# HUTCHMED

## Landmark FDA approval for fruquintinib

13 November 2023

- HUTCHMED's partner Takeda has received FDA approval for fruquintinib (branded FRUZAQLA) for previously treated metastatic colorectal cancer (mCRC). This marks an important milestone for HUTCHMED as the first approval in a major international market ex-China for an internally discovered and developed compound. US fruquintinib approval triggers a $35m milestone from Takeda, with HUTCHMED also eligible for undisclosed net sales royalties.
- Fruquintinib is a selective oral VEGF 1/2/3 inhibitor and is the first targeted therapy approved in the US for mCRC irrespective of biomarker status or prior type of treatment (including chemotherapy, anti-VEGF or anti-EGFR therapy) in over a decade. It is also a chemotherapy-free treatment option that can be administered at home. US approval was supported by data from the FRESCO-2 (multi-regional) and FRESCO (China) Phase III trials in 734 patients. These trials both met their primary and key secondary endpoints with a consistent overall survival benefit across trials and a manageable safety profile.
- The FRESCO and FRESCO-2 data also support the marketing authorisation application (MAA) filed with the European Medicines Agency (EMA) which was validated and accepted for review in June 2023, and the Japan PMDA which was submitted in September 2023. Approval decisions are anticipated in 2024.
- Under the ex-China global licence with Takeda for fruquintinib, HUTCHMED could receive significant downstream economics. The deal included a $400m upfront (received in H123) with potential for up to $730m in potential future regulatory, development, and commercial milestones (the first milestone of $35m was triggered on FDA approval), plus tiered royalties on annual net sales. While undisclosed, we assume that these royalties start from mid-teens.
- In China, fruquintinib (Elunate) has been commercially available for 3L mCRC (in partnership with Eli Lilly) since November 2018. For H123, HUTCHMED consolidated Elunate revenues of $42m (+25% at CER; H122: $36m) on in-market sales of $56m (+20% at CER; H122: $50m). Revenue from the three marketed oncology products in China (Elunate, Orpathys, Sulanda), coupled with partial recognition ($280m) of the Takeda upfront contribute to HUTCHMED FY23 revenue guidance of $450-550m.

**Trinity Delta view:** The FDA approval of fruquintinib (FRUZAQLA) for previously treated mCRC is a landmark achievement for HUTCHMED, and its pending launch will be the first of a HUTCHMED discovered and developed drug ex-China. Global fruquintinib sales are a key component of HUTCHMED's path to profitability, which is supported by the growing traction and market share capture of its China oncology products, further potential approvals and launches (by partner Takeda) of fruquintinib in other international markets (the European EMA and Japan PDMA decisions are anticipated in 2024), and a solid balance sheet. A second global asset, savolitinib, is completing multiple pivotal trials with potential for filing(s) in 2024. HUTCHMED is also on the cusp of first China filing(s) for its second-wave haem-oncology assets. 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) | $19.02 |
| (UK share) | 309.5p |
| (SEHK share) | HK$29.50 |
| Market Cap | US$3.29bn |
| | £2.80bn |
| | HK$25.69bn |
| 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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