EDISON

Hutchison China MediTech

Full-year results update

From innovation to oncology commercialisation

Pharma & biotech

Hutchison China MediTech's (HCM's) investment case is focused on evolution into a global R&D and commercial-stage biopharma company with a marketed portfolio of innovation-led oncology drugs. 2020 is a golden year as HCM moves towards multiple domestic drug launches and is progressing key assets into registration studies globally. We expect surufatinib (NET) and savolitinib (exon 14 deletion NSCLC) China launches in 2020 and 2021, respectively, following in the footsteps of Elunate (third-line CRC), which is establishing its presence by its inclusion on the National Reimbursement Drug List. HCM is investing in its oncology commercial presence in China and its global clinical and regulatory capabilities (in the US, Europe and Japan). 2022 and 2023 should benefit from global drug launches providing continued pipeline progression. We value HCM at $5.9bn.

Year end	Revenue (US$m)	Net profit* (US$m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
12/18	214.1	(74.8)	(11.3)	0.0	N/A	N/A
12/19	204.9	(106.0)	(15.9)	0.0	N/A	N/A
12/20e	216.8	(161.1)	(23.3)	0.0	N/A	N/A
12/21e	287.9	(165.2)	(23.9)	0.0	N/A	N/A

Note: *Net profit and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

China focus on sales, approvals and launches

As of 1 January 2020, Elunate is available in all state-run hospital pharmacies in China and patients on NHSA insurance schemes will be reimbursed. Eli Lilly reported Elunate sales of $6.6m in January-February 2020 vs $17.6m in FY19. We expect accelerated sales growth in 2020 and beyond. Surufatinib's China NDA has been accepted for non-pancreatic NET (potential approval and launch late 2020) and following positive data from SANET-p, the NDA for pancreatic NET will be filed in Q320. Surufatinib could be the first unpartnered asset to market; long-term economic value resides in HCM's ability to commercialise its basket of oncology products. HCM is on track to file the first ever NDA for savolitinib (exon 14 deletion NSCLC) in China within the next few months (launch 2021).

Powerhouse of innovation expands globally

HCM has eight oncology assets in development and is accelerating the global (ex-China) development of its unpartnered assets (fruquintinib, surufatinib, HMPL-523 and HMPL-689). Global registration studies are planned for this year for fruquintinib in 3/4L CRC and surufatinib in NET (the US FDA has granted Orphan Drug Designation for pancreatic NET). Savolitinib could be the first of HCM's innovation assets to launch globally in 2022 (for MET-positive EGFR refractory NSCLC in combination with Tagrisso, a blockbuster opportunity) through partner AZN.

Valuation: $5.9bn (£6.55/share)

We value HCM at $5.9bn (£6.55/share) vs $6.0bn (£6.74/share) previously. Our product forecasts remain unchanged but we increase our R&D expenses for 2020 to reflect progression of the global trials. Our valuation includes net cash of $190m at end December 2019 plus $110m net proceeds from the January 2020 capital raise.

23 March 2020

Price	**304.0p**
Market cap	**£2,099m**
	$1.30/£
Net cash ($m) and short-term investments at end 2019 + net proceeds of $110m raise	300
Shares in issue	690.6m
Free float	52%
Code	HCM
Primary exchange	AIM/Nasdaq
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(38.7)	(34.2)	(28.5)
Rel (local)	(10.3)	(8.1)	(29.7)
52-week high/low	476.0p		258.0p

Business description

Hutchison China MediTech is an innovative China-based biopharmaceutical company targeting the global market for novel, highly selective oral oncology and immunology drugs. Its established commercial platform business continues to expand its outreach.

Next events

Surufatinib China NDA file for pancreatic NET	H120
Surufatinib start global PIII NET trials	H120
Savolitinib China NDA file for NSCLC exon 14 deletion	H120
Fruquintinib start FRESCO2 global PIII CRC trial	2020

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Edison profile page

China leads, global innovation follows

2019 was a landmark year and we expect momentum to accelerate as HCM continues on its path to become a global biopharma with a marketed portfolio of innovation-led oncology drugs. Highlights of 2019 include the addition of Elunate on to China's exclusive National Reimbursement Drug List (NRDL) and surufatinib's first China NDA submission following impressive data in non-pancreatic neuroendocrine tumours (NET). We believe the long-term investment case is underpinned by multiple near-term catalysts that demonstrate HCM's ability to discover and develop drugs and its success rate as defined by drug approvals and launches. The launch of Elunate in China with partner Eli Lilly (LLY) and subsequent inclusion on China's exclusive NRDL are significant milestones, giving us confidence in the company's ability to execute on its R&D philosophy of building first- or best-in-class molecules with lower toxicity profiles to enable combination-based strategies for the treatment of cancers. 2020 is a golden year for HCM: it is scaling up its China oncology commercial presence ahead of surufatinib launch late in 2020 and the anticipated NDA submissions for surufatinib in pancreatic NET and savolitinib in exon 14 deletion NSCLC (anticipated 2021 launch). By mid-2021 HCM could have three of its internally developed assets launched in China. Exhibit 1 highlights the plethora of catalysts expected during 2020 alone. With HCM's financial strength and its drive to retain the economic value of its assets, the next steps for the company are to commercialise its own assets internationally (outside of current partnerships). Clinical and regulatory teams are now fully operational in the US and EU. HCM's first global approval (we forecast launch in 2022) in the US/EU could be for a savolitinib combination with AstraZeneca's (AZN) Tagrisso in MET-positive EGFRm non-small-cell lung carcinoma (NSCLC).

