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Hutchison China MediTech

Corporate update

WCLC highlights savolitinib combination potential

Pharma & biotech

Data presented at the World Conference on Lung Cancer (WCLC) on combination approaches to treat resistant EGFR-driven non-small cell lung cancer (NSCLC) highlight a widening of the patient population that could be eligible to receive savolitinib in combination with either Tagrisso or Iressa. Partner AZN now has the data set to make a decision on global Phase III trials and evaluate breakthrough therapy designation (BTD) potential in both 2L and 3L EGFR-resistant NSCLC; in our view, data to date supports both. BTD could offer earlier entry into the US market. Furthermore, Phase II data presented on fruquintinib in combination with Iressa (first line EGFRm NSCLC) showed encouraging efficacy and acceptable safety. We place our forecasts and valuation under review as we revisit our peak sales assumptions.

Year end	Revenue ($m)	Net profit ($m)	EPADS ($)	DPADS ($)	P/E (x)	Yield (%)
12/15	178.2	8.0	0.07	0.0	412	N/A
12/16	216.1	11.7	0.10	0.0	288	N/A
12/17e	N/A	N/A	N/A	N/A	N/A	N/A
12/18e	N/A	N/A	N/A	N/A	N/A	N/A

Note: Dividend yield excludes withholding tax. Investors should consult their tax advisor regarding the application of any domestic and foreign tax laws.

Savolitinib: Data in NSCLC demonstrates potential

Combinations of targeted therapies (TKI, monoclonal antibodies and immunotherapies) and chemotherapy is increasingly becoming the best approach to treating the complex and constantly mutating disease that is cancer. Savolitinib has the potential to be utilized across all lines of treatment in all MET-driven patients either as monotherapy or in combination. Data presented at the WCLC demonstrated positive efficacy for savolitinib in combination with Tagrisso or Iressa in EGFR-mutant, T790M +/-, MET-positive patients. Additionally, patients who had been previously treated with a third-generation T790M TKI (Tagrisso refractory) achieved a 33% PR (n=64). The importance of the data presented at WCLC is twofold; it underpins the scientific rationale at HCM in designing highly specific molecules that can be used both as monotherapy and in combinations to treat patients that are refractory to available EGFR therapies thereby opening up new treatment paradigms.

Fruquintinib: Impressive PR observed to date

Data were presented from an ongoing Phase II trial evaluating fruquintinib (VEGFR inhibitor) in combination with Iressa in EGFR-mutant NSCLC patients as first line therapy which supports this unique VEGFR inhibitor's role in combination therapy. 13/17 patients (76.5%) had a partial response and four had stable disease (23.5%). No patients as of the data cut-off had progressive disease. Overall, an acceptable safety profile was observed.

Valuation: Under review

We place our forecasts and valuation under review.

19 October 2017

Price	**US$28.82**
Market cap	**US$3,502m**
	ADR/Ord conversion ratio 1:0.5
Net cash ($m) as of 30 June 2017	65.7
ADSs in issue	121.5m
ADS code	HCM
ADS exchange	NASDAQ
Underlying exchange	AIM
Depository	NASDAQ

ADR price performance

52-week high/low	$31.2	$11.5

Business description

Hutchison China MediTech (Chi-Med; HCM) 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 in China is growing ahead of the market.

Next events

AZN decision on savolitinib PIII NSCLC	2017
Fruquintinib China NDA approval and launch	2018

