

Kelun-Biotech (6990 HK)

MSD has further expedited global clinical development of SKB264

- MSD has announced three additional global Ph3 trials of SKB264.** MSD is vigorously advancing the global clinical development of its prominent oncology asset, SKB264, through multiple global Ph3 trials. In late 2023, MSD launched three global Ph3 trials: 1) a Ph3 MRCT of SKB264 in 3L nsq-NSCLC with EGFR mutations or other genomic alterations (NCT06074588), 2) a Ph3 trial of SKB264+Keytruda vs Keytruda mono in 1L PD-L1 TPS \geq 50% NSCLC (NCT06170788), and 3) a Ph3 trial of SKB264 in post chemo and/or PD(L)-1 endometrial carcinoma (NCT06132958). Additionally, MSD has initiated three more trials, expanding the scope of SKB264's evaluation to include 1) 2L post TKI EGFRm nsq-NSCLC (NCT06305754), 2) adjuvant NSCLC (NCT06312137), and 3) 2L+ HR+/HER2- BC (NCT06312176). These studies encompass a wide range of NSCLC stages and further probe SKB264's utility in breast and endometrial cancers, highlighting its global market potential.
- SKB264 to unlock its commercial value with the approval in China in 2H24E.** In China, three Ph3 trials of SKB264 are ongoing. The NDA based on the Ph3 trial of SKB264 for 3L+ TNBC has been under NMPA's review since Dec 2023, with approval expected in 2H24, marking the first approved indication for SKB264. We expect Kelun-Biotech to start a Ph3 trial of SKB264 in 1L TNBC in 2024. In the Trop2 ADC space, Gilead is going to release Trodelvy's 1L TNBC Ph3 data (ASCENT-03) in 2H24, and we also expect the readout of Dato-DXd's Ph3 TROPION-Breast02 trial in 1L TNBC in 2H24. The Ph3 trial of SKB264 in EGFR-TKI-resistant NSCLC is ongoing since Jul 2023, and the company expects to file NDA of the 3L+ part of the study in 2H24, with the 2L part of the trial reaching pre-NDA stage by end-2024. Other Trop2 ADC competitors are still in early development for EGFR-TKI resistant NSCLC, while SKB264's preliminary results indicate potentially better efficacy for these patients compared to other innovative regimens (*refer to CMBI report, [link](#)*). We expect Kelun-Biotech to start Ph3 trials of SKB264 in 1L NSCLC in China in 2024. For HR+/HER2- BC, SKB264's Ph3 trial in 2L+ patients is ongoing since Nov 2023. Dato-DXd plans to file BLA in the US for the indication of 2L+ HR+/HER2- BC with submission pending acceptance by FDA as of Feb 2024.
- Intense clinical data disclosure to further validate the value of SKB264.** At the AACR meeting in April, updated Ph2 results for SKB264 in previously treated NSCLC and Ph2 data of SKB264 in GC will be disclosed. In June, additional data for first-line NSCLC treatments are slated for publication at ASCO. Also anticipated this year are Ph2 results for first-line TNBC and Ph3 results for 3L+ TNBC treatments.
- Maintain BUY.** Considering MSD's dedicated development of SKB264 globally which could enhance its future global commercialization and Kelun-Biotech's recent addition to the Stock Connect, we revise up our DCF-based TP to HK\$189.25 from HK\$152.26 (WACC: 10.47%, terminal growth rate: 3.0%).

