EDISON

Hutchison China MediTech

Outlook for 2021/22

Eye of the tiger

Pharma & biotech

Hutchison China MediTech (HCM) is on the brink of global launches of two assets from its internally developed oncology portfolio. In 2022 we expect US launches of surufatinib (broad NET indication) two years earlier than forecast as well as savolitinib (NSCLC). Recently the FDA granted fast-track designation to fruquintinib in mCRC and we forecast global launch in 2023. In China, HCM has laid the foundations to capitalise on the slew of additional novel oncology drugs (expected by end 2021). HCM is well funded (following the recent $100m equity investment from General Atlantic, plus warrants granted for an additional $100m in 18 months) as it accelerates the global development of its unpartnered assets and expands its global commercial outreach. Beyond 2024 we expect sustainable profitability and margin expansion. Our increased valuation is $6.3bn.

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	(163.4)	(23.0)	0.0	N/A	N/A
12/21e	283.9	(174.2)	(24.2)	0.0	N/A	N/A

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

Global launch potential in 2022

Surufatinib could be the first universal drug to treat NET in all patients regardless of tumour subtype, setting it apart from currently approved drugs. In the US HCM has agreed with the FDA that it can file the US NDA on the basis of the completed Phase III China-based trials together with existing US data on NET patients, saving the need for a US Phase III trial. Savolitinib approval in MET-positive Tagrisso refractory NSCLC depends on the strength of the data readout from SAVANNAH (expected 2021). Savolitinib's opportunity is increasingly being defined by Tagrisso moving up the treatment paradigm in NSCLC. At ASCO AZN presented overwhelmingly positive efficacy data on Tagrisso in adjuvant NSCLC (ADAURA). Tagrisso's potential use in earlier stages has positive implications for savolitinib (given its use in combination to treat Tagrisso resistance) could lead to significant future upgrades.

China hat-trick of products launched by end 2021

HCM's first innovation platform asset to launch, Elunate, is benefiting from NRDL inclusion (reimbursement from 1 January) and HCM is scaling up its China oncology commercial presence to capitalise on the potential launch of surufatinib. The NMPA accepted the NDA for savolitinib in MET exon 14 skipping NSCLC in May and we forecast launch during 2021 by partner AZN.

Valuation: $6.3bn (£6.85/share)

We value HCM at $6.3bn (£6.85/share) vs $5.9bn previously. The material changes to our valuation are the surufatinib and savolitinib peak forecast upgrades. We have adjusted our product timelines across the broader pipeline to reflect current progress and revisited our R&D and S&M costs accordingly.

6 July 2020

Price	**442.0p**
Market cap	**£3,141m**
	$1.26/£
Net cash ($m) and short-term investments at end 2019 + net proceeds of ~$210m raise	400
Shares in issue	710.6m
Free float	50%
Code	HCM
Primary exchanges	AIM/NASDAQ
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	24.2	61.6	27.8
Rel (local)	23.9	28.5	22.3

52-week high/low 258.0p 452.0p

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 filing for pancreatic NET	H220
Surufatinib US rolling NDA submission	Late 2020
Surufatinib approval and launch in China for epNET	H220

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Edison profile page

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Investment summary

Entering the international spotlight

HCM was established in 2000 as a wholly owned subsidiary of CK Hutchison. It is an innovative biopharma company focused on the highly lucrative global oncology and immunology markets. It has started to capitalise on years of investment in its substantial pipeline of potential first-in-class or best-in-class tyrosine kinase inhibitor (TKI) drugs, with the 2018 China launch of Elunate capsules (fruquintinib) in metastatic colorectal cancer (mCRC) (partner Eli Lilly (LLY)), the first novel China developed oncology drug to be fully approved in its domestic market. Momentum is set to continue with surufatinib's and savolitinib's debut launches in 2020 and 2021. HCM's global aspirations are set to become reality and 2022 is an inaugural year with the potential launch of wholly owned asset surufatinib (neuroendocrine tumours (NET)) and partnered product savolitinib (AstraZeneca, AZN) in the US. With a number of additional assets moving swiftly through the clinic we expect a series of global launches from the rest of the pipeline between 2023 and 2025, starting with fruquintinib in mCRC (US fast-track designation granted), cementing HCM as a premier, fully integrated global oncology player.

Valuation: $6.3bn (£6.85/share)

We value HCM at $6.3bn (£6.85/share) versus $5.9bn (£6.55/share) previously. We use a risk-adjusted NPV method to discount future cash flows for the innovation platform (IP) (valuation of $4,830m). The main causes of the valuation uplift are the global launch of surufatinib in 2022 (previously 2024), increased peak sales forecasts for the NET indication internationally and higher savolitinib peak sales in non-small cell lung cancer (NSCLC). We use earnings-based multiples for HCM's commercial platform (which yields a valuation of $966.6m). Our valuation reflects net cash of $190m at end December 2019 plus ~$210m net proceeds from post period equity raises. Our sum-of-the-parts (SOTP) valuation does not include HCM's early phase assets HMPL-453 (FGFR inhibitor), HMPL-306 (IDH1/2 inhibitor) or HMPL-309 (WT EGFR inhibitor), its preclinical assets or its discovery platform.

Sensitivities: Changing treatment landscapes

HCM is subject to the usual biotech and drug development risks, including clinical development delays or failures, regulatory risks, competitor successes, partnering setbacks, and financing and commercial risks. The rapidly advancing oncology treatment landscape remains a key sensitivity with potential for clinical trial programmes to become irrelevant while in progress, or for early efficacy readouts to bring forward regulatory submissions and potential launch dates. In China, regulatory and reimbursement changes mean drugs now have a potentially faster route to approval and reimbursement; China is becoming an increasingly important market for innovation drugs given supportive government policies and the population size.

Financials: Funding flexibility to support global launches

Full-year 2019 results were published in March and highlight that consolidated group revenues declined to $204.9m (FY18: $214.1m), and net losses widened to $106.0m (FY18: $74.8m), mainly driven by higher R&D expenses. R&D and S&M expenses will rise over the next few years to support the growing demands of the late-stage R&D portfolio to support monotherapy or combination clinical trials globally. HCM reported available cash resources of >$300m (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 2019 year-end reported cash additionally does not include the net proceeds of ~$110m raised from the January 2020 capital raise, or up to $95m (at the JV level) in property compensation payments expected from the

Guangzhou government in 2020/21. Furthermore recently HCM announced a $100m equity investment (net) by General Atlantic (a leading global growth equity firm that provides capital and strategic support for growth), plus the option to increase this to $200m through a warrant granted with a term of 18 months for an additional $100m (at a $30 ADR price), which we assume will be exercised in 2021. This investment validates HCM's strategy and importantly provides the funding flexibility for a period of intensive investment over 2020–23, as it accelerates the global development of its unpartnered assets and expands its China and international commercial outreach. Beyond 2024 we expect sustainable profitability and operating margin expansion.

Global opportunities drive upgrades

HCM continues to make rapid progress towards its goal of becoming an international biotech company with a marketed portfolio of innovative drugs (Exhibit 1). The launch of Elunate (HCM's first internally developed asset) in China (with China partner LLY) in November 2018 was a significant milestone for HCM and gives 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. Importantly, two key assets (surufatinib and fruquintinib) have been being granted fast-track designation in the US for NET and mCRC respectively, highlighting the FDA's acknowledgement that these products address unmet medical needs. With HCM's financial strength and drive to retain the economic value of its assets, the next steps for the company are to commercialise its wholly owned assets in China and internationally, in particular surufatinib, fruquintinib (ex-China) and the mid-stage assets HMPL-523 and HMPL-689. This note reviews our expectations across HCM's R&D portfolio given multiple data readouts and substantial regulatory progress made by key late-stage assets. The main beneficiaries for valuation and/or peak sales upgrades are surufatinib and savolitinib.

Capitalising on its established presence in China

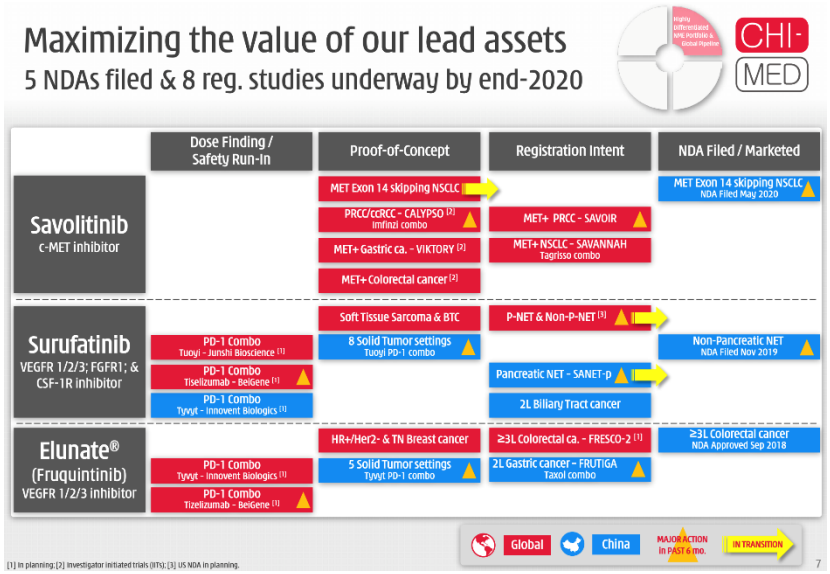
HCM will commercialise its unpartnered assets itself through its China commercial platform and has built a significant oncology presence ahead of the potential launch of surufatinib in late 2020 for non-pancreatic NET (epNET) (NDA accepted). HCM has 350 commercial personnel (including sales reps, marketing managers, product and medical marketing, distribution etc) in place in its newly established China oncology commercial team covering 1,300 cancer centres in China. Elunate is starting to benefit from inclusion on the national reimbursement drug list (NRDL) for CRC (effective 1 January). By end-2021 HCM could have three assets developed within its innovation platform launched in China. We expect next approvals for surufatinib in epNET (2020), pancreatic NET (pNET) (2021), savolitinib in MET exon 14 skipping NSCLC (2021) and fruquintinib in gastric cancer (2022).

