研究报告 Research Report

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信达生物 Innovent Biologics (1801 HK)

2024 ASCO：多项临床数据公布，彰显公司研发实力

2024 ASCO: Multiple Clinical Data Released, Showcasing the Company's R&D Strength

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热点速评 Flash Analysis

(Please see APPENDIX 1 for English summary)

事件

2024 年 5 月，信达生物在美国临床肿瘤学会（ASCO）2024 年大会公布多项临床数据摘要。包括公司在研的单抗、双抗以及 ADC：IBI363（PD-1/IL-2 双特异性抗体融合蛋白）、IBI389（CLDN18.2/CD3 双抗）、IBI343（CLDN18.2 ADC）、IBI310（抗 CTLA-4 抗体）等多项临床数据读出。

点评

IBI363 针对冷肿瘤结直肠癌和 IO 耐药肿瘤治疗显示出不错的安全性数据。IBI363 是一款 PD-1/IL-2R 双特异性融合蛋白，采取非对称二聚体设计，IL-2 经过改造保留 CD25（IL2Rα）活性以最大化疗效和高选择性，同时减少对 Rβγ 结合以降低系统毒性。IBI363 在晚期结直肠癌患者（既往中位治疗线数≥3 线）中的 I 期研究结果显示，IBI363 可以为患者带来初步临床疗效，特别是在 PD-L1 CPS≥1 的患者中，表现出不错的应答率和疾病控制率。同时 IBI363 展现了整体可接受的耐受性和可控的安全性。非头对头对比 PD-1/PD-L1 单药或者联合疗法在晚期 MSS/pMMR 型 CRC 患者中的荟萃分析数据，IBI363 在患者基线的经治线数更高的前提下，整体 ORR 率和 DCR 率相似。IBI363 相比 PD-1/PD-L1 单药或者联合疗法具备更低的 3 级及以上 TRAE 事件发生率，安全性数据略好。IBI363 针对其他晚期实体瘤（胆道癌、头颈鳞状细胞癌、宫颈癌和卵巢癌）以及黑色素瘤 IO 耐药人群中，也显示出不错的疗效，安全性整体可控。我们认为符合预期。但考虑到样本量依然较小，值得后续关注数据。

CLDN18.2 靶点布局丰富，ADC 和双抗在胰腺癌、胃癌领域前景可期。IBI389（CLDN18.2/CD3 双抗）目前在全球同靶点双抗药物中进度第一，从公布的晚期复发/转移性胰腺导管腺癌（PDAC）患者中的 I 期研究数据来看，非头对头相比 SOC 化疗，IBI389 具备更低的 3 级及以上 TRAE 事件发生率以及因 TEAEs 停药率。应答率和 SOC 化疗、CLDN18.2 ADC、CLDN18.2 CAR-T 等同靶点药物可比。CRS 发生率 51.6%，但未发生≥3 级 CRS，相较于 CLDN18.2 CAR-T 的 10% 的≥3 级 CRS 发生率略有优势。公司还同时公布了 IBI389 在晚期胃癌适应症的 I 期的耐受性和初步疗效数据。我们认为数据整体符合预期。

IBI343 是重组人源抗 CLDN18.2 ADC，由信达生物与 Synaffix 的合作设计，使用了 TOPO1i payload，采取定点偶联技术位点特异性将乙二醇与 Exatecan 偶联，DAR 为 3.6，具备旁观者效应。目前在全球同靶点 ADC 药物中进度靠前，具备一定先发优势。胰腺导管腺癌（PDAC）和胆道癌（BTC）中的 I 期研究数据显示，在 CLDN18.2 表达≥60%的患者人群中，IBI343 取得了不错的应答率。在 10 名 PDAC 患者的亚组中，ORR 为 40%，非头对头同靶点药物具备一定优势。随访时间较短，需要等待 DoR 和 PFS 数据成熟。

