Akeso (9926 HK)

HARMONi-3 remains the decisive catalyst

The FDA declined approval of ivonescimab plus chemotherapy for 2L EGFR-mutant NSCLC, concluding that PFS improvement without statistically significant overall survival did not establish a positive benefit-risk profile. The underlying global HARMONi trial achieved significant PFS improvement, but its primary OS analysis missed significance (HR 0.79, p=0.057); longer follow-up subsequently showed an OS HR of 0.76 across the overall, Asian and Western populations, but this was post-hoc and insufficient to change the FDA's assessment. Nevertheless, 2L EGFR-mutant NSCLC remains a relatively small indication, representing less than 5% of our global peak sales estimate for ivonescimab. Moreover, the limitations of HARMONi are not directly transferable to Summit's broader development programme. HARMONi combined Chinese and Western patients, with less mature Western follow-up at the primary analysis, whereas HARMONi-3 is a purpose-built, multiregional first-line study with separately powered squamous and non-squamous cohorts. We look forward to the upcoming HARMONi-3 readouts, and maintain our BUY rating on Akeso with a target price of HK$99.34.

- **HARMONi-3 is far more important in determining whether ivonescimab can outperform SoC in large indications.** In KEYNOTE-407, the first-line SoC of Keytruda plus chemotherapy achieved a mPFS of 6.4 vs 4.8 months for chemotherapy alone (HR 0.56), and a mOS of 15.9 vs 11.3 months (HR 0.64). These results set the benchmark ivonescimab will need to surpass. Investor sentiment was shaken in April when a newly introduced interim analysis of the squamous cohort in HARMONi-3 failed to reach statistical significance for PFS, although the comparison was made against a stringent interim efficacy boundary. The trial remains blinded, and the number of PFS events required for the primary analysis in the squamous cohort is expected to be reached in 4Q26, with a planned early interim OS analysis conducted in conjunction with it; a separate interim OS analysis is planned for 1H27. For the nsq-cohort, the PFS event threshold is expected to be met in 1H27.
- **Competitive pressure is intensifying, but the broadening combination strategy preserves substantial optionality.** In the PD-(L)1/VEGF space, Pfizer's tivunatamig, BioNTech/BMS's pumitamig, AbbVie's ABBV-1480, and Merck's MK-2010 are all advancing into global Ph3 development in first-line NSCLC, eroding ivonescimab's first-mover advantage. Offsetting this, AstraZeneca's US$2bn equity investment in Summit has provided significant capital to expand clinical development, with combination studies pairing ivonescimab with Datroway (TROP2 ADC) in lung and breast cancers and with sonesitatug vedotin (LDN18.2 ADC) in gastrointestinal tumours in planning. Meanwhile, ivonescimab is increasingly emerging as a preferred backbone for combination strategies across both proprietary and partnered assets, including Akeso's in-house HER3 ADC and TROP2/Nectin-4 ADC, GSK's B7-H3 ADC, Pfizer's Nectin-4 ADC, and Biokin's EGFR/HER3 ADC. Beyond ADCs, ivonescimab is also being evaluated in combination with RAS(ON) inhibitors, as well as with CD47 mAb, HIF-2α inhibitors, and FGFR inhibitors.
- **Maintain BUY**. The CRL delays US commercialization, while HARMONi-3 and successful combination trials remain central to the Akeso's investment case. We revise our DCF-derived TP from HK$138.42 to HK$99.34 (WACC: 9.67%, terminal growth: 3.0%).

Earnings Summary

(YE 31 Dec)	FY24A	FY25A	FY26E	FY27E	FY28E
Revenue (RMB mn)	2,124	3,056	4,482	6,638	9,519
YoY growth (%)	(53.1)	43.9	46.6	48.1	43.4
Net profit (RMB mn)	(501.1)	(1,140.8)	(827.0)	(17.8)	1,383.7
EPS (Reported) (RMB)	(0.59)	(1.26)	(0.88)	(0.02)	1.47

Source: Company data, Bloomberg, CMBIGM estimates

BUY (Maintain)