Global commercialisation the final evolutionary step

Since HCM's inception in 2000, a long-term goal for management has been to develop innovative drugs for use beyond its domestic market with the final evolutionary step of global commercialisation. The US market will likely be the first (followed by Europe) and we expect HCM's first approvals (we forecast launch in 2022) in the US could be for surufatinib in NET and a savolitinib plus Tagrisso combination in MET-positive Tagrisso refractory NSCLC patients. Surufatinib US fast-track designation in both pNET and the epNET subset, orphan drug designation in pNET and FDA agreement that the NDA can be filed on the basis of the China Phase III data plus US Phase I/IIb data are positive signals of surufatinib's first- and best-in-class position and its utility to treat the unmet need across the spectrum of NET cancers. Savolitinib's opportunity is increasingly being defined by AZN's Tagrisso (Bloomberg consensus peak sales estimates in 2025 of $7.7bn), which has quickly become the standard of care in first-line epidermal growth factor

receptor (EGFR) mutated NSCLC patients. Following Tagrisso treatment, the most common resistance mechanism is MET mutation. Savolitinib (in combination with Tagrisso) NDA submission for second-/third-line EGFRm+, Tagrisso refractory, MET-positive NSCLC depends on the strength of the data readout from SAVANNAH (expected in 2021). This is a blockbuster opportunity and future sales upgrades are a possibility if Tagrisso moves into Stage II–IIIA NSCLC (adjuvant setting). Fruquintinib has been granted FDA fast-track designation for refractory mCRC and HCM will commence the global development programme FRESCO-2 (mCRC global registration study); recruitment is expected mid-2020.

Exhibit 1: Development path of HCM's lead assets

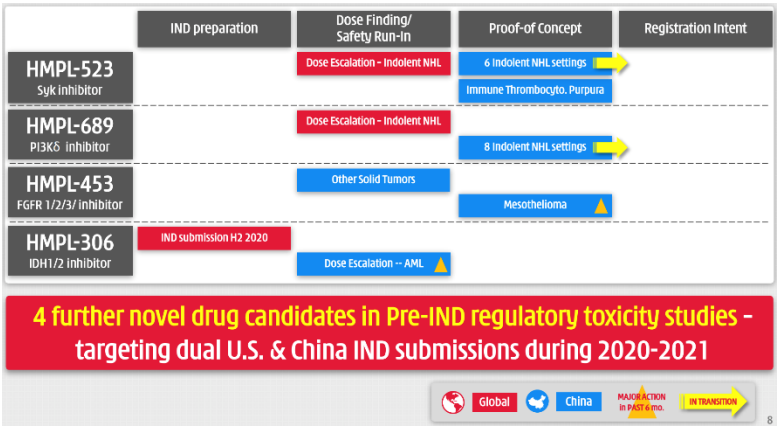


Source: HCM

Multiple waves of innovation to define longevity

Longevity for R&D-driven biopharmaceutical companies depends on having a pipeline of innovative assets that spans indications and development phases. The next wave of internally developed assets includes HMPL-523 (Syk inhibitor) and HMPL-689 (PI3Kδ inhibitor), which have a clinical focus on various haematological (blood) cancers; concurrent global (US/EU) and Chinese Phase I trials are ongoing for indolent non-Hodgkin's lymphoma (NHL). Recent early pipeline progress includes the HMPL-453 (FGFR inhibitor) China Phase II trial in mesothelioma and HMPL-306 (IDH1/2 inhibitor), with IND submission expected in the US in H220 (Exhibit 2). HCM's focus on target selectivity and the potential for lower toxicity should lend the portfolio to rational combination therapies based on tumour-specific features. The early-stage research strategy at HCM includes drug classes that are designed to target cancer immunity and HCM is hoping the third wave of assets can be combined with its existing drug portfolio. Four programmes against novel immuno-oncology targets could enter into clinical-phase development over the next three to four years (dual US and China IND submissions expected 2020–21). The early-stage research engine at HCM and strategy for combination therapies demonstrates a long-term commitment to innovation. By the end of 2022 HCM could have 12 discovered assets within its portfolio (spanning from Phase I to launched products).

Exhibit 2: Multiple waves of innovation progressing



Source: HCM

First lead asset: Surufatinib universal treatment for NET

Surufatinib forecast peaks sales increased to $815m in NET. Upgrades arise as a result of strong data sets and its unique MOA, thus positioning it as a universal drug treatment for all NET subtypes. We expect US launch two years ahead of schedule, in 2022.

HCM retains all rights to surufatinib worldwide. Its most advanced indication is as a monotherapy for the treatment of NETs and additional trials are ongoing for biliary tract carcinoma (BTC) and in combination with PD-1 inhibitors for solid tumours. Importantly, surufatinib utility across the full spectrum of NET was confirmed in two Phase III registration enabling trials (SANET-p and SANET-ep). In June 2019, HCM announced 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 progression-free survival (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. In January 2020, proof of surufatinib's unequalled utility across the breadth of NET tumours was supported by the early cessation of the pancreatic NET trial (SANET-p) as surufatinib again met its primary endpoint of PFS earlier than expected. China NDA submission preparations are already underway. In the US HCM can file the NDA for NET on the basis of existing data and the rolling submission is expected by year end. We note that the European and Japanese regulatory pathway requirements and subsequent timelines to approval will become apparent as discussions continue with the relevant bodies.

Peak sales potential of $815m in NET indication alone

We forecast global peak sales for surufatinib of $815m in NET ($169m in China, $646m ex-China). We have upgraded our peak forecasts for RoW (ex-China) to reflect: 1) higher reported prevalence rates in the US (170,000 vs 141,000 previously) and 2) the fact that we have expanded RoW to include Europe, which we had not previously due to the paucity of accurate prevalence rates for Europe historically; we now assume 50% of the prevalence rate for the US. We have maintained probability of success at 75% for RoW to reflect ongoing discussions with European and Japanese regulatory bodies. We have reduced our RoW pricing assumption from $5,000 to $4,000 per month to reflect increased pricing pressures as key competitor Afinitor becomes generic. However, we have maintained our penetration rates at 4% due to surufatinib's impressive data package and potential to be the first universal treatment for NETs. Our forecasts take into account both monotherapy opportunities and combinations with PD-1 inhibitors, which we believe offer significant opportunity for future peak sales upgrades. As novel treatments become available for NET, we

believe improved diagnosis of these highly heterogenous tumours will continue to drive up reported prevalence and incidence rates. We have reduced the probability of success in BTC to 50% to better reflect its current stage of clinical development (Phase IIb/III); all other assumptions remain unchanged. We forecast peak sales of $187m in BTC in China and $143m in RoW.

Unique MOA for an unmet need drives upgrades in NET

Surufatinib is an oral angio-immunokinase inhibitor that targets vascular endothelial growth factor receptors (VEGFR) 1, 2 and 3, fibroblast growth factor receptor (FGFR) 1 and colony stimulating factor 1 receptor (CSF-1R) kinases. NETs are cancers that arise out of cells in the endocrine and nervous systems, predominantly the digestive and respiratory tracts. NET tumours are highly prevalent, fragmented in primary origin and are an unmet medical need. Current treatment modalities are limited to subsets of NET with no broadly effective drugs across the NET spectrum (surgery can be curative, but most patients are diagnosed with advanced or metastatic disease when this is usually not an option). Surufatinib could be the first universal drug to treat NETs in all patients regardless of tumour subtype. Positive clinical data coupled with a swifter global commercialisation pathway and likely broad prescribing label has led to our NET forecast upgrades (see page 6).

US launch on the cards in 2022, two years ahead of expectation

Following HCM's pre-NDA meeting with the FDA, the agency has agreed that the completed SANET-ep (non-pancreatic NET) and SANET-p (pancreatic NET) China studies, along with existing data from a Phase Ib/II study in the US in both non-pancreatic and pancreatic NET patients, would be sufficient to form the basis of an NDA submission. A confirmatory Phase III trial is no longer required for FDA approval, saving a significant associated cost and, more importantly, bringing US launch forward by two years. The FDA had already granted surufatinib fast-track designation for both epNET and pNET and orphan drug designation for pNET, recognising the need for targeted treatments in this subset. HCM will utilise a fast-track rolling submission that allows completed sections of the NDA to be submitted to the FDA, which the agency will review on an ongoing basis.

The current prevalence rate of NET in the US is ~170,000. Data from Frost & Sullivan indicate that the global NET market in 2018 was worth approximately $5.8bn and is expected to grow to $21.2bn by 2030. We describe the competitive landscape in the US below, but believe surufatinib's unique positioning covering all origins of NET will enable broad uptake, setting it apart from competitor Afinitor (not approved for non-functional NET) and the somatostatin analogues. We also envisage that in time, increased awareness of NET could lead to earlier diagnosis of these highly fragmented tumours in clinical presentation.

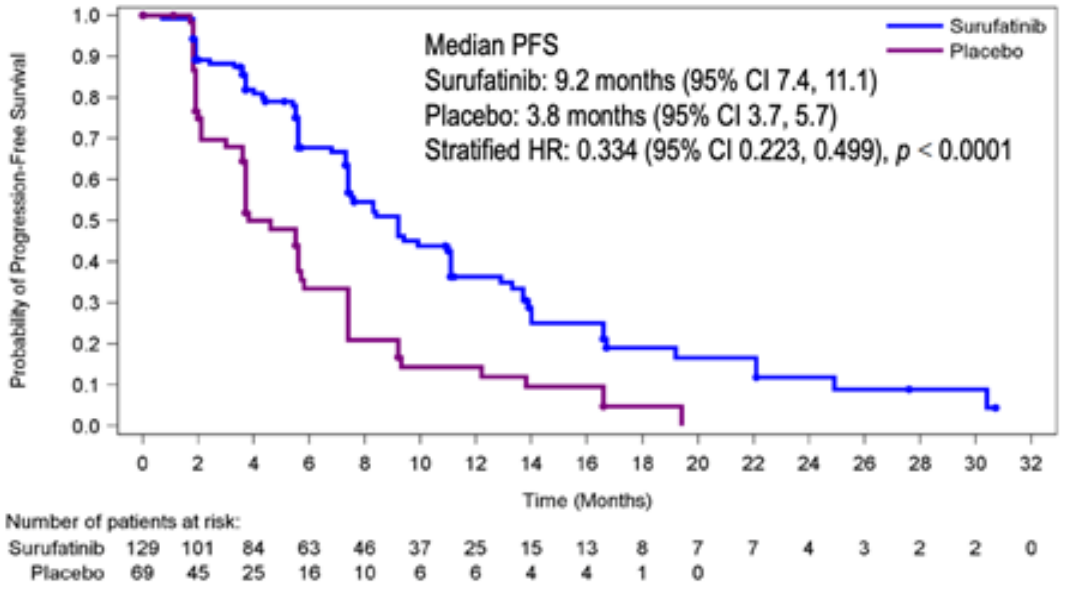
Second innovation platform asset to launch in China

HCM is building its China oncology commercial team ahead of surufatinib launch, with the intention of having full coverage of China in preparation for launch in late 2020. In China there is a significant market opportunity with reported incidence of NET in 2018 of approximately 67,600, with potentially ~300,000 patients living with NET (source: Frost & Sullivan). Non-pancreatic NET will be surufatinib's first (potential) approved indication. The China NDA for non-pancreatic NET was accepted in November 2019 and subsequently granted priority review; we anticipate approval and launch in late 2020. HCM estimates that non-pancreatic NET represents ~80% of NET cases in China. We expect that the China NDA for pancreatic NET will be filed in H220, with approval in this subset in 2021, which means a label encompassing all NETs regardless of origin. Pricing strategies and eventual NRDL inclusion in China will be important given competitor NRDL reference pricing of $2,007 per month for Sutent and $1,320 per month for Afinitor.