Rapid rise in investment in operations in 2019

Full-year 2019 results published in March 2020 highlight that HCM is in a rapid growth phase. Consolidated group revenues declined to $204.9m (FY18: $214.1m), affected by the termination of the Seroquel distribution agreement with AZN in May 2019. Net losses widened to $106.0m (FY18: $74.8m) driven by higher R&D expenses and cost of goods. R&D expenses will rise over the next few years to support the growing demands of the burgeoning late-stage R&D portfolio to support monotherapy/combination clinical trials China and globally. HCM is investing to establish its oncology commercial infrastructure, with the aim of 300–350 personnel hires by end 2020. HCM reported available cash resources of >$300m (at 31 December 2019) at the group level (cash and cash equivalents including short-term investments of $217.2m, and unutilised bank borrowing facilities of $119.3m). The recent capital raise of $110m (net proceeds) provides additional funding flexibility as R&D is set to increase to support global registration studies. We expect a period of intensive investment during 2020–23, however if global trials can replicate the efficacy and safety data seen to date in Chinese patients (surufatinib, fruquintinib and savolitinib) then we expect a transformation of the P&L with sustainable profitability and operating margin expansion thereafter. We summarise our expectations in 2020–22 for each key asset:

- **Savolitinib**: NDA submission in MET exon 14 deletion NSCLC in China in 2020, potential approval and launch in 2021. Complete enrolment of global Phase II registration potential SAVANNAH trial in combination with Tagrisso in NSCLC end 2020; data expected 2021. Revisit papillary renal cell carcinoma (PRCC) monotherapy development plans – SAVOIR mature data to be presented mid-2020.
- **Fruquintinib**: Elunate China colorectal cancer (CRC) sales uptake. Initiation of global Phase III registrational study (FRESCO2) in CRC in 2020. Second interim analysis from China Phase III study (FRUTIGA) in combination with Taxol in gastric cancer in 2020, potential approval in 2021 and launch in 2022. Progress Tyvyt (PD-1) combination in solid tumours.

- **Surufatinib**: Potential approval and launch in non-pancreatic NET in China in 2020. NDA submission in pancreatic NET in China in Q320, potential approval and launch in 2021. Initiation of global registrational studies in NET in 2020. Progress PD-1 combinations in solid tumours and monotherapy in biliary tract cancer (BTC).
- **HMPL-523**: Expansion of global Phase Ib study in indolent non-Hodgkin lymphoma (NHL) in 2020.
- **HMPL-689**: Potential initiation of registrational study for indolent NHL in China in 2020. Expansion of global Phase Ib study in indolent NHL.

Exhibit 1: 2020 catalysts

Product	Indication	Date	Next news
Global (ex-China)			
Savolitinib	PRCC/ccRCC	Early-2020	Clear cell RCC data (CALYPSO) is still to be announced (2020), investigator led study
		Mid-2020	**Data:** Mature Phase III data (SAVOIR) to be presented from terminated study for savolitinib monotherapy. AZ and HCM are evaluating the opportunity to restart clinical work in PRCC
	NSCLC	Late-2020	Enrolment completion of Phase II study (SAVANNAH) for savolitinib in combination with Tagrisso in second/third-line NSCLC
	NSCLC/RCC/GC	Late-2020	Potential announcement of plans for further US Phase II/III studies
Fruquintinib (Elunate)	CRC	Mid-2020	Initiation of a Phase III pivotal trial (FRESCO2) in third/fourth-line CRC*
	Solid tumours	TBD	Initiation of Phase I study for fruquintinib in combination with Tyvyt (PD-1)
Surufatinib	NET	H220	Initiation of a Phase II/III registration study (subjective to regulatory consultation). FDA granted orphan drug designation late 2019 for pNET
	Solid tumours	TBD	Initiation of Phase I study for surufatinib in combination with Tuoyi (PD-1)
HMPL-689	Indolent NHL (Hem malignancies)	Late-2020	Phase I expansion studies (subjective to supportive data)
HMPL-523	Indolent NHL (Hem malignancies)	Mid-2020	Phase I expansion studies (subjective to supportive data)
China			
Savolitinib	NSCLC	Early-2020	**NDA submission** for first-line NSCLC* (MET exon 14 deletion patients)
		Mid-2020	**Data:** Presentation of full Phase II study data at scientific conference
Fruquintinib (Elunate)	Gastric cancer	Mid-2020	**Data:** Second interim analysis from Phase III study (FRUTIGA) for fruquintinib in combination with Taxol for second-line gastric cancer
	CRC and advanced solid tumours	Early-2020	Phase II study for fruquintinib in combination with Tyvyt (PD-1) enrolling
Surufatinib	Non-pancreatic NET	Late-2020	**Approval and launch:** NDA filed H219 for first unpartnered oncology drug
	Pancreatic NET (pNET)	Q320	**NDA Submission:** Phase III interim data (SANET-p) presented and trial stopped early due to efficacy
		Mid-2020	**Data:** Presentation of full Phase III study data (SANET-p) at scientific conference
	Biliary tract cancer (BTC)	Late-2020	**Data:** Phase II/III interim data futility analysis for second-line BTC
	Solid tumours	Early-2020	Initiation of Phase II study for surufatinib in combination with Tuoyi (PD-1)
			Data: Presentation of preliminary Phase I study data for surufatinib in combination with Tuoyi (PD-1)
	Solid tumours	Early-2020	Initiation of Phase I study for surufatinib in combination with Tyvyt (PD-1)
HMPL-689	Indolent NHL	Late-2020	Initiation of a registration study (subject to supportive data)
HMPL-523	Indolent NHL	2020	Initiation of a registration study (subject to supportive data)
HMPL-453	Advanced malignant mesothelioma (solid tumours)	Early-2020	Initiation of Phase II study
HMPL-306	Solid tumours	Mid-2020	Initiation of Phase I first-in-human study for novel target IDH1/2 inhibitor

Source: Hutchison China MediTech presentations, Edison Investment Research. Note: *Subject to regulatory interaction.

Elunate: From China sales to global registrational trials

The November 2018 launch of Elunate (fruquintinib capsules) for metastatic colorectal cancer (third-line and above) by partner LLY was a defining moment for HCM, as it was the first of its internally developed IP assets to launch in China. While Elunate's sales evolution in CRC will be a

focus point in 2020; other milestones include progressing fruquintinib in other indications in China and starting the Phase III global studies (FRESCO2). The latter is important as HCM retains the full development and commercial rights to fruquintinib outside China. We forecast global peak sales for fruquintinib of $2.6bn across all indications under investigation (CRC, NSCLC and gastric cancer). The magnitude of fruquintinib's success in part will depend on the global opportunity; we forecast RoW launches from 2023.

