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HCM.L - Half Year 2018 Hutchison China MediTech Ltd Earnings Call

EVENT DATE/TIME: JULY 27, 2018 / 1:00PM GMT

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PRESENTATION

Operator

Hello, and welcome to the Chi-Med 2018 Half Year Financial Results Call. My name is Alicia, and I'll be your coordinator for today's event. (Operator Instructions) I will now hand over to your hosts, Mr. Christian Hogg; and Weiguo Su to begin today's conference. Thank you.

Christian Hogg - *Hutchison China MediTech Limited - CEO & Executive Director*

Okay. Thank you, Alicia, and thank you, everybody for joining. I intend to, kind of, go through the results presentation relatively quickly to give an update on the pipeline and where the business is at the moment. I'll try and do that in 30 minutes, maybe around that time and then open it up for questions from those on the line.

So if you saw it on Page 4 of the presentation, it's just the highlights slide. It just shows that everything continues to move along as planned. On the pipeline, fruquintinib, our VEGFR is a highly selective VEGFR inhibitor that's currently undergoing NDA -- the NDA process in China. I intend to give an update on that. But basically, everything is on track on that NDA process for colorectal cancer, and we expect to get approval sometime in the next few months, and hope to be able to launch in the second half of this year. I'll give more details about that later.

The second point under fruquintinib is we tend to release the top line results of our Phase III in third-line nonsmall cell lung cancer, probably in November. The study is a 527-patient study, it's fully enrolled in February. The date is now approaching full maturity. And so, I think, we're very much on track to publish those top lines in, sort of -- maybe October, November.

On breakthrough, under the section breakthrough, we talk about 4 global registration studies that are being planned, 2 of them are underway. The papillary renal cell carcinoma study for savolitinib. And the -- probably the news of this presentation is that we have been in dialogue with the Chinese regulatory authorities on our MET Exon 14-skipping study in nonsmall cell lung cancer, it's a Phase II, but it's progressed very well. We've engaged with the regulatory authorities, and they've now agreed with us a plan to use that Phase II study for submission, subject to continued levels of response that we've been seeing and getting up to around 50 patients. Currently, we're a little bit over 20 patients. So that's very exciting to see, potential -- almost accelerated approvals -- accelerated submission in MET Exon 14-skipping in China for us.

And then the 2 studies, the AstraZeneca planning with established enough Tagrisso studies, those are under planning and intend to start late this year and early next year, 2 different studies.

We have 7 registration studies that are currently underway and another 4 in late planning. So we have 11 shots at approvals. And we're hoping, to see 3 of our drugs approved over the next 3 years, that's our aim. And on top of that, 20-plus proof-of-concept studies on our 8 clinical drug candidates. And to help that -- and to help with the expansion -- the global expansion of these programs, we've now set up our new U.S. office to manage many of our clinical programs directly ourself. Our new Chief Medical Officer in the U.S. is a 25-year, Lilly, veteran in their oncology group, and we're ready to really get going there.

The discovery engine continues to produce. The team is now up to almost 400 scientists and staff. And Weiguo and the team are just very active in developing our pipeline of novel drug candidates, and we expect to see 1 or 2 per year coming out of our discovery organization over the next few years, as we've always had. The commercial team, to finish off, is -- has done very well this year. So far, the profit coming out of our commercial business has been very strong. And I'll talk you through that in a moment.

So Page 5, on a high level, in the first half, we invested about USD 67 million in our pipeline. You can see the Commercial Platform on -- chart on Page 5. The Commercial Platform net profit increased by 19% to $27 million after tax. So that was very encouraging. Sales were down a little bit, but they were down because of the Two-Invoice policy in China, which was a regulatory change by the government in China that has altered the way that we can account for the sales of our -- some of our third-party products, that's -- for example, Seroquel from AstraZeneca. Last year, we were able to report the sales of Seroquel under Chi-Med. This year, all we're able to do is report the service fees that we earn from detailing Seroquel across China. So more of a regulatory-driven change in the amount of sales that we can report. But as you can see, with the profits increasing, it's not affected our bottom line. I'll talk about that more later.

So moving on to Page 6. Just on a high level, the Innovation Platform, $67 million in investment in the pipeline. Slightly less revenue, we had a couple of milestones last year in 2017, 1 from Astro, 1 for Lilly. Our milestones in 2018 will be back-end loaded, the big milestone will be a $15 million milestone around the approval of fruquintinib in China. And just a general exhilaration in the growth of our clinical pipeline has led to the bigger investment. On the commercial side, as I've just said, net income up 19%, revenue's down because of the change in the way we report our third-party products.

