

Akeso (9926 HK)

OS data improved with longer follow-up

Summit updated data from the global HARMONi trial, evaluating AK112 + chemo vs chemo alone in 2L 3rd-gen EGFR-TKI resistant NSCLC. PFS HR in the Western cohort was less favorable compared to Chinese patients, and Western OS HR at extended follow-up similarly trailed the Chinese subgroup. Investors are concerned about the translatability of AK112's China data to the global market. However, we focus on the OS and believe the discrepancy in OS may be partially attributable to the shorter follow-up among Western patients, particularly those from Europe. Importantly, at a longer follow-up beyond the final OS analysis, a positive OS trend was observed. We also see strong OS results in the North America patient group. The 2L EGFRm setting represents <5% of AK112's long-term sales potential, and we see the primary value of AK112 in first-line NSCLC. We anticipate the presentation of results from the China HARMONi-6 study at ESMO 2025, along with further OS updates from the China HARMONi-2 study within the next six months per Summit.

- Chinese patients demonstrated more favorable PFS outcomes. In the primary PFS analysis (n=345, median follow-up (mFU) of 22.3 months), AK112 + chemo achieved a mPFS of 6.8 months vs 4.4 months with chemo (HR=0.52, p<0.001). Given the intensifying competition in the EGFR-TKI resistant landscape—including emerging TROP2 ADCs, HER3 ADCs, etc. —the PFS benefit observed with AK112 may not offer a strong standalone competitive edge. At extended follow-up (mFU 29.7 months), the PFS HR modestly worsened from 0.52 to 0.57, likely due to increased data maturity in the Western subgroup, where the HR was 0.67 for patients from North America and Europe, compared to 0.55 for Chinese patients.
- OS improved with longer follow-up. In the final OS analysis with mFU of 29.7 months (n=438; NA & EU mFU: 9.2 months, not yet mature), mOS was 16.8 months for the AK112+chemo arm versus 14.0 months for chemo alone, yielding an OS HR of 0.79 (0.62-1.01; p=0.0570). While this narrowly missed the pre-specified significance threshold of p=0.0448 required by the FDA for BLA submission, the OS trend was directionally positive. With an extended, non-pre-specified follow-up of 32.7 months (China cohort was locked and only Western patients continued follow-up to 13.7 months), median OS remained unchanged, while the OS HR improved to 0.78 (0.62-0.98; nominal p=0.0332). Although the FDA may base its judgment primarily on the pre-specified analysis, we believe the maturing longer-term OS data will be critical to assess the outcomes for Western patients.
- Strong OS results in the North America patients. During the longer follow-up period, OS HR for Western patients was slightly less favorable than that of Chinese patients (0.84 vs 0.76), likely due to the shorter followup duration especially for the Europe patients. Summit also indicated that the patient number and follow-up duration for European participants were limited compared to North America. Notably, North American patients demonstrated encouraging results, with an OS HR of 0.70, despite wide confidence intervals of 0.38-1.30.
- Maintain BUY. We believe the HARMONi trial demonstrated a favorable OS trend, which strengthens our confidence in the potential of first-line indications. We maintain DCF-based TP unchanged at HK\$182.12 (WACC: 8.37%, terminal growth rate: 4.5%).

Earnings Summary

(YE 31 Dec)	FY23A	FY24A	FY25E	FY26E	FY27E
Revenue (RMB mn)	4,526	2,124	3,181	5,021	8,449
YoY growth (%)	440.3	(53.1)	49.8	57.8	68.3
Net profit (RMB mn)	2,028.3	(501.1)	(862.8)	25.4	1,551.6
EPS (Reported) (RMB)	2.42	(0.59)	(0.96)	0.03	1.73

Source: Company data, Bloomberg, CMBIGM estimates

BUY (Maintain)