SANET-p and SANET-ep establish efficacy across NET spectrum

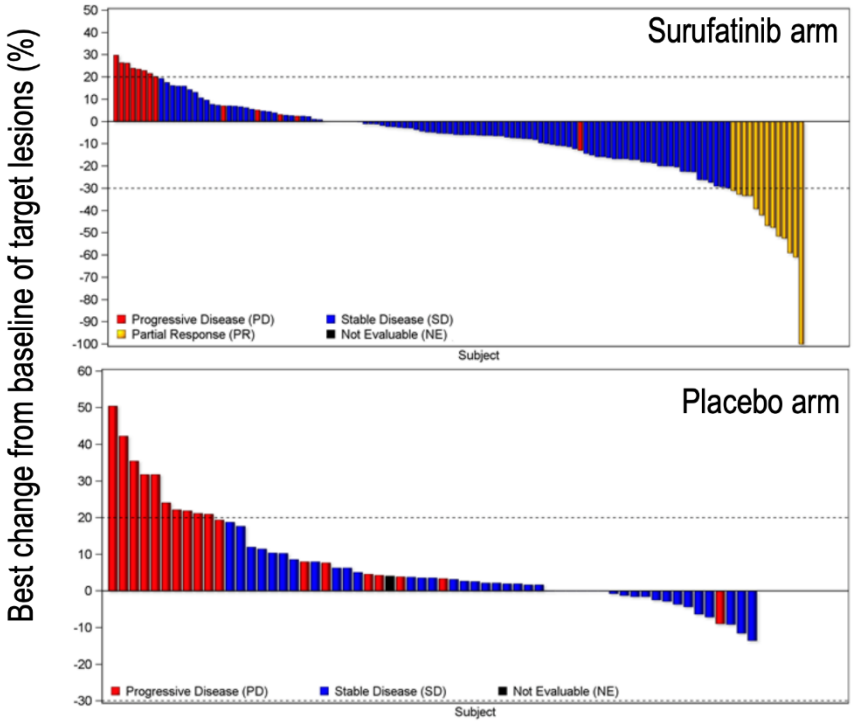
HCM conducted two pivotal Phase III studies in patients in China with NET: SANET-p in pancreatic NET and SANET-ep in non-pancreatic NET. The latter encompasses all NET that do not originate in the pancreas (including but not limited to lung, thymus and gastrointestinal tract). The successful efficacy readout of both led to the independent data monitoring committee stopping both trials early. At ESMO 2019, HCM presented data from SANET-ep, which evaluated surufatinib (300mg once daily) vs placebo in 198 (n=129 vs 69) patients with advanced non-pancreatic NET. The trial met its primary endpoint of PFS (investigator-assessed PFS 9.2 months vs placebo 3.8 months, hazard ratio (HR)=0.334, p<0.0001, Exhibit 3) and the trial was unblinded a year ahead of schedule. Surufatinib also met all secondary endpoints vs the placebo arm (objective response rate (ORR) 10.3% vs 0%, p=0.005; disease control rate (DCR) 86.5% vs 65.6%, p=0.002). On unblinding, patients on placebo had the opportunity to cross over to the surufatinib arm. Safety was in line with previous data, while the most common adverse events were medically manageable. Given surufatinib inhibits three different targets at therapeutic dosing, its tolerability with combination therapies is an important factor. However, median exposure days on surufatinib (217 days) and placebo (146 days) suggest that discontinuation rates were largely due to disease progression rather than tolerability issues.

Exhibit 3: Surufatinib PFS in SANET-ep



Source: HCM

Exhibit 4: Waterfall plot of SANET-ep tumour data



Source: HCM

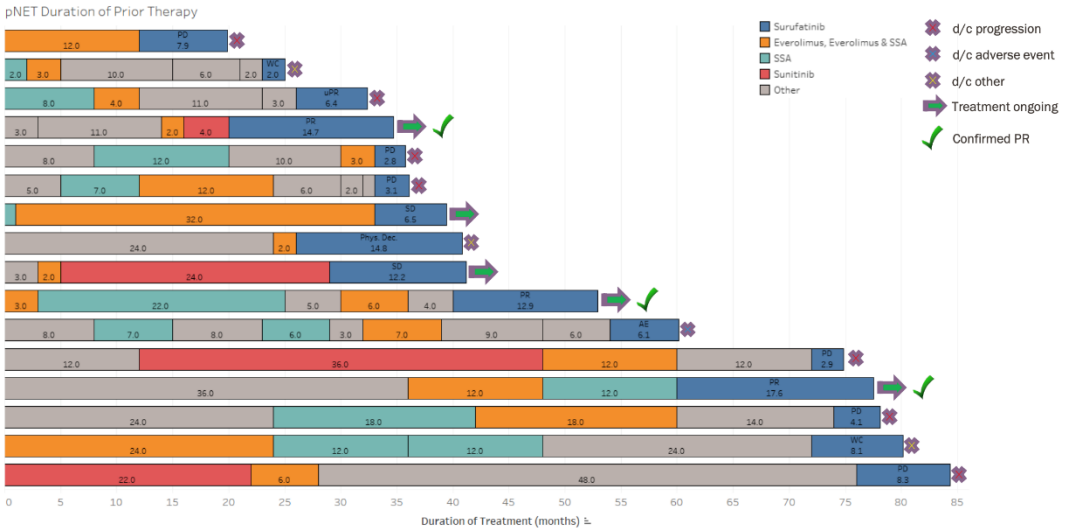
Importantly, the eligibility criteria for SANET-ep included patients with well differentiated, non-pancreatic (ep) NETs of pathological grade 1 or 2 with advanced disease, meaning that around 69% of patients on surufatinib had received prior systemic anti-tumour therapy (chemotherapy, somatostatin analogues, everolimus) vs 64% on placebo. Patients who responded to VEGF/VEGFR inhibitors in prior lines of therapy were excluded. Against the background of the patient demographic (84% grade 2 disease) and multiple prior lines of treatment received, the PFS data from SANET-ep are impressive. On the strength of the data presented, we believe that surufatinib could provide a universal treatment for NETs, which is further supported by the positive data from SANET-p. Full data are expected to be presented later this year at ESMO 2020.

US Phase Ib/II anti-tumour activity despite multiple prior treatment lines

At ASCO20, HCM reported data from the Phase Ib/II (NCT02549937) study of surufatinib in US solid tumour patients, which included patients with NETs. The two-part study design included dose escalation and dose expansion assessed safety and tolerability. The primary objective of the expansion phase was to evaluate anti-tumour activity in resistant patient groups and, importantly, clinical efficacy was observed irrespective of prior lines of therapy, including treatment with everolimus or sunitinib (median prior lines of treatment of four for pNET, and two for epNET). At the 21 April data cut-off, 32 heavily pre-treated progressive NET patients were evaluable (epNET n=16 and pNET n=16) and an ORR of 18.8% was observed in pNET patients, with zero epNET patients achieving a confirmed partial response (one unconfirmed PR). However, the data are still relatively immature, with a particularly short follow-up time for the epNET cohort. A significant clinical benefit was achieved in terms of disease stabilisation in both pNET (81.2%) and epNET (100%) and tumour growth was controlled in all NET patients (DCR=100% for pNET/epNET). The waterfall plot of the duration of treatment highlights the number of prior lines in pNET (Exhibit 5) and epNET (Exhibit 6); median prior lines of therapy received for these patients was three (range one to eight).

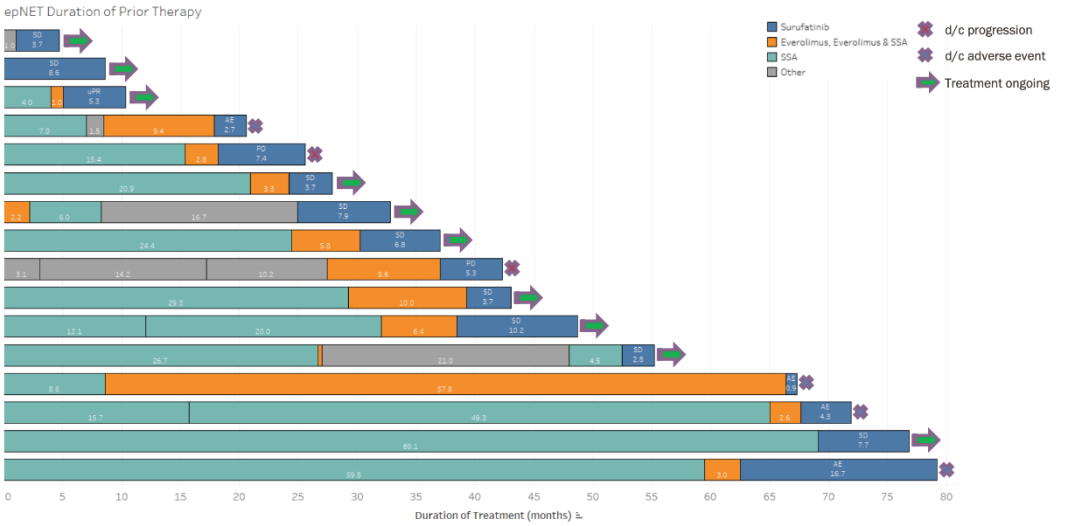
Importantly the data highlight that surufatinib demonstrated efficacy in patients regardless of the number of lines of prior therapy, including Afinitor or Sutent.