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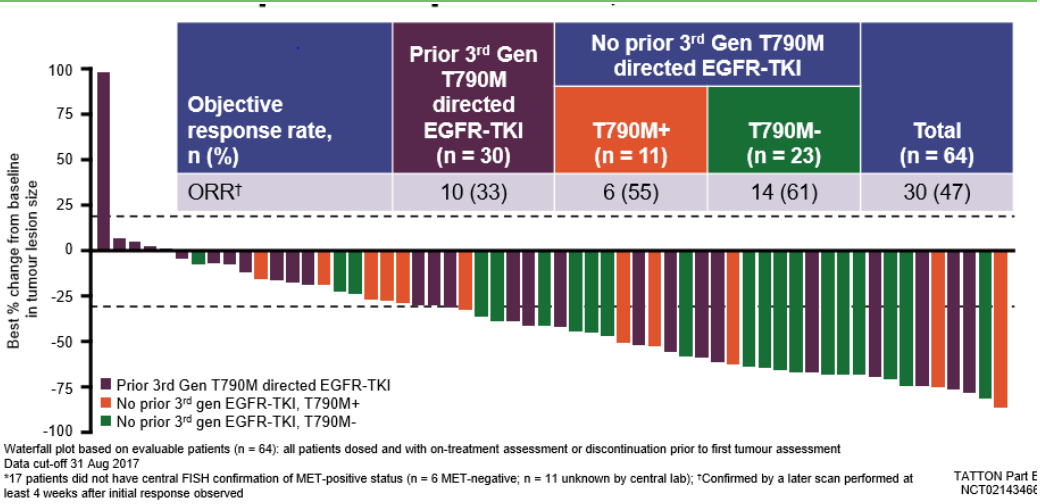
Savolitinib demonstrates utility in NSCLC

At the recent 18th (2017) WCLC, preliminary data were presented on two separate Phase Ib/II proof-of-concept clinical trials assessing savolitinib in combination with AstraZeneca's Tagrisso and Iressa for NSCLC patients. The data presented give an important insight into the potential utility of savolitinib in patients who have progressed following treatment with a first- (Iressa) or third- (Tagrisso) generation EGFR inhibitor. Patients treated were EGFR mutation-positive and presented with T790M and/or MET-driven disease, and, in our view, the data highlight savolitinib's potential for use in second- and third-line MET-amplified, EGFR-mutant patients, irrespective of EGFR inhibitor utilized and T790M status. Secondary resistance mechanisms in cancer patients that have received mutation-targeted medicines are emerging and as such savolitinib's place in addressing resistance in MET-driven lung cancers is becoming increasingly evident. The importance of the overall data is the potential widening of the NSCLC patient population that could be eligible to receive savolitinib as combination therapy. The safety profile across both the Iressa/savolitinib and Tagrisso/savolitinib combinations was consistent with the known safety profiles for each class of drugs.

Tagrisso and Savolitinib combination looks to US market

The Phase Ib/II TATTON trial is testing the combination of savolitinib and Tagrisso in patients with advanced EGFR-mutant MET-amplified NSCLC. Patients fell into three distinct groups: those who had prior third-generation T790M EGFR TKI treatment; those who had no prior third-generation T790M EGFR TKI treatment but were T790m-positive; and those who had also had no prior third-generation T790M EGFR TKI treatment but were T790m-negative. Sixty-four MET-positive patients were eligible for overall analysis of preliminary anti-tumor activity; of which 47 patients were confirmed centrally and 17 were confirmed locally (at the clinical site). Exhibit 1 highlights the preliminary anti-tumor activity in the savolitinib and Tagrisso group (based on all 64 C-MET positive patients). Patients with centrally confirmed MET-positive disease who had been previously treated with a third-generation T790M TKI had a 28% PR. This compared with 57% who had not been treated with a T790M TKI but were T790M-positive, and 53% who were T790M-negative. There were no complete responses in any of the patient groups, a result that is to be expected in this patient population with this class of drugs.

Exhibit 1: Preliminary anti-tumor activity of the combination of savolitinib and Tagrisso in patients with centrally and locally confirmed MET-positive NSCLC



Source: Ahn M-J, et al. TATTON Phase Ib Expansion Cohort: Osimertinib Plus Savolitinib for Patients with EGFR-mutant MET-amplified NSCLC After Progression on Prior EGFR-TKI. Abstract #8985. Presented at the World Lung Cancer Congress 2017, Yokohama, Japan, 15-18 October 2017.

