# HUTCHMED

## Fruquintinib clinical and commercial updates

12 February 2024

- Data from the Phase III FRUTIGA trial of fruquintinib in combination with paclitaxel for the treatment of 2L (second-line) advanced gastric cancer (GC) or gastro-esophageal junction adenocarcinoma (GEJ) in China were presented at the American Society of Clinical Oncology (ASCO) Plenary Series Session. These data supported the China NDA submission for fruquintinib in this setting, which was accepted for review in April 2023.
- FRUTIGA was a 1:1 randomised, double-blind, 703 patient Phase III study carried out at 35 sites in China evaluating fruquintinib in combination with paclitaxel vs paclitaxel monotherapy for treatment of advanced GC or GEJ. It met one of the dual primary endpoints: progression-free survival (PFS) with median PFS of 5.6 months for combination therapy vs 2.7 months for paclitaxel monotherapy (HR = 0.569; p<0.0001). Improvement in overall survival (OS), the other primary endpoint, was numerically but not statistically significant; pre-specified sensitivity analyses indicated this was likely due to an imbalance of patients receiving subsequent antitumour therapies across both arms. Improvements in secondary endpoints included objective response rate (ORR: 42.5% vs 22.4%), disease control rate (DCR: 77.2% vs 56.3%) and duration of response (DoR: 5.5 vs 3.7 months). Fruquintinib plus paclitaxel was well tolerated, with a safety profile consistent with prior studies.
- Assuming a positive approval decision in 2024, 2L GC/GEJ would be the second indication for fruquintinib in China. It is already approved in advanced metastatic colorectal cancer (mCRC) as a monotherapy in China and the US, and is currently under review for advanced mCRC in Europe and Japan, with approval decisions anticipated in 2024.
- Separately, global ex-China partner Takeda provided first insights into the US launch of fruquintinib (FRUZAQLA) for previously treated mCRC. Given the unmet need, it was made commercially available in November 2023 within 24 hours of FDA approval, and initial uptake has been strong. We note that FRUZAQLA is not yet a separate revenue line item but is included in 'Oncology Others'; Takeda reported Oncology Others sales of JPY3.3bn for Q324 (October-December 2023) vs JPY0.9bn for Q224.

**Trinity Delta view:** Fruquintinib'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, additional potential approvals and launches (by partner Takeda) of fruquintinib in international markets, and a solid balance sheet. Fruquintinib's potential approval in a second indication in China (2L gastric cancer) as well as tiered royalties on annual net sales in Takeda's markets (undisclosed but assumed to start from mid-teens) should drive significant future revenues. Nearer-term, the revenues from HUTCHMED's three marketed oncology products in China, coupled with partial recognition ($280m) of the Takeda licence upfront contribute to FY23 revenue guidance of $450-550m. FY23 results will report on February 28. Our last published valuation is $5.74bn/ £4.78bn/ HK$44.75bn, or $32.95/ADS and 549p/HK$51.40 per share.

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|---|---|
| Price (US ADS) | $14.01 |
| (UK share) | 221.0p |
| (SEHK share) | HK$21.80 |
| Market Cap | US$2.42bn<br>£1.93bn<br>HK$19.12bn |
| Exchanges | NASDAQ<br>AIM London<br>SEHK |
| Sector | Healthcare |
| Company codes | HCM<br>HCM.L<br>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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