HUTCHMED

Fruquintinib should continue to bear fruit

21 November 2022

- The China Phase III FRUTIGA study of fruquintinib in combination with paclitaxel in second-line (2L) gastric cancer met one of its dual endpoints, demonstrating a statistically significant and clinically meaningful benefit in progression-free survival (PFS). There was an improvement, albeit not statistically significant, in median overall survival (OS), the second dual endpoint. Statistically significant improvements were also shown in several secondary endpoints (objective response rate, disease control rate, and duration of response) and safety was consistent with the known profile.
- FRUTIGA, a 1:1 randomised double-blind Phase III, evaluated fruquintinib + paclitaxel vs paclitaxel monotherapy in 703 Chinese patients with advanced gastric or gastroesophageal junction (GEJ) adenocarcinoma unresponsive to first-line chemotherapy. Analysis is ongoing, with presentation of detailed data at an upcoming scientific meeting. These data and analyses will also be discussed with the China National Medical Products Administration (NMPA) to determine next steps for possible regulatory filing in 2L gastric cancer.
- We cannot second guess regulatory decisions, however, we note that the pivotal RAINBOW-Asia study of ramucirumab in 2L gastric cancer, which was the basis for Cymraza's March 2022 NMPA approval, reported a similar outcome albeit with co-primary endpoints (meeting PFS but not OS).
- Changes to the China gastric cancer competitive landscape since the start of the FRUTIGA study in 2017 (ie approvals of PD-1 checkpoint inhibitors and other innovative therapies) possibly impacted its outcome in our view. Post-progression therapy in both placebo and fruquintinib arms may have been a confounding factor for OS, as availability of new therapies and standards of care (SoC) provide more options for patients who have progressed. This may also affect fruquintinib's market potential in 2L gastric cancer, should approval be granted for this second indication in China.
- Fruquintinib (Elunate) has been marketed in China for 3L mCRC (metastatic colorectal cancer) since 2018. The China partner is Eli Lilly, but global rights are currently unencumbered. Ex-China, HUTCHMED is pursuing first regulatory filings following positive readout of the pivotal FRESCO-2 multi-regional clinical trial (September 2022 Update). Rolling US FDA filing could start around YE22, completing mid-H123, followed by EU and Japan filings.

Trinity Delta view: FRUTIGA was the first China combination trial initiated as part of HUTCHMED's broad fruquintinib development programme in China and globally as monotherapy and in combinations. The strategy has since evolved to focus on immuno-oncology combinations (detailed in our September 2022 Pipeline Update), reflecting advances in the SoC in several indications and leveraging fruquintinib's profile as a safe and highly selective potent VEGFR 1/2/3 inhibitor, with potentially synergistic mechanisms of action. Fruquintinib is a key contributor to HUTCHMED FY22 China revenue guidance of $160-$190m and, assuming a positive decision in 2024 from the FDA, EMA, and/or PMDA, could become its first approval ex-China.

Price (US ADS)	$10.77
(UK share)	184.2p
(SEHK share)	HK$17.36
Market Cap	US$1.94bn
	£1.63bn
	HK$15.01bn
Exchanges	NASDAQ
	AIM London
	SEHK
Sector	Healthcare
Company codes	HCM
	HCM.L
	0013.HK
Corporate client	Yes

Company description:

HUTCHMED is a biopharma currently focused on discovering, developing and commercializing innovative targeted therapeutics and immunotherapies for cancer and autoimmune diseases. It has a diverse pipeline of first-in-class/best-in-class selective oral tyrosine kinase inhibitors in development for China and global markets (notably the US).

Analysts

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

Philippa Gardner
pgardner@trinitydelta.org
+44 (0) 20 3637 5041

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

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