Exhibit 5: Duration of treatment pNET and number of lines of prior treatment



Source: HCM

Exhibit 6: Duration of treatment epNET and number of lines of prior treatment



Source: HCM

Surufatinib's safety profile in US patients was consistent with previously completed trials in China. 30 patients (93.8%) had reported at least one adverse event (AE) and 22 patients (68.8%) reported ≥ grade 3 AEs. Five patients discontinued treatment due to AE (pNET: one; epNET: four). HCM also presented health-related quality-of-life (HRQoL) results from the SANET-ep study for 197 (99.5%) of the patients, which highlighted surufatinib's acceptable toxicity, maintaining HRQoL while providing therapeutically significant efficacy, further supporting its use in patients with advanced non-pancreatic NET who have failed previous lines of therapy. PK and toxicity data presented at AACR 2020 highlighted similar profiles of surufatinib in US and Chinese patients, which suggests that ethnicity has no clinically meaningful impact on its safety and efficacy.

Competitive landscape

Although progress has been made in the treatment of NETs, the current treatment landscape is fragmented with most approved therapies for subsets of NET, dependent on the primary site or

origin, stage and grade (NETs are challenging due to their marked heterogeneity). Treatments focus on addressing symptoms and suppressing further tumour growth and include chemotherapy, somatostatin analogues, peptide receptor radionuclide therapy (PRRT) and targeted therapies (Exhibit 7). Lanreotide data (CLARINET) support use in pNET and GI-NET, Lutathera is only indicated for patients with somatostatin receptor-positive gastroenteropancreatic NET, while Sutent (SUN 1111) data support its use in pNET only. To date, no targeted therapies have been approved across the broad NET population and surufatinib's utility across all patients sets it apart from available products (Exhibit 8).

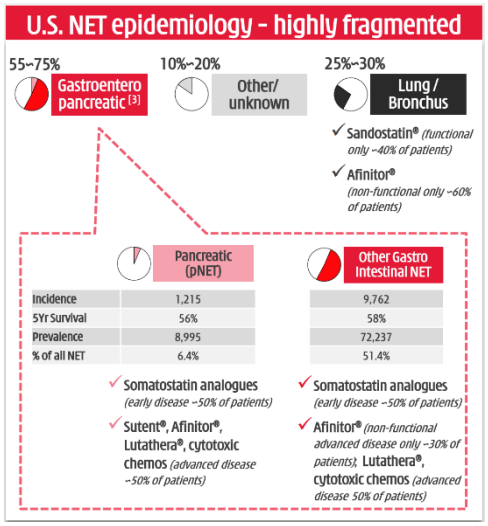
Surufatinib could be the first universal drug to treat NETs

For early-stage functional NETs (meaning they make and release hormones that lead to symptoms), the standard of care is surgery and long-term systemic treatment with somatostatin analogues such as Novartis's (NOVN) Sandostatin LAR (octreotide) and Ipsen's Somatuline (lanreotide). These analogues inhibit somatostatin receptors (SSTR 1-5), slowing the hormonal production that drives the formation of NETs (ex-lung), which provides symptomatic relief and disease stabilisation for many patients, although the duration of response is limited and tumour progression inevitable.

According to EvaluatePharma, consensus estimates in 2025 attribute NOVN's PRRT Lutathera (177Lu-dotatate) with the highest sales ($935m) of all approved therapies for the treatment of NET. Lutathera is a radioactive somatostatin analogue that also binds to SSTRs, facilitating the delivery of radioactive lutetium that damages tumour cells, ultimately resulting in cell death. The Phase III NETTER-1 study (n=229) found that patients with advanced gastroenteropancreatic NET treated with a combination of Lutathera and octreotide showed a 79% reduction in risk of disease progression or death vs octreotide alone (HR=0.21). However, due to its radioactive profile, prolonged treatment can lead to serious side effects including the development of blood and bone marrow cancers. Furthermore, disease progression on SSTR targeting therapies is believed to be driven by receptor downregulation and desensitisation, resulting in resistance to these treatments and continued tumour growth.

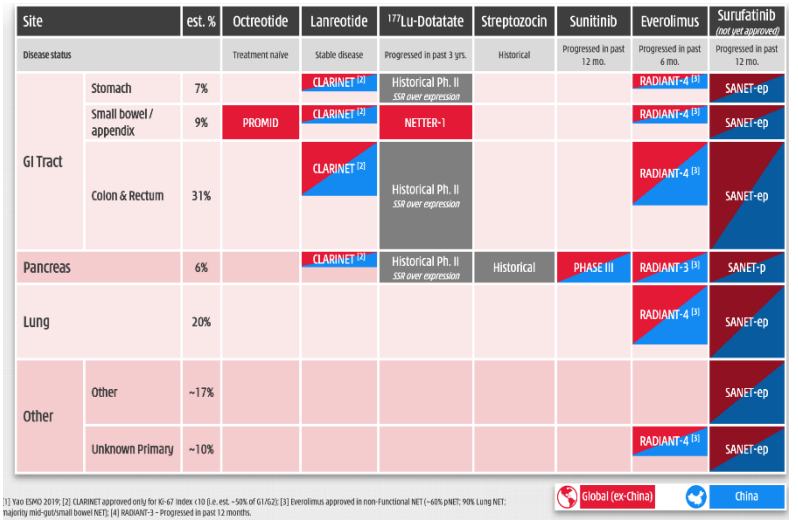
Targeted therapies such as Afinitor and Sutent have a synergistic effect with SSTR targeting therapies and are commonly used in combination to treat patients with progressive NETs. Targeted therapies include NOVN's mTOR inhibitor Afinitor (everolimus) and Pfizer's (PFE) VEGFR TKI Sutent (sunitinib). Targeting aberrant angiogenic VEGF signalling has been proven with Sutent in treating pNETs, demonstrating a 5.9-month improvement in median progression-free survival (mPFS) vs placebo (HR=0.42; p<0.001). However, Phase III efficacy for VEGFR inhibitors in treating non-pancreatic NETs had not been established until SANET-ep (PFS 9.2 months vs placebo 3.8 months, HR=0.334, p<0.0001). These data in our view could establish surufatinib as a leading treatment option.

Exhibit 7: Current NET treatment options



Source: HCM

Exhibit 8: Surufatinib SANET trials cover all subsets



Source: HCM

Afinitor is not approved for the broad spectrum of NET

NOVN's Afinitor (everolimus) will likely be surufatinib's main competitor in non-pancreatic NET. Afinitor has the broadest US and China labels to date, and is approved for pNET and non-functional NET of lung or GI primary site of origin (see the full US prescribing label). However, Afinitor is not approved for functional non-pancreatic NET, whereas surufatinib's data encompass all NET. Surufatinib's broad spectrum efficacy in NETs, including Sutent/Afinitor-refractory patients, in combination with its high tolerability and favourable safety profile, will likely garner significant market share. We note that there are a number of TKIs currently in late-stage clinical development for NETs, including PFE's Inlyta (axitinib) and Boehringer Ingelheim's Vargatef (nintedanib), both of which are expecting data readouts later this year.

Afinitor approval was based on the Phase III RADIANT-4 trial meeting its primary endpoint of investigator-assessed mPFS (11.0 months vs placebo 3.9 months based on HR=0.48, p <0.001) in patients (n=302) with advanced or metastatic, well differentiated, non-functional NETs of lung or GI origin. However, at the pre-planned interim analysis, although everolimus did show a trend towards improved overall survival (OS) (HR=0.64), it did not achieve the key secondary endpoint of OS with statistical significance. A limitation of Afinitor is that, as an immunosuppressive agent, patients have increased risk of localised and systemic infections including pneumonia, bacterial, viral and fungal inhibitions of a severe or fatal nature. In its registrational RADIANT-4 study, everolimus was discontinued due to adverse reactions in 29% of patients vs 7% in the placebo group and dose reduction or delay was required in 67% of everolimus-treated patients (vs 30% in the placebo group). Serious adverse reactions occurred in 42% of everolimus-treated patients and included three fatal events (cardiac failure, respiratory failure and septic shock). Afinitor selectively inhibits mTORc1 and not mTORc2, which can lead to feedback activation of the IGF-IR and Akt pathways, compromising the anti-cancer effects. It has also been shown to increase EGFR activation in tumour cells, leading to treatment resistance.

Combinations targeting solid tumours

Surufatinib selectivity inhibits three distinct kinases and thus modulates multiple different regulatory processes that enable cancer proliferation. Inhibition of VEGF receptors (1, 2 and 3) and FGFR1 have anti-angiogenesis effects primarily, while inhibition of CSF-1R limits the production of pro-tumour macrophages, which, among other functions, is believed to aid in tumour cell invasion and evasion of the immune system. Surufatinib's immunomodulation activity could provide additional

synergies in combination with a PD-1 antibody. Additionally, its low toxicity profile makes it an ideal candidate for use in combination-based strategies, as lack of tolerability is one of the key drivers of clinical attrition.

More recently, HCM entered into a clinical collaboration with BeiGene to evaluate separate combinations of surufatinib and fruquintinib with tislelizumab (anti-PD-1) for the treatment of solid tumours in the US, Europe, China and Australia. Global dose finding studies are expected to initiate in the near future. HCM has 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 to initiate a global Phase Ib/II study in the US in 2020. A China-based Phase I study of surufatinib in combination with Innovent Biologics PD-1 Tyvyt (sintilimab) in solid tumours is expected to initiate later in 2020. Tyvyt is approved in China for the treatment of relapsed or refractory classic Hodgkin's lymphoma and reported $57.4m of sales in Q120 (~$144m in FY19), following launch early last year and inclusion on China's NRDL in November.

Second lead asset: Savolitinib global launch potential

Our peak sales forecasts have been upgraded to $2.6bn in NSCLC. Increased Tagrisso use in earlier lines of therapy in metastatic NSCLC implies higher potential resistant patient populations. We expect increased use of savolitinib in combination with Tagrisso in MET+ patients.

Savolitinib, a highly selective inhibitor of the c-Met signalling pathway, has demonstrated its utility across a range of different resistant cancers that test positive for MET mutation, amplification or over expression. Partnered with AZN, the drug is being assessed in lung, kidney and gastric cancers. Its most advanced indication is for NSCLC – in China as monotherapy for MET exon 14 skipping NSCLC (NDA submission accepted for review by the China National Medical Products Administration (NMPA) in May 2020), and internationally in combination with AZN's Tagrisso for MET-positive Tagrisso refractory NSCLC (top-line results expected 2021). The latter is a blockbuster opportunity being increasingly driven by Tagrisso moving further up the treatment paradigm, and the SAVANNAH (second-/third-line EGFRm+, Tagrisso refractory, MET-positive NSCLC in combination with Tagrisso) top-line results expected in 2021 could be registration enabling in the US. HCM has indicated that it is actively reviewing its strategy in papillary renal cell carcinoma (PRCC) after the full analysis and presentation of the mature but early terminated SAVOIR data at ASCO20. This may lead to the initiation of SAVOIR2, a Phase III trial evaluating savolitinib monotherapy in PRCC. Other late-stage ongoing investigator-led trials include CALYPSO (papillary and clear cell RCC with/without PD-(L)1 Imfinzi) and VIKTORY (MET-positive gastric cancer).

