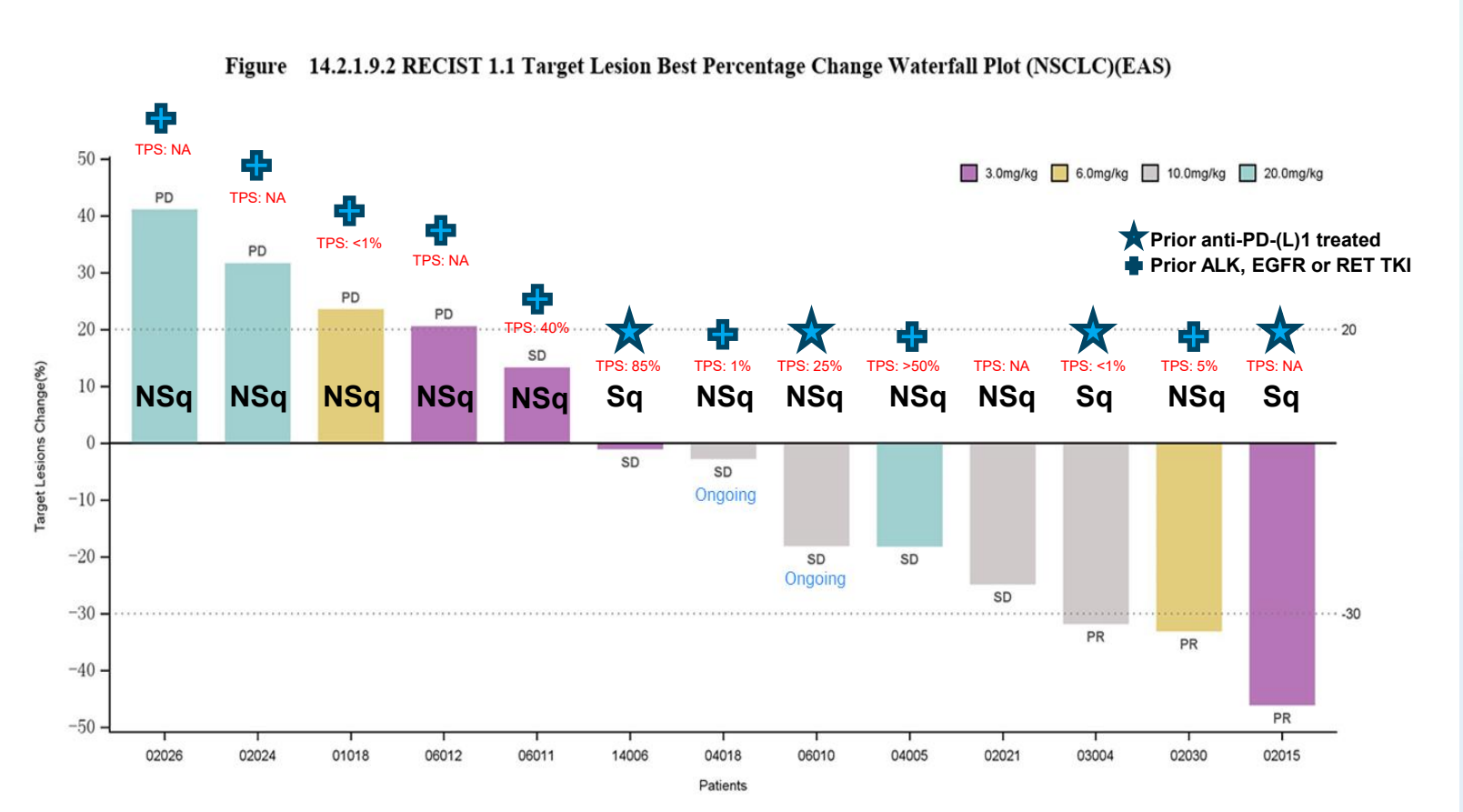
基线情况	剂量爬坡; n=51	剂量扩展; n=55
年龄: 中位 (min – max)	58 (36 – 75)	47 (22 – 49)
种族	Asian 100%	Asian 100%
性别: M / F (%)	43% / 57%	46% / 55%
ECOG 0/1 (%)	8% / 92%	9% / 91%
# 之前治疗线数: 中位 (min – max)	3 (1 - 13)	2 (0 – 12)
主要适应症	NSCLC: 35.3% 乳腺癌: 15.7% (大部分非TNBC)	软组织肉瘤: 41.8% TNBC: 18% HCC: 12.7%

