信达生物 Innovent Biologics (1801 HK)

2025 ASCO 数据超预期，创新潜力不断兑现

2025 ASCO Data Beats Expectations, Validating Sustained Innovation Execution

观点聚焦 Investment Focus

维持优于大市 Maintain OUTPERFORM

评级	优于大市 OUTPERFORM
现价	HK$73.15
目标价	HK$90.10
HTI ESG	3.6-1.4-3.5
E-S-G: 0-5, (Please refer to the Appendix for ESG comments)	
市值	HK$120.81bn / US$15.40bn
日交易额 (3 个月均值)	US$146.21mn
发行股票数目	1,652mn
自由流通股 (%)	93%
1 年股价最高最低值	HK$74.25-HK$30.00

注：现价 HK$73.15 为 2025 年 06 月 06 日收盘价

资料来源：Factset

	1mth	3mth	12mth
绝对值	33.2%	82.2%	97.2%
绝对值（美元）	31.6%	80.5%	96.3%
相对 MSCI China	31.2%	86.9%	74.4%

Rmb mn	Dec-24A	Dec-25E	Dec-26E	Dec-27E
Revenue	9,422	11,863	14,342	18,172
Revenue (+/-)	52%	26%	21%	27%
Net profit	-206	384	849	1,765
Net profit (+/-)	n.m.	-286%	121%	108%
Diluted EPS (Rmb)	-0.13	0.24	0.52	1.08
GPM	84.0%	83.7%	84.7%	88.0%
ROE	-1.6%	2.8%	5.9%	10.9%
P/E	n.m.	284	128	62

资料来源：公司信息, HTI

(Please see APPENDIX 1 for English summary)

事件

信达生物多项研究入选 ASCO 口头报告，彰显公司肿瘤创新药物研发的强大实力。公司在 2025 年美国临床肿瘤学会（ASCO）年会上公布肿瘤创新管线系列临床数据，共有 8 项口头报告，约占大会口头报告总数的 2%，涵盖 IBI363（PD-1/IL-2α-bias）和 IBI343（CLDN18.2 ADC）等药物多项研究成果。其中重点关注点在于 IBI363 相关研究包括在免疫治疗后晚期肢端及黏膜黑色素瘤、晚期结直肠癌、晚期非小细胞肺癌患者中的疗效与安全性研究；IBI343 的 I 期剂量扩展队列研究聚焦 Claudin18.2 在胰腺导管腺癌中的表达与疗效。

点评

我们认为 IBI363 在 IO 经治非小细胞肺癌、结直肠癌数据持续亮眼，再次验证了该分子成为下一代 IO 疗法基石药物的潜力。IBI363 在非小细胞肺癌、结直肠癌、黑色素瘤三项免疫耐药及冷肿瘤中，均以口头报告形式报道了令人鼓舞的 I/II 期临床数据，从肿瘤响应到长期生存获益，全面地展现了 IBI363 在各适应症的亮眼研究结果。

1）**IBI363 单药治疗 IO 耐药的晚期非小细胞肺癌 mPFS 数据超预期：**IBI363 单药用于晚期 NSCLC 受试者的更新数据（NCT05460767）。截止随访时间 2025 年 4 月 7 日，共 136 例 NSCLC 受试者接受了 IBI363 单药治疗（2μg/kg QW~4mg/kg Q3W），其中包括 67 例鳞状非小细胞癌和 58 例 EGFR 野生型腺癌。

67 例鳞状非小细胞肺癌均无已知的 EGFR 突变，其中 28 例接受了 1 mg/kg Q2W 或 1.5 mg/kg Q3W IBI363 治疗，31 例接受了 3 mg/kg Q3W IBI363 治疗。两组受试者既往系统性治疗线数≥2 线的比例为 64.3% vs 67.7%，既往抗 PD-1/PD-L1 治疗的比例为 100% vs 96.8%，PD-L1 TPS<1%的比例为 35.7% vs 41.9%。