Elunate sales uplift expected from NRDL inclusion

During FY19, LLY reported in-market sales of $17.6m (sales to third parties as provided by LLY) in its first full year on the market and HCM reported royalties of $2.7m. Elunate's most interesting opportunity relates to its inclusion on the NRDL in November 2019 with reimbursement effective from 1 January 2020. Elunate is now available in all state-run hospital pharmacies, and patients on NHSA insurance schemes will be reimbursed (albeit it at a 63% reduction to the original list price of $3,260 per cycle). At the FY19 results, HCM announced Elunate sales of $6.6m during the January-February 2020 period. HCM's target patient population for third-line CRC is ~55,000–60,000 patients (third-line CRC is 15% of incidence in China of 380,000 patients per year) and the company estimates that ~3,000 patients paid for treatment with Elunate in 2019 (5% of the eligible population). At the full year results presentation, HCM presented data on the sales evolution of oncology drugs by its international and domestic peers and the impact of inclusion on China's NRDL. Taking Roche's Avastin as an example, we note an 84% increase in sales (FY18: $385m; FY17: $209m) for its first full year on the NRDL and a 47% increase in the second year (FY19: $566m; FY18: $385m). Avastin was priced at a 62% discount per cycle post NDRL inclusion. We note that LLY has indicated it intends to ramp up sales coverage for Elunate following its NDRL inclusion. A fourfold ramp in Elunate sales in the second full year from launch would require us to revisit our overall peak sales expectations.

Global development: Phase III registrational trials to start

In the US, the Phase Ib/II CRC trial initiated in 2019 has completed enrolment and the US/Europe/Japan Phase III registration trial (FRESCO 2) in metastatic CRC is expected to initiate in mid-2020. In February 2020, HCM completed the end of Phase II meeting with the US FDA, and meetings with the European and Japanese regulators (the EMA and PMDA, respectively) are planned for Q220. In the US, the FDA has agreed that an NDA can be submitted on the basis of two Phase III trials (FRESCO and FRESCO2). We forecast $565m in peak sales (globally ex-China) in CRC (with launch in 2023) and China peak sales of $199m.

Other indications: Combination trials progressing

Life cycle management and extending the labelled use to other solid tumour types would expand Elunate's commercial opportunity further. In China we expect gastric cancer to be the next indication for fruquintinib's line extension strategies. The Phase III gastric cancer (FRUTIGA) clinical trial is ongoing, evaluating fruquintinib and established chemotherapy agent Taxol (paclitaxel) for the treatment of advanced gastric cancer patients after 1L standard chemotherapy (5-fluorouracil and platinum doublets). The second interim analysis by the Independent Data Monitoring Committee (IDMC) is expected in mid-2020, full enrolment is expected by end 2020 and we expect approval for this indication in 2021. If the FRUTIGA Taxol combination data are positive, this would enable fruquintinib's use in earlier lines of gastric cancer, which represents a sizeable opportunity given patient populations are two to five times larger than the CRC opportunity. Combination studies are key to establishing targeted therapies in many oncology settings given the rapid rise of the PD-1/PD-(L)1 class of therapeutics to treat a broad range of cancers regardless of PD-1 status. A Phase I dose finding study with Elunate plus Innovent's Tyvyt is near completion, and the Phase I of Elunate plus Genor's PD-1 genolimzumab has commenced.

Exhibit 2: Fruquintinib clinical trials

Treatment	Indication	Sites	Trial	Notes
Fruquintinib MT	Third-line CRC (chemotherapy refractory)	China	Phase III FRESCO	Approved and launched
Fruquintinib MT	Third-line/fourth-line CRC (Stivarga/Lonsurf refractory/intolerant)	US/EU	Phase III	US/EU registration study in planning
Fruquintinib and Taxol	Second-line gastric cancer	China	Phase III FRUTIGA	Second interim data analysis 2020
Fruquintinib MT	Third-line NSCLC (chemotherapy refractory)	China	Phase III FALUCA	Did not meet median over survival (OS) (primary endpoint), all secondary endpoints met
Fruquintinib and Iressa	NSCLC first-line (EGFRm+)	China	Phase II NCT02976116	Completed enrolment. Data presented at ESMO Asia in November 2019.
Fruquintinib and genolimzumab (PD-1)	Solid tumours	China	Phase I	Ongoing
Fruquintinib and Tyvyt (PD-1)	Solid tumours	China	Phase I	Ongoing

Source: Edison Investment Research, Hutchison China MediTech. Note: MT: monotherapy.

Savolitinib: China debut on the cards in 2021

Savolitinib is a highly selective inhibitor of the c-Met signalling pathway and targets patients with resistant cancers whose tumour type tests positive for MET mutation, amplification or over expression. Savolitinib is hypothesised to have a greater beneficial impact on c-Met-driven tumours than approved multi-kinase inhibitors, particularly in EGFR-resistant patient subgroups. Global development is currently focused on savolitinib (with partner AZN) with multiple late-stage trials in progress, including SAVANNAH (second/third-line EGFRm, Tagrisso refractory, MET-positive NSCLC with Tagrisso), CALYPSO (papillary and clear cell RCC with/without PD-(L)1 Imfinzi), and VIKTORY (MET-positive gastric cancer). Additionally, a proof-of-concept trial has initiated in Canada testing savolitinib in MET-positive prostate cancer. Renal cancer (PRCC) monotherapy development had been placed on hold but is being revisited. We forecast global peak sales for savolitinib of $4.3bn (PRCC, clear cell renal cell carcinoma (ccRCC), NSCLC and gastric cancer indications), of which NSCLC represents 48%.

China NDA submission for MET Exon 14 deletion NSCLC imminent

Primary data from the Phase II trial presented at CSCO 2019 demonstrated efficacy in MET exon 14 deletion NSCLC, and although the patient size is relatively small (36 patients evaluable out of 50), these are hard-to-treat patients. The NSCLC indication could be savolitinib's first China NDA submission in Q220 and its first monotherapy indication in the region (NDA submission expected H120, launch in 2021). An estimated 2–3% of newly diagnosed NSCLC patients have a specific mutation known as MET exon 14 skipping (exon 14 of the MET gene is not functioning or deleted) leading to c-Met over expression. In China, HCM estimates this to be >10,000 patients.