* 数据截至2024年12月24日，研究继续进行中，数据会随之变化。

13 例可评估的NSCLC患者

后线、重度治疗的患者(鳞癌和非鳞癌)

- 23.1% ORR
- 62% 患者肿瘤缩小
- PD-L1 TPS 评分低（≤ 5%）和/或既往接受过检查点抑制剂治疗的患者的反应



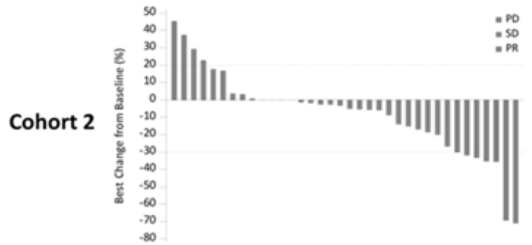
数据截至2024年12月24日，研究继续进行中，数据会随之变化。
TPS =肿瘤细胞阳性比例分数

I/II 期 NSCLC 单药治疗效果的比较

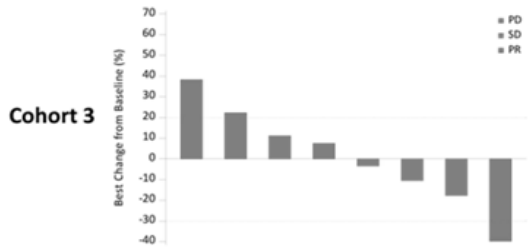
BNT327 NSCLC 2L+ 单药 (ASCO 2024)

疗效:
队列2 （36个可评估患者）
ORR为19.4%， DCR 69.4%， mPFS 5.5个月
队列3 （8个可评估患者）
ORR 12.5%， DCR 62.5%, mPFS 6.7个月