相较于 1/1.5 mg/kg 剂量组，3 mg/kg Q3W 剂量组观察到更突出的确认的 ORR：cORR 36.7%，DCR 90%，mPFS 9.3 个月（mPFS 比肩标准疗法多西他赛 OS 数据，超越 PD-L1+CTLA-4 等 IO 组合疗法 mPFS），mOS 尚未成熟（中位随访时间 11.3 个月），我们认为未来随着随访时间延长，mOS 将有可能大幅度优于现有疗法。此外，3mg 剂量组的 mDoR 也比较长，随访 9.7 个月后事件数达 36.4%，意味着在响应人群中药物持续有效时间较长。安全性整体可控，Gr≥3 TRAEs 43.9%，最常见的 Gr≥3 TRAEs 是关节痛和皮疹，7.0%的受试者发生了导致永久停药的 TRAE，TRAEs 导致的死亡发生率 0%；

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图1 IBI363 在 IO 经治非小细胞肺癌数据（ NCT05460767）

	EGFR 野生型肺腺癌		鳞状非小细胞肺癌	
	0.6/1/1.5 mg/kg (n=30)	3 mg/kg (n= 25)	1/1.5 mg/kg (n=28)	3 mg/kg (n=31)
确认的ORR,%(95%CI)*	13.8 (3.9, 31.7)	24.0 (9.4, 45.1)	25.9 (11.1, 46.3)	36.7 (19.9, 56.1)
DCR, % (95% CI)*	62.1 (42.3, 79.3)	76.0 (54.9, 90.6)	66.7 (46.0 83.5)	90.0 (73.5, 97.9)
中位PFS,月 (95% CI)	2.7 (1.4, 5.1)	5.6 (3.1, 9.4)	5.5 (1.5, 8.3)	9.3 (6.2, 11.7)
PFS中位随访时间,月(95%CI)	21.9 (3.1, 21.9)	10.1 (6.1, 11.2)	16.5 (14.1, 19.5)	11.3 (10.1, 14.0)
中位OS,月 (95% CI)	17.5 (5.6, NC)	NC (9.4, NC)	15.3 (7.6, NC)	NC (10.4, NC)
12个月OS率,% (95% CI)	58.2 (38.3, 73.8)	71.6 (45.9, 86.6)	58.2 (37.3, 74.3)	70.9 (49.5,84.5)
OS 中位随访时间 ,月(95%CI)	17.7 (17.1, 20.9)	10.2 (9.1, 11.4)	17.3 (15.3, 20.2)	11.3 (10.3, 11.6)

58 例非小细胞肺腺癌均无已知的 EGFR 突变，其中 30 例接受了 0.6mg/kg Q2W, 1 mg/kg Q2W 或 1.5 mg/kg Q3W IBI363 治疗（56.7%有过往吸烟史），25 例接受了 3 mg/kg Q3W IBI363 治疗（60%过往吸烟史）。

3 mg/kg Q3W 剂量组的 cORR 为 24.0%，mPFS 5.6 个月， mOS 尚未成熟（中位随访时间 10.2 个月）。我们认为以上数据也优于现有的免疫疗法。

资料来源：2025 ASCO，HTI

2） **IBI363 单药治疗冷肿瘤 3L+结直肠癌 mOS 数据相比现有疗法延长约 6 个月：**针对 3L+治疗失败的 MSS 型结直肠癌患者，单药治疗组中，63 名患者（4L+63.2%，MSS 占比 86.8%）。ORR 为 12.7%，mDoR 为 7.5 个月，mOS 为 16.1 个月（对比现有疗法 mOS 9-10 个月有显著延长），其中肝转（14.4 个月）和无肝转组（17 个月）OS 获益都优异，显示了免疫治疗持续的拖尾效应所带来的长期生存获益，有望逆转 IO 疗法在免疫冷肿瘤的无效表现。联合贝伐治疗组 ORR 23.5%，mDoR 和 mOS 均未成熟，但亚组分析显示 3mg 高剂量组的 ORR，PFS 表现优异，令我们期待高剂量组更长随访时间后的生存获益数据。

3） **IO 经治的黑色素瘤疗效出色：**两项 I、II 期临床研究（NCT05460767，NCT06081920），截至 2025 年 4 月 7 日，31 例不可切除局部晚期或转移性肢端型及黏膜型黑色素瘤患者，接受 1 mg/kg Q2W 剂量治疗，所有患者均为免疫治疗耐药，其中 20 例（64.5%）既往接受过 2 线或以上的抗肿瘤治疗。患者 cORR 23.3%（对比化疗等 SOC 7%-11%），PFS 5.7 个月（对比 TIL 疗法 4.1 个月），mOS 为 14.8 个月。

