Trinity Delta Lighthouse

Hutchison China MediTech (Chi-Med)

Acceptance of surufatinib China NDA in epNET

12 November 2019

- Chi-Med's NDA (new drug application) for surufatinib in the treatment of patients with advanced non-pancreatic neuroendocrine tumours (epNET) has been accepted for review by the China National Medical Products Administration (NMPA).
- This NDA is supported by the pivotal Phase III SANET-ep trial. Positive data was presented at ESMO 2019 (see our October 2019 Update), and showed an investigator assessed PFS of 9.2 months for surufatinib vs 3.8 months for placebo (hazard ratio = 0.334, p<0.0001), as well as encouraging broad utility across epNET subtypes.
- Subject to regulatory approval in epNET, Chi-Med could launch surufatinib in as early as c 12 months, in late 2020, based on an extrapolation from the China approval timeline for fruquintinib (Elunate).
- Ahead of an approval decision, Chi-Med is building a dedicated commercial oncology organisation, which it expects will cover all relevant hospitals and clinics in China by the time of potential surufatinib launch.
- Ep-NET is surufatinib's lead indication; it is also under investigation in multiple solid tumour types in both China (Phase III SANET-p in pancreatic NET; Phase IIb/III in advanced biliary tract cancer), and the US/Europe (Phase Ib NET). Due to its dual mechanism of action surufatinib is also being studied in combination with PD-1 immunotherapies in China.
- Chi-Med retains all worldwide rights to surufatinib.

Price (US ADS) (UK share)	$22.40 360p
Market Cap	$2.99bn £2.40bn
Exchanges	NASDAQ AIM London
Sector	Healthcare
Company codes	HCM HCM.L
Corporate client	Yes

Company description:

Hutchison China MediTech is a Hong Kong headquartered biopharma with an established Commercial Platform in China, and a diverse pipeline of first-in-class/best-in-class selective oral tyrosine kinase inhibitors (Innovation Platform). Its pipeline, discovered in-house, is in development for the China and global oncology markets.

Trinity Delta view: Confirmation of the acceptance of the surufatinib China NDA is an important strategic step for Chi-Med. Subject to regulatory approval, Chi-Med could launch its first wholly owned oncology drug in late-2020, commercialising it through its own China Oncology commercial organisation.

Prior to an approval decision, we expect further clinical news flow related to surufatinib in NET during H120, with the interim analysis of the China SANET-p Phase III in pNET and initiation of the US/Europe registration study.

We also anticipate various other clinical, regulatory, and commercial catalysts during 2019 and 2020 that will unlock further value. The first is expected to be an imminent NRDL inclusion decision for fruquintinib (Elunate) in 3L CRC. Elunate was approved and launched in China by partner Eli Lilly in H218; NRDL inclusion should significantly boost its market penetration and future revenues.

H120 should also see the first savolitinib regulatory submission, with filing of the China NDA for MET exon 14m/del 1L NSCLC.

We currently value Chi-Med at $5.14bn ($38.55/ADS) or £3.95bn (£5.93/share).

Analysts

Franc Gregori
fgregori@trinitydelta.org
+44 (0) 20 3637 5041

Mick Cooper PhD
mcooper@trinitydelta.org
+44 (0) 20 3637 5042

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

Mick Cooper PhD CFA mcooper@trinitydelta.org +44 20 3637 5042

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

Franc Gregori fgregori@trinitydelta.org +44 20 3637 5041

Disclaimer

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