Global development: Tagrisso resistant NSCLC is the main driver

HCM's first global (ex-China) approval (we forecast launch in 2022) could be for a savolitinib plus Tagrisso combination in MET-positive NSCLC patients. In the field of lung cancer, AZN's Tagrisso is raising the bar as it moves into the first-line setting in EGFR mutation-positive NSCLC (median OS of 38.6 months Tagrisso vs 31.8 months on Iressa/Tarceva FLAURA first-line treatment study), reporting sales of $3.2bn in FY19, its second full year on the market since the broadening of the label to include first-line NSCLC patients (accelerated approval in 2015, full approval in 2017, first-line approval in 2018). The implication here is that savolitinib's largest opportunity could be in combination with Tagrisso in EGFRm MET-positive NSCLC patients, as MET mutations are the biggest driver in Tagrisso resistance. The savolitinib/Tagrisso combination could rewrite the second-line/third-line treatment paradigm and our forecast peak sales could be conservative. Following the

encouraging data from the TATTON study, in December 2018, AZN and HCM initiated the global Phase II study SAVANNAH for Tagrisso-refractory NSCLC patients (enrolment is expected to complete by end 2020). This specific subset of patients has an unmet medical need. SAVANNAH has the potential for registrational use, and interim data are expected in mid-2020. The strength of the data will determine whether a larger Phase III trial is required as part of the US regulatory submission package, although it could be sufficient for an NDA filing. We forecast a 2022 launch and note if there is a requirement for a Phase III trial then we would need to push out our launch date. We note that in the US competitor Novartis has received priority review from the US FDA for its c-Met inhibitor, capmatinib, in exon 14 deletion NSCLC and will likely be first to market in this indication, while in China savolitinib will likely be the first. We note capmatinib is currently in a number of other clinical trials as a monotherapy: Phase II in PRCC (US/NCT02019693), Phase II in advanced hepatocellular carcinoma (China/NCT01737827), as well as in combination with selected immunotherapies including a Phase II in NSCLC with PD-1 inhibitor Opdivo.

Savoir faire in kidney cancer as SAVOIR data matures

The savolitinib registration strategy for kidney cancers, in particular PRCC, is being reassessed. In December 2018 AZN/HCM terminated enrolment of patients into SAVOIR, a Phase III global registration study evaluating savolitinib monotherapy (vs sunitinib monotherapy) in MET-driven PRCC patients. This decision was made taking into account findings from the molecular epidemiology study (MES) in PRCC patients and the realisation that treatment paradigms for RCC have shifted with the approval of PD-(L)1 inhibitors. Savolitinib is also being evaluated in CALYPSO, an investigator sponsored Phase II study combining savolitinib with AZN's PD-(L)1 inhibitor Imfinzi (durvalumab) in kidney cancer (both ccRCC and PRCC). In clear cell renal cell carcinoma (ccRCC), PD-(L)1 immune checkpoint inhibitors are revolutionising the treatment landscape. The combination of MET inhibition with PD-(L)1 inhibition could have utility in this space, as underlined by the promising preliminary data (median OS 12.3m, 12m OS rate 52%) from CALYPSO presented at ASCO GU 2020.

At the FY19 results HCM indicated that it is actively revisiting its efforts in PRCC after the full analysis and presentation of the SAVOIR data that has matured during 2019 (expected at a scientific conference mid-2020). HCM has indicated that this may lead to initiation of SAVOIR2, a Phase III trial evaluating savolitinib monotherapy in PRCC. HCM has indicated that its renal cancer regulatory plans will be determined post data presentation at ASCO 2020.

Exhibit 3: Savolitinib key clinical trials

Treatment	Indication	Sites	Trial	Notes
Savolitinib +Tagrisso	NSCLC (2/3L EGFRm (TKI refractory; MET+)	Global	Phase Ib/II TATTON	Completed, interim data presented at AACR 2019 and ESMO Asia 2019
Savolitinib +Tagrisso	NSCLC (2/3L EGFRm (Tagrisso refractory; MET+)	Global	Phase II SAVANNAH	Initiated December 2018
Savolitinib MT	NSCLC (1L MET exon 14 skipping)	China	Phase II NCT02897479	Enrolment completed
Savolitinib MT	Papillary RCC (MET+)	Global	Phase III SAVOIR	Suspended due to MES study and CALYPSO study. Data on the preliminary cohort to be submitted for presentation at ASCO
Savolitinib +Imfinzi	Papillary RCC	UK/Spain	Phase II CALYPSO	Interim data presented at ASCO GU 2020, primary completion expected
Savolitinib +Imfinzi	Clear cell RCC (VEGFR TKI refractory)	UK/Spain	Phase II CALYPSO	Investigator-sponsored study; data expected early-2020
Savolitinib MT	Gastric cancer (MET amplification)	South Korea	Phase II VIKTORY	Completed, data published H219
Savolitinib MT	Metastatic castration-resistant prostate cancer (mCRPC)	Canada	Phase II CCTG 1234B	Investigator-sponsored study, primary completion end-2020

Source: Edison Investment Research, Hutchison China MediTech. Note: MT = monotherapy.

Small victory in gastric cancer

Results from the VIKTORY Phase II umbrella trial run by Samsung Medical Centre were published in Cancer discovery. The study molecularly screened patients and consequently allocated them to a relevant treatment arm that included savolitinib monotherapy (MT). VIKTORY sequenced 715 metastatic gastric cancer patients and MET amplification was observed in 5.3%. MET amplification patients receiving savolitinib MT met pre-specified six-week progression-free survival (PFS) and reported an overall response rate (ORR) of 50%.

Surufatinib NETs solid data across the board

Surufatinib is an oral angio-immunokinase inhibitor that targets VEGFR1, 2 and 3; FGFR1 and colony stimulating factor 1 receptor (CSF-1R) kinases. This asset will likely be the first of HCM's non-partnered assets to reach the market (late 2020). HCM filed the China NDA for surufatinib in non-pancreatic NETs, the NDA was accepted in November 2019 and priority review was granted in December. NET tumours are highly prevalent, fragmented in primary origin and are an unmet medical need. Surufatinib could be the first universal drug to treat NET in all patients regardless of tumour subtype. Ahead of potential launch, HCM expects to have 300–350 reps in place in its newly established China oncology commercial team. We forecast global peak sales for surufatinib of $953m across the NET and BTC indications.