4） **CLDN18.2 ADC 治疗晚期胰腺癌，展现了 PFS 和 OS 潜力。**2025 ASCO 公布了 Ia/Ib 期剂量递增和剂量扩展研究（NCT05458219）扩展队列的最新研究数据：截至 2025 年 3 月 14 日，共有 83 例胰腺癌患者接受了至少一次 IBI343 治疗，中位随访时间为 11.1 个月。6mg/kg 剂量组 CLDN18.2 1+2+3+≥60%的 44 例受试者中，cORR 为 22.7%，DCR 为 81.8%，mPFS 为 5.4 个月，mOS 为 9.1 个月。其中既往仅接受过

一线治疗受试者（N=17）的 mPFS 为 5.4 个月，mOS 长达 12.1 个月；既往仅接受过两线治疗受试者（N=18）的 mPFS 为 5.3 个月，mOS 为 9.1 个月。安全性方面，总体耐受性良好，消化道毒性低，未出现新的安全信号。TEAE 事件发生率 98.8%。考虑到目前针对晚期胰腺癌的 1~2L 治疗方案仍以化疗为主，其中 2L 治疗的临床选择尤为有限，化疗响应率仅为 6-16%，mPFS 约 2~5 个月，mOS 大约 6~9 个月，我们认为 IBI343 有望为胰腺癌末线患者提供新的治疗方案。

盈利预测及估值建议

结合公司 IBI363 数据优异，分子成药性提高，考虑到海外肺鳞癌、结直肠癌药物市场空间较大，我们调整盈利预测及估值模型。我们预计 2025-27 年总收入为 118.6/143.4/181.7 亿元（前值：118.6/143.4/180.9），同比+26/+21/+27%。2025 年扭亏为盈，实现净利润 3.8 亿元（前值：不变）。我们采用 DCF 模型对公司进行估值，采用 FY26-37 现金流进行测算，基于 WACC 9.8%（不变），永续增长率 3.5%（不变），假设汇率 RMB:HKD=1:1.14，调整目标价至 90.1 HKD/股（前值：62.5 HKD/股），维持“优于大市”评级。