TKI治疗失败的EGFRm NSCLC

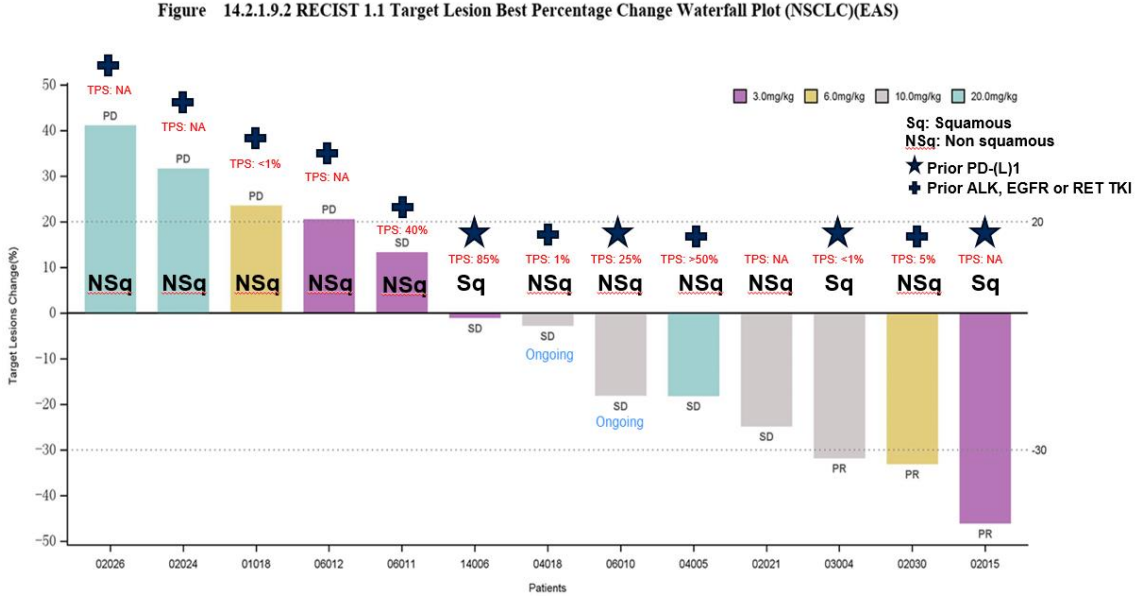


PD-1/L1 和铂类化疗失败的EGFR/ALK 野生型患者



IMM2510 NSCLC 2L+ 单药

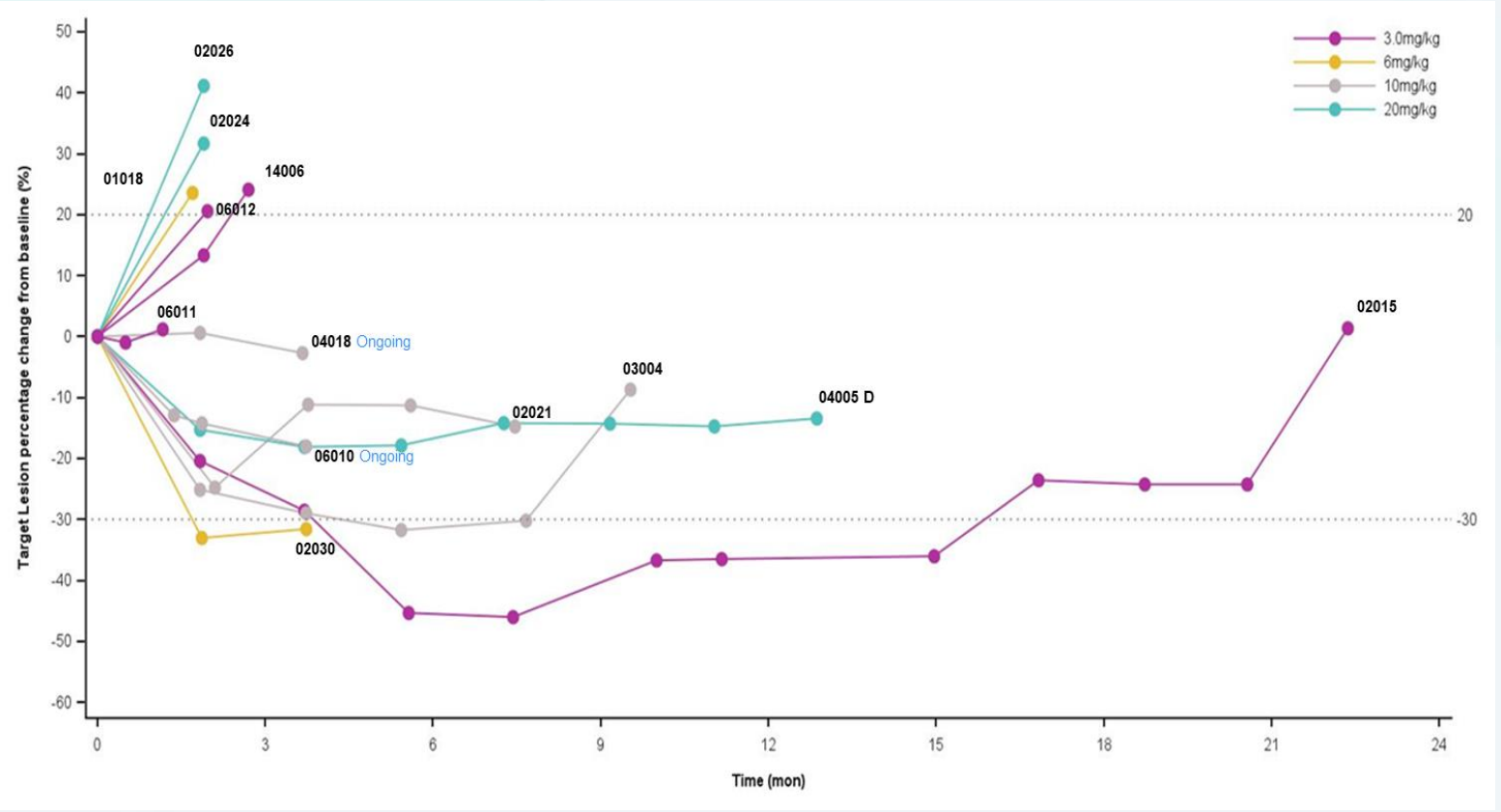
13 可评估患者: **ORR = 23.1%**; DCR = 69.2%



数据来源: Wu et al, ASCO 2024; 非来自头对头的试验。人群的差异使交叉试验比较本身具有局限性
ORR = 客观缓解率| DCR = 疾病控制率

13 例疗效可评估的 NSCLC 患者接受IMM2510单药治疗

数例患者获益延长



数据截至2024年12月24日，研究继续进行中，数据会随之变化

IMM2510 在 NSCLC 中疗效优于竞品的单药治疗 I 期数据

	IMM2510[1]	依沃西单抗[2]	BNT327[3]	BNT327[3]
人群	全人群	EGFR/ALK/ROS 野生型	EGFR突变	EGFR/ALK 野生型
适应症	NSCLC	NSCLC	NSCLC	NSCLC
剂量	3-20 mg/kg Q2W	10-30 mg/kg Q2/3W	20 mg/kg Q2W	20 mg/kg Q2W
n (eff. eval.)	13	15	36	8
# 接受过的治疗线数	1 线及以上 （中位3线）	**1**	1 线及以上	1 线及以上
之前接受过抗PD-1 治疗（如适用）	是	**否***	不适用	是
ORR	**23%**	**33%**	**19%**	**13%**

