BofA SECURITIES

HUTCHMED

FRUTIGA results more likely to impress NMPA, FDA not impossible

Maintain Rating: BUY | PO: 29.00 USD | Price: 13.51 USD

Significant PFS but insignificant OS in FRUTIGA

Phase 3 exploring fruquintinib and paclitaxel for the treatment of 2L gastric cancer exhibited somewhat mixed results in ASCO plenary readout, with company finding significant PFS improvement while unable to report significance in OS improvement (although an improvement in OS with mOS of 9.6mo vs. 8.4mo was reported). This trend continues from the 2022 November readout where similar results were reported. In our view, the insignificant OS is an overhang given the importance regulatory agencies have placed upon that specific metric. Although past evidence has shown that PFS is enough to convince NMPA, which leads us to still assess high LoS for China approval (45%), we see FDA's stance unlikely to budge which could make US label expansion approval. That said, China still represents a much larger market (China: 478k incidence; US: 130k incidence; based on 2020 estimate) and hence should be priority. Maintain Buy, $29 PO.

NMPA approval on PFS seen before, FDA likes rare disease

While OS is still considered the "gold standard" for both FDA and NMPA, approval based on PFS alone has been reported in the past (although we note that FDA standard is more stringent than NMPA). For example, Cyramza was approved in China on significant PFS which was 4.14 mo in the ramucirumab plus paclitaxel group compared with 3.15 months in the placebo. Median OS was 8.71 months in the ram/pac group and 7.92 months in the placebo group. While US approval without significant OS is low, we do see possibility for regulatory flexibility from the FDA with gastric cancer being a rare disease with current standard of care treatment in the US remaining unmet need (consists of chemotherapy, targeted therapy includes Cyramza). Past cases of FDA promising lower scrutiny include Junshi's PD-1 targeting NPC (rare in US), which is expected to receive approval on China-only data, showing FDA's willingness to compromise in some areas. While chances are low, we do not rule out the possibility of US capture yet.

Imbalance of antitumor therapy could confound results

While OS was not statistically significant, we note that there was an imbalance reported of patients receiving subsequent antitumor therapies across the two groups, with 52.7% in the fruq/paclitaxel group vs. 72.2% in the paclitaxel monotherapy group. The company also noted that pre-specified sensitivity analyses demonstrated that in patients without these subsequent antitumor therapies, OS improvement was indeed statistically significant (6.9mo vs. 4.8mo). That said, while we do think that the existence of more antitumor therapy administration in the placebo group could have skewed results in the more unfavorable direction for fruquintinib, we note that regulatory agency will be unlikely to be lenient towards any overhangs in data and hence will likely not speculate "what could have been". Nevertheless, the imbalance favoring the placebo arm does brush off some concerns regarding the combo therapy's fundamental clinical profile.

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Refer to important disclosures on page 3 to 5. Analyst Certification on page 2. Price Objective Basis/Risk on page 2. **12656674**
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Equity

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Stock Data

Price	13.51 USD
Price Objective	29.00 USD
Date Established	4-Aug-2023
Investment Opinion	C-1-9
52-Week Range	10.68 USD - 20.73 USD
Mrkt Val (mn) / Shares Out (mn)	2,354 USD / 174.2
Free Float	0%
Average Daily Value (mn)	1.26 USD
BofA Ticker / Exchange	HCM / NAS
Bloomberg / Reuters	HCM US / HCM.OQ
ROE (2023E)	3.2%
Net Dbt to Eqty (Dec-2022A)	-49.2%
ESGMeter™	Medium

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Abbreviations:
ASCO: American Society of Clinical Oncology
PFS: Progression free survival
OS: Overall survival
ORR: Overall response rate
DCR: Disease control rate
DOR: Duration of response
KOL: Key opinion leader
FDA: Food and drug administration
GC: Gastric cancer
HR: Hazard ratio
LoS: Likelihood of success
NDA: New drug application
NPC: Nasopharyngeal cancer
PD-1: Programmed death-1
NMPA: national medical pharmaceutical association

Price objective basis & risk

HUTCHMED (HCM)

Our PO of $29 is derived from a probability-adjusted net present value (NPV) analysis, including $7/share for savolitinib, $10/share for fruquintinib, $4/share for surufatinib, $1/share for amdizalisib, $1/share for sovleplenib, -$2/share for other pipeline assets, $3/share for the commercial platform and $5/share for net cash. We use a weighted-average cost of capital (WACC) value ranging from 7% (commercial platform) to 11% (future pipeline) and terminal value ranging from -5% (legacy business) to 2% (future pipeline).

Downside risks to our price objective are 1) unfavorable efficacy and/or safety data for savolitinib, fruquintinib and surufatinib in clinical trials, 2) weaker-than-expected revenue for commercial platform, and 3) earlier-than-expected or more-than-expected competition for the above-mentioned three leading clinical assets.

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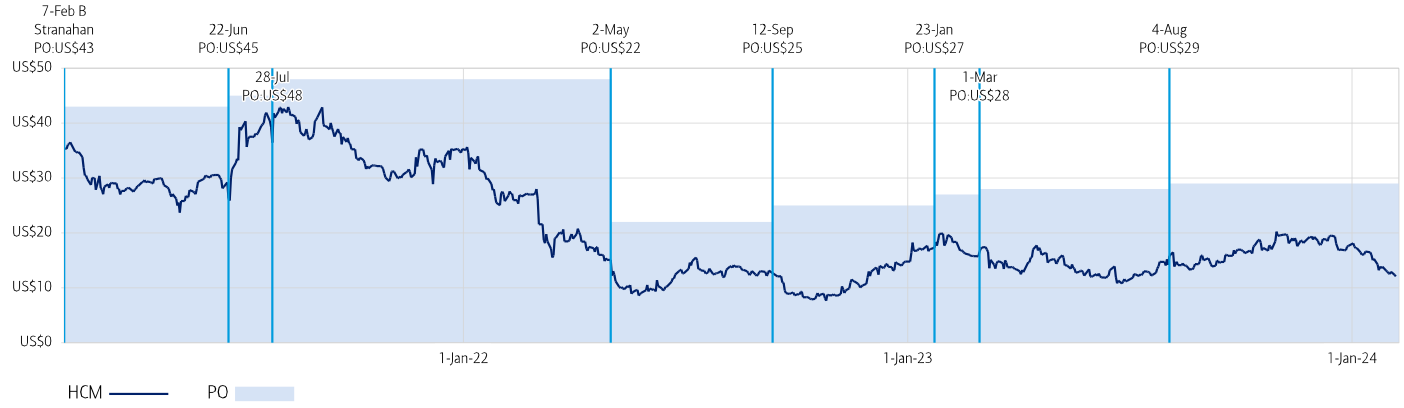
Hutchmed China Ltd (HCM) Price Chart



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Equity Investment Rating Distribution: Health Care Group (as of 31 Dec 2023)

Coverage Universe	Count	Percent	Inv. Banking Relationships [R1]	Count	Percent
Buy	234	60.94%	Buy	115	49.15%
Hold	80	20.83%	Hold	36	45.00%
Sell	70	18.23%	Sell	29	41.43%

Equity Investment Rating Distribution: Global Group (as of 31 Dec 2023)

Coverage Universe	Count	Percent	Inv. Banking Relationships [R1]	Count	Percent
Buy	1895	53.62%	Buy	1083	57.15%
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Sell	807	22.84%	Sell	383	47.46%

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