信迪利单抗两项新辅助治疗数据读出，为免疫新辅助增添新证据。IBI310（CTLA-4 单抗）联合信迪利单抗（PD-1）用于 MSI-H/dMMR CRC 患者的新辅助治疗的 Ib 期结果显示，与信迪利单抗单药方案对比，IBI310（CTLA-4 单抗）联合信迪利单抗方案显著提高了 pCR 率。两个方案整体安全性可控且具有可比性。新辅助方案信迪利单抗、白蛋白结合紫杉醇和卡铂的治疗晚期可切除食管鳞状细胞癌（ESCC）Phase II 期数据显示，初步证明了该方案的临床获益和可控的安全性。

风险

新药研发风险，新药审批风险，新药上市风险。

Figure 1 IBI363 mCRC 数据整理

mCRC				
药物	IBI363（PD-1/IL-2）		PD-1/PD-L1疗法（单药/联合）	呋喹替尼+信迪利单抗
阶段	Ph 1		Ph 1	Ph 2
试验	NCT05460767		荟萃分析	NCT04695470
患者数量	24	20	1503	55
患者基线	3 lines+: 76.5%		2 lines+	3 lines+
MSS/pMMR	83.8%		100%	100%
随访时间	5.3 months		-	
疗效				
剂量	600 ug/kg Q2W	1 mg/kg Q2W	-	呋喹替尼口服 5mg Q3W+sintilimab 200mg Q3W
ORR	12.7%		4.0%-33.0%	16.0%
ORR with liver metastasis	13.2%			
ORR pts with PD-L1 CPS ⩾ 1	30.8%			
DCR pts with PD-L1 CPS ⩾ 1	76.9%		32.0%-65.0%	77.0%
PFS	-		1.6-3.6	4.1 m
OS	-		-	13.3 m
安全性				
TEAEs	95.6%		-	
⩾ 3 TEAEs	32.4%		-	
TRAEs	91.2%		85.0%	
⩾ 3 TRAEs	23.5%		33.0%	18.6%
sTRAE	17.6%		-	
因TRAEs中断	36.8%		-	
因TRAEs停药	2.9%		-	
irAEs	32.4%		-	
⩾ 3 irAEs	5.9%		-	

资料来源：2024 ASCO，HTI

Figure 2 CLDN 18.2 靶点胰腺癌数据整理

类型	SOC化疗	CD3/Claudin18.2双抗	Claudin18.2 ADC	CLDN18.2 CAR T	
药品	吉西他滨联合白蛋白紫杉醇	IBI389	IBI343	CT041	
试验	NCT04083235	NCT05164458	NCT05458219	NCT04404595	
阶段	phase 3	phase 1	phase 1	Phase 1b/2	
适应症	胰腺癌	胰腺癌	胰腺癌	胰腺癌	
患者数量	387	64	10（CLDN18.2 expression ⩾ 60%）	12	5
患者基线	1	3	3	4	4
给药剂量	白蛋白紫杉醇 125 mg/m²+ 吉西他滨 1000 mg/m²	600 μg/kg	6 mg/kg	DL1: 250-300×10^6 DL2: 375-400×10^6	DL1: 250-300×10^6 DL2: 375-400×10^6 DL3: 600×10^6
疗效					
ORR	36-20%	30.40%	40.00%	16.70%	40%
DCR		69.60%	-	-	-
安全性					
TRAEs	99%	96.90%	-	-	-
⩾3 TRAEs	86%	54.70%	-	-	-
sTRAE	-	-	-	-	-
因TEAEs中断	-	37.50%	-	-	-
因TEAEs停药	30%	4.70%	-	-	-
CRS	-	51.60%	-	-	-
Grade 3 CRS	-	0%	-	10%	