Savolitinib: Upgrade to our NSCLC peak sales expectations

We forecast global peak sales for savolitinib of $2.6bn in NSCLC ($387m in China, $2.2bn ex-China). We have upgraded our peak forecasts for RoW (ex-China) to reflect the increased uptake of Tagrisso in first-line as well as broadening use in the second-/third-line NSCLC setting. Additionally, we have reassessed our expected launch dates (and thus peak year of sales) and have pushed back launch years across ccRCC and gastric cancer indications. In the longer term, we believe our savolitinib forecasts could prove conservative. As AZN focuses on Tagrisso life cycle management in EGFRm+ disease beyond metastatic NSCLC into use in early NSCLC as assessed by ADAURA (adjuvant setting), NeoADAURA (neoadjuvant setting) and LAURA (unresectable NSCLC), it is potentially expanding the eligible patient population by another 50%. The critical questions on savolitinib's potential in earlier disease stages will depend on the percentage of

patients who become resistant to Tagrisso monotherapy and the proportion of resistance that is MET-driven, and whether this is comparable to the numbers seen in metastatic NSCLC. If significant, a clinical trial evaluating the combination in the treatment of early disease is warranted, which we believe is likely to be a few years away.

Exhibit 9: Savolitinib peak sales forecasts

Product	Indication	Launch year/ peak sales China	Launch year/ peak sales RoW	Assumptions
Savolitinib	PRCC	2024/2028 $64m	2024/2028 $267m	RoW new cases (43,913), China new cases (8,443). China penetration 10.0%, $5,000 per month, 12-month treatment duration. RoW penetration 4.5%, $10,000 per month, 12-month treatment duration.
	ccRCC	2025/2030 $169m	2025/2030 $678m	RoW new cases (224,770), China new cases (58,451). China penetration 4.0%, $5,000 per month, 12-month treatment duration. RoW penetration 2.0%, $10,000 per month, 12-month treatment duration.
	NSCLC	2021/2027 $387m	2022/2027 $2.2bn	RoW new cases (1,154,955), China new cases (674,355). China penetration 0.8%, $5,000 per month, 12-month treatment duration. RoW penetration 1.3%, $10,000 per month, 12-month treatment duration.
	Gastric cancer	2023/2027 $326m	2025/2029 $765m	RoW new cases (627,810,653), China new cases (491,420). China penetration 1.0%, $5,000 per month, 12-month treatment duration. RoW penetration 0.8%, $10,000 per month, 12-month treatment duration.
	Deal economics			$20m upfront fee (received in December 2011); $120m in development & regulatory milestones ($25m received as of December 2018) with hundreds of millions in commercial milestones (not disclosed); 30% royalty rate in China and 14–18% royalty rate in RoW (subject to approval for PRCC and providing aggregate sales remain below $5bn); AZN cover 100% RoW development costs (excl $50m covered by HCM) and 75% of China development costs.

Source: Edison Investment Research. Note: FX rate $1.26/£.

China NDA accepted for MET exon 14 skipping NSCLC

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. HCM filed the China NDA on the basis of the Phase II registration study of savolitinib monotherapy in MET exon 14 skipping NSCLC patients (n=70) who had failed prior systemic therapy or were unable to receive chemotherapy. We forecast launch in 2021, representing savolitinib's China debut. In the longer term in China, our forecasts assume that a savolitinib plus Tagrisso combination will expand use in NSCLC.

Data presented at ASCO20 highlights efficacy in a Phase II China study

HCM published data from the open-label, single-arm Phase II (NCT02897479) trial at ASCO20 and the results were particularly encouraging given the challenging demographic of the patient population (median age 68.7 years, 92.9% stage IV, 60.0% having received previous treatments) and that among treated patients, 35.7% had pulmonary sarcomatoid carcinoma (PSC), a rare, hard-to-treat form of NSCLC, with a high incidence of MET exon 14 mutations and a particularly poor prognosis. Specifically, savolitinib demonstrated promising anti-tumour activity (ORR in 49.2% of efficacy-evaluable patients (n=61) and disease control was seen in 93.4% of efficacy-evaluable patients at the 31 March 2020 cut-off) and acceptable tolerability. Secondary endpoints included duration of response (DoR), PFS and OS, but we note these data were not yet mature. Median DoR was 9.6 months with maturity of approximately 40%. Median PFS was 6.9 months with maturity of 50% and median OS of 14.0 months with maturity of 46%. The safety profile was consistent with prior observations; savolitinib was well tolerated in most patients, with only a 41.4% incidence of ≥ grade 3 treatment-related adverse events, of which 14.3% resulted in treatment discontinuation.

NSCLC: Forecast global launch in combination with Tagrisso in 2022

Savolitinib's single largest opportunity resides in combination with Tagrisso in EGFRm+ MET+ NSCLC patients as MET mutations are the biggest driver of Tagrisso resistance. 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). SAVANNAH has the potential for registrational use, and interim data expected in mid-2020 could potentially warrant breakthrough therapy designation. Primary data completion is expected in 2021. The primary endpoint in SAVANNAH is ORR and secondary endpoints include PFS, OS, DoR and percentage change in tumour size. The strength of the efficacy data will determine whether a larger Phase III trial is required as part of the US regulatory submission package, although we believe SAVANNAH will be sufficient for an NDA filing for accelerated approval prior to performing a confirmatory Phase III study for full approval.

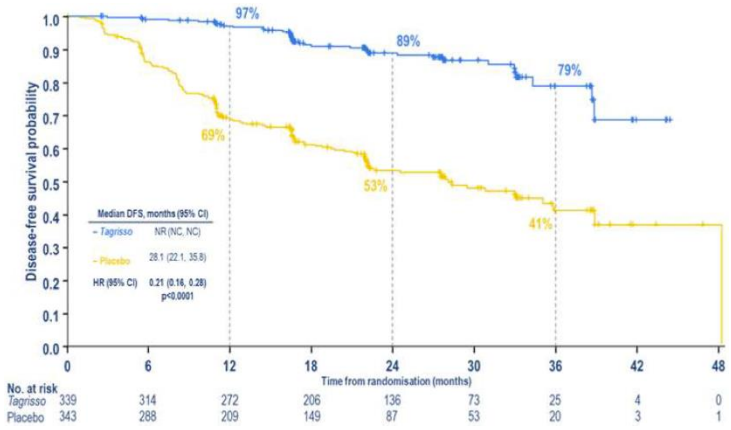
Tagrisso rewriting NSCLC paradigm in metastatic disease

In the field of lung cancer, AZN's Tagrisso (oral once-daily EGFR inhibitor) is raising the bar as it moves into the first-line setting in EGFR mutation-positive NSCLC. It reported 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). Since the advent and success of Tagrisso, there has been increasing industry recognition that MET amplification in NSCLC is implicated in acquired resistance to EGFR inhibitors in ~20% of cases with EGFR inhibitor resistance. A 2018 analysis of plasma samples from Tagrisso's AURA3 trial identified that MET implication was the cause of Tagrisso resistance in 19% of these patients in second-line treatment and above. Data from the Tagrisso FLAURA trial suggest that MET amplification is implied in 15% of cases in first-line resistance. In both cases, plasma samples were measured, and scientists thought that the frequency of MET amplification could be higher in tissue samples; as the sensitivity of a plasma-based test is typically less than a test on a tumour biopsy. This provides further therapeutic rationale for combinations of MET inhibitors with EGFR inhibitors for resistant NSCLC and the question is how high up the treatment paradigm savolitinib can be used (in combination with Tagrisso). The SAVANNAH and ORCHARD studies should go some way to answering these questions.

ADAURA addresses use in earlier NSCLC stages in adjuvant setting

AZN recently disclosed detailed results from the Phase III ADAURA trial of Tagrisso in post-surgery patients with EGFR-mutated NSCLC, ahead of numerous presentations planned for ASCO20. In mid-April, at the recommendation of the independent data monitoring committee, AZN unblinded the Phase III trial two years ahead of schedule. Adjuvant treatment (after surgery) with Tagrisso decreased the risk of death or disease recurrence by a ground-breaking 83% in patients with Stage II and IIIA disease, satisfying the primary endpoint of disease-free survival (DFS) based on a hazard ratio of 0.17.

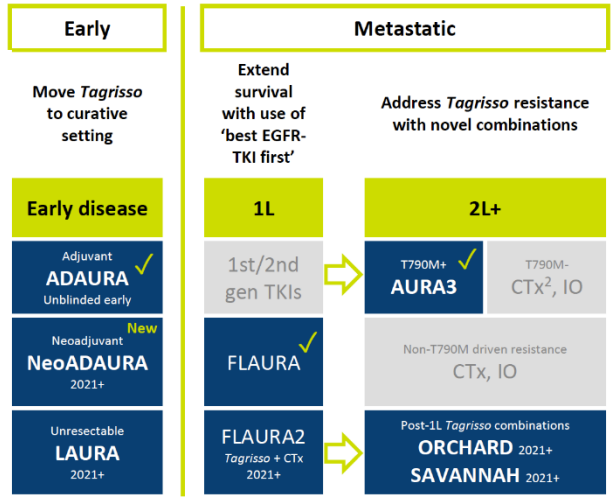
Exhibit 10: Tagrisso DFS in the adjuvant setting (ADAURA) Kaplan-Meier curve



Source: AZN

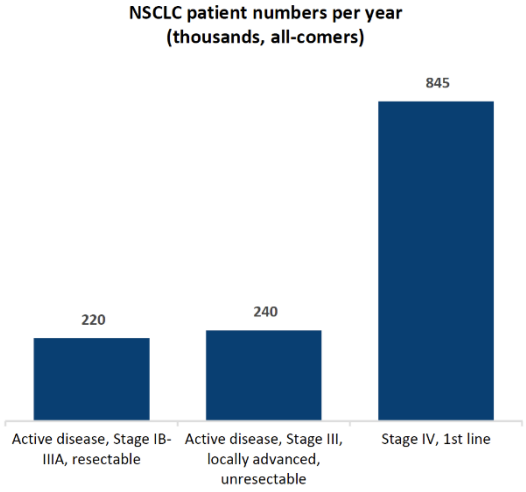
A DFS of 79% (based on an HR of 0.21) was achieved in the overall trial population (Stage IB to IIIA), a key secondary endpoint (Exhibit 10). Although OS data will not mature for a couple of years, 89% of patients treated with Tagrisso were disease free at two years, compared to 53% in the placebo group. These data strongly support the use of Tagrisso as an adjuvant for patients with EGFRm+ NSCLC who currently face high relapse rates after successful surgery and adjuvant chemotherapy. This represents a significant opportunity for both Tagrisso (Exhibits 11 and 12) and potentially for savolitinib.