SANET-p and SANET-ep support broad NET approval

HCM filed the first China NDA for surufatinib based on data from Phase III SANET-ep trial for advanced non-pancreatic NETs. Surufatinib's China Phase III programme consists of two studies evaluating the drug (vs placebo) in pancreatic NET (SANET-p, planned n=195) and non-pancreatic NET (SANET-ep, actual n=198), thus covering all NET patient types. In June 2019, HCM announced that the independent data monitoring committee had recommended stopping the Phase III SANET-ep non-pancreatic NET trial early following positive interim data. This was based on the trial meeting its primary endpoint of PFS and the trial was unblinded a year ahead of schedule. Subsequently, on the basis of these data, HCM filed the China NDA in October 2019. More recently, proof of surufatinib's unequalled utility across the breadth of NET tumours was supported by the early cessation of the pancreatic NET (SANET-p) trial as surufatinib again met its primary endpoint of PFS earlier than expected. We expect data from SANET-p to be submitted to the China regulatory body in Q320 and this could potentially lead to a broader label encompassing all NETs regardless of origin thus widening the market potential of surufatinib. In China there is a significant market opportunity; HCM estimates incidence of NET in 2018 of approximately 67,600.

International development for NET and BTC

HCM is developing surufatinib internationally: the global Phase Ib/II study (NCT02549937) in pancreatic NET (second-line in Sutent/Afinitor refractory cancer), non-pancreatic NET, soft tissue sarcomas and BTC started enrolling US patients in July 2018. Surufatinib's global registration trial is at the planning stage, with US, Europe and Japan Phase III trials estimated to start in H220. The FDA has granted orphan drug designation for the pancreatic NET indication. SANET-p and SANET-ep may form the basis of a regulatory package with the requirement for one broad Phase III NET trial, but this will be determined by the regulators. While the current prevalence of NET in the US is ~175,000 patients (incidence of ~12,000 new cases per year), current treatment modalities are limited to subsets of NET with no broadly effective drugs across the NET spectrum. Data from Frost & Sullivan indicate the global NET market in 2018 was worth approximately $5.8bn and is expected to grow to $21.2bn by 2030. Current treatment modalities are typically limited to subsets of NET

with only Afinitor approved for a broad range of NETs (pancreatic, GI and lung). BTC represents a high unmet need due to limited treatment options and an increasing patient population.

Beyond its ability to inhibit fibroblast growth factor receptors (FGFR1), surufatinib's ability – immunomodulation activity through CSF-1R inhibition – could provide additional synergies in combination with a PD-(L)1 antibody or small molecule drug. This is the rationale for the combination development strategy: HCM recently initiated a China Phase II study, NCT04169672, in patients with advanced tumours in combination with Shanghai Junshi Biosciences' PD-1 inhibitor Tuoyi (toripalimab), which was recently approved in China for melanoma, and reported ~$110m in sales in FY19, following launch early last year. Additionally, HCM is planning a global Phase Ib/II study to initiate in the US in 2020.

Exhibit 4: Surufatinib clinical development

Treatment	Indication	Sites	Trial	Notes
Surufatinib MT	Pancreatic NET	China	Phase III SANET-p	Positive interim analysis in January 2020 will support an NDA submission in Q320
Surufatinib MT	Non-pancreatic NET	China	Phase III SANET-ep	Met primary endpoint of PFS. NDA accepted in November 2019
Surufatinib MT	Biliary tract cancer (chemotherapy refractory)	China	Phase IIb/III NCT03873532	First patient dosed 22 March 2019
Surufatinib MT	Pancreatic NET (second-line; Sutent/Afinitor refractory), Biliary tract cancer (chemotherapy refractory), ep-NET and soft tissue sarcoma	US	Phase Ib NCT02549937	US/EU registration study in planning
Surufatinib + Tuoyi (PD-1)	Solid tumours	China	Phase II NCT04169672	Trial enrolling patients
Surufatinib + Tuoyi (PD-1)	Solid tumours	US	Phase I	Safety run-in in planning

Source: Edison Investment Research, Hutchison China MediTech. Note: NET = neuroendocrine tumours, MT = monotherapy.

Other pipeline assets moving forward

The next wave of internally developed assets, HMPL-523 (Syk inhibitor) and HMPL-689 (PI3Kδ inhibitor), are kinase inhibitors, which have a clinical focus for various haematological (blood) cancers and autoimmune conditions. Concurrent global and Chinese clinical programmes are ongoing as outlined below and, importantly, both are moving rapidly towards global registration studies. HMPL-523 and HMPL-689 are being evaluated for a broad range of haematological malignancies and HMP-523 has potential in less-common autoimmune disorders (such as ITP). These could add up to much larger commercial opportunities than our conservative peak sales for HMPL-523 ($143m in China, $584m RoW) and HMPL-689 ($102m in China, $468m RoW).

HMPL-523: Phase Ib dose expansion is ongoing (>190 patients enrolled) in separate Chinese and Australian studies and will be used to guide a Chinese Phase II/III registration study, which is planned to start in 2020. Following the IND approval in June 2019, an EU/US Phase I clinical study for HMPL-523 has started in advanced relapsed or refractory lymphoma (NCT03779113). Outside oncology, HMPL-523 is in a Phase I/Ib study in patients with immune thrombocytopenia (ITP) in China (NCT03951623).

HMPL-689 is in a Phase Ib dose escalation study in Chinese patients with haematological malignancies, with top-line data expected to inform registration study decisions in China in 2020. Recent IND approval has enabled the start of a parallel US/EU Phase I/Ib study in patients with indolent NHL (NCT03786926).