Target Price	**HK$99.34**
(Previous TP	HK$138.42)
Up/Downside	**55.0%**
Current Price	**HK$64.10**

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Stock Data

Mkt Cap (HK$ mn)	60,327.3
Avg 3 mths t/o (HK$ mn)	1,151.0
52w High/Low (HK$)	151.00/64.10
Total Issued Shares (mn)	941.1

Source: FactSet

Shareholding Structure

Green Court Capital	4.7%
Sunny Beach Living	4.6%

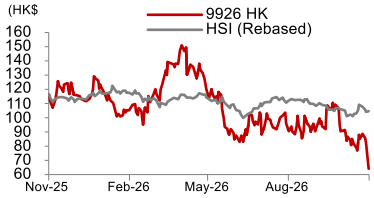
Source: Bloomberg

Share Performance

	Absolute	Relative
1-mth	-29.8%	-28.5%
3-mth	-33.2%	-29.4%
6-mth	-46.7%	-41.7%

Source: FactSet

12-mth Price Performance



Source: FactSet

Figure 1: Risk-adjusted DCF valuation

DCF Valuation (RMB mn)	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
EBIT	**-1,108**	**-186**	**1,486**	**2,875**	**4,533**	**5,943**	**7,769**	**8,620**	**9,413**	**9,991**
Tax rate	*0%*	*0%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*
EBIT*(1-tax rate)	-1,108	-186	1,263	2,444	3,853	5,052	6,603	7,327	8,001	8,492
+ D&A	251	243	235	228	222	216	210	205	199	195
- Change in working capital	-387	-148	-345	-338	-446	-206	-183	-34	129	241
- Capex	-100	-100	-100	-100	-100	-100	-100	-100	-100	-100
FCFF	**-1,345**	**-191**	**1,053**	**2,234**	**3,530**	**4,962**	**6,530**	**7,397**	**8,230**	**8,827**
Terminal value										**136,363**
FCF + Terminal value	**-1,345**	**-191**	**1,053**	**2,234**	**3,530**	**4,962**	**6,530**	**7,397**	**8,230**	**145,190**

Present value of enterprise (RMB mn)	74,278
Net debt (RMB mn)	-5,056
Non-controlling interests (RMB mn)	-134
Equity value (RMB mn)	**79,468**
No. of shares (mn)	941
DCF per shares (RMB)	**84.44**
DCF per shares (HK$)	**99.34**
Terminal growth rate	**3.0%**
WACC	**9.67%**
Cost of Equity	13.5%
Cost of Debt	3.0%
Equity Beta	1.0
Risk Free Rate	3.5%
Market Risk Premium	10.0%
Target Debt to Asset ratio	35.0%
Effective Corporate Tax Rate	15.0%

Source: CMBIGM estimates. Note: we adjusted the terminal growth rate from 4% to 3% to align with covered biopharmas/biotechs in our coverage.

Figure 2: Sensitivity analysis (HK$)

	WACC				
Terminal growth rate	**8.67%**	**9.17%**	**9.67%**	**10.17%**	**10.67%**
4.0%	140.52	124.88	112.06	101.39	92.36
3.5%	129.69	116.32	105.19	95.77	87.73
3.0%	120.77	109.15	**99.34**	90.95	83.70
2.5%	113.30	103.06	94.31	86.75	80.16
2.0%	106.95	97.82	89.93	83.06	77.03

Source: CMBIGM estimates

Figure 3: CMBIGM estimates revision

	New			Old			Diff(%)		
RMB mn	**FY26E**	**FY27E**	**FY28E**	**FY26E**	**FY27E**	**FY28E**	**FY26E**	**FY27E**	**FY28E**
Revenue	4,482	6,638	9,519	4,354	7,534	9,875	3%	-12%	-4%
Gross profit	3,357	5,174	7,738	3,299	6,064	8,034	2%	-15%	-4%
Operating profit	-1,108	-186	1,486	-881	692	1,588	N/A	N/A	-6%
Net profit	-827	-18	1,384	-632	673	1,435	N/A	N/A	-4%
EPS (RMB)	(0.88)	(0.02)	1.47	(0.69)	0.73	1.56	N/A	N/A	-6%
Gross margin	74.90%	77.95%	81.29%	75.77%	80.48%	81.35%	-0.88 ppt	-2.53 ppt	-0.07 ppt