风险

新药研发风险，新药审批风险，新药商业化不及预期风险。

Table 1 DCF 估值模型

RMB m	FY24A	FY25E	FY26E	FY27E	FY28E	FY29E	FY30E	FY31E	FY32E	FY33E	FY34E	FY35E	FY36E	FY37E
	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037
Forecast Year		1	2	3	4	5	6	7	8	8	8	8	8	8
Time Factor	0.0	0.6	1.6	2.6	3.6	4.6	5.6	6.6	7.6	8.6	9.6	10.6	11.6	12.6
(fraction of year to next FY end)														
Sales	**9422**	**11863**	**14342**	**18172**	**21406**	**24853**	**27878**	**30302**	**32524**	**34136**	**35517**	**36524**	**37485**	**38416**
... Growth	*51.8%*	*25.9%*	*20.9%*	*26.7%*	*17.8%*	*16.1%*	*12.2%*	*8.7%*	*7.3%*	*5.0%*	*4.0%*	*2.8%*	*2.6%*	*2.5%*
Gross Profit	7912	9929	12146	15991	18837	21871	24533	26666	28621	30039	31255	32141	32987	33806
... GP Margin	*84.0%*	*83.7%*	*84.7%*	*88.0%*	*88.0%*	*88.0%*	*88.0%*	*88.0%*	*88.0%*	*88.0%*	*88.0%*	*88.0%*	*88.0%*	*88.0%*
SG&A	-8668	-10043	-11714	-14481	-16297	-17074	-18095	-19155	-20185	-20811	-21270	-21855	-22412	-22952
... SG&A Margin	*92.0%*	*84.7%*	*81.7%*	*79.7%*	*76.1%*	*68.7%*	*64.9%*	*63.2%*	*62.1%*	*61.0%*	*59.9%*	*59.8%*	*59.8%*	*59.7%*
Depreciation & Amortisation	581	488	691	648	627	623	634	658	689	726	765	805	844	881
EBIT	**-122**	**519**	**1066**	**2144**	**3823**	**6732**	**9027**	**11113**	**13036**	**14035**	**14998**	**15309**	**15606**	**15894**
Add: Amortisation	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EBITA	**-122**	**519**	**1066**	**2144**	**3823**	**6732**	**9027**	**11113**	**13036**	**14035**	**14998**	**15309**	**15606**	**15894**
... Margin	*-1.3%*	*4.4%*	*7.4%*	*11.8%*	*17.9%*	*27.1%*	*32.4%*	*36.7%*	*40.1%*	*41.1%*	*42.2%*	*41.9%*	*41.6%*	*41.4%*
... Growth														
Add: Depreciation	581	488	691	648	627	623	634	658	689	726	765	805	844	881
EBITDA	**458**	**1,008**	**1,757**	**2,791**	**4,450**	**7,354**	**9,662**	**11,771**	**13,724**	**14,761**	**15,763**	**16,114**	**16,450**	**16,775**
... Margin	*4.9%*	*8.5%*	*12.3%*	*15.4%*	*20.8%*	*29.6%*	*34.7%*	*38.8%*	*42.2%*	*43.2%*	*44.4%*	*44.1%*	*43.9%*	*43.7%*
Less: Tax	116	-16	-68	-150	-311	-563	-1,000	-1,344	-1,657	-1,945	-2,095	-2,240	-2,286	-2,331
Less: Minority Interests	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Less: Increase of Working Capital	3,047	-226	-113	226	226	453	453	453	453	453	453	453	453	453
Less: Capex	-283	-356	-430	-545	-642	-746	-836	-909	-976	-1,024	-1,066	-1,096	-1,125	-1,152
... Capex:Depreciation	*0.5x*	*0.7x*	*0.6x*	*0.8x*	*1.0x*	*1.2x*	*1.3x*	*1.4x*	*1.4x*	*1.4x*	*1.4x*	*1.4x*	*1.3x*	*1.3x*
Less: Acquisitions	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Free Cash Flow	**3,339**	**409**	**1,146**	**2,323**	**3,723**	**6,498**	**8,279**	**9,971**	**11,545**	**12,244**	**13,055**	**13,232**	**13,492**	**13,745**
... FCF Growth	*-285.6%*	*-87.7%*	*179.9%*	*102.7%*	*60.3%*	*74.5%*	*27.4%*	*20.4%*	*15.8%*	*6.1%*	*6.6%*	*1.4%*	*2.0%*	*1.9%*
PV of FCF	**3,339**	**389**	**990**	**1,828**	**2,670**	**4,244**	**4,924**	**5,401**	**5,696**	**5,502**	**5,343**	**4,932**	**4,581**	**4,250**
Bull Case														

WACC		**DCF Valuation**	
Risk Free Rate	3.0%	Sum of PV of FCF	50,363
Market Risk Premium	9.5%	PV of Terminal Value	69,883
Equity Beta	0.88	Enterprise Value	120,246
Cost of Equity	11.4%	Add: Net Cash FY24	7,508
Cost of Debt (Pre-tax)	6.0%	Equity Value (RMB mn)	127,754
Cost of Debt (After tax)	5.1%		
Target Debt weight	25.0%	Equity Value (USD mn)	$ 16,484
Target Equity weight	75.0%	Equity Value (HKD mn)	140,529
Tax Rate	15.0%	FX	1.10
		Diluted weighted shares outstanding	1,560
WACC	**9.8%** **Terminal Growth** **3.5%**	**Value per Share, HKD**	**HK$ 90.1**

资料来源：公司财报，HTI

Table 2 财务模型以及盈利预测

Key financials	Dec-24E	Dec-25E	Dec-26E	Dec-27E
Revenue (Rmbm)	9422	11863	14342	18172
Operating Profit /Loss (RMBm)	-756	-114	432	1,510
Pre-tax profit / Loss (RMBm)	-190	452	998	2,076
Net income to ord equity (RMBm)	(206)	384	849	1,765
Revenue growth	52%	26%	21%	27%
Net profit growth	n.a.	n.a.	121.0%	107.9%
Adjusted net income to ord equity (Rmbm)	(206)	384	849	1,765
ROE	-1.6%	2.8%	5.9%	10.9%