Target Price HK\$182.12 Up/Downside 30.0% **Current Price** HK\$140.10

China Healthcare

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Stock Data

Mkt Cap (HK\$ mn)	125,752.8
Avg 3 mths t/o (HK\$ mn)	1,731.0
52w High/Low (HK\$)	176.90/55.40
Total Issued Shares (mn)	897.6
0 5 10 1	

Shareholding Structure

Yu Xia	12.1%
Baiyong Li	6.4%

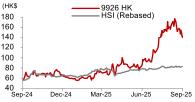
Source: Bloomberg

Share Performance

	Absolute	Relative
1-mth	-12.7%	-16.3%
3-mth	60.6%	49.7%
6-mth	92 2%	79.5%

Source: FactSet

12-mth Price Performance



Source: FactSet



Figure 1: Main clinical data of the HARMONi and HARMONi-A at different follow-ups

Leading company	Akeso	Sumn	nit					
Trial ID	HARMONi-A	HARM	ONi					
Region	China	China, EU, NA 438 (219 vs 219; 273 from China, 165 (38%) from EU&NA)						
Patient No.	322 (276 pre-treated with 3 rd -gen EGFR TKI)							
Follow-up (mFU, month)	7.89, 10.2 and 17.6	22.3 and 29.7 (9.2 for NA&EU)	29.7 and 32.7 (13.7 for NA&EU)					
mPFS vs chemo (month); PFS HR	7.06 vs 4.80; HR 0.46 (p<0.001) (3rd-gen TKI pre-treated subgroup HR=0.48) ; 7.89 mFU	6.8 vs 4.4; HR 0.52 (0.41-0.66, P<0.001); primary analysis (N=345), 22.3 mFU; NA&EU HR 0.30 Asia HR 0.56	mPFS not released; HR 0.57 (0.46-0.71); Longer term follow up (n=438), 29.7 mFU NA&EU HR 0.67 Asia HR 0.55					
mOS vs chemo (month); OS HR	 HR 0.72 (0.48-1.09, 30% data maturity; not significant; 10.2 mFU). 17.1 vs 14.5; HR 0.80 (0.59-1.08, 52% data maturity; not significant; 17.6 mFU). in Aug 2025, Akeso announced in its 1H25 report that the China HARMONi-A trial met the OS endpoint, achieving statistical significance. Detailed data to be released in a later conference. 	16.8 vs 14.0; 0.79 (0.62-1.01, p=0.0570, < 0.0448 for significance); Final OS, 29.7 mFU (n=438) (NA&EU mFU 9.2 months and not mature) Subgroup mOS not released	16.8 vs 14.0; 0.78 (0.62-0.98, p=0.0332); Longer term follow up (n=438), (Asia mFU 32.7 months, NA&EU mFU 13.7 months, NA mFU 14.6 months) NA&EU 17.0 vs 14.0; HR=0.84 (NA NR vs 14.0; HR=0.70) Asia 16.7 vs 14.0; HR=0.76					
ORR	50.6% and 35.4%	45% vs	34%					
TRAE Grade ≥3	61.5% vs 49.1%	50.0% vs	42.2%					
VEGF-blocking TRAEs Grade ≥3	3.1% vs 2.5%	7.3% vs	3.2%					
Hemorrhage Grade ≥	3	0.9% vs	5 0%					
irAE Grade ≥3	6.2% vs 2.5%	9.6% vs	6.0%					
TRAEs leading to death	No TRAE leading to death in AK112 arm	1.8% vs	2.3%					
TRAEs leading to discontinuation	5.6% in AK112 arm	7.3% vs	5.0%					

Source: Company data, CMBIGM



Figure 2: Comparison of clinical data of medicine (candidates) in TKI-post EGFRm NSCLC