Exhibit 11: Tagrisso lifecycle management



Source: AZN

Exhibit 12: Covering a high number of lung cancers



Source: AZN

SAVOIR data mature in PRCC

In July 2017, HCM initiated SAVOIR, a global Phase III study that planned to recruit 180 patients to evaluate savolitinib monotherapy in molecularly selected (via next-generation sequencing) c-Met driven (MET and/or HGF amplification, chromosome 7 gain and/or MET kinase domain mutations) patients, with locally advanced or metastatic PRCC. The trial was an open-label, randomised study that used standard of care Sutent (sunitinib) as a comparator arm. The primary endpoint of the trial was PFS assessed by a blinded independent review committee. In December 2018, AZN/HCM terminated enrolment of patients into SAVOIR. This decision took into account the realisation that treatment paradigms for RCC had shifted with the approval of PD-(L)1 inhibitors and findings from an external, observational molecular epidemiology study (MES), which showed smaller than expected applicable MET+ status. The study also suggested that patients with MET-driven disease

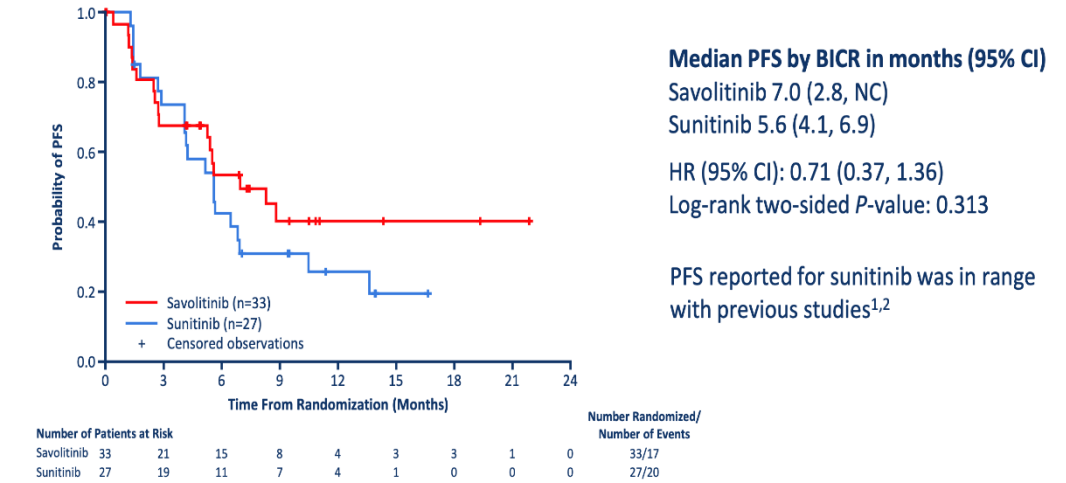
had comparable outcomes on standard-of-care sunitinib as those with disease not considered MET-driven.

SAVOIR2 Phase III trial in PRCC planning now underway

Subsequently, at the FY19 results, HCM indicated that it and partner AZN are actively revisiting their efforts in PRCC after full analysis and presentation of the SAVOIR data that matured during 2019. These data were presented at ASCO20. At the 19 August 2019 data cut-off, the primary endpoint of PFS was not achieved with statistical significance due to the limited number of patients, although savolitinib exhibited a numerically higher mPFS of 7.0 months (vs sunitinib at 5.6 months) based on an HR of 0.71, Exhibit 13. The key secondary endpoint of OS was not yet reached for savolitinib and is expected to be materially longer than the 13.2 months achieved by sunitinib given the impressive HR of 0.51. Savolitinib also exceeded sunitinib in other secondary endpoints, Exhibit 14, with an ORR of 27% (vs 7%) and a DCR of 48% (vs 37%) at six months. We note that it was not possible to calculate DoR from the data as none of the nine responders on savolitinib treatment experienced disease progression at the data cut-off (vs one out of two responders in the sunitinib arm). Following treatment discontinuation, more patients from the savolitinib arm (36%) received subsequent anticancer therapy than the sunitinib arm (19%). Interestingly, the sunitinib comparator arm did not perform as well in MET-driven patients as had been previously expected from the external MES study.

Savolitinib demonstrated promising efficacy, and a superior safety and tolerability profile to sunitinib. Although early termination of patient recruitment has prevented definitive conclusions being drawn due to the small data set, the emerging data warrant further investigation of savolitinib as a monotherapy treatment option for MET-driven PRCC. HCM is planning the Phase III SAVOIR2.

Exhibit 13: SAVOIR PFS data



Data cut-off August 19, 2019.
1. Albiges et al. J Clin Oncol 2018;36:3624–3631; 2. Ravaud et al. Ann Oncol 2015;26:1123–1128. BICR, blinded independent central review; CI, confidence interval; HR, hazard ratio; NC, not calculated; PFS, progression-free survival

Source: HCM

Exhibit 14: SAVOIR anti-tumour activity

Endpoint, n (%) [95% CI]	Savolitinib (N=33)	Sunitinib (N=27)
ORR by BICR,* *All partial responses*	9 (27) [13.3, 45.5]	2 (7) [0.9, 24.3]
Disease control rate by BICR,#		
At 6 months	16 (48) [30.8, 66.5]	10 (37) [19.4, 57.6]
At 12 months	10 (30) [15.6, 48.7]	6 (22) [8.6, 42.3]

- As of the data cut-off, no responding patients in the savolitinib group had disease progression, compared with 1 of 2 responding patients in the sunitinib group; response rate reported for sunitinib was in range with previous studies[1,2]
- It was not possible to calculate median DoR from the data as there were too few events
- Three responders on savolitinib were followed for >6 months after onset of response

Data cut-off August 19, 2019.
1. Albiges et al. J Clin Oncol 2018;36:3624–3631; 2. Ravaud et al. Ann Oncol 2015;26:1123–1128. *Response did not need confirmation. #Disease control rate = complete response + partial responses + stable disease at time point.
BICR, blinded independent central review; CI, confidence interval; DoR, duration of response; NC, not calculated; ORR, objective response rate

Source: HCM

Competitive landscape focus on capmatinib and tepotinib

In the emerging competitive landscape (globally) of targeted treatments for MET exon 14 skipping NSCLC patient populations, both Merck's c-Met inhibitor tepotinib and NOVN's capmatinib have demonstrated impressive ORR when used in treatment-naive patients (59% and 68% respectively) and as second-/third-line treatments (45% and 41% respectively).

In May 2020, the FDA granted Tabrecta (capmatinib) approval for MET exon 14 skipping NSCLC on the basis of the efficacy demonstrated in the Phase II GEOMETRY mono-1 trial presented at AACR 2020 (abstract CT082). At the 15 April 2019 data cut-off, 97 patients (69 in cohort 4 (second-/third-line patients) and 28 in cohort 5b (treatment-naive)) were evaluable for efficacy. For cohorts 4 and 5b respectively, ORR was 41% and 68%, median DoR was 9.72 months and 11.14 months, and median PFS was 5.42 months and 9.69 months, as judged by the blinded independent review committee. This indication is a smaller subset of the overall NSCLC population than the Tagrisso plus savolitinib combination is targeting. We note that NOVN is evaluating combinations of capmatinib with its EGFR inhibitor nazartinib, although it is at a much earlier stage of development (Phase Ib/II). Data from the open-label, single-arm Phase II study (NCT02019693) assessing NOVN's capmatinib in PRCC were also presented at ASCO20; 20 patients enrolled with MET-driven PRCC and reported modest efficacy, with three patients (15%) achieving a confirmed partial response.

Merck's TEPMETKO (tepotinib) was approved in Japan for MET exon 14 skipping NSCLC in March 2020 and US submission for this subset is expected later in 2020 (FDA breakthrough therapy designation granted). We note that Merck is conducting a Phase II trial (INSIGHT 2) evaluating tepotinib combined with Tagrisso in EGFR-mutated NSCLC; this 90-patient study is due to complete in 2022.

Third lead asset: Elunate US fast-track designation

Elunate's focus for the year is China sales evolution post NRDL inclusion in January. The US fast-track designation means fruquintinib could be the third innovation asset to launch in the US in 2023.

The November 2018 launch of Elunate (fruquintinib capsules) for third-line and above mCRC by partner LLY was a defining moment for HCM, as it was the first of its innovation platform oncology

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 the first global launch in mCRC.

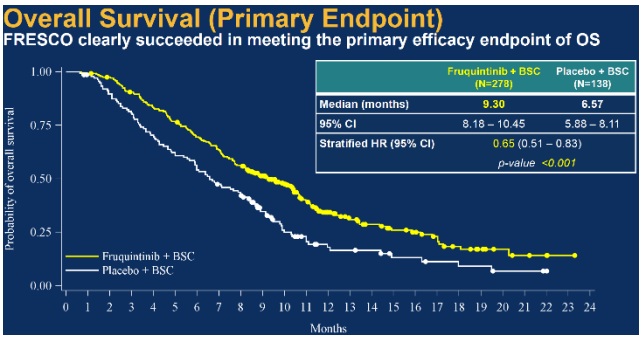
US launch on the cards for 2023

HCM retains the full development and commercial rights to fruquintinib outside China. In June 2020, following the end of Phase II meeting with the US FDA, HCM announced that fruquintinib has been awarded fast-track designation and the FDA has agreed that an NDA can be submitted on the basis of two Phase III trials (FRESCO and FRESCO-2). Regulatory meetings with the European and Japanese regulators (the EMA and PMDA, respectively) are currently ongoing. FRESCO is the China-based Phase III trial that formed the basis of Elunate's approval (see below); the global Phase III registration trial (FRESCO-2) in third- and fourth-line metastatic CRC is expected to initiate in mid-2020.