Balance Sheet (Rmb'm)	Dec-24E	Dec-25E	Dec-26E	Dec-27E
Total cash and equivalents	7,508	7,988	9,173	11,456
Inventories	822.2	588.3	66.0	65.6
Account and other receivables	376	786	1,487	413
Trade receivables	1,184	1,923	2,325	2,945
Other current assets	383	383	383	383
Total current assets	**10,273**	**11,667**	**13,434**	**15,263**
Property, plant and equipment	5,280	5,147	4,886	4,784
Other non-current assets	6,050	6,050	6,050	6,050
Total non-current assets	**11,330**	**11,197**	**10,936**	**10,834**
Total assets	**21,603**	**22,864**	**24,370**	**26,097**
Contract liabilities	256	256	256	256
Trade and other payable	358	634	720	715
Bank borrowing	405	405	405	405
Other current liabilities	3,350	4,241	4,812	4,779
Total current liabilities	**4,369**	**5,536**	**6,194**	**6,156**
Bank borrowing	2,412	2,412	2,412	2,412
Contract liabilities	568	568	568	568
Other liabilities	1,136	846	846	846
Total non-current liabilities	**4,116**	**3,826**	**3,826**	**3,826**
Total liabilities	**8,485**	**9,362**	**10,020**	**9,982**
Shareholder's equity	**13,118**	**13,502**	**14,350**	**16,115**
Minority interests	-	-	-	-
Total equity	13,118	13,502	14,350	16,115
Total liabilities & shareholders' equity	**21,603**	**22,864**	**24,370**	**26,097**

Cash flow (Rmb'm)	Dec-24E	Dec-25E	Dec-26E	Dec-27E
Operating profit	**(756)**	**(114)**	**432**	**1,510**
Deprecation and amortisation	581	488	691	648
Changes in working capital	(3,047)	226	113	(226)
Other operating cash flow	6,901	302	447	965
Cash generated from operations	**3,679**	**903**	**1,684**	**2,896**
Capex	(283)	(356)	(430)	(545)
Other investing cash flow	-	-	-	-
Net cash flow from investing activities	**(283)**	**(356)**	**(430)**	**(545)**
Change in borrowings	(704)	-	-	-
Proceeds from changes in capital	-	-	-	-
Other financing cash flow	(68)	(68)	(68)	(68)
Net cash flow from financing activities	**(772)**	**(68)**	**(68)**	**(68)**
Cash at beginning of period	7,508	7,988	9,173	11,456
Net change in cash	**2,624**	**480**	**1,186**	**2,283**
Forex effects	-	-	-	-
Implied cash at end of period	7,988	9,173	11,456	15,057
Free cash flow	**3,396**	**547**	**1,253**	**2,351**

Profit & Loss (Rmb'm)	Dec-24E	Dec-25E	Dec-26E	Dec-27E
Total turnover	9,422	11,863	14,342	18,172
Cost of sales	1,510	1,935	2,196	2,181
Gross profit	7,912	9,929	12,146	15,991
Total operating costs	8,668	10,043	11,714	14,481
Operating profit	(756)	(114)	432	1,510
Operating EBITDA	648	1,197	1,947	2,981
Depreciation and amortisation	581	488	691	648
Operating EBIT	(122)	519	1,066	2,144
Interest income (expense)	190	190	190	190
Share of loss from an associate/JV	-	-	-	-
Pre-tax profit	(190)	452	998	2,076
Taxation	16	68	150	311
Net Income	(206)	384	849	1,765
Minorities	-	-	-	-
Net Income to ord equity	(206)	384	849	1,765
One-off expense	-	-	-	-
Normalized net income	**(206)**	**384**	**849**	**1,765**

