

# Akeso (9926 HK)

## Promising Ph3 data of cadonilimab in 1L GC

- Promising Ph3 data of cadonilimab in 1L GC, especially for patients with low PD-L1 expression.** The interim Ph3 (NCT05008783) data of cadonilimab in 1L GC was recently released at the AACR meeting ([link](#)). With a median follow-up of 18.7 months, cadonilimab + chemo (XELOX) extended the mOS by 4.2 months for the 610 ITT patients and reduced the risk of death by 38% (mOS 15.0 vs 10.8 months, HR=0.62, P<0.001). In a cross-trial comparison, when combined with chemotherapy, sintilimab, nivolumab and pembrolizumab reduced the risk of death by 32%, 21% and 22%, according to ORIENT-16, Checkmate-649, and KEYNOTE-859 trials, respectively. It's important to note that, only 42% of the patients enrolled in cadonilimab's trial had PD-L1 CPS $\geq$ 5, vs 61% and 60% in sintilimab and nivolumab's trials, respectively. For patients with CPS $\geq$ 5, cadonilimab lowered the risk of death by 44%, compared to 41%, 30% and 26% of sintilimab, nivolumab and tislelizumab (Rationale305). Notably, for patients with CPS<5, cadonilimab + chemo also reduced the risk of death by 30%, underscoring its benefits for the underserved patients with low PD-L1 expression.
- Anticipating a more active NRDL strategy for cadonilimab to accelerate market penetration.** In Nov 2023, the above-mentioned Ph3 trial of cadonilimab in 1L GC met the OS endpoint, and an sNDA was submitted to the CDE in Jan 2024, with approval expected by end-2024/early-2025. The competitive landscape for the large 1L GC indication appears relatively moderate. In combination with chemo, sintilimab, nivolumab, and pembrolizumab have been approved in China for 1L HER2- GC, regardless of PD-L1 expression. Tislelizumab + chemo has been approved for PD-L1 high 1L GC, while the sBLA for patients regardless of PD-L1 expression is under review by the CDE. Sintilimab and tislelizumab are included in the NRDL for 1L GC at annual costs of around RMB37.4K and RMB43.5K, vs cadonilimab's current annual cost of c. RMB158.6K. Following the approval of cadonilimab for the large indication of 1L GC, we expect its inclusion in the NRDL from early 2026, which could further accelerate sales. Sales of cadonilimab in FY23 reached RMB1.36bn with 2H23 sales up 24% HoH. We expect FY24E sales of cadonilimab to reach RMB1.79bn (+31% YoY).
- Near-term data readout of AK112's head-to-head study.** The H2H Ph3 study of AK112 mono vs pembrolizumab for PD-L1+ (TPS $\geq$ 1%) NSCLC was fully enrolled in Aug 2023, with interim PFS readout expected in 2Q24. Akeso submitted the NDA of AK112 in Aug 2023 for post-TKI EGFR-m nsq-NSCLC, with the approval and relevant data release expected in 2H24. The MRCT HARMONi trial conducted by Summit is on track to complete enrolment in 2H24. The Ph3 trial in China evaluating AK112 + chemo vs tislelizumab + chemo in 1L sq-NSCLC is expected to complete enrolment in 2024 or early 2025. We expect Akeso to initiate more Ph3 trials of AK112 to fully explore the potential of the drug.
- Maintain BUY.** We see the blockbuster potential of AK104 and AK112. Akeso's non-oncology assets are near commercialization with NDAs of PCSK9 and IL12/23 under review. We maintain our TP unchanged at HK\$59.61 (WACC: 10.97%, terminal growth rate: 3.0%).

### Earnings Summary

(YE 31 Dec)	FY22A	FY23A	FY24E	FY25E	FY26E
Revenue (RMB mn)	838	4,526	2,715	4,291	7,819
YoY growth (%)	271.3	440.3	(40.0)	58.0	82.2
Net profit (RMB mn)	(1,168)	2,028	(130)	230	1,884
EPS (Reported) (RMB)	(1.42)	2.42	(0.16)	0.27	2.24
R&D expenses (RMB mn)	(1,323)	(1,254)	(1,379)	(1,517)	(1,761)
Admin expenses (RMB mn)	(199)	(200)	(271)	(428)	(614)

Source: Company data, Bloomberg, CMBIGM estimates

### BUY (Maintain)

Target Price	HK\$59.61
(Previous TP)	HK\$59.61)
Up/Downside	27.8%
Current Price	HK\$46.65