资料来源：2024 ASCO，HTI

Figure 3 信达生物 2024 年 ASCO 大会数据整理

肿瘤	编号	药物	靶点	试验阶段	N	基线	疗效					安全性						
							ORR	CR	PR	SD	DCR	TRAE	≥3 TRAE	≥3 CRS	irAE	≥3 irAE	TRAEs 中断治疗率	TRAEs 停止治疗率
晚期 CRC	3593	IBI363	PD-1/IL-2 双抗	phase 1	68	既往中位治疗线数≥3 线 77% MSS/pMMR 83%	13% 31%（PD-L1 CPS ≥1）	-	-	-	77%（PD-L1 CPS ≥1）	96%	24%	-	32%	6%	37%	3%
晚期黑色素瘤	9562	IBI363	PD-1/IL-2 双抗	phase 1	67	既往中位治疗线数≥2 线 60% 既往 IO 治疗 90%	28%	-	28%	44%	72%	-	18%	-	-	-	-	-
晚期胆道癌 头颈鳞状细胞癌 宫颈癌和卵巢癌	e14593	IBI363	PD-1/IL-2 双抗	phase 1	24	-	22%	-	9%（BTC）	81%（BTC）	78%	-	-	-	-	-	-	-
胰腺导管腺癌或胆道癌	3037	IBI343	CLDN18.2 ADC	phase 1	35	-	40%（PDAC）	-	28%	-	80%	80%	26%	-	-	-	20%	3%
胰腺导管腺癌	4011	IBI389	CLDN18.2/CD3 双抗	phase 1	64	既往中位治疗线数≥2 线	30%	-	-	-	70%	97%	55%	0%	-	-	38%	5%
胃或胃食管癌	2519	IBI389	CLDN18.2/CD3 双抗	phase 1	114	既往中位治疗线数≥2 线	31%	-	31%	42%	73%	97%	55%	1%	-	-	39%	7%
MSI-H/dMMR 晚期 CRC 新辅助治疗	3505	IBI310+sintilimab	CTLA-4+PD-1	phase Ib	52	1 线	-	80%	-	-	-	89%	25%	-	42%	-	-	-
		sintilimab	CTLA-4+PD-1	phase Ib	49		-	48%	-	-	-	80%	18%	-	37%	-	-	-
食管鳞状细胞癌 新辅助治疗	e16097	sintilimab 白蛋白结合紫杉醇 卡铂	PD-1+化疗	phase 2	24	-	-	33%	-	-	-	-	29%	-	-	-	-	-

资料来源：2024 ASCO，HTI

APPENDIX 1

Events

In May 2024, Innovent Biologics released multiple clinical data summaries at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting. These include clinical data for the company's monoclonal antibodies, bispecific antibodies, and antibody-drug conjugates (ADCs): IBI363 (PD-1/IL-2 bispecific antibody fusion protein), IBI389 (CLDN18.2/CD3 bispecific antibody), IBI343 (CLDN18.2 ADC), and IBI310 (anti-CTLA-4 antibody), among others.

IBI363 has demonstrated promising safety data in the treatment of cold tumors, and IO-resistant tumors. IBI363 is a PD-1/IL-2R bispecific fusion protein designed with an asymmetric dimer structure. The IL-2 arm of IBI363 has been engineered to maximize efficacy and reduce toxicity, whereas the PD-1 binding arm achieves PD-1 blockade and selective IL-2 delivery. Therefore, IBI363 has both functions of simultaneously blocking PD-1/PD-L1 pathway and activating IL-2 pathway. Phase I study results in patients with advanced colorectal cancer (median of ≥3 prior lines of treatment) indicate that IBI363 can provide initial clinical benefits, particularly showing good response and disease control rates in patients with PD-L1 CPS≥1. Additionally, IBI363 exhibited overall acceptable tolerability and manageable safety. Indirect comparisons with PD-1/PD-L1 monotherapies or combination therapies in advanced MSS/pMMR-type CRC patients suggest that, despite higher baseline treatment lines, IBI363 has similar overall response rates (ORR) and disease control rates (DCR). IBI363 also demonstrates a lower incidence of grade 3 and above treatment-related adverse events (TRAEs) compared to PD-1/PD-L1 monotherapies or combination therapies, indicating slightly better safety data. Furthermore, IBI363 has shown promising efficacy and manageable safety in other advanced solid tumors, such as biliary tract cancer, head and neck squamous cell carcinoma, cervical cancer, ovarian cancer, and in IO-resistant melanoma patients. Although these results are encouraging, the sample size is still relatively small, warranting further data collection and analysis.