Going on to Page 7. From a cash standpoint, we're on -- we're sitting on cash of $323 million, plus unutilized banking facilities of about $94 million. So around $417 million in available resources, so we're well positioned to fund our programs. And then, on the guidance. We try to give guidance to give people a sense of what to expect. The only change that we've made on our guidance, relative to what was published in March, is an increase in the R&D expenditures of about USD 20 million. So going from $110 million to $120 million, now up to $130 million to $140 million. And the reason for that is, frankly, a couple of things. First of all, we made a pretty significant share option grant to about 40, 45 people in our middle management team on the innovation side. The competition for talent and resources in China is very active. And we felt it important to ensure that these key people in our middle management organization in the R&D operation were well entrenched. So that was important. And that's about $7 million impact this year, $20 million overall over 3 or 4 years. And then, the inflation of cost of the clinical trial is pretty significant. There's a lot of interest in China these days. There's a great deal of investment going in. There's a lot of activity and that tends to bring costs up. But they still are a fraction of the costs of the United States or Europe.

So moving on to the pipeline on Page 9. This is just the 11 registration studies that we are either -- we either have underway or are in final planning on. You can see, savolitinib, the papillary renal cell carcinoma Phase III -- global Phase III, it's in 7 -- 6, 7 countries worldwide, running the study in about 60, 70 centers. And it's moving along nicely. We have a molecular epidemiology strategy, separate study that'll end -- that we'll read out later this year. It'll be an important study for us.

The 2 light pink studies on savolitinib are the 2 Tagrisso combo that AstraZeneca's planning for savolitinib and Tagrisso. And we'll talk more about them later, but they're progressing quite nicely.

The MET Exon14-deletion study was this new -- the fourth study on this Page 9. This started out as a single arm Phase II study in China. We started it about 12 months ago. It was intended to be a relatively small Phase II study, with around 20 patients in it. But we enrolled those 20-or-so patients and took the preliminary data to the China FDA about 2 months ago for dialogue. We shared the data with them and they agreed, that if we expanded the protocol to about 50 patients, and we're able to see a response rate of over 50% in that expended Phase II study that would be sufficient for a submission or approval. So that's what we are firmly focused on doing. And so, our small Phase II study has transformed now into a registration study. We're very excited about this and moving as quickly as we can. It's a important patient population. I'll share a bit more on that later.

Fruquintinib, the 3 Phase IIIs, I won't talk in more detail, other than to say, we're waiting on approval on colorectal, I'll talk more about that in a moment. The third-line nonsmall cell lung cancer, again, we'll report the top lines in probably October, November. And the second-line gastric-cancer

combo with paclitaxel is enrolling well and is underway, and we'll see an interim for proof-of-concept middle of next year. And that proof-of-concept interim will, if positive, trigger a $10 million milestone from Eli Lilly. So it's an important step mid-next year on that pivotal Phase III study.

The 2 Phase IIIs on sulfatinib, in neuroendocrine tumors are moving well. They will also have interim analysis in 2019. And in both cases, we are hopeful that subject to sufficient patient enrollment that if the signal is strong enough, there is an opportunity or a chance that we could stop those studies and submit them if we're -- if we see the levels of efficacy we saw in our Phase II. So that's -- those are moving and should reach a -- some kind of a readout next year, certainly around the interims.

The second new study on this list is a Phase III in biliary tract cancer on sulfatinib. We've completed -- not completed fully, but we've been enrolling a Phase II in China for the last year or so. We're encouraged by what we see. And we intend to start a Phase III in China around early next year. Very difficult patient population with -- in the second-line setting, median OS of just, sort of, 4 or 5 months. So we believe sulfatinib can really benefit these patients. And based on the Phase II data, it looks like that's the case.

Then, epitinib the Phase III in brain met nonsmall cell lung cancer patients, I'll talk more about that later. But it's a highly complex protocol that we're working on designing. It's almost ready and we're almost ready. Had a lot of regulatory discussion on epitinib, and we're almost ready to go.

So Page 10 is fruquintinib. You can see it's been a long, arduous process bringing fruquintinib through it's NDA submission and through all the inspections and the various parts of the process. We're now, really, at the end of it. Our PAI -- preapproval inspection, in our GMP manufacturing facility in Suzhou as well as at our API manufacturer in Shanghai, have both concluded the samples from those GMP inspections have been sent off for analysis. Those analyses are complete. All the products meet specifications. So pretty much the whole inspection and the whole NDA validation process is now complete. So we now await the CFDI to hand off the dossier with all of the inspection reports to the CDE. At, which point, they'll review it. And hopefully, we will reach our approval. We're hoping that can happen in Q3, late Q3 maybe. And if that's the case, we should be able to launch in 2018. So this would be an enormous achievement for the company and be the first time a Chinese company has taken an asset from discovery, all the way through to CFDA approval in a mainstream oncology indication. So we will be extremely proud of that when that happens.