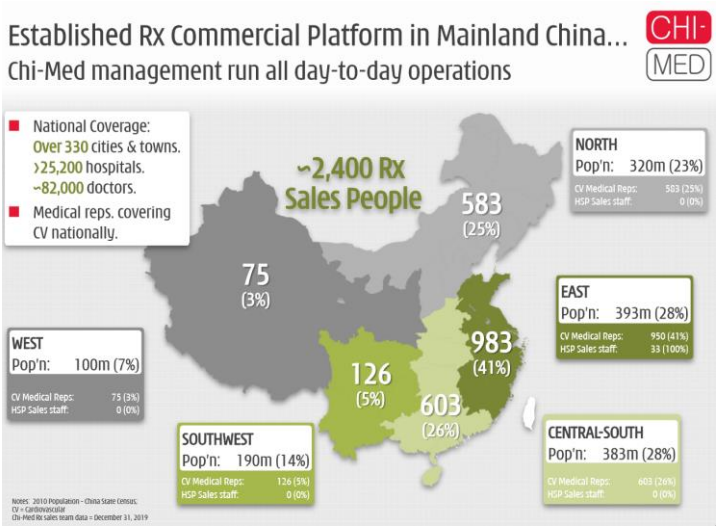
HMPL-689: A Phase Ib dose expansion in Chinese patients with indolent NHL is ongoing after successfully establishing a Phase II dose. A parallel US/EU Phase I/Ib study in patients with indolent NHL (NCT03786926) is now enrolling patients.

China commercial platform expands into oncology

HCM's China commercial platform (CP) is a nationwide, large-scale drug marketing and distribution platform that covers over 330 cities and towns with ~2,400 medical sales reps. Exhibit 5 highlights the breadth of coverage in China. The CP is subdivided into two main business areas: prescription drugs and consumer health. The prescription drugs business includes innovation platform asset Elunate (launched in November 2018) and consists of JVs with Hutchison Sinopharm and Shanghai Hutchison Pharmaceuticals (SHPL). The consumer health business consists of a non-consolidated JV with Hutchison Baiyunshan (HBYS).

During 2019 HCM established its in-house oncology commercial organisation (Oncology Business Department, OBD) under Hutchison Sinopharm, which will be utilised primarily to market and distribute its in-house developed oncology products. Ahead of surufatinib's potential approval for non-pancreatic NET in China, HCM has established over 140 commercial personnel (including sales reps, marketing managers, product and medical marketing, distribution, etc) and plans to expand this number to 300–350 by end 2020 to support launch activities to cover 1,300 hospitals across 30 provinces/municipalities (Exhibit 6). HCM plans to increase its oncology presence to over 900 personnel by end 2023 to support future product launches. We note that under the revised China deal terms for Elunate commercialisation in China, HCM may be able to promote the product in certain provinces, enabling further leverage of its oncology field force.

Exhibit 5: CP in China



Source: Hutchison China MediTech

Exhibit 6: Building oncology presence in China

Source: Hutchison China MediTech

In FY19, total consolidated prescription drug sales increased by 13% to $154.5m (FY18: $136.4m) and consolidated net income attributable to HCM grew 10% to $37.5m (FY18: $34.1m) excluding one-time gains. Prescription drugs consist of two pharmaceutical JVs and innovation platform asset Elunate commercial sales. In FY19 consumer health consolidated sales declined by 14% to $34.4m due to rationalisation of certain low-margin products, and non-consolidated joint venture sales were flat at $215.4m; total consolidated net income attributable to HCM from consumer health increased 7% to $9.9m. We note performance by division below:

- **Shanghai Hutchison Pharma (SHPL)** is a 50/50 joint venture with Shanghai Pharmaceuticals (SHA: 601607) that focuses on prescription traditional Chinese medicines (TCMs). SHPL holds a large portfolio of registered drug licences, including its own and third-party licences. In FY19, sales fell by 1% to $272.1m, affected by the termination of the Seroquel distribution agreement in May and the depreciation of the Chinese renminbi versus the US dollar. SHPL's main

product, the She Xiang Bao Xin (SXBX) pill for coronary heart disease ($239.5m, +3%), now has 18% market share for China's botanical prescriptions market in this indication.

- **Hutchison Sinopharm** is a prescription drugs commercial services business, which commercialises HCM products (Oncology Business Department) and provides third-party prescription logistics and distribution service. It reported sales of $143.7m in FY19 (+8%).
- **Hutchison Baiyunshan (HBYS**) is a 50/50 joint venture with Guangzhou Baiyunshan (SHE: 000522), principally focused on OTC TCM with 185 registered TCM products. Sales of HBYS's two main products fell to $111.3m in FY19 (FY18: $118.9m), with a decline (-17%) in Fu Fang Dan Shen tablets for angina (FY19: $47.0m) partially offset by Banlangen granules (anti-viral cold/flu), sales of which grew by 3% to $64.3m. Sales of HBYS's second wave of products, including Nao Xin Qing tablets (cerebrovascular diseases) and Kou Yan Qing granules (periodontitis), grew 14% to $64.3m.

Contributions from non-consolidated JVs, primarily SHPL and HBYS, are reported below the loss from operations line under US GAAP as equity in earnings of equity investee, net of tax. HCM receives the majority of profits generated from this division as dividends, which the company has reinvested in its innovation pipeline since inception. HCM's non-consolidated JV HBYS's vacant land (Plot 2) in Guangzhou has been listed for sale as part of the Guangzhou municipal government urban development scheme for a few years. This plot has now been cleared for sale by the Guangzhou mayor's office and is expected to be completed over the next 12 months. We expect that half of the proceeds of the sales would make their way to HCM via special dividends and would likely be reinvested in the business, although this is not reflected in our forecasts given the uncertainty on timing.

Valuation $5.9bn (£6.55/share)

We value HCM at $5.9bn (£6.55/share) vs $6.0bn (£6.74/share) previously. Our product forecasts remain unchanged. Our valuation reflects forecast net cash of $190m at end December 2019 plus $110m net proceeds from the January 2020 capital raise, and we roll forward our model and update for FX. We use a risk-adjusted net present value (rNPV) method to discount future cash flows for the innovation platform (savolitinib, fruquintinib, surufatinib, epitinib, HMPL-523 and HMPL-689, valuation of $4,440.4m). Our overall valuation of HCM has been affected by the lower valuation of the CP business; due to market falls the peer multiple has seen contraction. We use earnings-based multiples for HCM's commercial platform (subsidiaries and JVs). We apply a 16.4x multiple to our forecast 2020 net attributable profit (equity in earnings of equity investees, net of tax) for the JVs of $42.8m yields a valuation of $701.4m (Exhibit 7). Our sum-of-the-parts (SOTP) valuation does not include HCM's early phase assets HMPL-453 (FGFR inhibitor), HMPL-306 (IDH1/2 inhibitor) and HMPL-309 (EGFR WT) or its discovery platform.