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### Stock Data

Mkt Cap (HK\$ mn)	39,235.3
Avg 3 mths t/o (HK\$ mn)	218.6
52w High/Low (HK\$)	51.95/31.25
Total Issued Shares (mn)	841.1

Source: FactSet

### Shareholding Structure

Gemstone Living Trust	6.9%
Yu Xia	5.6%

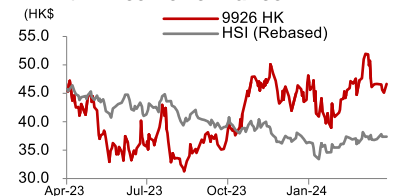
Source: Bloomberg

### Share Performance

	Absolute	Relative
1-mth	-1.3%	-3.5%
3-mth	6.4%	3.2%
6-mth	32.5%	38.5%

Source: FactSet

### 12-mth Price Performance



Source: FactSet

Figure 1: Cross-trial comparison of medicines for 1L HER2-negative GC

	AK104	AK104	Nivolumab	Sintilimab	Tislelizumab	Pembrolizumab
<b>Trial</b>	NCT05008783)	NCT03852251	Checkmate-649	ORIENT-16	Rationale 305	KEYNOTE-859
<b>Trial stage</b>	Ph3 (China)	Ph1/2 (China)	Ph3 (global)	Ph3 (China)	Ph3 (global)	Ph3 (global)
<b>Regimen</b>	AK104+chemo vs chemo	AK104+chemo	nivolumab + chemo vs chemo	sintilimab + chemo vs chemo	Tislelizumab + chemo vs chemo	Pembrolizumab + chemo vs chemo
<b>Target</b>	PD-1/CTLA-4	PD-1/CTLA-4	PD-1	PD-1	PD-1	PD-1
<b>Primary endpoint</b>	OS	ORR	PFS, OS	OS	OS	OS
<b>Patient number</b>	610 (305 vs 305)	94	1581 (789 vs 792)	650 (327 vs 323)	997	1,579 (785 vs 787)
<b>PD-L1 expression</b>	42% pts CPS≥5	15% pts CPS≥5	60% pts CPS≥5	61% pts CPS≥5		78% pts CPS≥1; 35% pts CPS≥10
<b>Sub-group</b>	all pts	all pts	all pts pts with CPS≥5 (473 vs 482)	all pts pts with CPS≥5	all pts pts with PD-L1 score≥5 (274 vs 272)	all pts pts with CPS≥1 pts with CPS≥10
<b>ORR</b>	65.2% vs 48.9%	68.2%	50.6% vs 46.0% 59.8% vs 45.1%	58.2% vs 48.8%	-	50.4% vs 43.0% 51.3% vs 42.0% 52.1% vs 42.6% 60.6% vs 43.0%
<b>CR</b>	3.6% vs 1.0%	5.7%	13% vs 7% 11% vs 6%			3.3% vs 1.8% 9.5% vs 6.2%
<b>mPFS (mo)</b>	7.0 vs 5.3 HR=0.53	9.2	7.7 vs 6.9, HR=0.79 8.1 vs 6.1, HR=0.70	HR=0.638 HR=0.621	-	7.2 vs 5.9, HR=0.67 6.9 vs 5.6, HR=0.76 6.9 vs 5.6, HR=0.72 8.1 vs 5.6, HR=0.62
<b>mOS (mo)</b>	15.0 vs 10.8 HR=0.62 (HR=0.7 for CPS < 5; HR=0.56 for CPS ≥5)	17.4 for all pts; 20.24 for pts with CPS≥5; 17.28 for pts with CPS<5	13.8 vs 11.6, HR=0.79 14.4 vs 11.1, HR=0.70	15.2 vs 12.3, HR=0.68 19.2 vs 12.9, HR=0.59	-	17.2 vs 12.6, HR=0.74 12.9 vs 11.5, HR=0.78 13.0 vs 11.4, HR=0.74 15.7 vs 11.8, HR=0.65
<b>Grade ≥3 TRAEs</b>	65.9%	70.2%	59.1% vs 44.5%	59.8% vs 52.5%	-	52.6% vs 48.5% 59.4% vs 51.1%
<b>Approval status in US and China for 1L GC (HER2-)</b>	sBLA accepted in China in Jan 2024	not approved yet	approved in the US and China	approved in China	sBLA in China in Aug 2023; BLA in the US accepted (PDUFA Dec 2024)	approved in China for 1L PD-L1+ GC approved in the US and China
<b>Data source</b>	<a href="#">Link</a>	<a href="#">Link</a>	<a href="#">Link</a>	<a href="#">Link1</a> , <a href="#">Link2</a>	<a href="#">Link</a>	<a href="#">Link</a>