Earnings Summary

(YE 31 Dec)	FY21A	FY22A	FY23E	FY24E	FY25E
Revenue (RMB mn)	32	804	1,351	1,039	1,079
YoY growth (%)	na	2,387.3	68.1	(23.1)	3.9
Net profit (RMB mn)	(890)	(616)	(337)	(440)	(653)
EPS (Reported) (RMB)	(9.62)	(6.45)	(1.54)	(2.01)	(2.98)
R&D expenses (RMB mn)	(728)	(846)	(931)	(977)	(1,026)
Admin expenses (RMB mn)	(96)	(95)	(160)	(192)	(230)
CAPEX (RMB mn)	(94)	(34)	(50)	(200)	(200)

Source: Company data, Bloomberg, CMBIGM estimates

BUY (Maintain)

Target Price HK\$189.25
(Previous TP) HK\$152.26
Up/Downside 28.7%
Current Price HK\$147.10

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Stock Data

Mkt Cap (HK\$ mn)	32,243.7
Avg 3 mths t/o (HK\$ mn)	29.5
52w High/Low (HK\$)	175.00/60.60
Total Issued Shares (mn)	219.2

Source: FactSet

Shareholding Structure

Kelun Pharma	68.5%
MSD	6.1%

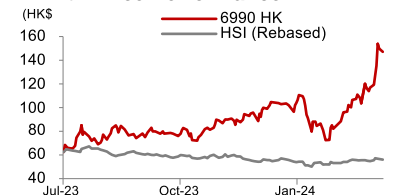
Source: Bloomberg

Share Performance

	Absolute	Relative
1-mth	53.2%	47.9%
3-mth	48.6%	47.6%
6-mth	77.2%	89.9%

Source: FactSet

12-mth Price Performance



Source: FactSet

Related report:

- INITIATION - Kelun-Biotech (6990 HK) - A trailblazer in ADC arena ([link](#)) - 6 Mar 2024

Figure 1: Clinical trials of SKB264 conducted by MSD

Indication	Trial ID	Stage	Regimen	Primary endpoint	Location	Start date	Primary completion date (est)
Previously treated nsq-NSCLC with EGFR mutations or other genomic alterations (ALK, ROS1, BRAF, NTRK, MET, RET, etc) (pre-treated with TKI, and chemo)	NCT06 074588	Ph3	Open label, randomized	Mono vs chemo (docetaxel or pemetrexed)	PFS, OS	US, HK, AU, Israel, etc	Nov 2023 May 2027
1L PD-L1 TPS \geq 50% NSCLC	NCT06 170788	Ph3	Open label, randomized	+ Keytruda vs Keytruda mono	OS	US, AU, Turkey	Dec 2023 Jan 2028
post EGFR-TKI nsq-NSCLC (pre-treated with TKI)	NCT06 305754	Ph3	Open label, randomized	Mono vs chemo (pemetrexed + carboplatin)	PFS, OS	--	Jun 2024 (est) Sep 2028
Adjuvant NSCLC (Stage II, IIIA, IIIB resectable NSCLC not achieving pCR)	NCT06 312137	Ph3	Open label, Non-randomized	SKB264+ Keytruda vs Keytruda	DFS	--	Apr 2024 (est) Feb 2034
Endometrial carcinoma (post chemo and PD(L)-1)	NCT06 132958	Ph3	Open label, randomized	Mono vs chemo	PFS, OS	AU, Israel, etc	Dec 2023 Jan 2028
HR+/HER2- BC (post endocrine therapies with one in combo with a CDK4/6 inhibitor)	NCT06 312176	Ph3	Open label, randomized	Mono vs +Keytruda vs chemo	PFS	--	Mar 2024 (est) Jul 2027