Source: Company data, CMBIGM estimates

Figure 4: CMBIGM estimates vs consensus

	CMBIGM			Consensus			Diff (%)		
RMB mn	**FY26E**	**FY27E**	**FY28E**	**FY26E**	**FY27E**	**FY28E**	**FY26E**	**FY27E**	**FY28E**
Revenue	4,482	6,638	9,519	4,514	7,004	9,807	-1%	-5%	-3%
Gross profit	3,357	5,174	7,738	3,571	5,704	8,024	-6%	-9%	-4%
Operating profit	-1,108	-186	1,486	-309	873	2,306	N/A	N/A	-36%
Net profit	-827	-18	1,384	-307	772	2,034	N/A	N/A	-32%
EPS (RMB)	(0.88)	(0.02)	1.47	(0.34)	0.81	2.22	N/A	N/A	-34%
Gross margin	74.90%	77.95%	81.29%	79.12%	81.43%	81.82%	-4.22 ppt	-3.48 ppt	-0.53 ppt

Source: Company data, Bloomberg, CMBIGM estimates

Risks: 1) Competition from other PD(L)-1/VEGF bsAbs; 2) Potential of HARMONi-3 missing the OS endpoint.

Financial Summary

INCOME STATEMENT	2023A	2024A	2025A	2026E	2027E	2028E
YE 31 Dec (RMB mn)						
Revenue	**4,526**	**2,124**	**3,056**	**4,482**	**6,638**	**9,519**
Cost of goods sold	(133)	(289)	(652)	(1,125)	(1,463)	(1,781)
Gross profit	**4,393**	**1,835**	**2,404**	**3,357**	**5,174**	**7,738**
Operating expenses	**(2,363)**	**(2,268)**	**(3,414)**	**(4,079)**	**(5,056)**	**(5,935)**
Selling expense	(890)	(1,002)	(1,436)	(1,966)	(2,247)	(2,696)
Admin expense	(200)	(204)	(296)	(410)	(591)	(755)
R&D expense	(1,254)	(1,188)	(1,575)	(1,894)	(2,328)	(2,607)
Others	(19)	125	(106)	192	111	123
Operating profit	**1,862**	**(667)**	**(1,309)**	**(1,108)**	**(186)**	**1,486**
Net Interest income/(expense)	**(87)**	**(68)**	**(131)**	**(137)**	**(137)**	**(137)**
Pre-tax profit	**1,943**	**(501)**	**(1,141)**	**(859)**	**(18)**	**1,666**
Income tax	(0)	0	0	0	0	(250)
After tax profit	**1,942**	**(501)**	**(1,141)**	**(859)**	**(18)**	**1,416**
Minority interest	(86)	0	0	(32)	(1)	33
Net profit	**2,028**	**(501)**	**(1,141)**	**(827)**	**(18)**	**1,384**