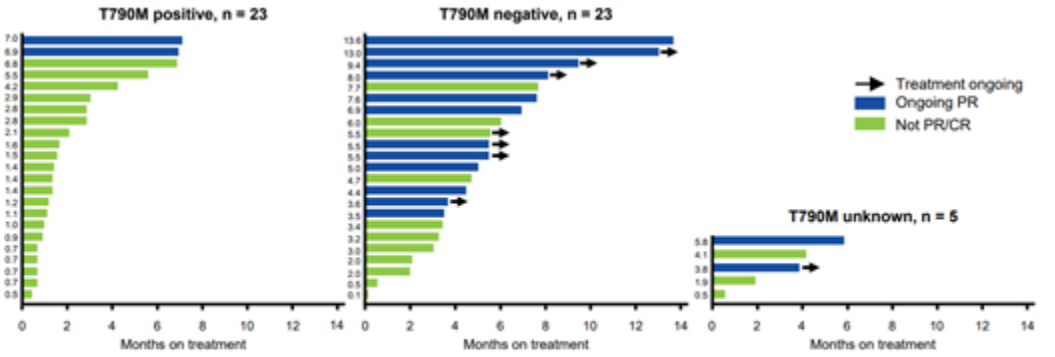
While these data demonstrate the potential of savolitinib in second- and third-line settings, the expected move of Tagrisso to a first-line treatment following the positive FLAURA data could open up further opportunities for savolitinib as 2L treatment option in Tagrisso refractory patients. Data presented so far by HCM appear to indicate that around 30% of patients are MET-positive after Tagrisso treatment, compared with around 6% who are MET-positive and T790M-positive, and 10% who are MET-positive and T790M-negative after first-line, first-generation EGFR TKI (Iressa/Tarceva) treatment. While the percentage of patients who are MET-positive once Tagrisso is utilized as first-line treatment is unknown at this time, these data suggest that a larger patient population may be addressable by savolitinib once this shift in standard of care is made ie the use of savolitinib (2L and 3L) in Tagrisso resistance patient populations.

Opportunities in Asia in combination with first-generation EGFR inhibitors

We anticipate HCM to move forward with a strategy in Asia for NSCLC that focuses on combinations with first-generation TKI inhibitors such as AstraZeneca's Iressa and Roche's Tarceva, which are now off-patent in China. The Phase Ib/II expansion cohort tested a combination of savolitinib and Iressa in EGFR-mutant, MET-amplified NSCLC patients.

Preliminary anti-tumor activity was available in all 51 patients who were treated. 52% (n=12/23) who were T790M-negative, achieved a PR an expected result as Tagrisso (or another T790M targeting compound) was not utilized. As demonstrated in Exhibit 2, many of the responding patients in the T790M-negative arm are still receiving ongoing treatment and have ongoing partial responses.

Exhibit 2: Duration of treatment in MET-amplified, EGFR mutation-positive patients who are treated with a combination of savolitinib and Iressa, N = 51



Source: Hutchison China MediTech reports

As expected response in T790M-positive patients was low, 9% (n=2/23) achieving a PR, we highlight that Iressa was not designed to address this patient subgroup (Tagrisso is now approved for this subgroup of patients). Stable disease at and beyond six weeks was similar in both groups, achieved in 30% (n=7/23) of T790M-negative patients and 39% (n=9/23) of T790M-positive patients. However, deaths occurred at a substantially increased rate in the T790M-positive arm (30% vs 13% in T790M-negative patients).

Fruquintinib

Fruquintinib is an oral small molecule that is a highly selective VEGFR1, VEGFR2 and VEGFR3 inhibitor, which in preclinical trials demonstrated fewer off-target toxicities, allowing higher drug exposure that translates to 24 hours a day VEGFR receptor inhibition. Fruquintinib's unique

selectivity (lack of CYP450 inhibition/inducing) is favorable for potential in combination treatment regimens, given that many drugs are metabolized through the cytochrome p450 enzyme pathway.

Data were presented from an ongoing Phase II trial testing fruquintinib (VEGFR inhibitor) in combination with Iressa in EGFR-mutant NSCLC patients which supports this unique VEGFR inhibitor's role in combination therapy. The trial tested fruquintinib at 4mg or 5mg once daily for three weeks on/one week off in combination with 250mg of Iressa once daily. Seventeen patients were eligible for efficacy evaluation, of which 13 (four PRs not confirmed as of data cut-off) patients (76.5%) had a partial response and four had stable disease (23.5%). No patients as of data cut-off had progressive disease and the median time to response was 56 days. 4mg dosing of Fruquintinib was determined to be the most suitable dose for further investigation as liver enzyme elevation was observed at 5mg. 8/26 (30.8%) patients reported a Grade 3-4 AEs, five of which were increases in alanine transaminase (ALT) as result of damage to the liver. Previously as a monotherapy, fruquintinib (plus best supportive care) in a Phase II trial in third-line NSCLC demonstrated median progression-free survival of 3.81 months vs 1.15 months for placebo (HR=0.275, $p<0.001$).