在更具挑战性的患者群体中与依沃西单抗 的 ORR 相似
在相似患者群体的 ORR 与 BNT327 相似

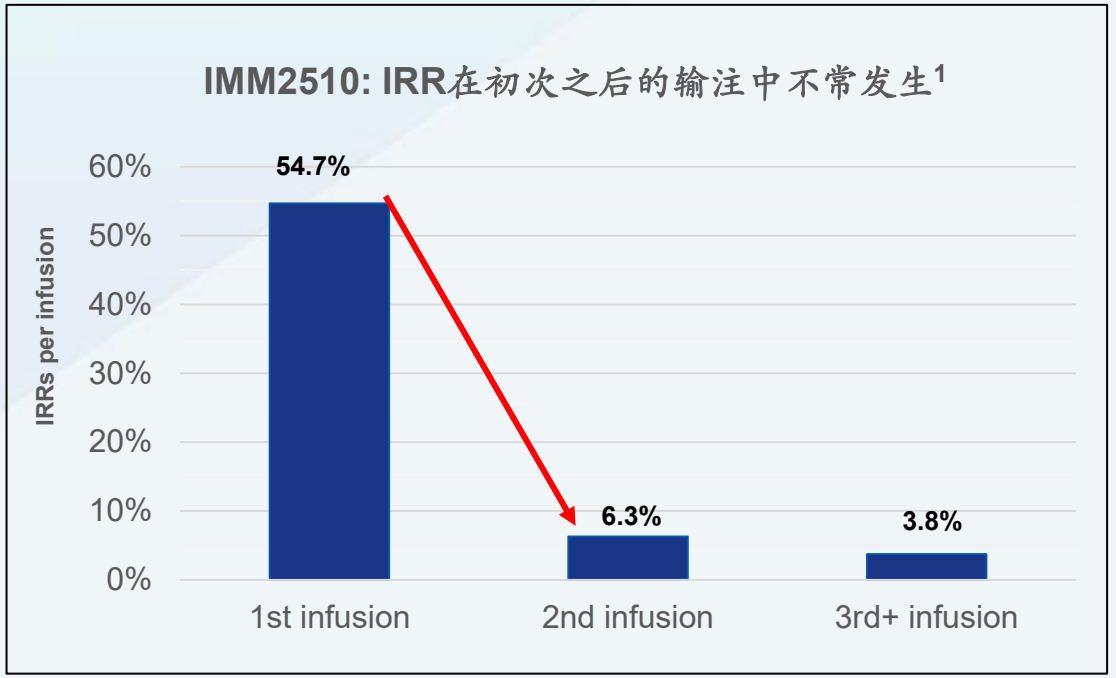
非头对头数据.人群的差异使交叉试验比较本质上受到限制。
来源: [1]截至2024年12月24日，研究继续进行中，数据会随之变化。[2] Wang et al, J Thor Onc 2024 (补充表格：S6; Second-line only); [3] Wu et al ASCO 2024
* 1 例患者既往 PD-1xCTLA-4 双特异性加铂类化疗失败。