	AK112	amivantamab	SKB264	Dato-DXd	BL-B01D1	HER3-DXd
MoA	PD1/VEGF bsAb	EGFR/MET bsAb	TROP2 ADC	TROP2 ADC	EGFR/HER3 ADC	HER3 ADC
Company	Akeso, Summit	Janssen, Genmab	Kelun Biotech, MSD	Daiichi Sankyo, AstraZeneca	Baili Pharm, BMS	Daiichi Sankyo, MSD
Trial ID	HARMONi	MARIPOSA-2	OptiTROP-Lung03, NCT05631262	TROPION-Lung05, and others		HERTHENA- Lung02
Trial stage	Ph3, global	Ph3, global	Ph2, China	Ph2, global	Ph1/2, China	Ph3, global
Baseline	2L post 3rd-gen TKI	Osimertinib as 1st line (70%) or 2nd line (30%) line of therapy	post EGFR TKI and chemo	71.5% received at least three lines of prior therapies	post TKI and chemo naïve	
Treatment line	2L	2L+	3L+	4L+	2L	
Regimen	AK112+chemo vs chemo	amivantamab+chemo vs chemo	SKB264 vs docetaxel	Dato-DXd	BL-B01D1	HER3-DXd vs chemo
Patient No.	219 vs 219	131 vs 263	91 vs 46	114	50	586
Median follow up (month)	22.3 months for PFS, 29.7 months for OS	8.7	12.2		15.4	10.7
mPFS (month)	6.8 vs 4.4, HR=0.52	6.3 vs 4.2, HR=0.48	6.9 vs 2.8, HR=0.30	5.8	12.5	5.8 vs 5.4, HR=0.77
mOS (month)	16.8 vs 14.0, HR=0.79, p=0.0570	HR=0.77 (0.49-1.21)	NR vs NR, HR=0.49, p=0.007	18.3	NR	16 vs 15.9, HR=0.98, not significant
ORR	45% vs 34%	64% vs 36%	45.1% vs 15.6%	44%	58%	35.2% vs 25.3%
Grade 3–5 TRAEs	50.0% vs 42.2%	67% vs 35%	56.0% vs 71.7%	28.5%		
SAE		32% vs 20%	16.5% vs 41.3%	26%		
Gr ≥3 immune- related	9.6% vs 6.0%					
Gr ≥3 VEGF-related	1 7.3% vs 3.2%					
TRAEs leading to discontinuation	7.3% vs 5.0%	8% vs 2%		5.1%	1.7%	
TRAEs leading to death	1.8% vs 2.3%	1.5% vs 0.4%		0.7%	0	
Source	Link	Link	Link	Link	<u>Link</u>	<u>Link</u>

Source: Pubmed, CMBIGM



Figure 3: Risk-ad	justed	DCF	valuation
DCF Valuation (RMB r	nn)		202

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DCF Valuation (RMB mn)	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
EBIT	-1,003	-85	1,807	2,739	4,434	6,512	8,727	10,820	11,619	12,250	12,161
Tax rate	0%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%
EBIT*(1-tax rate)	-1,003	-72	1,536	2,328	3,769	5,535	7,418	9,197	9,876	10,413	10,337
+ D&A	193	189	186	182	179	176	173	170	168	165	163
- Change in working capital	-123	-604	-234	-324	-351	-234	-139	3	33	154	227
- Capex	-200	-100	-100	-100	-100	-100	-100	-100	-100	-100	-100
FCFF	-1,133	-587	1,387	2,086	3,497	5,377	7,352	9,271	9,977	10,632	10,627
Terminal value											287,155
FCF + Terminal value	-1,003	-85	1,807	2,739	4,434	6,512	8,727	10,820	11,619	12,250	12,161
Present value of enterprise (RMB mn)	148,412										
Net debt (RMB mn)	-1,923										
Non-controlling interests (RMB mn)	-60										
Equity value (RMB mn)	150,396										
No. of shares (mn)	898										
DCF per shares (RMB)	167.55										
DCF per shares (HK\$)	182.12										
Terminal growth rate	4.5%										
WACC	8.37%										
Cost of Equity	11.5%										
Cost of Debt	3.0%										

