Trinity Delta

Hutchison China MediTech

Update

China approval clears Sulanda in epNET

4 January 2021

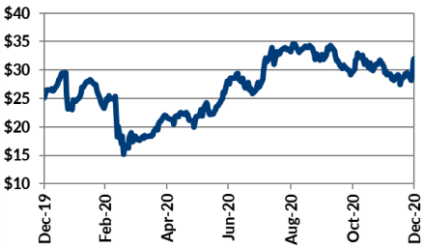
The China regulator has approved Hutchison China MediTech's (Chi-Med's) second internally discovered cancer drug, surufatinib (brand name Sulanda) for the treatment of epNET (non-pancreatic [extra-pancreatic] neuroendocrine tumours). Sulanda will be Chi-Med's first unpartnered oncology drug launch in China, with potential for a label extension in pancreatic NET (pNET) later in 2021. Surufatinib is also on track to become Chi-Med's first marketed drug in the US with the recent initiation of a rolling NDA submission for advanced NETs. The totality of the clinical data package shows a significant benefit to NET patients irrespective of tumour origin; with surufatinib addressing a major unmet need it has the potential to be the first global treatment option for NETs. Our valuation is increased to £6.45/share or $41.94/ADS.

Year-end: December 31	2018	2019	2020E	2021E
Sales (US$m)	214.1	204.9	214.8	318.7
Adj. PBT (US$m)	(86.7)	(141.1)	(202.6)	(187.3)
Net Income (US$m)	(71.3)	(103.7)	(132.9)	(140.3)
Earnings per ADS (US$)	(0.57)	(0.80)	(0.98)	(0.99)
Cash (US$m)	301.1	217.2	379.7	318.0*
Adj. EBITDA (US$m)	(69.7)	(100.7)	(121.7)	(125.2)

Source: Trinity Delta Note: Adjusted PBT excludes exceptionals, Cash includes short-term investments, Adjusted EBITDA includes equity in earnings of equity investees. *2021E cash includes $100m from assumed warrant exercise.

- **2021 China launch in epNET** Sulanda will be launched in early 2021 by Chi-Med's dedicated China Oncology commercial team. Label expansion following potential approval in a second indication (pNET) is expected in 2021 and would allow positioning of surufatinib as an effective treatment option for NETs irrespective of tumour origin. Broad utility has been demonstrated in both pivotal Phase III NET trials, with results published in The Lancet Oncology (SANET-ep; SANET-p).
- **Commercial leverage in China** Chi-Med's China Oncology Commercial team has grown to 400 and covers over 2,000 hospitals, with plans for further expansion (>900 by end-2023, with full coverage of all mainland provinces). This infrastructure will sell both Elunate (from October 1, 2020 under the amended Eli Lilly agreement) and Sulanda (from 2021). Sulanda's commercial strategy and pricing are not yet disclosed, but we expect Chi-Med to employ a similar strategy as with Elunate: ie establishing a patient access programme ahead of potential NRDL inclusion in 2022.
- **First US NDA submission initiated** The FDA rolling NDA submission for surufatinib in advanced NETs began in December 2020 and should complete in H121. NDA acceptance is subject to FDA review of the complete dossier. Pending FDA clearance Chi-Med intends to initiate an Expanded Access Protocol, which could begin enrolling in Q121, ahead of potential NDA approval and US launch in late 2021/early 2022. MAA filing with the EMA is anticipated in 2021.
- **Valuation upgrade to £6.45/share or $41.94/ADS** Following surufatinib China approval in epNET and initiation of the US NET rolling NDA, we raise our success probabilities in these regions and indications. Our DCF-based sum-of-the-parts model now ascribes a valuation of £6.45/share ($41.94/ADS) vs £5.84/share ($37.95/ADS) previously. Multiple clinical, regulatory, and commercial catalysts should unlock further value during 2021.

Price (UK share) (US ADS)	460p $32.02
Market Cap	£3.35bn $4.66bn
Enterprise Value	£3.06bn $4.28bn
Shares in issue (shares) (ADS)	727.7m 145.5m
12 month range	249p-530p $14.74-$34.90
Free float	54.3%
Exchanges	AIM NASDAQ
Sector	Healthcare
Company codes	HCM.L HCM
Corporate client	Yes



Company description

Hutchison China MediTech is a Hong Kong headquartered biopharma focused on discovering, developing and commercializing 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 tyrosine kinase inhibitors in development for the China and global markets.