Exhibit 7: HCM SOTP valuation

Product	Indication	Launch/peak	Peak sales	Value ($m)	Probability	rNPV ($m)	rNPV/share ($)	rNPV/ share (£)	rNPV/ADS ($/ADS)	NPV per share (£)
Savolitinib	PRCC	2024/28 (China)	$64m (China)	96.8	50%	56.2	0.08	0.06	0.41	0.11
		2022/26 (RoW)	$267m (RoW)	87.4	75%	63.4	0.09	0.07	0.46	0.10
	ccRCC	2025/29 (China)	$169m (China)	100.4	35%	30.9	0.04	0.03	0.22	0.11
		2023/27 (RoW)	$658m (RoW)	104.7	35%	36.6	0.05	0.04	0.27	0.12
	NSCLC	2021/26 (China)	$387m (China)	280.4	75%	209.0	0.30	0.23	1.52	0.31
		2022/26 (RoW)	$1.7bn (RoW)	395.4	75%	296.6	0.43	0.33	2.15	0.44
	Gastric cancer	2023/27 (China)	$326m (China)	162.0	35%	55.6	0.08	0.06	0.40	0.18
		2024/28 (RoW)	$757m (RoW)	142.8	35%	50.0	0.07	0.06	0.36	0.16
Fruquintinib	CRC	2018/22 (China)	$199m (China)	106.5	100%	106.5	0.15	0.12	0.77	0.12
		2023/27 (RoW)	$565m (RoW)	1,281.6	75%	957.6	1.39	1.07	6.95	1.43
	NSCLC	2025/29 (China)	$393m (China)	93.4	50%	40.5	0.06	0.05	0.29	0.10
		2025/29 (RoW)	$721m (RoW)	860.9	50%	405.8	0.59	0.45	2.95	0.96
	Gastric cancer	2022/25 (China)	$340m (China)	183.4	75%	136.4	0.20	0.15	0.99	0.20
		2025/29 (RoW)	$392m (RoW)	530.6	50%	258.4	0.38	0.29	1.88	0.59
Surufatinib	NET	2020/25 (China)	$169m (China)	442.0	90%	397.6	0.58	0.44	2.89	0.49
		2024/28 (RoW)	$454m (RoW)	706.5	50%	337.7	0.49	0.38	2.45	0.79
	BTC	2022/26 (China)	$187m (China)	434.6	75%	325.0	0.47	0.36	2.36	0.49
		2024/28 (RoW)	$143m (RoW)	194.2	50%	89.9	0.13	0.10	0.65	0.22
Epitinib	Glioblastoma	2023/27 (China)	$42m (China)	149.2	30%	42.4	0.06	0.05	0.31	0.17
HMPL-523	Haematological cancers	2023/27 (China)	$143m (China)	304.9	30%	83.0	0.12	0.09	0.60	0.34
		2025/29 (RoW)	$584m (RoW)	847.3	30%	237.6	0.34	0.27	1.72	0.95
HMPL-689	Haematological cancers	2024/28 (China)	$102m (China)	172.5	30%	45.9	0.07	0.05	0.33	0.19
		2025/29 (RoW)	$468m (RoW)	635.5	30%	177.9	0.26	0.20	1.29	0.71
Commercial platform				701.4	100%	701.4	1.02	0.78	5.08	0.78
Unallocated costs				(582.0)	100%	(582.0)	(0.84)	(0.65)	(4.21)	(0.65)
Est cash December 2019*				300.4	100%	300.4	0.43	0.33	2.17	0.34
Terminal Value				1,020.8	100%	1,020.8	1.48	1.14	7.39	1.14
Valuation				**$9,753.5**		**$5,880.8**	**$8.50**	**£6.55**	**$42.57**	**£10.86**
Valuation of IP only				$6,657.7		$4,440.4	$6.43	£4.95	$32.14	£7.41

Source: Edison Investment Research. Note: *Includes the $110m net proceeds from January 2020 capital raise. Non-risk adjusted NPV per share assumes 100% probability of success. FX rate = $1.30/£. Number of shares outstanding = 690.6m.

Financials

HCM reported consolidated group revenues of $204.9m in FY19 (FY18: $214.1m) and a group net loss of $106.0m (FY18: $74.8m). The depreciation of the Chinese renminbi versus the US dollar has affected top-line growth as reported in US dollars given the translation impact, as all revenues related to its China commercial platform (CP) business are generated in Chinese renminbi.

CP reported consolidated FY19 sales of $188.9m (+7% as reported, +11% CER; FY18: $176.5m), driven by the prescription drugs business, which now includes Elunate related manufacturing sales and royalties (HCM reported revenues of $10.8m FY19 vs $3.6m in FY18) offsetting the impact of the termination of the Seroquel distribution agreement. Total consolidated net income from CP increased 9% to $47.4m (FY18: $43.4m). We forecast consolidated CP revenues of $196.6m in 2020 and $204.7m in 2021. Innovation platform (IP) reported consolidated revenues of $16.0m in FY19 compared to $37.6m in FY18, as FY18 benefited from the $13.5m Elunate approval related milestone received from LLY. In FY19, IP reported a net segment loss of $133.3m (FY18: $104.6m).

The profit before tax and equity in earnings of equity investees at group level reported a loss of $141.1m in FY19 (vs a loss of $86.7m in FY18). R&D expenses increased significantly to $138.2m in FY19 ($114.2m in FY18), reflecting investment throughout the portfolio, expansion of the US and international clinical and regulatory operations, and establishment of the China oncology commercial infrastructure. For FY20, HCM has guided adjusted non-GAAP Innovation Platform segment operating loss to $180–210m and adjusted non-GAAP group net cash flow excluding financing activities to $140–160m.