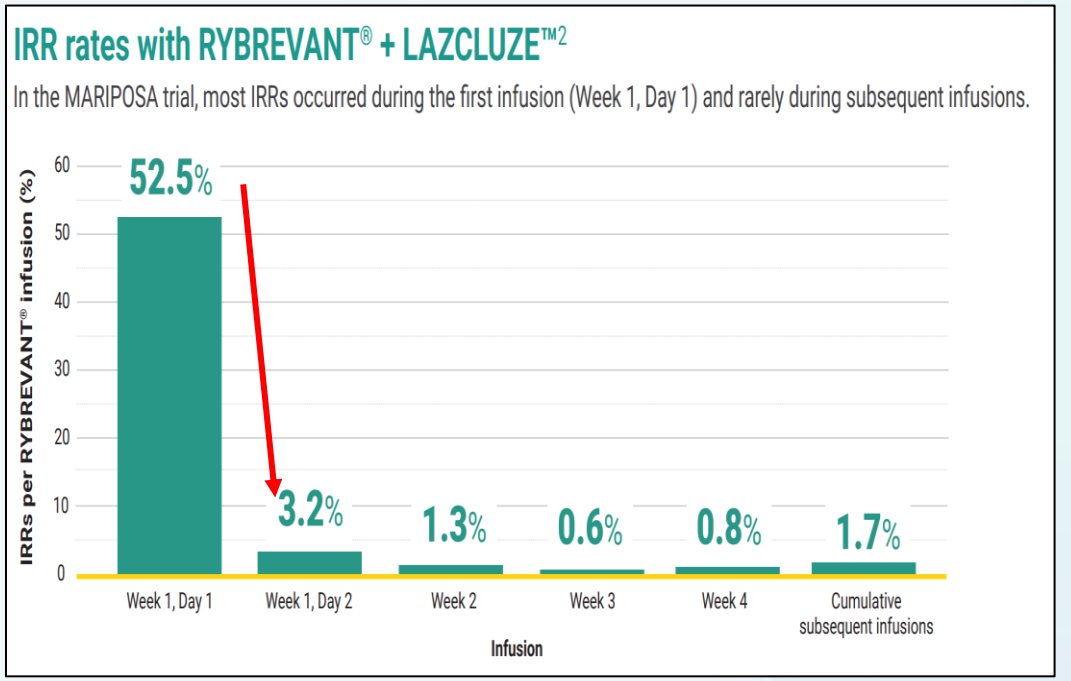
IMM2510安全性与其他 PD-（L）1xVEGF 双特异性抗体相当

类别	依沃西单抗 Ia期 (n=51)[1]	BNT327 Ia期 (n=80) [2]	IMM2510 I期[3] (n=106)
TRAEs	74.5%	77.5%	94.3%
TRAEs 3级	27.5%	22.5%	21.7%
严重TRAEs	5.9%	N/R	12.3%
TRAEs 导致的治疗中断	7.8%	10%	4.7%
TRAEs 导致的死亡	0%	N/R	0.9%*
输液反应（IRR）**	7.8%	NR	60.4%
3级以上	*0%*	*NR*	*3.8%*
Grade 3以上 免疫相关	N/R	0%	3.8%
可能的VEGF相关不良反应(3级以上)			
高血压 (3级以上)	*13.7%*	*6.3%*	*0.9%*
蛋白尿 (3级以上)	*0.9%*	*0%*	*0%*

**一名20mg/kg剂量组的患者死于超敏反应事件（未报告为 IRR）。
**可能提示激活的 ADCC，一种差异化机制
数据来源: [1] Frentzas et al, JITC 2024; [2] Guo et al, SITC 2022; [3]截至2024年12月24日，研究继续进行中，数据会随之变化。

IMM2510 IRR主要出现在初次输注





- IRR 在输注 Fc 活性抗体或双特异性抗体时并不少见。
- 与RYBREVANT® + LACLUZE™ 的经验相似,在 IMM2510 的初次输注后，IRR 率显着下降。

[1] 公司数据, n=106.
[2] RYBREVANT® + LAZCLUZE™: IRR监测和管理

与Instil Bio的全球合作

国际合作

2024年8月1日，我们与Axion Bio, Inc. (曾用名：SynBioTx Inc.）（Instil Bio, Inc. (NASDAQ:TIL)的全资附属公司），达成授权及合作协议。据此，Axion Bio将获全球（大中华地区以外）权限引入我们专有的PD-L1xVEGF双特异性分子IMM2510以及新一代抗CTLA-4抗体(ADCC+) IMM27M。

我们将收取不超过**5000万美元**的首付款及潜在近期付款，以及不超过**21亿美元**的潜在额外开发、监管及商业里程碑付款，另收取全球（大中华地区以外）销售净额的个位数至低两位数比例计算的特许权使用费。

截至2025年5月31日，我们已收到**2000万美元**。

发展自有专利家族

- *1* 项在美国、日本的已授权专利；*1* 项在中国的已获批专利
- *1* 项在欧盟和美国的待批准专利申请

已获批的抗PD-(L)1和抗VEGF的药物联用疗法

	PD-L1	VEGF	PD-(L)1 联用[1]
分子	TECENTRIQ BAVENCIO IMFINZI	AVASTIN	
一线疗法	UC, SCLC, NSCLC	CRC, NSCLC	**RCC, HCC, NSCLC**
其他疗法	NSCLC, HNSCC, Melanoma HCC, RCC, UC, HL	GBM, CRC, NSCLC, RCC, OC, CC	**EAC, CC**

注： 已获批的抗 PD-(L)1 和抗 VEGF 联用疗法

宜明昂科
ImmuneOnco

谢谢!