FRESCO demonstrated efficacy in difficult patient population

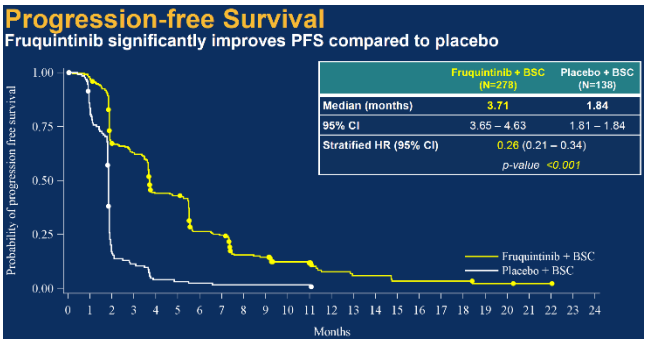
The FRESCO China study randomised 416 patients (519 screened) 2:1 into fruquintinib (+ best standard of care (BSC) (n=278)) and placebo (+ BSC (n=138)) arms with an 80% powering to detect a hazard ratio of 0.65 (corresponding to a median OS improvement from 6.57 to 9.30 months). Inclusion criteria included a range of factors, but notably patients had to have been diagnosed with stage IV mCRC and have failed on two prior treatments (with fluoropyrimidine, oxaliplatin and irinotecan), and were allowed to have prior anti-VEGF or anti-EGFR targeted therapy. Both OS and PFS (Exhibits 15 and 16) demonstrated statistical significance over placebo, a notable clinical achievement when considering the difficult patient population in which fruquintinib was tested. Key points include: a positive hazard ratio of 0.65, median OS of 9.30 months in the fruquintinib group vs 6.57 months in the placebo group (p< 0.001), and mPFS was 3.71 months vs 1.84 for placebo with a hazard ratio of 0.26 (p<0.001).

Exhibit 15: Fruquintinib OS in FRESCO



Source: HCM

Exhibit 16: Fruquintinib PFS in FRESCO



Source: HCM

Elunate sales uplift expected from NRDL inclusion

At the FY19 results, HCM announced Elunate sales of $6.6m during the January/February 2020 period (we note that as NRDL inclusion began on 1 January this number likely includes a lot of channel filling). 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). Elunate is now available in all state-run hospital pharmacies, and patients on National Healthcare Security Administration (NHSA) insurance schemes will be reimbursed (albeit at a 63% reduction to the original list price of $3,260 per cycle). A fourfold ramp in Elunate sales in the second full year from launch would require us to revisit our overall peak sales expectations. In June 2020 HCM announced that the Phase III FRUTIGA study evaluating fruquintinib and established

chemotherapy agent Taxol (paclitaxel) for the treatment of advanced gastric cancer patients after first-line standard chemotherapy (5-fluorouracil and platinum doublets) had successfully completed a second interim data analysis and had passed futility. If the final 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.

Fruquintinib (Elunate) peak sales assumptions

We forecast global peak sales for fruquintinib of $2.6bn across all indications under investigation (CRC, NSCLC and gastric cancer). We have reflected the NRDL pricing of $1,180 per month but increased our penetration rates to reflect reimbursement coverage under NRDL. Fruquintinib is due to start global proof-of-concept trials in breast cancer; this indication is not included in our valuation until we have more clarity on clinical trial timelines for specific patient subgroups. We highlight that our NSCLC and gastric cancer indications reflect combination therapy approvals.

Exhibit 17: Fruquintinib peak sales forecasts

Product	Indication	Launch year/ peak sales China	Launch year/ peak sales RoW	Assumptions
Fruquintinib	CRC	2018/2023 $202m	2023/2027 $565m	RoW new cases (1,194,000), China new cases (306,328). China penetration 10.0%, $1,180 per month, five months' reimbursement as per patient access programme. RoW penetration 0.7%, $5,000 per month, 12-month treatment duration.
	NSCLC	2025/2029 $393m	2025/2029 $721m	RoW new cases (1,067,000), China new cases (623,000). China penetration 4.2%, $1,180 per month, 12-month treatment duration. RoW penetration 1.0%, $5,000 per month, 12-month treatment duration.
	Gastric cancer	2022/2025 $341m	2025/2029 $392m	RoW new cases (580,000), China new cases (454,000). China penetration 5.6%, $1,180 per month, 12-month treatment duration. RoW penetration 1%, $5,000 per month, 12-month treatment duration.
	Deal economics			Deal economics: recently amended deal terms with an improved royalty rate of 15–29% in China, with HCM now funding majority of development costs but will receive $20m for every new indication in which Fruquintinib is approved (up to three) in China. HCM retains all other global rights (ex-China) and will fund development and commercial costs worldwide.

Source: Edison Investment Research. Note: FX rate $1.26/£.

Valuation

We value HCM at $6.3bn (£6.85/share) vs $5.9bn (£6.55/share) previously. The main changes to our forecasts are:

- Surufatinib: Our previous assumptions included only US patient numbers at a prevalence rate of 141,000; we have updated this number to reflect a higher apparent prevalence rate of 170,000 in NET, and we add in a prevalence rate to encapsulate the European opportunity at 50% of the US. We have moved RoW launch to 2022 (previously 2024). We have maintained probability of success at 75% for RoW to reflect ongoing discussions with European and Japanese regulatory bodies and expect that launches in these territories could be after 2022. We have reduced our RoW pricing assumption from $5,000 to $4,000 per month to reflect increased pricing pressures, but have maintained our penetration rates at 4% due to surufatinib's impressive data package and potential to become a leading treatment option for all NETs. Our forecasts take into account both monotherapy opportunities and combinations with PD-1 inhibitors. We also reduced the probability of success in BTC to better reflect its current stage of clinical development (Phase IIb/III); all other assumptions remain unchanged.
- Savolitinib: We have upgraded our RoW peak sales forecasts to reflect the increased uptake of Tagrisso in first-line as well as use in the second-/third-line NSCLC setting, and pushed back launch years across ccRCC and gastric cancer indications by one year to 2025. We assume initial pricing of $5,000 per month in China but note the pricing may be different on launch. If

included in the NRDL, we would expect the pricing to be significantly lower, but the penetration rate to increase due to better patient access. Our China peak sales forecasts for NSCLC include savolitinib in combination with Tagrisso in EGFRm+, Tagrisso refractory, MET-positive NSCLC and as a monotherapy in MET exon 14 skipping NSCLC.

- Fruquintinib: We have reduced the pricing from $3,300 to $1,180 per month in China to reflect NRDL inclusion pricing but increased our penetration rates to reflect reimbursement coverage under NRDL.
- Epitinib: We have pushed back launch to 2024 and lowered the probability of success to 10%.
- HMPL-523 and HMPL-689 RoW (ex-China) launch pushed back by one year to 2025.
- For the rest of the pipeline we have tweaked launch dates and corresponding peak sales year accordingly, and that has affected the valuation per asset slightly. However, we highlight the main near-term value drivers by indication are surufatinib (NET), savolitinib (NSCLC) and fruquintinib (CRC).
- We have increased our unallocated cost assumption per year over multiple years to reflect the global commercial expansion requirements needed, which are not allocated to any individual asset.

We use a risk-adjusted NPV method to discount future cash flows for the innovation platform (IP) (valuation of $4,830m). We use earnings-based multiples for HCM's commercial platform (subsidiaries and JVs). We apply a 22.6x multiple to our forecast 2020 net attributable profit (equity in earnings of equity investees, net of tax) for the JVs of $42.8m, which yields a valuation of $966.6m. Our valuation reflects net cash of $190m at end December 2019 plus $110m net proceeds from the January 2020 capital raise plus net proceeds of $100m from the General Atlantic equity investment in July 2020. Our SOTP valuation does not include HCM's early phase assets HMPL-453 (FGFR inhibitor), HMPL-306 (IDH1/2 inhibitor) or HMPL-309 (WT EGFR inhibitor), the preclinical assets or its discovery platform.

Exhibit 18: HCM SOTP valuation

Product	Indication	Launch/peak	Peak sales	Value ($m)	Probability	rNPV ($m)	rNPV/ share ($)	rNPV/ share (£)	rNPV/ ADS ($)	NPV/ share (£)
Savolitinib	PRCC	2024/2028 (China)	$64m (China)	98.8	75%	77.7	0.11	0.08	0.55	0.11
		2024/2028 (RoW)	$267m (RoW)	58.0	75%	40.1	0.06	0.04	0.28	0.06
	ccRCC	2025/2030 (China)	$169m (China)	102.4	35%	31.4	0.04	0.03	0.22	0.11
		2025/2030 (RoW)	$678m (RoW)	70.3	35%	24.6	0.03	0.03	0.17	0.08
	NSCLC	2021/2027 (China)	$387m (China)	295.5	75%	220.7	0.31	0.24	1.55	0.32
		2022/2027 (RoW)	$2.2bn (RoW)	489.9	75%	367.4	0.52	0.40	2.59	0.53
	Gastric cancer	2023/2027 (China)	$326m (China)	166.6	35%	57.2	0.08	0.06	0.40	0.18
		2025/2029 (RoW)	$765m (RoW)	128.4	35%	44.9	0.06	0.05	0.32	0.14
Fruquintinib	CRC	2018/2023 (China)	$202m (China)	116.6	100%	116.6	0.16	0.13	0.82	0.13
		2023/2027 (RoW)	$565m (RoW)	1,318.1	75%	984.9	1.39	1.07	6.93	1.43
	NSCLC	2025/2029 (China)	$393m (China)	94.2	50%	40.7	0.06	0.04	0.29	0.10
		2025/2029 (RoW)	$721m (RoW)	885.4	50%	417.3	0.59	0.45	2.94	0.96
	Gastric cancer	2022/2025 (China)	$341m (China)	188.8	75%	140.1	0.20	0.15	0.99	0.20
		2025/2029 (RoW)	$392m (RoW)	545.7	50%	265.7	0.37	0.29	1.87	0.59
Surufatinib	NET	2020/2025 (China)	$169m (China)	454.6	90%	409.0	0.58	0.44	2.88	0.49
		2022/2029 (RoW)	$646m (RoW)	958.7	75%	711.9	1.00	0.77	5.01	1.04
	BTC	2022/2026 (China)	$187m (China)	447.0	50%	221.5	0.31	0.24	1.56	0.48
		2024/2028 (RoW)	$143m (RoW)	199.8	50%	92.5	0.13	0.10	0.65	0.22
Epitinib	Glioblastoma	2024/2029 (China)	$43m (China)	118.1	10%	8.6	0.01	0.01	0.06	0.13
HMPL-523	Haematological cancers	2024/2027 (China)	$143m (China)	306.5	30%	82.1	0.12	0.09	0.58	0.33
		2025/2029 (RoW)	$584m (RoW)	871.4	30%	244.3	0.34	0.26	1.72	0.94
HMPL-689	Haematological cancers	2024/2028 (China)	$102m (China)	177.5	30%	47.2	0.07	0.05	0.33	0.19
		2025/2029 (RoW)	$468m (RoW)	653.6	30%	182.9	0.26	0.20	1.29	0.71
Commercial platform				966.6	100%	966.6	1.36	1.05	6.80	1.05
Unallocated costs				(904.2)	100%	(904.2)	(1.27)	(0.98)	(6.36)	(0.98)
Net cash at end 2019*				400.4	100%	400.4	0.56	0.43	2.82	0.43
Terminal value				1,030.9	100%	1,030.9	1.45	1.12	7.25	1.12
Valuation				**$10,239.5**		**$6,323.2**	**$8.90**	**£6.85**	**$44.49**	**£11.08**
Valuation of IP only				$7,043.4		$4,829.5	$6.80	£5.23	$33.98	£7.62

Source: Edison Investment Research. Note: Non-risk adjusted NPV per share assumes 100% probability of success. FX rate $1.26/£. Number of shares outstanding 710.6m. *Plus 2020 equity raise proceeds.