The CLDN18.2 target is being developed comprehensively, with ADCs and bispecific antibodies showing promising prospects in pancreatic and gastric cancer. The Phase I study data of IBI389 (CLDN18.2/CD3 bispecific antibody) in patients with advanced recurrent/metastatic pancreatic ductal adenocarcinoma (PDAC) reveal that, compared to standard-of-care (SOC) chemotherapy, IBI389 has a lower incidence of grade 3 and above treatment-related adverse events (TRAEs) and a lower discontinuation rate due to treatment-emergent adverse events (TEAEs). The response rate is comparable to SOC chemotherapy, CLDN18.2 ADCs, and CLDN18.2 CAR-T therapies. Cytokine release syndrome (CRS) occurred in 51.6% of cases, but no ≥ grade 3 CRS was reported, which is an advantage over the 10% incidence of ≥ grade 3 CRS observed with CLDN18.2 CAR-T therapies. The company also released IBI389's Phase I tolerability and preliminary efficacy data for advanced gastric cancer. Overall, the data met expectations.
IBI343 is a recombinant human anti-CLDN18.2 ADC, co-developed by Innovent Biologics and Synaffix. It utilizes a TOPO1i payload and site-specific conjugation technology to link glycol and exatecan, with a drug-to-antibody ratio (DAR) of 3.6, offering a bystander effect. IBI343 is among the leading ADCs targeting CLDN18.2 globally, providing a first-mover advantage. Phase I study results in PDAC and biliary tract cancer (BTC) indicate that IBI343 achieved a notable response rate in patients with CLDN18.2 expression ≥60%. In a subgroup of 10 PDAC patients, the overall response rate (ORR) was 40%, suggesting a potential advantage over other drugs targeting the same antigen. However, the follow-up period is short, and further data on duration of response (DoR) and progression-free survival (PFS) are needed for a more comprehensive assessment

Two new neoadjuvant therapy data readouts for sintilimab add new evidence to the field of immunotherapy. Phase Ib results of IBI310 (CTLA-4 antibody) combined with sintilimab (PD-1 antibody) for neoadjuvant treatment of MSI-H/dMMR CRC patients show that this combination significantly increases the pathological complete response (pCR) rate compared to sintilimab monotherapy. Both treatment regimens demonstrated manageable and comparable safety profiles. Additionally, Phase II data for a neoadjuvant regimen of sintilimab combined with albumin-bound paclitaxel and carboplatin in treating resectable advanced esophageal squamous cell carcinoma (ESCC) preliminarily demonstrate the clinical benefits and manageable safety of this regimen.

Risks: New drug development risk; New drug approval risk; New drug market entry risk

APPENDIX 2

ESG Comments

Environmental:

the overall performance of company on environment is good

Social:

the overall performance of company on society is good

Governance:

the overall performance of company on government is good

附录 APPENDIX

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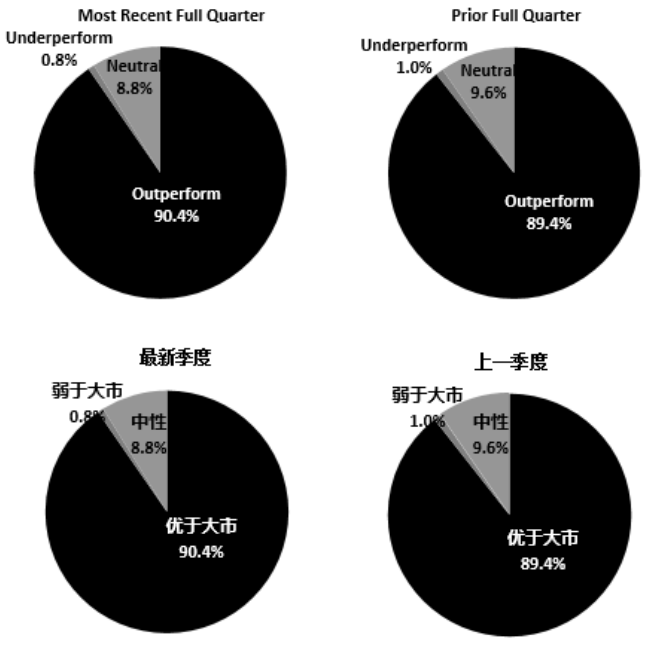

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	Outperform	Neutral (hold)	Underperform
HTI Equity Research Coverage	90.4%	8.8%	0.8%
IB clients*	3.3%	4.9%	0.0%

*Percentage of investment banking clients in each rating category.