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Per Share Data	Dec-24E	Dec-25E	Dec-26E	Dec-27E
EPS (Rmb)	(0.13)	0.24	0.52	1.08
Revenue per share (Rmb)	5.79	7.29	8.81	11.17
Operating EBITDA per share (Rmb)	0.28	0.62	1.08	1.71
BVPS (Rmb)	8.06	8.30	8.82	9.90
DPS (Rmb)	-	-	-	-
Recurrent cash flow per share (Rmb)	1.61	0.29	0.73	1.40
Shares in issue (million)	1,627	1,627	1,627	1,627
Year end adjusted shares in issue (million)	1,627	1,627	1,627	1,627

x

Key Ratios	Dec-24E	Dec-25E	Dec-26E	Dec-27E
Growth				
Revenue growth	51.8%	25.9%	20.9%	26.7%
Operating profit growth	56.1%	25.5%	22.3%	31.7%
Net profit growth	-80.0%	-286.4%	121.0%	107.9%
Margins				
Gross margin	84.0%	83.7%	84.7%	88.0%
Operating EBITDA margin	4.9%	8.5%	12.3%	15.4%
Operating margin	-8.0%	-1.0%	3.0%	8.3%
Pretax profit margin	-2.0%	3.8%	7.0%	11.4%
Tax rate	0.0%	15.0%	15.0%	15.0%
Net profit margin	-2.2%	3.2%	5.9%	9.7%
Key Ratios				
ROE	-1.6%	2.8%	5.9%	10.9%
ROA	-1.0%	1.7%	3.5%	6.8%
Capex/revenue	-3.0%	-3.0%	-3.0%	-3.0%
Current ratio (x)	2.4	2.1	2.2	2.5
Creditor days	120	120	120	120
Debtor days	59	59	59	59
Inventory days	111	11	11	11
Sales/avg assets	0.8	1.1	1.1	1.3
Credit analysis				
Debt/EBITDA (x)	7.7	3.2	1.9	1.2
Debt/equity	28%	27%	25%	23%
Net debt to equity	-16%	-13%	-16%	-28%

资料来源：公司财报，HTI

APPENDIX 1

Summary

Innovent Biologics Showcases Strong Oncology Innovation Capabilities with Multiple Studies Selected for Oral Presentation at ASCO

Innovent Biologics demonstrated its robust oncology R&D strength at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting, presenting a series of clinical data from its innovative oncology pipeline. A total of eight studies were selected for oral presentation, accounting for approximately 2% of all oral presentations at the conference. These include key research findings on IBI363 (PD-1/IL-2α-bias) and IBI343 (CLDN18.2 ADC). Of particular interest, the IBI363-related presentations covered efficacy and safety data in patients with advanced acral and mucosal melanoma, advanced colorectal cancer, and advanced non-small cell lung cancer (NSCLC) who had previously received immunotherapy. The Phase I dose-expansion study of IBI343 focused on Claudin18.2 expression and clinical activity in pancreatic ductal adenocarcinoma (PDAC).

We think the continued strong data from IBI363 in IO-pretreated non-small cell lung cancer (NSCLC) and colorectal cancer (CRC) further validates its potential to become a backbone therapy for the next generation of immuno-oncology (IO) treatments.

At the 2025 ASCO Annual Meeting, Innovent presented encouraging Phase I/II data for IBI363 across three challenging tumor types characterized by IO resistance and immune-cold profiles—NSCLC, CRC, and melanoma—all selected as oral presentations. The data demonstrated robust tumor responses and long-term survival benefits, underscoring IBI363's broad clinical potential across indications.

1) IBI363 monotherapy shows stronger-than-expected mPFS in IO-resistant advanced NSCLC:

Updated results were shared for IBI363 monotherapy in advanced NSCLC patients (Study NCT05460767). As of the data cutoff on April 7, 2025, a total of 136 NSCLC patients had received IBI363 monotherapy (ranging from 2 μg/kg QW to 4 mg/kg Q3W), including 67 patients with squamous NSCLC and 58 patients with EGFR wild-type adenocarcinoma.

Among the 67 squamous NSCLC patients (all with no known EGFR mutations), 28 received IBI363 at 1 mg/kg Q2W or 1.5 mg/kg Q3W, and 31 received 3 mg/kg Q3W. In these two groups, the proportion of patients with ≥2 prior lines of systemic therapy was 64.3% vs. 67.7%, prior anti–PD-1/PD-L1 exposure was 100% vs. 96.8%, and the proportion with PD-L1 TPS <1% was 35.7% vs. 41.9%, respectively.