Page 11. Just shows that fruquintinib is more than just a CRC, the colorectal cancer approval. In nonsmall cell lung cancer, great Phase II data in terms of median PFS. The Phase III is now mature and you're -- closing in on maturity and we'll report it late this year, as I said. Gastric cancer, that Phase III, the interim, also as I've said, planned for the middle of next year and likely to trigger a milestone if it's positive. And then the global expansion. Now -- we're now setting up the organization in the U.S. to start developing fruquintinib outside of China. We're going to start looking at I/O combinations on fruquintinib. I think that's the area of most opportunity and I will talk more about that in a moment. Actually, we'll talk about it now.

So going on Page 12. Looking at the VEGFR landscape, you can see it's an $18 billion category, probably the largest targeted therapy category that exists today. You got VEGFR inhibitors, whether they're monoclonal antibodies or the small molecules approved in about 20 -- sorry, 30 different solid tumor types. So cutting off the blood flow to the tumor is just really important. And we believe that fruquintinib is best-in-class, in terms of selectivity and it's ability to hit the target without hitting off-target kinases. So that should give us a big advantage in the context of combination.

On Page 13, you can see what makes everybody so excited about VEGFR and PD-1 combinations. Axitinib in first-line clear cell renal cell carcinoma, delivers an objective response rate of about 34%. Pembrolizumab, the level is about 38% in the same patient population. So both very effective monotherapies. But when you put the 2 together, you get the third block, the axitinib and pembrolizumab combination in first-line clear cell renal cell carcinoma. And you see 73% ORR and a complete response of 8%. That Breakthrough Therapy -- it was -- it achieved Breakthrough Therapy designation from the U.S. FDA. That's the power of a VEGFR inhibitor plus a PD-1. And so, we're quite excited about this and are moving very rapidly.

If you go to Page 14, you can see why we're excited. On this chart, which lays out 6 or so of the main, approved small molecule VEGFR inhibitors, you can see that they're all multi-kinase inhibitors, hitting VEGFR but they hit a multitude of other kinase targets. Whereas, fruquintinib, at the -- on the far right of this chart, really just hits VEGFR 1, 2 and 3 and nothing else. So that selectivity gives it great combined ability. And a lot lower off-target toxicity. Sulfatinib , our second VEGFR inhibitor is attractive for combinations with PD-1s for a different reason. And that being, it's inhibition of CSF 1R and the inhibition of tumor-associated macrophage production. So allowing the PD-1 to induce immuno response more

efficiently. So in both cases, we intend to collaborate with PD-1 players to bring these assets into combinations globally as well as in China, where there exist many, many opportunities.

So moving on to savolitinib. Just to give a brief update, Page 15, we don't need to talk other than to say savolitinib is just a really selective MET inhibitor, and MET is very important in many different solid tumor types. The biggest and most important is on Page 16, is lung cancer. This is a chart that we've presented many times, it's just a really important chart for us, showing how MET is relevant in the first-line setting. It becomes a bigger resistance pathway to VEGFR inhibitors in the second-line setting and now, is proving to be probably the major pathway resistance to Tagrisso in second, and now it's for -- it's being used in first-line setting. So Tagrisso, they just -- Astra just published their data -- their results yesterday for the first half. USD 760 million in sales in the first half of the year, so on track for $1.5 billion. That's just its third year -- second or third year of sale. So being the right partner for Tagrisso, post-Tagrisso failure is a big opportunity for savolitinib.

Looking at Page 17, you can see just some visuals of efficacy of savolitinib in these patient populations, first-, second-, and third-line patient populations. I think the most startling efficacy is in the first line there, in this Exon 14-skipping patient, and you can see a 9-centimeter diameter tumor in the lung, after almost a year on savolitinib monotherapy reduced in size dramatically. So it's 70% tumor shrinkage. And also, you can see the tumor on the brain there on that picture on Page 17 is just 112 days, it's totally gone. So it's a highly effective drug in -- or drug candidate in MET-driven patient populations, whether that's first, second or third line, and we are now pushing very hard in all of these lines of treatment.

