

Hutchmed (13 HK)

Big milestone achieved with fruquintinib successfully approved by US FDA

- A landmark step of globalization with fruquintinib's FDA approval.** HCM's partner Takeda received FDA approval for fruquintinib for the treatment of mCRC patients who were previously treated with chemo therapy, an anti-VEGF therapy, and, if RAS wild-type, an anti-EGFR therapy. The approval was received under Priority Review more 20 days ahead of the scheduled PDUFA date of 30th Nov. Fruquintinib has become the only selective inhibitor of all three VEGF receptor kinases approved in the US for CRC. The approval was based on the Ph3 MRCT FRESCO-2 (18% patients enrolled from the US) as well as the China FRESCO trial, implying the recognition of China clinical data by the FDA. As fruquintinib has demonstrated superior efficacy and safety in treating late-line CRC patients to regorafenib and TAS-102 in cross-trial comparisons, (*CMBI report link*), we expect fruquintinib to take a majority market share in 3L+ CRC market in the US and other overseas regions.
- Expect lucrative milestone and royalties income from fruquintinib overseas sales.** HCM licensed out the ex-China rights of fruquintinib to Takeda in Jan 2023 and has received US\$400mn upfront payment. HCM is also eligible to receive up to US\$730mn milestone payments and royalties on net sales. The approval of fruquintinib in the US triggered the first milestone payment of US\$35mn. We expect Takeda to start commercializing fruquintinib in the US before this year-end. In addition, the NDAs of fruquintinib for CRC are also under review in the EU and Japan (NDAs submitted in Jun and Sep 2023, respectively). We expect fruquintinib, as an oral chemo-free treatment option for metastatic CRC patients with superior efficacy, to take a significant market share in the global CRC market and will achieve over US\$1bn peak sales from the overseas CRC market.
- Multiple registration milestones in coming quarters.** Fruquintinib has become a leader in the China CRC market, with a volume share of 47% in 1H23 (vs regorafenib's 26%). Fruquintinib may receive approval in China for the treatment of the highly underserved 2L gastric cancer in mid-2024. We also expect HCM/AZ to seek US FDA's accelerated approval for savolitinib based on the global Ph2 SAVANNAH study in 2/3L tagrisso-refractory MET+ NSCLC, with the NDA filing expected in 2024. Additionally, HCM has initiated the registration stage of a Ph2 trial of savolitinib in 2L MET+ GC in Mar 2023. We think sovleplenib (Syk) could become the next blockbuster drug with global out-licensing potential. HCM targets to file NDA of sovleplenib for treatment of ITP in China before this year-end and the Ph3 data release may happen in end-2023 or early 2024. HCM may also file NDA of amdizalisib (PI3Kδ) in China in late 2023 based on the registration Ph2b trial in 3L FL.
- Maintain BUY.** We are positive about fruquintinib's global commercialization and China's label expansion. We revised our TP from HK\$35.67 to HK\$36.77 based on DCF valuation (WACC: 10.25 %, terminal growth rate: 3.0%).

Earnings Summary

(YE 31 Dec)	FY21A	FY22A	FY23E	FY24E	FY25E
Revenue (US\$ mn)	356	426	833	867	1,032
YoY growth (%)	56.2	19.7	95.3	4.1	19.1
Net profit (US\$ mn)	(167)	(360)	(48)	(55)	21
EPS (Reported) (US\$)	(0.25)	(0.43)	(0.06)	(0.06)	0.02
R&D expenses (US\$ mn)	(299)	(387)	(300)	(347)	(341)
CAPEX (US\$ mn)	(16)	(37)	(15)	(10)	(10)

Source: Company data, Bloomberg, CMBIGM estimates

BUY (Maintain)

Target Price	HK\$36.77
(Previous TP)	HK\$35.67)
Up/Downside	24.9%
Current Price	HK\$29.45

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Stock Data

Mkt Cap (HK\$ mn)	25,532.9
Avg 3 mths t/o (HK\$ mn)	69.0
52w High/Low (HK\$)	32.45/14.54
Total Issued Shares (mn)	867.0

Source: FactSet

Shareholding Structure

CK Hutchison Holdings	38.4%
Deutsche Bank Trust	17.9%

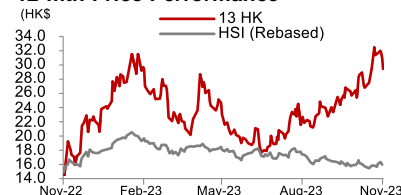
Source: HKEx

Share Performance

	Absolute	Relative
1-mth	11.3%	11.4%
3-mth	29.7%	42.6%
6-mth	28.0%	45.3%

Source: FactSet

12-mth Price Performance



Source: FactSet

Figure 1: Risk-adjusted DCF valuation

DCF Valuation (in US\$ mn)	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
EBIT	(119)	(127)	(47)	61	202	351	517	612	673	703	689	713	738
Tax rate	0%	0%	0%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%
EBIT*(1-tax rate)	(119)	(127)	(47)	52	172	299	439	520	572	597	586	606	628
+ D&A	9	9	9	10	10	10	10	10	10	10	10	10	10
- Change in working capital	(7)	(59)	(11)	(37)	(63)	(63)	(54)	(49)	(44)	(39)	(28)	(20)	(38)
- Capex	(15)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
FCFF	(133)	(187)	(59)	15	109	236	385	470	528	558	557	585	590
Terminal value													8,386