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 in 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. The 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 operating 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 to an adjusted non-GAAP IP segment

operating loss of $180–210m and adjusted non-GAAP group net cash flow excluding financing activities of $140–160m.

We forecast R&D expenses to increase to $183.0m in 2020 and $210.0m in 2021 (on a 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. With the likely launch of surufatinib in China by end 2020 and the US in 2022, we expect sales and marketing expenses to accelerate significantly as HCM builds out its global commercial operations. 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 $163.4m in 2020 and $174.2m 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). Furthermore, HCM raised net proceeds of $110m from capital issuance in January 2020 and $100m (net) from the equity investment from General Atlantic. We believe the share price in 2021 will likely be higher than the exercise price of the warrant and thus forecast the additional $100m net proceeds is raised. Additionally, HCM's non-consolidated joint ventures (Shanghai Hutchison Pharmaceuticals (SHPL) and Hutchison Baiyunshan (HBYS)) held $63.0m (at 31 December 2019). We note the JV Nutrition Science Partners (NSPL) has been acquired leading to a consolidated net cash inflow of $8.1m.

HCM recently announced that HBYS has come to an agreement with the Guangzhou government for the planned return of HBYS's vacant land (HBYS Plot 2, a ~30,000 square metre site). HBYS will receive cash compensation of up to $95m in several stages over the next year as the transaction progresses to completion. We expect that ~40% of the compensation received will make its way to HCM via special dividends, which will be reinvested in the business.

Exhibit 19: Financial summary

US$'000s	2017	2018	2019	2020e	2021e
Year end 31 December	US GAAP	US GAAP	US GAAP	US GAAP	US GAAP
PROFIT & LOSS					
Revenue	241,203	214,109	204,890	216,750	283,912
Cost of Sales	(175,820)	(143,944)	(160,152)	(175,919)	(196,866)
Gross Profit	65,383	70,165	44,738	40,831	87,046
Research and development	(75,523)	(114,161)	(138,191)	(183,000)	(210,000)
Other overheads	(43,277)	(48,645)	(52,934)	(60,021)	(87,679)
EBITDA	(50,692)	(88,975)	(141,250)	(194,454)	(196,924)
Operating Profit (before amort. and except.)	(53,417)	(92,641)	(146,387)	(202,190)	(210,633)
Intangible Amortisation	0	0	0	0	0
Operating Profit	(53,417)	(92,641)	(146,387)	(202,190)	(210,633)
Net Interest	(235)	4,969	3,914	4,295	3,035
Exceptionals	0	0	0	0	0
Profit Before Tax (norm)	(53,536)	(86,655)	(141,106)	(197,895)	(207,597)
Profit Before Tax (reported)	(53,536)	(86,655)	(141,106)	(197,895)	(207,597)
Tax	(3,080)	(3,964)	(3,274)	(3,300)	(5,000)
Equity investments, after tax	33,653	19,333	40,700	42,769	43,418
Profit After Tax (norm)	(22,963)	(71,286)	(103,680)	(158,426)	(169,179)
Profit After Tax (reported)	(22,963)	(71,286)	(103,680)	(158,426)	(169,179)
Minority	(3,774)	(3,519)	(2,345)	(5,000)	(5,000)
Discontinued operations	0	0	0	0	0
Net profit (norm)	(26,737)	(74,805)	(106,025)	(163,426)	(174,179)
Net profit (reported)	(26,737)	(74,805)	(106,025)	(163,426)	(174,179)
Average Number of Shares Outstanding (m)	617.2	664.3	665.7	710.6	718.9
EPS - normalised (c)	(4.3)	(11.3)	(15.9)	(23.0)	(24.2)
EPS - normalised and fully diluted (c)	(4.3)	(11.3)	(15.9)	(23.0)	(24.2)
EPS - (reported) (c)	(4.3)	(11.3)	(15.9)	(23.0)	(24.2)
Average number of ADS outstanding (m)	123.4	132.9	133.1	142.1	143.8
Earnings per ADS - normalised ($)	(0.02)	(0.06)	(0.08)	(0.11)	(0.12)
Earnings per ADS ($)	(0.02)	(0.06)	(0.08)	(0.11)	(0.12)
BALANCE SHEET					
Fixed Assets	165,737	161,577	148,100	153,133	194,348
Intangible Assets	3,738	3,533	3,387	3,000	2,315
Tangible Assets	14,220	16,616	20,855	33,506	62,381
Investments	147,779	141,428	123,858	116,627	129,653
Current Assets	432,195	370,541	317,022	374,327	256,131
Stocks	11,789	12,309	16,208	14,459	16,181
Debtors	53,566	56,392	59,023	53,445	23,335
Cash	85,265	86,036	121,157	281,800	191,992
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)	(125,870)	(125,067)
Creditors	(25,344)	(26,180)	(25,789)	(38,558)	(37,755)
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)	(39,118)
Long term borrowings	0	(26,739)	(26,818)	(26,818)	(26,818)
Other long term liabilities	(8,366)	(7,644)	(12,300)	(12,300)	(12,300)
Net Assets	484,966	412,256	312,903	362,472	286,294
Minority	(23,233)	(23,259)	(24,891)	(29,891)	(34,891)
Shareholder equity	461,733	388,997	288,012	332,581	251,403
CASH FLOW					
Operating Cash Flow	(8,943)	(32,847)	(80,912)	(123,364)	(140,910)
Net Interest	0	0	0	0	0
Tax	0	0	0	0	0
Capex	(5,019)	(6,364)	(8,565)	(20,000)	(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)	210,000	95,000
Other	(255,761)	50,116	118,904	96,006	0
Net Cash Flow	20,420	7,301	36,739	160,643	(89,808)
Opening net debt/(cash)	(56,914)	(328,309)	(274,212)	(190,350)	(254,982)
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)	(254,982)	(165,174)

Source: HCM accounts, Edison Investment Research

Contact details	Revenue by geography
Level 18, The Metropolis Tower 10 Metropolis Drive Hung Hom, Kowloon Hong Kong +852 2121 8200 www.chi-med.com	N/A

Management team

Chairman: Simon To	CEO: Christian Hogg
Mr To has been a director since 2000 and an executive director and chairman of Hutchison China MediTech Limited since 2006. He is managing director of Hutchison Whampoa (China) Limited (Hutchison China) and has been with Hutchison China for over 39 years, building its business from a small trading company to a multi-billion-dollar investment group. Mr To's career in China spans more than 44 years. He is the original founder of the China healthcare business of Hutchison Whampoa Limited (HWL) (currently a subsidiary of CK Hutchison Holdings Limited (CKHH)) and has been instrumental in the acquisitions made to date. He received a bachelor's degree in mechanical engineering from Imperial College, London and a master in business administration from Stanford University's Graduate School of Business.	Mr Hogg has been the chief executive officer and an executive director of the company since 2006. He joined the business in 2000, as its first employee, and has since led all aspects of the creation, implementation and management of the company's strategy, business and listings. This includes the establishment of the innovation platform, Hutchison MediPharma, which now comprises eight drug candidates that are being investigated in clinical studies around the world and a scientific team of about 500 people. Furthermore, Mr Hogg oversaw the acquisition and operational integration of assets that led to the formation of the company's commercial platform, which manufactures, markets and distributes prescription drugs and consumer health products, covering an extensive network of hospitals across China. Prior to joining the company, Mr Hogg spent 10 years with P&G, starting in the United States in finance and then brand management in the laundry and cleaning products division. Mr Hogg then moved to China to manage P&G's detergent business, followed by a move to Brussels to run P&G's global bleach business. Mr Hogg received a bachelor's degree in civil engineering from the University of Edinburgh and a master in business administration from the University of Tennessee.
CFO: Johnny Cheng	**CSO: Weiguo Su**
Mr Cheng has been CFO since 2008. Prior to joining the company, Mr Cheng was vice president, finance of Bristol Myers Squibb in China and was a director of Sino-American Shanghai Squibb Pharmaceuticals Ltd. And Bristol-Myers Squibb (China) Investment Co. Ltd. in Shanghai between late 2006 and 2008. Mr Cheng started his career as an auditor with Price Waterhouse (currently PricewaterhouseCoopers) in Australia and then KPMG in Beijing before spending eight years with Nestlé China where he was in charge of a number of finance and control functions in various operations. Mr Cheng received a bachelor of economics, accounting major from the University of Adelaide and is a member of Chartered Accountants Australia and New Zealand.	Dr Su has been the executive vice president and chief scientific officer of the company since 2012. Dr Su has headed all drug discovery and research since he joined the company, including master-minding the company's scientific strategy, being a key leader of the Innovation Platform, and responsible for the discovery of each and every small molecule drug candidate in the company's product pipeline. Prior to joining the company in 2005, Dr Su spent 15 years with the US research and development department of Pfizer, Inc. with his last position as director of the medicinal chemistry department. Dr Su received a bachelor of science degree in chemistry from Fudan University in Shanghai. He completed a PhD and post-doctoral fellowship in chemistry at Harvard University under the guidance of Nobel Laureate Professor EJ Corey.

Principal shareholders	(%)
CK Hutchison Holdings Ltd (through its wholly owned subsidiary Hutchison Healthcare Holdings)	46.79
The Capital Group Companies Inc.	7.22
M&G plc	4.28
Schroders plc	3.59
Fidelity International Ltd	3.55
Invesco Ltd	2.55
BlackRock Inc.	2.55
Mitsui & Co. Ltd	2.27

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