Source: Clinicaltrial.gov, CMBIGM

Figure 2: Risk-adjusted DCF valuation

DCF Valuation (RMB mn)	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
EBIT	(437)	(631)	(535)	128	1,965	3,107	4,262	5,261	6,140	6,745	7,018	6,920
Tax rate	0%	0%	0%	15%	15%	15%	15%	15%	15%	15%	15%	15%
EBIT*(1-tax rate)	(437)	(631)	(535)	109	1,670	2,641	3,622	4,472	5,219	5,733	5,966	5,882
+ D&A	37	44	51	61	72	73	74	76	77	78	79	80
- Change in working capital	(91)	(87)	(173)	(262)	(237)	(241)	(183)	(96)	(17)	36	84	78
- Capex	(200)	(200)	(200)	(300)	(300)	(100)	(100)	(100)	(100)	(100)	(100)	(100)
FCFF	(692)	(874)	(857)	(392)	1,205	2,374	3,414	4,352	5,179	5,747	6,028	5,941
Terminal value												81,899
FCF + terminal value	(692)	(874)	(857)	(392)	1,205	2,374	3,414	4,352	5,179	5,747	6,028	87,840
Present value of enterprise (RMB mn)	36,300											
Net debt (RMB mn)	(1,450)											
Equity value (RMB mn)	37,749											
No. of shares (mn)	219											
DCF per share (RMB)	172.22											
DCF per share (HK\$)	189.25											
Terminal growth rate	3.0%											
WACC	10.47%											
Cost of equity	14.1%											
Cost of debt	4.5%											
Equity beta	1.1											
Risk-free rate	2.5%											
Market risk premium	10.5%											
Target debt to asset ratio	35.0%											
Effective corporate tax rate	15.0%											

Source: CMBIGM estimates

Figure 3: Sensitivity analysis (HK\$)

Terminal growth rate	WACC				
	9.47%	9.97%	10.47%	10.97%	11.47%
4.0%	261.71	233.51	209.85	189.75	172.49
3.5%	244.87	219.96	198.81	180.65	164.91
3.0%	230.63	208.36	189.25	172.69	158.24
2.5%	218.43	198.31	180.89	165.68	152.30
2.0%	207.86	189.52	173.51	159.44	147.00

Source: CMBIGM estimates

Figure 4: CMBIGM estimates revision

RMB mn	New			Old			Diff (%)		
	FY23E	FY24E	FY25E	FY23E	FY24E	FY25E	FY23E	FY24E	FY25E
Revenue	1,351	1,039	1,079	1,351	1,039	1,079	0%	0%	0%
Gross profit	878	729	819	878	729	819	0%	0%	0%
Operating profit	-168	(409)	(610)	(168)	(409)	(610)	N/A	N/A	N/A
Net profit	(337)	(440)	(653)	(337)	(440)	(653)	N/A	N/A	N/A
EPS (RMB)	(1.54)	(2.01)	(2.98)	(1.54)	(2.01)	(2.98)	N/A	N/A	N/A
Gross margin	65.00%	70.21%	75.92%	65.00%	70.21%	75.92%	0.00 ppt	0.00 ppt	0.00 ppt

Source: Company data, Bloomberg, CMBIGM estimates

Figure 5: CMBIGM estimates vs consensus

RMB mn	CMBIGM			Consensus			Diff (%)		
	FY23E	FY24E	FY25E	FY23E	FY24E	FY25E	FY23E	FY24E	FY25E
Revenue	1,351	1,039	1,079	1,577	1,397	1,781	-14%	-26%	-39%
Gross profit	878	729	819	1,074	1,022	1,367	-18%	-29%	-40%
Operating profit	-168	(409)	(610)	(276)	(505)	(663)	N/A	N/A	N/A
Net profit	(337)	(440)	(653)	(262)	(516)	(680)	N/A	N/A	N/A
EPS (RMB)	(1.54)	(2.01)	(2.98)	(1.56)	(2.06)	(3.11)	N/A	N/A	N/A
Gross margin	65.00%	70.21%	75.92%	68.11%	73.14%	76.77%	-3.11 ppt	-2.93 ppt	-0.85 ppt