Effective Corporate Tax Rate Source: CMBIGM estimates

Target Debt to Asset ratio

Equity Beta

Risk Free Rate

Market Risk Premium

Figure 4: Sensitivity analysis (HK\$)

	WACC						
Terminal growth rate	7.37%	7.87%	8.37%	8.87%	9.37%		
5.5%	373.96	289.17	234.08	195.46	166.92		
5.0%	302.47	244.72	204.25	174.34	151.36		
4.5%	255.91	213.48	182.12	158.05	139.00		
4.0%	223.18	190.31	165.07	145.10	128.94		
3.5%	198.91	172.44	151.52	134.57	120.60		

0.9

2.5%

10.0%

35.0%

15.0%

Source: CMBIGM estimates

Figure 5: CMBIGM estimates vs consensus

	CMBIGM			(Consensus Diff (%)				
RMB mn	FY25E	FY26E	FY27E	FY25E	FY26E	FY27E	FY25E	FY26E	FY27E
Revenue	3,181	5,021	8,449	3,760	5,951	8,959	-15%	-16%	-6%
Gross profit	2,559	4,087	7,094	3,210	5,142	7,809	-20%	-21%	-9%
Operating profit	-1,003	-85	1,807	-171	979	2,583	N/A	N/A	-30%
Net profit	-863	25	1,552	-285	731	2,072	N/A	-97%	-25%
EPS (RMB)	(0.96)	0.03	1.73	(0.30)	0.84	2.32	N/A	-97%	-25%
Gross margin	80.45%	81.41%	83.97%	85.38%	86.41%	87.16%	-4.93 ppt	-5.00 ppt	-3.19 ppt

Source: Bloomberg, CMBIGM estimates



Financial Summary

INCOME STATEMENT	2022A	2023A	2024A	2025E	2026E	2027E
YE 31 Dec (RMB mn)						
Revenue	838	4,526	2,124	3,181	5,021	8,449
Cost of goods sold	(94)	(133)	(289)	(622)	(934)	(1,355)
Gross profit	744	4,393	1,835	2,559	4,087	7,094
Operating expenses	(2,122)	(2,363)	(2,268)	(3,264)	(3,937)	(5,101)
Selling expense	(553)	(890)	(1,002)	(1,399)	(1,892)	(2,549)
Admin expense	(199)	(200)	(204)	(300)	(460)	(682)
R&D expense	(1,323)	(1,254)	(1,188)	(1,462)	(1,720)	(1,957)
Others	(48)	(19)	125	(102)	134	86
Operating profit	(1,406)	1,862	(618)	(1,003)	(85)	1,807
Net Interest income/(expense)	(43)	(87)	(68)	(158)	(119)	(119)
Pre-tax profit	(1,422)	1,943	(501)	(863)	31	1,875
Income tax	0	(0)	0	0	(5)	(281)
After tax profit	(1,422)	1,942	(501)	(863)	26	1,593
Minority interest	(254)	(86)	0	0	1	42
Net profit	(1,168)	2,028	(501)	(863)	25	1,552
BALANCE SHEET	2022A	2023A	2024A	2025E	2026E	2027E
YE 31 Dec (RMB mn)						
Current assets	3,058	5,677	8,692	7,895	7,749	9,206
Cash & equivalents	2,092	1,542	6,918	5,875	5,336	6,421
Account receivables	271	296	525	637	992	1,524
Inventories	342	392	707	841	879	718
Prepayment	157	95	116	116	116	116
Financial assets at FVTPL	196	852	426	426	426	426
Other current assets	0	2,500	0	0	0	0
Non-current assets	2,437	3,211	3,665	3,672	3,583	3,497
PP&E	2,000	2,824	3,231	3,257	3,187	3,120
Right-of-use assets	163	338	320	300	281	262
Intangibles	8	6	12	12	12	12
Financial assets at FVTPL	10	12	16	16	16	16
Other non-current assets	256	30	87	87	87	87
Total assets	5,496	8,888	12,356	11,567	11,331	12,703
Current liabilities	1,361	1,205	1,687	1,760	1,498	1,586
Short-term borrowings	446	391	535	535	535	535
Account payables	309	355	425	498	237	325
Other current liabilities	600	445	716	716	716	716
Lease liabilities	6	15	10	10	10	10
Non-current liabilities	1,587	2,826	3,697	3,697	3,697	3,697
Long-term borrowings	1,421	2,577	3,406	3,406	3,406	3,406
Deferred income	1,421	2,377	290	290	3,406 290	290
Other non-current liabilities		240 9	290 1		290 1	
Total liabilities	6 2,948	4,030	5,384	1 5,457	5,195	5, 283
	_	_	_	_	_	
Share capital	0	0	0	0	0	0
Other reserves	2,636	4,692	6,814	5,951	5,977	7,218
Total shareholders equity	2,636	4,692	6,814	5,951	5,977	7,218
Minority interest	(88)	(174)	(60)	(60)	(59)	(18)
Total equity and liabilities	5,496	8,888	12,356	11,567	11,331	12,703