Present value of enterprise (US\$ mn)	3,627
Net debt (US\$ mn)	(486)
Equity value (US\$ mn)	4,113
Equity value (HK\$ mn)	31,878
No. of outstanding shares (mn)	867
DCF per share (HK\$)	36.77

Terminal growth rate	3.0%
WACC	10.25%
Cost of Equity	13.0%
Cost of Debt	4.5%
Equity Beta	1.00
Risk Free Rate	3.0%
Market Risk Premium	10.0%
Target Debt to Asset ratio	30.0%
Effective Corporate Tax Rate	15.0%

Source: CMBIGM estimates

Figure 2: Sensitivity analysis (HK\$)

		WACC				
		9.25%	9.75%	10.25%	10.75%	11.25%
Terminal growth rate	4.00%	50.00	44.76	40.38	36.68	33.52
	3.50%	46.97	42.35	38.44	35.10	32.21
	3.00%	44.43	40.30	36.77	33.72	31.06
	2.50%	42.27	38.53	35.31	32.51	30.05
	2.00%	40.40	37.00	34.03	31.43	29.14

Source: CMBIGM estimates

Figure 3: CMBIGM estimates revision

US\$ mn	New			Old			Diff (%)		
	FY23E	FY24E	FY25E	FY23E	FY24E	FY25E	FY23E	FY24E	FY25E
Revenue	833	867	1,032	823	852	998	1%	2%	3%
Gross Profit	339	337	412	333	328	391	2%	3%	5%
Operating Profit	(119)	(127)	(47)	(124)	(128)	(53)	N/A	N/A	N/A
Net profit	(48)	(56)	21	(52)	(57)	14	N/A	N/A	N/A
EPS (US\$)	(0.06)	(0.06)	0.02	(0.06)	(0.07)	0.02	N/A	N/A	N/A
Gross Margin	40.70%	38.85%	39.93%	40.45%	38.47%	39.17%	+0.25 ppt	+0.38 ppt	+0.76 ppt

Source: CMBIGM estimates

Figure 4: CMBIGM estimates vs consensus

US\$ mn	CMBIGM			Consensus			Diff (%)		
	FY23E	FY24E	FY25E	FY23E	FY24E	FY25E	FY23E	FY24E	FY25E
Revenue	833	867	1,032	798	763	895	4%	14%	15%
Gross profit	339	337	412	423	385	476	-20%	-12%	-13%
Operating profit	(119)	(127)	(47)	(45)	104	(39)	N/A	N/A	N/A
Net profit	(48)	(56)	21	(2)	(55)	12	N/A	N/A	N/A
EPS (US\$)	(0.06)	(0.06)	0.02	(0.13)	(0.06)	0.30	N/A	N/A	N/A
Gross margin	40.70%	38.85%	39.93%	53.00%	50.40%	53.21%	-12.3ppt	-11.6ppt	-13.3ppt