Page 18 summarizes what I've already said in that target patient population number 7, the pink patient population post Tagrisso, that global study will start up. Astra is starting it and it'll start up late in this year. In the orange patient population TPP 6, this is savo plus Tagrisso in Iressa/Tarceva refractory patients. This is where we've seen in the TATTON study, a 61% response rate. And we are likely to walk down the Breakthrough Therapy designation pathway on this one to engage in dialogue on it, with the U.S. FDA, and that's to be determined shortly. And Astra is committed to starting a global study in this orange patient population, the post-Iressa/Tarceva MET positive patient -- MET positive T790M negative patient population earlier next year. And then, TPP 10 is the Exon 14-skipping patient population, where -- our Phase II right now is now being converted into -- with a protocol adjustment -- amendment, it's been converted into a registration intent Phase II. So that's what's happening in lung, very aggressive.

Page 19, though. It shows that -- so savolitinib it's not just about lung cancer. We've had very promising efficacy in gastric cancer and kidney cancer, obviously, with the papillary renal cell carcinoma Phase II. But in gastric cancer, the chart in the bottom left of Page 19, you can see, MET positive, MET-gene amplified gastric cancer, the median overall survival is less than 2 years, whereas, for MET negative, the median overall survival is over 10 years. So this is a gastric -- I mean sorry, MET-gene amplification in gastric cancer, it's just a terrible thing. And what we see in the picture here, in the PET/CT scan, is just what savolitinib can do for these type of patients. So the point being of this chart is that lung cancer isn't all we're doing. We're working very rapidly in gastric and kidney cancer. In gastric cancer, the victory study from South Korea, it's an IT -- it's an investigator-led study that will potentially publish later next year sometime. And we've seen super efficacy in gastric cancer. So we'll be looking to see what we do globally on gastric.

Page 20, just a brief update on sulfatinib. The top box is the 2 big Phase IIIs, the SANET-p and SANET-ep, the neuroendocrine tu pancreatic NET and non-pancreatic NET studies with the interim analyses next year, in 2019. These have been slow enrolling studies. It's been a hard work, but we're getting there. And we're hopeful that these interim analyses will yield a positive outcome.

On the bottom left, biliary tract cancer. The Phase II has been encouraging. And we start -- we'll start the Phase III in China early '19. And then, on the bottom right, the U.S. development for sulfatinib is now started to expand. So we began a Phase Ib/II study in pancreatic NET and biliary tract cancer in the U.S. a few -- a week ago, and we announced that. So sulfatinib is the first drug candidate and we've taken through proof-of-concept in China and now are developing ourselves in the United States, which is encouraging.

Page 21, a brief update on epitinib. The brain-penetrating EGFR inhibitor, no doubt about efficacy in the brain. We've already presented data at the World Conference on Lung Cancer showing 68% ORR in the lungs, 70% in measurable brain lesions. This is world-class efficacy in the brain, safe and well tolerated. So we're ready to go from a -- from an efficacy standpoint, but box number 2 explains why it's been taking us a while. Designing this protocol for this Phase III is not easy. It's required a lot of interaction with the CDE and our principal investigators. You can see the visuals on the right-hand side of the chart here. The 2 scans. To just give an indication of the differences in brain METs. I mean, the top picture is a

-- sort of a start in the stars in the sky brain metastasis. A lot of small brain METs across the brain. This is generally asymptomatic, very challenging to evaluate, can be very slow to PD. Whereas in the picture in the CT scan in the bottom, you can see a much larger lesion, over 10 millimeters, it's measurable under RECIST. Generally, they progress faster and often they're symptomatic. So as we design this Phase III, we've got to be very careful in how we define the patient population. And also we've got to be very clear, what is it we're trying to do? Are we trying to establish the statistical significance as far as intracranial PFS or overall PFS? And that's been the subject of all our dialogue with the regulatory authorities, as we've put this protocol together. I think we're now very close and we're almost ready to proceed. So that's exciting to us.

Page 22, is the Syk inhibitor. So we've completed dose escalation in both China and Australia. It's -- there have been big dose escalation studies because we started at very low doses. We covered 13 different dose cohorts. We've had 60 patients. And those 2 studies have been treated and dosed. In some cases the patients in the early cohorts, call it, 100 milligrams, were allowed to trade up to higher doses as time went by. So we've got a lot of data on these 60 patients. And we plan to present that data at ASH in 2018. So I think that's early December.