CASH FLOW	2022A	2023A	2024A	2025E	2026E	2027E
YE 31 Dec (RMB mn)						
Operating						
Profit before taxation	(1,422)	1,943	(501)	(863)	31	1,875
Depreciation & amortization	106	143	194	193	189	186
Tax paid	0	0	0	0	(5)	(281)
Change in working capital	60	418	(200)	(123)	(604)	(234)
Others	16	(36)	(20)	108	69	69
Net cash from operations	(1,240)	2,468	(528)	(685)	(320)	1,613
Investing						
Capital expenditure	(776)	(719)	(586)	(200)	(100)	(100)
Net proceeds from disposal of short-term investments	(200)	(3,055)	(1,024)	0	0	0
Others	86	(223)	87	0	0	0
Net cash from investing	(890)	(3,997)	(1,523)	(200)	(100)	(100)
Financing						
Dividend paid	0	0	0	0	0	(310)
Net borrowings	1,005	1,099	962	0	0	0
Proceeds from share issues	495	(3)	2,823	0	0	0
Share repurchases	0	0	0	0	0	0
Others	(15)	(135)	(396)	(158)	(119)	(119)
Net cash from financing	1,486	961	3,389	(158)	(119)	(429)
Net change in cash						
Cash at the beginning of the year	2,642	2,092	1,542	6,918	5,875	5,336
Exchange difference	95	19	35	0	0	0
Cash at the end of the year	2,092	1,542	2,916	5,875	5,336	6,421
GROWTH	2022A	2023A	2024A	2025E	2026E	2027E
YE 31 Dec						
Revenue	271.3%	440.3%	(53.1%)	49.8%	57.8%	68.3%
Gross profit	282.5%	490.8%	(58.2%)	39.5%	59.7%	73.6%
Net profit	na	na	na	na	na	6,001.2%
PROFITABILITY	2022A	2023A	2024A	2025E	2026E	2027E
YE 31 Dec	00.00/	07.40/	00.40/	00.50/	04.40/	0.4.00/
Gross profit margin	88.8%	97.1%	86.4%	80.5%	81.4%	84.0%
Operating margin Return on equity (ROE)	(167.9%) (40.3%)	41.1% 55.4%	(29.1%) (8.7%)	(31.5%) (13.5%)	(1.7%) 0.4%	21.4% 23.5%
GEARING/LIQUIDITY/ACTIVITIES	2022A	2023A	2024A	2025E	2026E	2027E
YE 31 Dec	ZUZZA	2023A	2024A	2023L	2020L	2027L
Current ratio (x)	2.2	4.7	5.2	4.5	5.2	5.8
VALUATION	2022A	2023A	2024A	2025E	2026E	2027E
YE 31 Dec						
YE 31 Dec P/E	ns	53.0	ns	ns	4,525.8	74.2

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



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