Source: Pubmed, CMBIGM

**Figure 2: Risk-adjusted DCF valuation**

DCF Valuation (RMB mn)	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
EBIT	(226)	226	2,299	3,121	4,198	5,281	6,185	6,894	7,166	7,410	7,442	7,258
Tax rate	0%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%
EBIT*(1-tax rate)	(226)	192	1,954	2,653	3,568	4,489	5,257	5,860	6,091	6,299	6,326	6,170
+ D&A	127	130	129	128	128	127	126	126	125	125	124	124
- Change in working capital	(37)	(247)	(369)	196	(197)	(133)	(31)	76	132	139	161	173
- Capex	(300)	(200)	(100)	(100)	(100)	(100)	(100)	(100)	(100)	(100)	(100)	(100)
<b>FCFF</b>	<b>(437)</b>	<b>(125)</b>	<b>1,614</b>	<b>2,877</b>	<b>3,399</b>	<b>4,382</b>	<b>5,252</b>	<b>5,961</b>	<b>6,248</b>	<b>6,463</b>	<b>6,512</b>	<b>6,366</b>
<b>Terminal value</b>												<b>82,328</b>
<b>FCF + Terminal value</b>	<b>(437)</b>	<b>(125)</b>	<b>1,614</b>	<b>2,877</b>	<b>3,399</b>	<b>4,382</b>	<b>5,252</b>	<b>5,961</b>	<b>6,248</b>	<b>6,463</b>	<b>6,512</b>	<b>88,694</b>
Present value of enterprise (RMB mn)	44,334											
Net debt (RMB mn)	(550)											
Non-controlling interests (RMB mn)	(168)											
<b>Equity value (RMB mn)</b>	<b>45,118</b>											
No. of shares (mn)	841											
<b>DCF per shares (RMB)</b>	<b>53.64</b>											
<b>DCF per shares (HK\$)</b>	<b>59.61</b>											
<b>Terminal growth rate</b>	<b>3.0%</b>											
<b>WACC</b>	<b>10.97%</b>											
Cost of equity	14.0%											
Cost of debt	4.5%											
Equity beta	1.1											
Risk-free rate	3.0%											
Market risk premium	10.5%											
Target debt to asset ratio	30.0%											
Effective corporate tax rate	15.0%											

Source: CMBIGM estimates

**Figure 3: Sensitivity analysis (HK\$)**

Terminal growth rate	WACC				
	9.97%	10.47%	10.97%	11.47%	11.97%
4.0%	77.33	70.37	64.43	59.30	54.84
3.5%	73.49	67.25	61.86	57.16	53.04
3.0%	70.21	64.54	<b>59.61</b>	55.27	51.44
2.5%	67.36	62.17	57.62	53.59	50.01
2.0%	64.87	60.09	55.86	52.09	48.72

Source: CMBIGM estimates

**Figure 4: CMBIGM estimates vs consensus**

RMB mn	CMBIGM			Consensus			Diff (%)		
	FY24E	FY25E	FY26E	FY24E	FY25E	FY26E	FY24E	FY25E	FY26E
Revenue	2,715	4,291	7,819	2,699	4,321	6,101	1%	-1%	28%
Gross profit	2,519	3,951	7,117	2,446	3,904	5,505	3%	1%	29%
Operating profit	(226)	226	2,299	(454)	316	1,443	N/A	-28%	59%
Net profit	(130)	230	1,884	(410)	300	1,194	N/A	-23%	58%
EPS (RMB)	(0.16)	0.27	2.24	(0.48)	0.39	1.51	N/A	-29%	48%
Gross margin	92.76%	92.07%	91.02%	90.63%	90.35%	90.23%	+2.13 ppt	+1.72 ppt	+0.79 ppt