Compared with the 1/1.5 mg/kg dosing group, the 3 mg/kg Q3W cohort demonstrated a more pronounced confirmed objective response rate (cORR): cORR: 36.7%，Disease Control Rate (DCR): 90%，Median Progression-Free Survival (mPFS): 9.3 months. This mPFS is comparable to the median overall survival (mOS) of 7–9 months typically observed with combination regimens such as PD-L1 plus CTLA-4 inhibitors, highlighting the strong potential of IBI363 monotherapy. We believe that as overall survival (OS) data matures, it will likely show significant extension in patient survival. The safety profile was generally manageable. Grade ≥3 treatment-related adverse events (TRAEs) occurred in 43.9% of patients. The most common Grade ≥3 TRAEs were arthralgia and rash. 7.0% of patients experienced TRAEs leading to permanent treatment discontinuation. There were no treatment-related deaths (0%).

2) IBI363 Monotherapy Shows ~6-Month OS Extension in Cold Tumor 3L+ Colorectal Cancer:

In patients with MSS-type colorectal cancer who had failed at least third-line therapy, IBI363 monotherapy demonstrated a median OS (mOS) of 16.1 months—approximately six months longer than the 9–10 months typically reported for current therapies. Among the 63 patients in this cohort (63.2% had received ≥4 lines of prior therapy; 86.8% were MSS), the confirmed ORR was 12.7%, and median duration of response (mDoR) was 7.5 months. Notably, both patients with liver metastasis (mOS: 14.4 months) and those without (mOS: 17 months) showed significant OS benefit, suggesting a strong tail effect of immunotherapy in cold tumors, potentially reversing the current lack of efficacy of IO agents in this setting.

In the combination cohort with bevacizumab, the ORR reached 23.5%. While mDoR and mOS were not yet mature, subgroup analyses revealed encouraging efficacy signals in the 3 mg/kg high-dose subgroup, especially in terms of ORR and PFS, supporting further follow-up to assess long-term survival benefits.

3) Strong Efficacy of IBI363 in IO-Refractory Acral and Mucosal Melanoma

In two Phase I/II clinical studies (NCT05460767, NCT06081920), as of April 7, 2025, 31 patients with unresectable locally advanced or metastatic acral or mucosal melanoma were treated with IBI363 at 1 mg/kg Q2W. All patients were IO-refractory, and 64.5% (n=20) had received ≥2 prior lines of systemic therapy. IBI363 achieved a confirmed ORR of 23.3%, significantly outperforming chemotherapy and other standards of care (ORR ~7–11%). Median PFS was 5.7 months (vs. ~4.1 months for TIL therapy), and median OS was 14.8 months, demonstrating robust antitumor activity in this historically difficult-to-treat population.

4) IBI343 (CLDN18.2 ADC) Shows Promising PFS and OS in Advanced Pancreatic Cancer

At ASCO 2025, updated results from the dose escalation and expansion cohorts of the ongoing Phase Ia/Ib trial (NCT05458219) were presented. As of March 14, 2025, 83 patients with advanced pancreatic cancer had received at least one dose of IBI343, with a median follow-up of 11.1 months. Among 44 patients with high CLDN18.2 expression (1+/2+/3+ ≥60%) treated at 6 mg/kg, the confirmed ORR was 22.7%, DCR was 81.8%, mPFS was 5.4 months, and mOS reached 9.1 months.

Notably, in patients who had only received one prior line of therapy (n=17), mOS reached 12.1 months, while those with two prior lines (n=18) had a comparable mOS of 9.1 months. Safety was generally manageable, with low incidence of GI-related toxicity and no new safety signals observed. The treatment-emergent adverse event (TEAE) rate was 98.8%.

Given the current lack of effective therapies for advanced pancreatic cancer—especially in the second-line setting, where chemotherapy response rates range from 6–16%, mPFS is 2–5 months, and mOS is ~6–9 months—we believe IBI343 offers a potentially valuable new option for late-line pancreatic cancer patients.