BUY, Neutral, and SELL in the above distribution correspond to our current ratings of Outperform, Neutral, and Underperform.

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Previous rating system definitions (until 30 Jun 2020):

BUY: The stock's total return over the next 12-18 months is expected to exceed the return of its relevant broad market benchmark, as indicated below.

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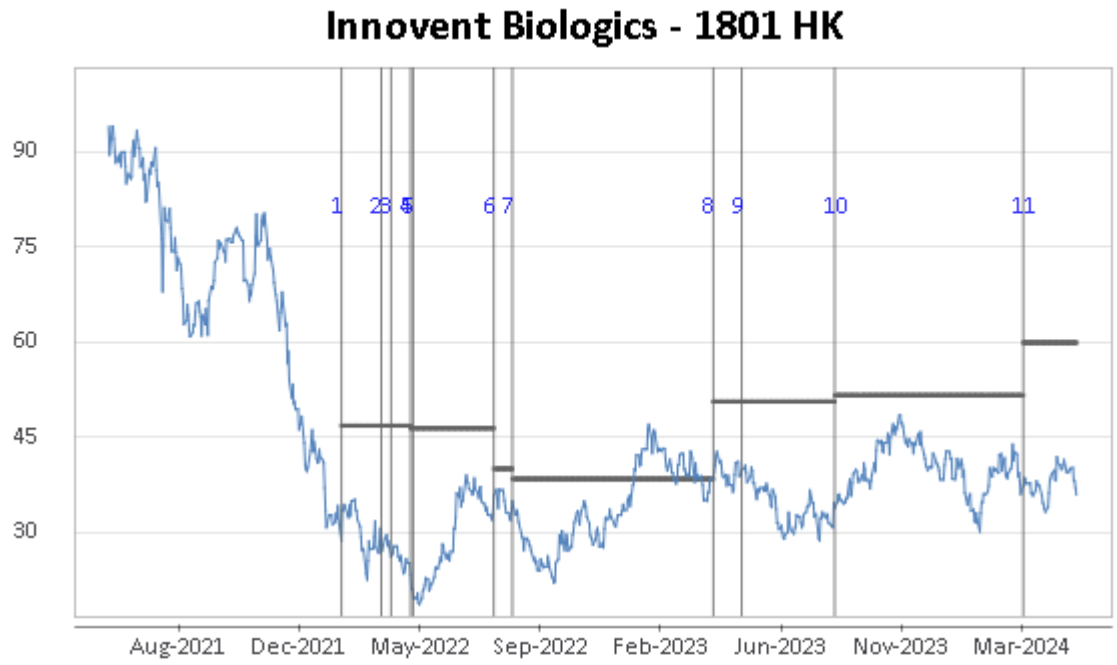
Recommendation Chart



1. 14 Feb 2022 OUTPERFORM at 31.6 target 46.8.
2. 31 Mar 2022 OUTPERFORM at 30.6 target 46.8.
3. 11 Apr 2022 OUTPERFORM at 28.55 target 46.8.
4. 3 May 2022 OUTPERFORM at 25.15 target 46.4.
5. 6 May 2022 OUTPERFORM at 21.05 target 46.4.
6. 7 Aug 2022 OUTPERFORM at 35.8 target 40.0.
7. 26 Aug 2022 OUTPERFORM at 33.6 target 38.4.
8. 10 Apr 2023 OUTPERFORM at 38.35 target 50.6.
9. 12 May 2023 OUTPERFORM at 39.75 target 50.6.
10. 25 Aug 2023 OUTPERFORM at 34.65 target 51.6.
11. 25 Mar 2024 OUTPERFORM at 36.0 target 59.9.

Source: Company data Bloomberg, HTI estimates