Source: Company data, Bloomberg, CMBIGM estimates

## Financial Summary

INCOME STATEMENT	2021A	2022A	2023A	2024E	2025E	2026E
YE 31 Dec (RMB mn)						
<b>Revenue</b>	<b>226</b>	<b>838</b>	<b>4,526</b>	<b>2,715</b>	<b>4,291</b>	<b>7,819</b>
Cost of goods sold	(31)	(94)	(133)	(197)	(340)	(702)
<b>Gross profit</b>	<b>194</b>	<b>744</b>	<b>4,393</b>	<b>2,519</b>	<b>3,951</b>	<b>7,117</b>
<b>Operating expenses</b>	<b>(1,442)</b>	<b>(2,122)</b>	<b>(2,363)</b>	<b>(2,602)</b>	<b>(3,608)</b>	<b>(4,688)</b>
Selling expense	(179)	(553)	(890)	(1,195)	(1,880)	(2,543)
Admin expense	(244)	(199)	(200)	(271)	(428)	(614)
R&D expense	(1,123)	(1,323)	(1,254)	(1,379)	(1,517)	(1,761)
Others	103	(48)	(19)	243	217	230
<b>Operating profit</b>	<b>(1,271)</b>	<b>(1,406)</b>	<b>1,862</b>	<b>(226)</b>	<b>226</b>	<b>2,299</b>
<b>Net Interest income/(expense)</b>	<b>(10)</b>	<b>(43)</b>	<b>(87)</b>	<b>(107)</b>	<b>(107)</b>	<b>(107)</b>
<b>Pre-tax profit</b>	<b>(1,258)</b>	<b>(1,422)</b>	<b>1,943</b>	<b>(190)</b>	<b>236</b>	<b>2,322</b>
Income tax	0	0	(0)	0	(35)	(348)
<b>After tax profit</b>	<b>(1,258)</b>	<b>(1,422)</b>	<b>1,942</b>	<b>(190)</b>	<b>200</b>	<b>1,974</b>
Minority interest	(183)	(254)	(86)	(60)	(30)	90
<b>Net profit</b>	<b>(1,075)</b>	<b>(1,168)</b>	<b>2,028</b>	<b>(130)</b>	<b>230</b>	<b>1,884</b>
<b>BALANCE SHEET</b>						
	<b>2021A</b>	<b>2022A</b>	<b>2023A</b>	<b>2024E</b>	<b>2025E</b>	<b>2026E</b>
YE 31 Dec (RMB mn)						
<b>Current assets</b>	<b>3,152</b>	<b>3,058</b>	<b>5,677</b>	<b>5,340</b>	<b>5,563</b>	<b>7,686</b>
Cash & equivalents	2,642	2,092	1,542	1,042	825	2,358
Account receivables	102	271	296	418	727	1,102
Inventories	197	342	392	433	564	779
Prepayment	212	157	95	95	95	95
Financial assets at FVTPL	0	196	852	852	852	852
Other current assets	0	0	2,500	2,500	2,500	2,500
<b>Non-current assets</b>	<b>1,654</b>	<b>2,437</b>	<b>3,211</b>	<b>3,384</b>	<b>3,454</b>	<b>3,425</b>
PP&E	1,353	2,000	2,824	3,007	3,087	3,068
Right-of-use assets	152	163	338	328	318	308
Intangibles	4	8	6	6	6	6
Financial assets at FVTPL	0	10	12	12	12	12
Other non-current assets	145	256	30	30	30	30
<b>Total assets</b>	<b>4,806</b>	<b>5,496</b>	<b>8,888</b>	<b>8,724</b>	<b>9,017</b>	<b>11,111</b>
<b>Current liabilities</b>	<b>656</b>	<b>1,361</b>	<b>1,205</b>	<b>1,232</b>	<b>1,324</b>	<b>1,445</b>
Short-term borrowings	46	446	391	391	391	391
Account payables	206	309	355	382	474	595
Other current liabilities	396	600	445	445	445	445
Lease liabilities	8	6	15	15	15	15
<b>Non-current liabilities</b>	<b>870</b>	<b>1,587</b>	<b>2,826</b>	<b>2,826</b>	<b>2,826</b>	<b>2,826</b>
Long-term borrowings	804	1,421	2,577	2,577	2,577	2,577
Deferred income	64	160	240	240	240	240
Other non-current liabilities	2	6	9	9	9	9
<b>Total liabilities</b>	<b>1,526</b>	<b>2,948</b>	<b>4,030</b>	<b>4,057</b>	<b>4,150</b>	<b>4,271</b>
Share capital	0	0	0	0	0	0
Other reserves	3,164	2,636	4,692	4,562	4,792	6,676
<b>Total shareholders equity</b>	<b>3,164</b>	<b>2,636</b>	<b>4,692</b>	<b>4,562</b>	<b>4,792</b>	<b>6,676</b>
Minority interest	116	(88)	(174)	(234)	(264)	(174)
<b>Total equity and liabilities</b>	<b>4,806</b>	<b>5,496</b>	<b>8,549</b>	<b>8,386</b>	<b>8,679</b>	<b>10,773</b>