Exhibit 3: Financial summary

$000s	2014	2015	2016
December	US GAAP	US GAAP	US GAAP
PROFIT & LOSS			
Revenue	87,329	178,203	216,080
Cost of Sales	(58,849)	(110,777)	(156,328)
Gross Profit	28,480	67,426	59,752
Research and development	(29,914)	(47,368)	(66,871)
Other overheads	(16,825)	(29,829)	(39,578)
EBITDA	(16,994)	(7,756)	(44,264)
Operating Profit (before amort. and except.)	(18,259)	(9,771)	(46,697)
Intangible Amortization	0	0	0
Operating Profit	(18,259)	(9,771)	(46,697)
Net Interest	(957)	(953)	(1,129)
Exceptionals	0	0	0
Profit Before Tax (norm)	(19,957)	(10,540)	(47,356)
Profit Before Tax (reported)	(19,957)	(10,540)	(47,356)
Tax	(1,343)	(1,605)	(4,331)
Equity investments, after tax	15,180	22,572	66,244
Profit After Tax (norm)	(6,120)	10,427	14,557
Profit After Tax (reported)	(6,120)	10,427	14,557
Minority	(3,220)	(2,434)	(2,859)
Discontinued operations	2,034	0	0
Net profit (norm)	(9,340)	7,993	11,698
Net profit (reported)	(7,306)	7,993	11,698
Average Number of Shares Outstanding (m)	52.6	54.7	59.7
EPS - normalized (c)	(17.8)	14.6	19.6
EPS - normalized and fully diluted (c)	(17.8)	14.6	19.5
EPS - (reported) (c)	(13.9)	14.6	19.6
Average number of ADS outstanding (m)	105.1	109.3	119.4
Earnings per ADS - normalized ($)	(0.09)	0.07	0.10
Earnings per ADS ($)	(0.07)	0.07	0.10
BALANCE SHEET			
Fixed Assets	120,992	140,087	175,057
Intangible Assets	4,096	3,903	3,606
Tangible Assets	7,482	8,507	9,954
Investments	109,414	127,677	161,497
Current Assets	89,842	89,675	167,380
Stocks	4,405	9,555	12,822
Debtors	27,924	38,628	49,349
Cash	38,941	31,949	79,431
St investments	12,179	0	24,270
Other	6,393	9,543	1,508
Current Liabilities	(75,299)	(81,062)	(95,119)
Creditors	(20,427)	(24,086)	(35,538)
Short term borrowings	(26,282)	(23,077)	(19,957)
Other	(28,590)	(33,899)	(39,624)
Long Term Liabilities	(37,584)	(46,415)	(43,258)
Long term borrowings	(26,923)	(26,923)	(26,830)
Other long term liabilities	(10,661)	(19,492)	(16,428)
Net Assets	97,951	102,285	204,060
Minority	(17,764)	(18,921)	(19,790)
Shareholder equity	80,187	83,364	184,270
CASH FLOW			
Operating Cash Flow	8,359	(9,385)	(9,569)
Net Interest	0	0	0
Tax	0	0	0
Capex	(3,729)	(3,324)	(4,327)
Acquisitions/disposals	689	0	0
Dividends	(1,179)	(590)	(564)
Equity financing and capital movements	5,860	(1,676)	97,076
Other	(12,179)	12,179	(29,270)
Net Cash Flow	(2,179)	(2,796)	53,346
Opening net debt/(cash and ST investments)	4,645	2,085	18,051
Increase/(decrease) in ST investments	12,179	(12,179)	24,270
Other	(7,440)	(991)	(2,651)
Closing net debt/(cash and ST investments)	2,085	18,051	(56,914)

Source: Hutchison China MediTech reports, Edison Investment Research. Note: Equity investments after tax include the net profit contribution from JVs.

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