Earnings Forecast and Valuation Recommendation

Given the strong data from IBI36, along with the large market potential for lung squamous cell carcinoma and colorectal cancer treatments overseas, we have updated our earnings forecast and valuation model. We estimate total revenue for 2025–2027 to be RMB 11.86/14.34/18.17 billion (previous: RMB 11.86/14.34/18.09 billion), representing year-on-year growth of +26%/+21%/+27%. The company is expected to turn profitable in 2025, with a projected net profit of RMB 380 million (previous forecast: unchanged). We apply a DCF model for valuation, using FY26–37 cash flows. Based on a WACC of 9.8% (unchanged) and a terminal growth rate of 3.5% (unchanged), and assuming an exchange rate of RMB:HKD = 1:1.14, we raise our target price to HKD 90.1 per share (previous: HKD 62.5), and maintain an “Outperform” rating.

Risks

Risks include new drug R&D risk, regulatory approval risk, and commercialization underperformance 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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	Outperform	Neutral (hold)	Underperform	Outperform	Neutral (hold)	Underperform
HTI Equity Research Coverage	92.2%	7.5%	0.3%	91.9%	7.6%	0.4%
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*Percentage of investment banking clients in each rating category.

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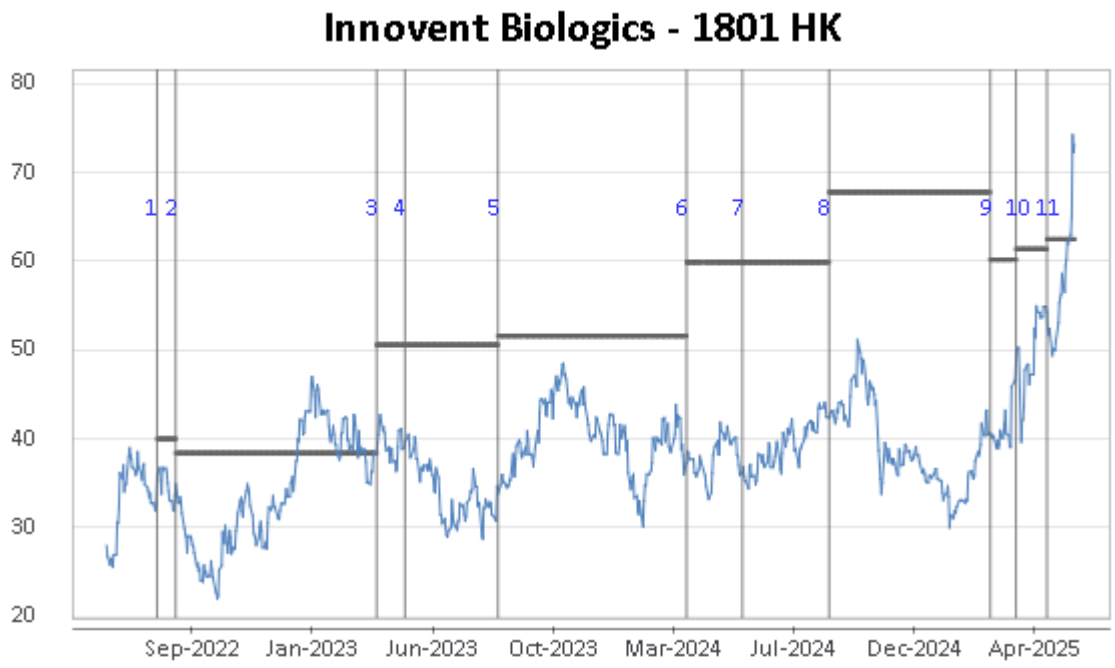
Recommendation Chart



1. 7 Aug 2022 OUTPERFORM at 35.80 target 40.00.
2. 26 Aug 2022 OUTPERFORM at 33.60 target 38.40.
3. 10 Apr 2023 OUTPERFORM at 38.35 target 50.60.
4. 12 May 2023 OUTPERFORM at 39.75 target 50.60.
5. 25 Aug 2023 OUTPERFORM at 34.65 target 51.60.
6. 25 Mar 2024 OUTPERFORM at 36.00 target 59.90.
7. 27 May 2024 OUTPERFORM at 35.90 target 59.90.
8. 2 Sep 2024 OUTPERFORM at 42.45 target 67.80.
9. 3 Mar 2025 OUTPERFORM at 43.20 target 60.20.
10. 1 Apr 2025 OUTPERFORM at 46.60 target 61.40.
11. 6 May 2025 OUTPERFORM at 54.30 target 62.50.

Source: Company data Bloomberg, HTI estimates