<b>CASH FLOW</b>	<b>2021A</b>	<b>2022A</b>	<b>2023A</b>	<b>2024E</b>	<b>2025E</b>	<b>2026E</b>
<b>YE 31 Dec (RMB mn)</b>						
<b>Operating</b>						
Profit before taxation	(1,258)	(1,422)	1,943	(190)	236	2,322
Depreciation & amortization	58	106	120	127	130	129
Tax paid	0	0	(0)	0	(35)	(348)
Change in working capital	107	60	(4)	(37)	(247)	(369)
Others	92	16	(31)	7	7	7
<b>Net cash from operations</b>	<b>(1,001)</b>	<b>(1,240)</b>	<b>2,027</b>	<b>(94)</b>	<b>90</b>	<b>1,740</b>
<b>Investing</b>						
Capital expenditure	(712)	(776)	(500)	(300)	(200)	(100)
Net proceeds from disposal of short-term investments	120	(200)	0	0	0	0
Others	12	86	0	0	0	0
<b>Net cash from investing</b>	<b>(580)</b>	<b>(890)</b>	<b>(500)</b>	<b>(300)</b>	<b>(200)</b>	<b>(100)</b>
<b>Financing</b>						
Dividend paid	0	0	0	0	0	0
Net borrowings	645	1,005	0	0	0	0
Proceeds from share issues	978	495	0	0	0	0
Share repurchases	(52)	0	0	0	0	0
Others	15	(15)	(87)	(107)	(107)	(107)
<b>Net cash from financing</b>	<b>1,587</b>	<b>1,486</b>	<b>(87)</b>	<b>(107)</b>	<b>(107)</b>	<b>(107)</b>
<b>Net change in cash</b>						
Cash at the beginning of the year	2,684	2,642	2,092	1,542	1,042	825
Exchange difference	(49)	95	0	0	0	0
<b>Cash at the end of the year</b>	<b>2,642</b>	<b>2,092</b>	<b>3,532</b>	<b>1,042</b>	<b>825</b>	<b>2,358</b>
<b>GROWTH</b>	<b>2021A</b>	<b>2022A</b>	<b>2023A</b>	<b>2024E</b>	<b>2025E</b>	<b>2026E</b>
<b>YE 31 Dec</b>						
Revenue	na	271.3%	440.3%	(40.0%)	58.0%	82.2%
Gross profit	na	282.5%	490.8%	(42.7%)	56.9%	80.1%
Operating profit	na	na	na	na	na	917.0%
Net profit	na	na	na	na	na	717.4%
<b>PROFITABILITY</b>	<b>2021A</b>	<b>2022A</b>	<b>2023A</b>	<b>2024E</b>	<b>2025E</b>	<b>2026E</b>
<b>YE 31 Dec</b>						
Gross profit margin	86.1%	88.8%	97.1%	92.8%	92.1%	91.0%
Operating margin	(563.1%)	(167.9%)	41.1%	(8.3%)	5.3%	29.4%
Return on equity (ROE)	(33.9%)	(40.3%)	55.4%	(2.8%)	4.9%	32.8%
<b>GEARING/LIQUIDITY/ACTIVITIES</b>	<b>2021A</b>	<b>2022A</b>	<b>2023A</b>	<b>2024E</b>	<b>2025E</b>	<b>2026E</b>
<b>YE 31 Dec</b>						
Current ratio (x)	4.8	2.2	4.7	4.3	4.2	5.3
<b>VALUATION</b>	<b>2021A</b>	<b>2022A</b>	<b>2023A</b>	<b>2024E</b>	<b>2025E</b>	<b>2026E</b>
<b>YE 31 Dec</b>						
P/E	ns	ns	17.2	ns	152.1	18.6
P/B	10.4	13.5	7.7	8.1	7.7	5.4

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

# Disclosures & Disclaimers

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<b>BUY</b>	: Stock with potential return of over 15% over next 12 months
<b>HOLD</b>	: Stock with potential return of +15% to -10% over next 12 months
<b>SELL</b>	: Stock with potential loss of over 10% over next 12 months
<b>NOT RATED</b>	: Stock is not rated by CMBIGM
<b>OUTPERFORM</b>	: Industry expected to outperform the relevant broad market benchmark over next 12 months
<b>MARKET-PERFORM</b>	: Industry expected to perform in-line with the relevant broad market benchmark over next 12 months
<b>UNDERPERFORM</b>	: Industry expected to underperform the relevant broad market benchmark over next 12 months

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