We now expect R&D expenses to increase to $184.0m in 2020 and $210.5m in 2021 (reported GAAP basis), reflecting the substantial need for investment in the burgeoning clinical trial programmes across the IP division, including the increased investment in China and global trials plus the initiation of combination strategies across the portfolio. We expect an increase in capex in 2021 to support investment in a new manufacturing facility: we forecast ~$42m per annum in 2021 and 2022.

We forecast net losses at group level of $161.1m in 2020 and $165.2m in 2021. HCM reported a strong cash position, with available cash resources of over $300m (at 31 December 2019) at group level (cash and cash equivalents and short-term investments of $217.2m, and unutilised bank borrowing facilities of $119.3m). However, given the level of R&D requirements, we believe additional capital will be required in 2021, which is likely to be in the form of an equity raise. For simplicity we include an illustrative debt raise of $175m in our 2021 forecasts. Additionally, HCM's non-consolidated joint ventures (SHPL, and HBYS) held $63.0m (at 31 December 2019). We note the JV in NSP has been acquired leading to a consolidated net cash inflow of $8.1m. In terms of cash utilisation by operations, we forecast $143.1m in 2020.

Exhibit 8: Financial summary

USD'000s	2017	2018	2019	2020e	2021e
December	US GAAP	US GAAP	US GAAP	US GAAP	US GAAP
PROFIT & LOSS					
Revenue	241,203	214,109	204,890	216,750	287,863
Cost of Sales	(175,820)	(143,944)	(160,152)	(175,913)	(196,289)
Gross Profit	65,383	70,165	44,738	40,836	91,574
Research and development	(75,523)	(114,161)	(138,191)	(184,000)	(210,500)
Other overheads	(43,277)	(48,645)	(52,934)	(54,521)	(76,679)
EBITDA	(50,692)	(88,975)	(141,250)	(191,948)	(183,546)
Operating Profit (before amort. and except.)	(53,417)	(92,641)	(146,387)	(197,684)	(195,605)
Intangible Amortisation	0	0	0	0	0
Operating Profit	(53,417)	(92,641)	(146,387)	(197,684)	(195,605)
Net Interest	(235)	4,969	3,914	2,129	(2,991)
Exceptionals	0	0	0	0	0
Profit Before Tax (norm)	(53,536)	(86,655)	(141,106)	(195,555)	(198,596)
Profit Before Tax (reported)	(53,536)	(86,655)	(141,106)	(195,555)	(198,596)
Tax	(3,080)	(3,964)	(3,274)	(3,300)	(5,000)
Equity investments, after tax	33,653	19,333	40,700	42,769	43,418
Profit After Tax (norm)	(22,963)	(71,286)	(103,680)	(156,086)	(160,178)
Profit After Tax (reported)	(22,963)	(71,286)	(103,680)	(156,086)	(160,178)
Minority	(3,774)	(3,519)	(2,345)	(5,000)	(5,000)
Discontinued operations	0	0	0	0	0
Net profit (norm)	(26,737)	(74,805)	(106,025)	(161,086)	(165,178)
Net profit (reported)	(26,737)	(74,805)	(106,025)	(161,086)	(165,178)
Average Number of Shares Outstanding (m)	617.2	664.3	665.7	690.7	690.7
EPS - normalised (c)	(4.3)	(11.3)	(15.9)	(23.3)	(23.9)
EPS - normalised and fully diluted (c)	(4.3)	(11.3)	(15.9)	(23.3)	(23.9)
EPS - (reported) (c)	(4.3)	(11.3)	(15.9)	(23.3)	(23.9)
Average number of ADS outstanding (m)	123.4	132.9	133.1	138.1	138.1
Earnings per ADS - normalised ($)	(0.02)	(0.06)	(0.08)	(0.12)	(0.12)
Earnings per ADS ($)	(0.02)	(0.06)	(0.08)	(0.12)	(0.12)
BALANCE SHEET					
Fixed Assets	165,737	161,577	148,100	163,759	206,624
Intangible Assets	3,738	3,533	3,387	3,100	2,497
Tangible Assets	14,220	16,616	20,855	23,970	54,412
Investments	147,779	141,428	123,858	136,689	149,714
Current Assets	432,195	370,541	317,022	266,040	270,085
Stocks	11,789	12,309	16,208	14,459	16,133
Debtors	53,566	56,392	59,023	53,445	23,660
Cash	85,265	86,036	121,157	173,513	205,669
St investments	273,031	214,915	96,011	0	0
Other	8,544	889	24,623	24,623	24,623
Current Liabilities	(104,600)	(85,479)	(113,101)	(125,868)	(124,956)
Creditors	(25,344)	(26,180)	(25,789)	(38,556)	(37,644)
Short term borrowings	(29,987)	0	0	0	0
Other	(49,269)	(59,299)	(87,312)	(87,312)	(87,312)
Long Term Liabilities	(8,366)	(34,383)	(39,118)	(39,118)	(249,118)
Long term borrowings	0	(26,739)	(26,818)	(26,818)	(236,818)
Other long term liabilities	(8,366)	(7,644)	(12,300)	(12,300)	(12,300)
Net Assets	484,966	412,256	312,903	264,813	102,635
Minority	(23,233)	(23,259)	(24,891)	(29,891)	(34,891)
Shareholder equity	461,733	388,997	288,012	234,922	67,744
CASH FLOW					
Operating Cash Flow	(8,943)	(32,847)	(80,912)	(143,085)	(133,945)
Net Interest	0	0	0	0	0
Tax	0	0	0	0	0
Capex	(5,019)	(6,364)	(8,565)	(8,565)	(41,898)
Acquisitions/disposals	0	0	8,689	0	0
Dividends	(1,594)	(1,282)	(1,282)	(2,000)	(2,000)
Equity financing and capital movements	291,737	(2,322)	(95)	110,000	0
Other	(255,761)	50,116	118,904	96,006	0
Net Cash Flow	20,420	7,301	36,739	52,356	(177,844)
Opening net debt/(cash)	(56,914)	(328,309)	(274,212)	(190,350)	(146,695)
Increase/(decrease) in ST investments	248,761	(58,116)	(118,904)	(96,011)	0
Other	2,214	(3,282)	(1,697)	0	0
Closing net debt/(cash)	(328,309)	(274,212)	(190,350)	(146,695)	31,149

Source: company accounts, Edison Investment Research

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