Trinity Delta Lighthouse

Hutchison China MediTech (Chi-Med)

Impressive data means SANET-ep trial stopped early

14 June 2019

- Chi-Med has announced that the China Phase III SANET-ep study of surufatinib in advanced extra-pancreatic neuroendocrine tumours (NET) has been terminated early as it has already met its primary endpoint of progression free survival (PFS) at the planned interim stage analysis.
- The Independent Data Monitoring Committee (IDMC) determined that the trial has already met the pre-defined primary endpoint and so the study result is viewed as achieved. Full data will be presented at a future scientific conference.
- Chi-Med intends to schedule a pre-NDA (New Drug Application) with the NMPA (China National Medical Products Administration) to discuss the process for the NDA submission. As a precedent, the fruquintinib NDA was submitted within 4 months following pivotal top line data and then it took about 15 months for approval to be granted.
- The earlier nature of SANET-ep data suggests some extra time may be needed to prepare the NDA submission. However, given that surufatinib will be manufactured at the same GMP certified facility as fruquintinib, we might expect a more rapid CMC review as a number of components are already validated. Consequently, we suspect that the 15 month post-NDA approval timeline may be shorter.
- Clearly, the impressive outcome of the SANET-ep trial means that our forecast timelines for approval and marketing will be accelerated. We will review our model, and valuation, but a rough assessment suggests a benefit of c 12 months compared to our previous expectations.

Price (US ADS) (UK share)	$27.04 418p
Market Cap	$3.61bn £2.79bn
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: The encouraging result of SANET-ep suggest that surufatinib (previously known as HMPL-012 or sulfatinib) will be the first approved and marketed product where Chi-Med holds worldwide rights. Our base case scenario was that the trial would run to completion (enrolment completing by year-end and top line data in mid-2020), hence our current Chi-Med valuation of $4.742bn ($35.57/ADS) or £3.648bn (£5.47/share) will be reviewed following this positive outcome. We also highlight that we anticipate additional clinical, regulatory, and commercial catalysts during 2019 and 2020 that will unlock further value.

Analysts

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