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Chi-Med: a second product on the cusp of launch

Hutchison China MediTech (Chi-Med) has achieved a major milestone with the China approval of surufatinib (branded as Sulanda) in epNET (non-pancreatic neuroendocrine tumours). Surufatinib is the second of its internally discovered oncology drugs to be approved by the NMPA (National Medical Products Administration) but the first to be wholly internally developed and the first to be self-commercialised, with launch in early 2021. Approval of a label extension, to include pancreatic NET (pNET), is expected in 2021. Chi-Med holds global rights to surufatinib and has also progressed the asset for the ex-China market with the December 2020 initiation of a rolling NDA submission with the FDA. The NDA submission is expected to be completed in H121; FDA acceptance is subject to review of the entire dossier. Surufatinib regulatory developments in China and the US bring Chi-Med a step closer to its goal of becoming a global biopharmaceutical company with a portfolio of innovative targeted oncology drugs marketed to patients worldwide. Our revised valuation is £4.7bn (equivalent to £6.45/share) or $6.1bn ($41.94/ADS) vs £4.25bn (£5.84/share) or $5.52bn ($37.95/ADS) previously.

Pipeline delivery shifts investor focus to commercial execution

Chi-Med continues to make progress on multiple fronts despite the COVID-19 pandemic. Two of the company's first-in-class and/or best-in-class tyrosine kinase inhibitors have now been approved in China, evidencing the strength and relevance of Chi-Med's in-house R&D capabilities. The execution of its plans to self-commercialize these, and other assets in the future, will exploit the local knowledge built up since inception over 20 years ago. The current clinical pipeline is advancing, both for China and the Global market, with the recent initiation of the pivotal fruquintinib FRESCO-2 study in metastatic colorectal cancer (mCRC) indicative of this progress. We expect Chi-Med's three lead assets (fruquintinib, surufatinib, savolitinib) to deliver key clinical and regulatory news flow, both in China and globally, over the coming 24 months. In addition, the next wave of product candidates, likely to be developed in parallel in both regions, is increasing in visibility and will, over time, make a growing contribution to the pipeline.

China to drive near-term revenues, with Global launches expected in medium-term

Commercial traction in China is translating into meaningful revenues, with further product approvals/launches (eg surufatinib in pNET; savolitinib in MET exon 14 skipping non-small cell lung cancer, NSCLC, subject to approval) expected in the near-term. Future Global launches should enhance medium-term earnings potential, with the first US approvals/launches possible in 2022 for surufatinib (as a monotherapy for advanced NET) and savolitinib (in combination with osimertinib [Tagrisso] in MET positive osimertinib refractory NSCLC).

Solid cash resources allow for continued pipeline investment

The c $318m of funds raised in 2020 ($200m from two PIPEs, with the residual from the January 2020 ADR offering) have strengthened Chi-Med's balance sheet and brought new investors to the shareholder register. Our end-FY20 net cash forecast of c $380m provides the resources to maintain momentum and fund necessary investments in infrastructure to support the development pipeline. This includes the ongoing clinical development of the three leading assets and the next wave of product candidates, expansion of the China Oncology Commercial footprint and US infrastructure, and increased manufacturing capacity in Shanghai to support upcoming launches as new approvals come through.

Surufatinib: from the clinic to commercialisation

Impressive clinical profile backed by compelling data

Surufatinib's profile suggests that it has the potential to become a new standard of care across the NET spectrum, with its clinical benefit confirmed in two pivotal Phase III trials (SANET-ep and SANET-p). These trials supported China NDA filings for epNET (approval granted in December 2020) and pNET (NDA acceptance in September 2020, with a potential approval decision expected in 2021). Several of our earlier reports explore in depth the SANET-ep data presented at ESMO 2019 (October 2019 Update), SANET-p data at ESMO 2020 (September 2020 Update), and the wider surufatinib NET opportunity (February 2020 Update).

