HUTCHMED

Strong US Fruzaqla Q1; EU approval could come soon

13 May 2024

- Takeda, HUTCHMED's ex-China partner for fruquintinib, has reported Fruzaqla in-market sales of JPY10.1bn for FY23 (for the 12 months ending March 2024), equating to c $68m (based on FX of JPY148/$). With US launch in November and $15.1m of in-market sales for calendar Q423 (October-December), as previously disclosed by HUTCHMED (February 2024 Lighthouse), this suggests calendar Q124 (January-March) in-market sales of c $53m in the US alone. Assuming some initial stocking, this suggests US sales alone in 2024 could reach $150-200m, ahead of our current $100m forecast (which includes initial EU sales assuming approval this year) and Evaluate Pharma consensus of $52m. Takeda is forecasting >100% growth of Fruzaqla for FY24 (12 months ending March 2025).
- Takeda received a positive EU CHMP (Committee for Medicinal Products for Human Use) opinion in April, recommending Fruzaqla approval for adult patients with previously treated metastatic colorectal cancer (mCRC). Per EU regulatory procedures, a formal approval decision will be made within 67 days of the CHMP opinion, and whilst not a foregone conclusion, this typically follows the CHMP recommendation. Hence, we expect EU approval by early July 2024. Fruquintinib is also under regulatory review in Japan (submitted in September 2023), with a decision expected later this year.
- HUTCHMED is entitled to future potential milestones, plus tiered royalties on in-market sales of Fruzaqla, with the latter one of the components underpinning HUTCHMED's growth targets. Although specific milestone triggering events have not been disclosed, we believe these may become due on events such as approvals and on development of new indications, as would be typical in such a licensing deal. Recall HUTCHMED has already received an upfront of $400m and a US approval milestone of $35m, with a further c $695m of milestones remaining, and recorded $2.1m of royalties on $15.1m of in-market sales (suggesting a starting royalty rate of c 14%).
- Beyond initial fruquintinib approvals in mCRC in Europe and Japan, we also expect China approval decisions for the next indications of 2L gastric cancer and 2L endometrial cancer in combination with PD-1 inhibitor sintilimab, with regulatory reviews for both ongoing.

Trinity Delta view: Partner Takeda has executed an impressive initial launch of Fruzaqla in the US, which provides confidence in future successful launches in Europe and Japan (once regulatory approvals are secured), and for Fruzaqla's longer-term growth prospects with expansion to additional indications. Fruzaqla's commercial prospects are a key contributor to HUTCHMED's path to profitability, which is supported by the growing traction and market share capture of its China oncology products, plus launches of new products. The latter include sovleplenib, where detailed data in 2L immune thrombocytopenia (under Priority Review in China), potentially at the EHA congress in June, are much anticipated. Our last published valuation was $5.81bn/£4.84bn/HK$45.35bn, or $33.36/ADS and 556p/HK$52.05 per share.

Price (US ADS)	$21.75
(UK share)	352.0p
(SEHK share)	HK$34.70
Market Cap	US$3.71bn
	£3.00bn
	HK$29.62bn
Exchanges	NASDAQ
	AIM London
	SEHK
Sector	Healthcare
Company Codes	HCM
	HCM.L
	0013.HK
Corporate client	Yes

Company description:

HUTCHMED is a Hong Kong headquartered biopharma focused on discovering, developing and commercialising innovative targeted therapeutics and immunotherapies to treat cancer and autoimmune diseases. It has a diverse pipeline of first-in-class/best-in-class selective oral TKIs in development for the China and global markets.

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