Source: Company data, Bloomberg, CMBIGM estimates

Financial Summary

INCOME STATEMENT	2021A	2022A	2023E	2024E	2025E
YE 31 Dec (RMB mn)					
Revenue	32	804	1,351	1,039	1,079
Cost of goods sold	(21)	(277)	(473)	(309)	(260)
Gross profit	12	527	878	729	819
Operating expenses	(789)	(946)	(1,047)	(1,138)	(1,430)
Selling expense	0	0	0	(27)	(224)
Admin expense	(96)	(95)	(160)	(192)	(230)
R&D expense	(728)	(846)	(931)	(977)	(1,026)
Others	35	(4)	44	59	51
Operating profit	(777)	(419)	(168)	(409)	(610)
Net Interest income/(expense)	(113)	(149)	(97)	(32)	(43)
Pre-tax profit	(890)	(567)	(265)	(440)	(653)
Income tax	0	(49)	(72)	0	0
After tax profit	(890)	(616)	(337)	(440)	(653)
Minority interest	0	0	0	0	0
Net profit	(890)	(616)	(337)	(440)	(653)
BALANCE SHEET					
YE 31 Dec (RMB mn)					
Current assets	298	332	2,486	1,744	1,383
Cash & equivalents	82	93	2,242	1,548	1,151
Restricted cash	37	26	26	26	26
Account receivables	79	99	0	7	59
Inventories	79	53	156	102	85
Financial assets at FVTPL	0	0	0	0	0
Other current assets	23	62	62	62	62
Non-current assets	515	661	681	845	1,001
PP&E	432	530	556	724	885
Right-of-use assets	42	117	112	107	102
Intangibles	0	3	3	3	3
Other non-current assets	40	10	10	10	10
Total assets	813	993	3,167	2,589	2,384
Current liabilities	3,445	4,167	1,361	1,223	1,671
Short-term borrowings	2,388	2,891	1	1	501
Account payables	185	243	327	189	137
Other current liabilities	761	787	787	787	787
Lease liabilities	2	82	82	82	82
Contract liabilities	109	164	164	164	164
Non-current liabilities	12	52	52	52	52
Deferred income	11	11	11	11	11
Other non-current liabilities	1	41	41	41	41
Total liabilities	3,457	4,219	1,413	1,275	1,723
Share capital	107	107	107	107	107
Other reserves	(2,751)	(3,334)	1,647	1,207	553
Total shareholders equity	(2,644)	(3,226)	1,754	1,314	661
Total equity and liabilities	813	993	3,167	2,589	2,384

CASH FLOW	2021A	2022A	2023E	2024E	2025E
YE 31 Dec (RMB mn)					
Operating					
Profit before taxation	(890)	(567)	(265)	(440)	(653)
Depreciation & amortization	23	67	29	37	44
Tax paid	0	(49)	(72)	0	0
Change in working capital	279	35	80	(91)	(87)
Others	102	195	97	32	43
Net cash from operations	(486)	(320)	(132)	(463)	(654)
Investing					
Capital expenditure	(94)	(34)	(50)	(200)	(200)
Net proceeds from disposal of short-term investments	0	1	0	0	0
Others	(1)	1	0	0	0
Net cash from investing	(94)	(32)	(50)	(200)	(200)
Financing					
Dividend paid	0	0	0	0	0
Net borrowings	155	318	(390)	0	500
Proceeds from share issues	534	0	2,818	0	0
Others	(42)	(5)	(97)	(32)	(43)
Net cash from financing	647	313	2,331	(32)	457
Net change in cash					
Cash at the beginning of the year	16	82	93	2,242	1,548
Exchange difference	(1)	1	0	0	0
Cash at the end of the year	82	44	2,242	1,548	1,151
GROWTH	2021A	2022A	2023E	2024E	2025E
YE 31 Dec					
Revenue	na	2,387.3%	68.1%	(23.1%)	3.9%
Gross profit	na	4,368.1%	66.6%	(17.0%)	12.4%
PROFITABILITY	2021A	2022A	2023E	2024E	2025E
YE 31 Dec					
Gross profit margin	36.5%	65.6%	65.0%	70.2%	75.9%
Operating margin	(2,404.6%)	(52.1%)	(12.5%)	(39.3%)	(56.6%)
Return on equity (ROE)	na	na	na	(28.7%)	(66.2%)
GEARING/LIQUIDITY/ACTIVITIES	2021A	2022A	2023E	2024E	2025E
YE 31 Dec					
Current ratio (x)	0.1	0.1	1.8	1.4	0.8
VALUATION	2021A	2022A	2023E	2024E	2025E
YE 31 Dec					
P/B	na	na	16.9	22.6	44.9

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

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