US regulatory process is well advanced, with 2021 a key year

Outside of China, the FDA and EMA have confirmed that data from both SANET studies, as well as a separate bridging study with US epNET and pNET patients, would be sufficient to support NDA and MAA submissions for the broader NET indication. Chi-Med recently initiated a rolling NDA filing with the FDA, which should complete in H121. An MAA is expected to be filed in 2021. These timelines point towards a potential late-2021/early-2022 approval decision. In the US, Fast Track Designation has been granted for surufatinib for both epNET and pNET, with Orphan Drug Designation in the latter. Chi-Med also plans to begin enrolling a US Expanded Access Protocol in Q121, subject to FDA clearance.

China commercial team poised to exploit this major asset

In China, Sulanda will be Chi-Med's first wholly self-commercialized asset, with management having expanded its China Oncology Commercial team in preparation for launch. The 400-strong commercial team (including sales reps, marketing managers, medical liaison etc) covers more than 2,000 hospitals across China, and is targeting further expansion, to over 900 providing full coverage of all provinces in mainland China by end-2023. Since October 1, following a July 2020 amendment to the 2013 agreement with Eli Lilly, Chi-Med's commercial team has had a more extensive role in Elunate commercialization. With potential for label extensions for both products (Sulanda in pNET in 2021; Elunate for 2L gastric cancer in 2022), there is further leverage potential.

Elunate experience suggests a similar approach for Sulanda

Chi-Med has provided little detail on its commercial strategy for Sulanda at this point; however, we expect that this will be similar to that employed with Elunate following its approval for 3L mCRC in 2018. Sulanda pricing is not yet confirmed, but we would anticipate that launch would be associated with a Patient Access Programme that would limit out of pocket costs while inclusion on the NRDL (National Reimbursement Drug List) is pursued. Should Sulanda be included on the NRDL, potentially in 2022, any pricing discount granted would be more than offset by greater volumes resulting from improved market access.

Further potential in addition to NET indications, and as part of combination regimens

We note that surufatinib is also being evaluated outside of NET. China trials are ongoing in 2L biliary tract cancer (China Phase IIb/III) and in combination with PD-1 inhibitors for solid tumours. Chi-Med has several surufatinib collaborations evaluating PD-1 combinations with Shanghai Junshi for toripalimab (Tuoyi), BeiGene (tislelizumab), and Innovent Biologics (sintilimab, Tyvyt). Global combination studies are in planning. Surufatinib's dual mechanism of action (angio-immuno kinase inhibition) could have synergistic anti-tumour effects with PD-1 inhibitors, facilitated by its favourable safety profile. The Tuoyi collaboration is the most clinically advanced: a Phase II study initiated in January 2020, and first promising combination data, while preliminary, from the completed China Phase I dose-finding study was presented at AACR 2020 (April 2020 Update).