BALANCE SHEET	2023A	2024A	2025A	2026E	2027E	2028E
YE 31 Dec (RMB mn)						
Current assets	**5,677**	**8,692**	**11,277**	**12,198**	**12,348**	**13,634**
Cash & equivalents	1,542	6,918	8,822	9,612	9,537	10,410
Account receivables	296	525	1,022	1,134	1,675	2,194
Inventories	392	707	932	950	635	529
Prepayment	95	116	152	152	152	152
Financial assets at FVTPL	852	426	349	349	349	349
Other current assets	2,500	0	0	0	0	0
Non-current assets	**3,504**	**4,063**	**4,723**	**4,573**	**4,430**	**4,294**
PP&E	2,824	3,231	3,880	3,747	3,621	3,503
Right-of-use assets	338	320	319	301	284	267
Intangibles	6	12	19	19	19	19
Financial assets at FVTPL	12	16	23	23	23	23
Other non-current assets	30	87	166	166	166	166
Total assets	**9,181**	**12,755**	**16,000**	**16,771**	**16,778**	**17,928**
Current liabilities	**1,205**	**1,687**	**2,195**	**1,883**	**1,905**	**1,916**
Short-term borrowings	391	535	586	586	586	586
Account payables	355	425	452	140	162	173
Other current liabilities	445	716	1,151	1,151	1,151	1,151
Lease liabilities	15	10	7	7	7	7
Non-current liabilities	**3,458**	**4,315**	**4,859**	**4,859**	**4,859**	**4,859**
Long-term borrowings	2,577	3,406	3,955	3,955	3,955	3,955
Deferred income	240	290	323	323	323	323
Other non-current liabilities	9	1	9	9	9	9
Total liabilities	**4,662**	**6,001**	**7,054**	**6,742**	**6,765**	**6,775**
Share capital	0	0	0	0	0	0
Other reserves	4,692	6,814	9,048	10,162	10,148	11,255
Total shareholders equity	**4,692**	**6,814**	**9,048**	**10,162**	**10,148**	**11,255**
Minority interest	(174)	(60)	(102)	(134)	(134)	(102)
Total equity and liabilities	**9,181**	**12,755**	**16,000**	**16,771**	**16,778**	**17,928**

CASH FLOW	2023A	2024A	2025A	2026E	2027E	2028E
YE 31 Dec (RMB mn)						
Operating						
Profit before taxation	**1,943**	**(501)**	**(1,141)**	**(859)**	**(18)**	**1,666**
Depreciation & amortization	143	194	262	251	243	235
Tax paid	0	0	0	0	0	(250)
Change in working capital	418	(200)	(606)	(387)	(148)	(345)
Others	(36)	(20)	537	81	81	81
Net cash from operations	**2,468**	**(528)**	**(948)**	**(915)**	**157**	**1,387**
Investing						
Capital expenditure	(719)	(586)	(777)	(100)	(100)	(100)
Net proceeds from disposal of short-term investments	(3,055)	(1,024)	(3,345)	0	0	0
Others	(223)	87	9	0	0	0
Net cash from investing	**(3,997)**	**(1,523)**	**(4,113)**	**(100)**	**(100)**	**(100)**
Financing						
Dividend paid	0	0	0	0	4	(277)
Net borrowings	1,099	962	655	0	0	0
Proceeds from share issues	(3)	2,823	3,179	1,941	0	0
Share repurchases	0	0	0	0	0	0
Others	(135)	(396)	(375)	(137)	(137)	(137)
Net cash from financing	**961**	**3,389**	**3,458**	**1,804**	**(133)**	**(413)**
Net change in cash						
Cash at the beginning of the year	2,092	1,542	6,918	8,822	9,612	9,537
Exchange difference	19	35	(33)	0	0	0
Cash at the end of the year	**1,542**	**6,918**	**8,822**	**9,612**	**9,537**	**10,410**

GROWTH	2023A	2024A	2025A	2026E	2027E	2028E
YE 31 Dec						
Revenue	440.3%	(53.1%)	43.9%	46.6%	48.1%	43.4%
Gross profit	490.8%	(58.2%)	31.0%	39.6%	54.1%	49.5%

PROFITABILITY	2023A	2024A	2025A	2026E	2027E	2028E
YE 31 Dec						
Gross profit margin	97.1%	86.4%	78.7%	74.9%	78.0%	81.3%
Operating margin	41.1%	(31.4%)	(42.8%)	(24.7%)	(2.8%)	15.6%
Return on equity (ROE)	55.4%	(8.7%)	(14.4%)	(8.6%)	(0.2%)	12.9%

GEARING/LIQUIDITY/ACTIVITIES	2023A	2024A	2025A	2026E	2027E	2028E
YE 31 Dec						
Current ratio (x)	4.7	5.2	5.1	6.5	6.5	7.1

VALUATION	2023A	2024A	2025A	2026E	2027E	2028E
YE 31 Dec						
P/E	22.5	ns	ns	ns	ns	37.1
P/B	10.1	6.9	5.5	5.1	5.1	4.6

Source: Company data, CMBIGM estimates. Note: The calculation of net cash includes financial assets.

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