Source: Bloomberg, CMBIGM estimates

Financial Summary

INCOME STATEMENT	2020A	2021A	2022A	2023E	2024E	2025E
YE 31 Dec (US\$ mn)						
Revenue	228	356	426	833	867	1,032
Cost of goods sold	(189)	(258)	(311)	(494)	(530)	(620)
Gross profit	39	98	115	339	337	412
Operating expenses	(236)	(426)	(523)	(458)	(464)	(459)
Selling expense	(11)	(38)	(44)	(75)	(74)	(77)
Admin expense	(50)	(89)	(92)	(83)	(43)	(41)
R&D expense	(175)	(299)	(387)	(300)	(347)	(341)
Operating profit	(197)	(328)	(408)	(119)	(127)	(47)
Other income	5	2	2	0	0	0
Other expense	(0)	(13)	(14)	0	0	0
Gain/loss on financial assets at FVTPL	2	1	9	12	12	8
Other gains/(losses)	0	121	0	0	0	0
Pre-tax profit	(190)	(216)	(410)	(108)	(115)	(39)
Income tax	(5)	(12)	0	0	0	0
Others	79	61	50	60	60	60
Minority interest	(10)	(28)	(0)	(0)	(0)	(0)
Net profit	(116)	(167)	(360)	(48)	(55)	21
BALANCE SHEET						
	2020A	2021A	2022A	2023E	2024E	2025E
YE 31 Dec (US\$ mn)						
Current assets	531	1,212	840	710	627	594
Cash & equivalents	236	378	313	492	317	266
Account receivables	48	84	98	92	180	188
Inventories	20	36	57	54	58	68
Financial assets at FVTPL	200	634	318	18	18	18
Other current assets	28	81	54	54	54	54
Non-current assets	193	161	190	256	317	377
PP&E	24	41	76	82	83	83
Deferred income tax	2	9	15	15	15	15
Investment in JVs & assos	140	76	74	134	194	254
Other non-current assets	28	33	24	24	24	24
Total assets	724	1,373	1,029	966	943	971
Current liabilities	158	312	691	338	371	377
Short-term borrowings	0	27	0	0	0	0
Account payables	32	41	71	55	88	94
Tax payable	1	16	1	1	1	1
Other current liabilities	126	228	619	282	282	282
Non-current liabilities	47	21	39	39	39	39
Long-term borrowings	27	0	18	18	18	18
Obligations under finance leases	6	7	5	5	5	5
Deferred income	0	0	0	0	0	0
Other non-current liabilities	13	14	15	15	15	15
Total liabilities	205	333	729	377	409	416
Share capital	73	86	86	86	86	86
Capital surplus	822	1,505	1,497	1,497	1,497	1,497
Retained earnings	(416)	(610)	(971)	(1,020)	(1,075)	(1,055)
Other reserves	4	6	(2)	(2)	(2)	(2)
Total shareholders equity	484	987	610	562	507	527
Minority interest	35	53	27	27	27	28
Total equity and liabilities	519	1,040	637	589	534	555

CASH FLOW	2020A	2021A	2022A	2023E	2024E	2025E
YE 31 Dec (US\$ mn)						
Operating						
Profit before taxation	(190)	(216)	(410)	(108)	(115)	(39)
Depreciation & amortization	6	7	9	9	9	9
Tax paid	(5)	(12)	0	0	0	0
Change in working capital	29	33	57	(7)	(59)	(11)
Others	97	(16)	76	0	0	0
Net cash from operations	(62)	(204)	(269)	(106)	(165)	(40)
Investing						
Capital expenditure	(8)	(16)	(37)	(15)	(10)	(10)
Acquisition of subsidiaries/ investments	0	0	0	0	0	0
Net proceeds from disposal of short-term investments	(104)	(435)	316	300	0	0
Others	(14)	145	17	0	0	0
Net cash from investing	(125)	(306)	297	285	(10)	(10)
Financing						
Dividend paid	(1)	(10)	(26)	0	0	0
Net borrowings	0	(1)	(9)	0	0	0
Proceeds from share issues	319	717	0	0	0	0
Share repurchases	(13)	(27)	(48)	0	0	0
Others	(8)	(30)	(0)	0	0	0
Net cash from financing	296	650	(83)	0	0	0
Net change in cash						
Cash at the beginning of the year	121	236	378	313	492	317
Exchange difference	6	2	(9)	0	0	0
Cash at the end of the year	236	378	313	492	317	266
GROWTH	2020A	2021A	2022A	2023E	2024E	2025E
YE 31 Dec						
Revenue	11.3%	56.2%	19.7%	95.3%	4.1%	19.1%
Gross profit	(11.8%)	148.1%	17.8%	193.9%	(0.7%)	22.4%
PROFITABILITY	2020A	2021A	2022A	2023E	2024E	2025E
YE 31 Dec						
Gross profit margin	17.3%	27.5%	27.0%	40.7%	38.9%	39.9%
Operating margin	(86.3%)	(92.2%)	(95.6%)	(14.3%)	(14.6%)	(4.6%)
Return on equity (ROE)	(29.9%)	(22.7%)	(45.1%)	(8.1%)	(10.3%)	4.1%
GEARING/LIQUIDITY/ACTIVITIES	2020A	2021A	2022A	2023E	2024E	2025E
YE 31 Dec						
Net debt to equity (x)	(0.8)	(1.0)	(1.0)	(0.9)	(0.6)	(0.5)
Current ratio (x)	3.4	3.9	1.2	2.1	1.7	1.6
Receivable turnover days	70.5	66.1	77.2	78.0	78.0	78.0
Inventory turnover days	34.8	39.2	54.2	40.0	40.0	40.0
Payable turnover days	53.8	51.4	65.9	65.0	65.0	65.0
VALUATION	2020A	2021A	2022A	2023E	2024E	2025E
YE 31 Dec						
P/E	na	na	na	na	na	158.3
P/B	na	5.6	4.2	5.5	6.1	5.9

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

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