Exhibit 1: Summary of financials

Year-end: December 31	$'000s	2017	2018	2019	2020E	2021E
INCOME STATEMENT						
Revenues		**241,203**	**214,109**	**204,890**	**214,825**	**318,711**
Cost of goods sold		(175,820)	(143,944)	(160,152)	(164,035)	(212,608)
Gross Profit		**65,383**	**70,165**	**44,738**	**50,791**	**106,103**
R&D expenses		(75,523)	(114,161)	(138,190)	(194,554)	(223,819)
Selling expenses		(19,322)	(17,736)	(13,724)	(14,736)	(19,597)
G&A expenses		(23,955)	(30,909)	(39,210)	(43,587)	(50,959)
Underlying operating profit		**(53,417)**	**(92,641)**	**(146,386)**	**(202,086)**	**(188,271)**
Other revenue/expenses		0	0	0	0	0
EBITDA		**(50,839)**	**(89,051)**	**(141,444)**	**(196,558)**	**(178,606)**
Operating Profit		**(53,417)**	**(92,641)**	**(146,386)**	**(202,086)**	**(188,271)**
Interest income/expense		(235)	4,969	3,914	250	1,716
Other income/expense		116	1,017	1,367	(758)	(758)
Profit Before Taxes		**(53,536)**	**(86,655)**	**(141,105)**	**(202,595)**	**(187,313)**
Adj. PBT		**(53,536)**	**(86,655)**	**(141,105)**	**(202,595)**	**(187,313)**
Current tax income		(3,080)	(3,964)	(3,274)	(5,204)	(6,370)
Equity in earnings of equity investees, net of tax		33,653	19,333	40,700	74,888	53,356
Net Income		**(22,963)**	**(71,286)**	**(103,679)**	**(132,911)**	**(140,327)**
Minority interests		(3,774)	(3,519)	(2,345)	(8,960)	(4,360)
Net income attributable to equityholders		**(26,737)**	**(74,805)**	**(106,024)**	**(141,870)**	**(144,687)**
EPS ($)		**(0.04)**	**(0.11)**	**(0.16)**	**(0.20)**	**(0.20)**
Earnings per ADS ($)		**(0.22)**	**(0.57)**	**(0.80)**	**(0.98)**	**(0.99)**
DPS ($)		**0.00**	**0.00**	**0.00**	**0.00**	**0.00**
Average no. of shares (m)		617.2	664.3	665.7	706.5	731.9
Gross margin		*27%*	*33%*	*22%*	*24%*	*33%*
EBITDA margin		*N/A*	*N/A*	*N/A*	*N/A*	*N/A*
Underlying operating margin		*N/A*	*N/A*	*N/A*	*N/A*	*N/A*
BALANCE SHEET						
Current assets		**432,195**	**370,541**	**317,022**	**477,543**	**443,950**
Cash and cash equivalents		85,265	86,036	121,157	198,664	161,978
Short-term investments		273,031	214,915	96,011	181,074	156,074
Accounts receivable		42,270	42,958	43,254	47,085	69,854
Inventories		11,789	12,309	16,208	17,976	23,300
Other current assets		19,840	14,323	40,392	32,744	32,744
Non-current assets		**165,737**	**161,577**	**148,100**	**171,418**	**192,661**
Property, plant & equipment		14,220	16,616	20,855	34,745	47,985
Intangible assets		3,738	3,533	3,387	0	0
Investments in equity investees		144,237	138,318	98,944	113,644	121,648
Other non-current assets		3,542	3,110	24,914	23,028	23,028
Current liabilities		**(104,600)**	**(85,479)**	**(113,101)**	**(121,051)**	**(134,992)**
Short-term debt		(29,987)	0	0	0	0
Accounts payable		(24,365)	(25,625)	(23,961)	(26,965)	(40,774)
Other current liabilities		(50,248)	(59,854)	(89,140)	(94,086)	(94,218)
Non-current liabilities		**(8,366)**	**(34,384)**	**(39,118)**	**(39,127)**	**(39,127)**
Long-term debt		0	(26,739)	(26,818)	(26,839)	(26,839)
Other non-current liabilities		(8,366)	(7,645)	(12,300)	(12,288)	(12,288)
Equity		**484,966**	**412,255**	**312,903**	**488,783**	**462,492**
CASH FLOW STATEMENTS						
Operating cash flow		**(8,943)**	**(32,847)**	**(80,912)**	**(113,143)**	**(138,781)**
Net income		(22,963)	(71,286)	(103,679)	(132,911)	(140,327)
Non-cash adjustments & other operating cash flow		28,525	31,276	6,662	17,207	15,829
Change in working capital		(14,505)	7,163	16,105	2,561	(14,283)
Investing cash flow		**(260,780)**	**43,752**	**119,028**	**(105,631)**	**2,095**
CAPEX		(5,019)	(6,364)	(8,565)	(20,568)	(22,905)
Change in short term investments		(248,761)	58,116	118,904	(85,063)	25,000
Investment in an equity investee		(7,000)	(8,000)	8,689	0	0
Financing cash flow		**273,196**	**(8,231)**	**(1,493)**	**296,343**	**100,000**
Proceeds from equity		291,737	(2,322)	(95)	297,574	100,000
Increase in loans		(16,947)	(4,627)	(116)	0	0
Other financing cash flow		(1,594)	(1,282)	(1,282)	(1,231)	0
Net increase in cash		**3,473**	**2,674**	**36,623**	**77,570**	**(36,686)**
Exchange rate effects		2,361	(1,903)	(1,502)	(63)	0
Cash at start of year		79,431	85,265	86,036	121,157	198,664
Cash at end of year		**85,265**	**86,036**	**121,157**	**198,664**	**161,978**
Net cash at end of year		**328,309**	**274,212**	**190,350**	**352,899**	**291,213**

Source: Company, Trinity Delta Note: Adjusted PBT excludes exceptionals, Cash includes short-term investments, Adjusted EBITDA includes equity in earnings of equity investees. *2021E cash figure includes assumed receipt of $100m in new funds from warrant exercise

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Disclaimer

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