

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.

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.

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 soveplenib, 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.

Analysts

Lala Gregorek

lgregorek@trinitydelta.org
+44 (0) 20 3637 5043

Philippa Gardner

pgardner@trinitydelta.org
+44 (0) 20 3637 5042

Philippa Gardner

pgardner@trinitydelta.org

+44 (0) 20 3637 5042

Lala Gregorek

lgregorek@trinitydelta.org

+44 (0) 20 3637 5043

Franc Gregori

fgregori@trinitydelta.org

+44 (0) 20 3637 5041

Disclaimer

Trinity Delta Research Limited ("TDRL"; firm reference number: 725161), which trades as Trinity Delta, is an appointed representative of Equity Development Limited ("ED"). The contents of this report, which has been prepared by and is the sole responsibility of TDRL, have been reviewed, but not independently verified, by ED which is authorised and regulated by the FCA, and whose reference number is 185325.

ED is acting for TDRL and not for any other person and will not be responsible for providing the protections provided to clients of TDRL nor for advising any other person in connection with the contents of this report and, except to the extent required by applicable law, including the rules of the FCA, owes no duty of care to any other such person. No reliance may be placed on ED for advice or recommendations with respect to the contents of this report and, to the extent it may do so under applicable law, ED makes no representation or warranty to the persons reading this report with regards to the information contained in it.

In the preparation of this report TDRL has used publicly available sources and taken reasonable efforts to ensure that the facts stated herein are clear, fair and not misleading, but make no guarantee or warranty as to the accuracy or completeness of the information or opinions contained herein, nor to provide updates should fresh information become available or opinions change.

Any person who is not a relevant person under section of Section 21(2) of the Financial Services & Markets Act 2000 of the United Kingdom should not act or rely on this document or any of its contents. Research on its client companies produced by TDRL is normally commissioned and paid for by those companies themselves ('issuer financed research') and as such is not deemed to be independent, as defined by the FCA, but is 'objective' in that the authors are stating their own opinions. The report should be considered a marketing communication for purposes of the FCA rules. It has not been prepared in accordance with legal requirements designed to promote the independence of investment research and it is not subject to any prohibition on dealing ahead of the dissemination of investment research. TDRL does not hold any positions in any of the companies mentioned in the report, although directors, employees or consultants of TDRL may hold positions in the companies mentioned. TDRL does impose restrictions on personal dealings. TDRL might also provide services to companies mentioned or solicit business from them.

This report is being provided to relevant persons to provide background information about the subject matter of the note. This document does not constitute, nor form part of, and should not be construed as, any offer for sale or purchase of (or solicitation of, or invitation to make any offer to buy or sell) any Securities (which may rise and fall in value). Nor shall it, or any part of it, form the basis of, or be relied on in connection with, any contract or commitment whatsoever. The information that we provide is not intended to be, and should not in any manner whatsoever be, construed as personalised advice. Self-certification by investors can be completed free of charge at www.fisma.org. TDRL, its affiliates, officers, directors and employees, and ED will not be liable for any loss or damage arising from any use of this document, to the maximum extent that the law permits.

Copyright 2024 Trinity Delta Research Limited. All rights reserved.

More information is available on our website: www.trinitydelta.org