Meanwhile, we've started the dose expansion and it's a big dose expansion. It's now enrolling in both Australia and China. And you can see, 192 patients are intended to be treated in those dose expansion studies. So big dose expansion study in many different hematological malignancy subtypes. So I think the Syk inhibitor is now getting to a point, where we're very -- we're keen to just build that data set and get it out there, so people can understand how good a drug this has the potential to be.

Page 24, 25, I won't go through it all again. But on Page 24, we see a lot of activity, late-stage clinical activity.

Page 25, theliatinib continues to go in its Phase Ib expansion in esophageal cancer. Extremely difficult patient population, those EGFR wild-type patients. So we're seeing modest efficacy, I think, in general. We're still positive and we'll continue to expand that study. 689, our PI3K delta compound is in -- it's in early development, dose escalation. But we are very excited about 689. So we continue to work that rapidly in -- primarily in China. And really look forward to the potential for combinations with our Syk inhibitor or even use in monotherapy in many indications. Our FGFR inhibitors that had some challenges of late in Australia. We've encountered some very much FGFR target-related toxicities that have been common across many other FGFR inhibitors. We've seen them in Australia. They're not life threatening, but they're sufficiently serious that we've chosen to hold on Australia and stop that Phase I escalation. But we're not seeing the same level of toxicities in China. Chinese patients appear to be quite different than Australian patients in this context. So we continue to enroll in China. We have put in very strict monitoring around that toxicity to ensure patient safety. But what we're seeing is room to explore at lower dose levels, where there's no sign of these toxicities and where we are already seeing encouraging signs of efficacy. So we'll continue that.

So overall, on Page 25, you see, we've dosed over 4,000 patients now in all our studies and over 400 in the first half of the year. And that is the reason for the higher burn on R&D spend.

Page 26, very briefly, the sort of major targets and news flow for the next, call it, 6 to 9 months. The startup of the savolitinib studies with Tagrisso. 2 of them, 1 at the end of this year, 1 early next year. The molecular epidemiology study early -- sorry, late this year. Fruquintinib approval and launch late this year. The top lines for the Phase III in lung cancer late this year. Also late this year will be the start of the Phase III on epitinib. Early next year will be the sulfatinib Phase III and biliary tract cancer. And then, the data coming from our Phase I dose escalations on the Syk inhibitor and the PI3K delta, they'll play out -- well the Syk inhibitor will be at ASH in December and then PI3K delta will be later, probably, early next year. So we're very positive and moving quite rapidly.

On China, the commercial business, Page 27 -- 28 rather, you can see, we've had a great first half in China, while the number shown on the chart in the bottom left of Page 28 shows total sales of our joint ventures and our subsidiaries, a $360 million in the first half, we obviously don't consolidate all of that. I think only about $80 million or $88 million is consolidated. The rest of it -- the sales of our JVs are not consolidated in our top line. But the scale of our business is large and doing well.

On the Commercial Platform, what we do consolidate is the net income. And you can see the net income has grown -- over the last 11 years, it's grown 37% compound annually to last year, full year was $38 million. This first half of this year was $27 million, up 19% versus last year. So the commercial business, generally, generating a lot of cash.

Page 29 just shows the results of some of our activities on third-party products, but we now are no longer able to report in our top lines, we're only allowed to report the fees that we earn from detailing these drugs in China, exclusively. So Seroquel, had a great first half on Seroquel, up 36% in terms of sales. Our service fees increased from $5.5 million last year to $9.6 million in the first half of this year. Our targets have continued to retain the exclusive rights on Seroquel. So this year, it would be 22%. So in the first half, we did 36%. So we're, obviously, pretty encouraged by that and are hopeful that we'll be able to retain the rights on Seroquel for some years to come, despite the fact that AstraZeneca has sold Seroquel to a local company in China called Luye. So we expect that should make no difference to us, subject to us continuing to deliver against our sales targets, we will continue, contractually, to retain the rights to commercialize Seroquel all the way through 2025.

Concor is another great example in Merck Serono's beta blocker, we've done very well here. Sales up 25% in the territories that we market Concor in, and our service fees up a 100% from USD 1.1 million to USD 1.2 million. So I'll leave it there. That's about 35 minutes. I've covered the pipeline. I've covered a high-level look at what's going on in the commercial business. Basically, Chi-Med today is very active. We're working on a lot of deals. We're working closely with Astro, with Lilly on our collaborations. And the deals that we're working on and looking at are in the context of potential combinations with PD-1s and fruquintinib and sulfatinib. And I think, as company, we're very positive. It's been a good half year, and we're very excited about the second half of the year. So on that, I'll open it up for questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) We have a guest in the queue by the name of Ying Huang from Bank of America.

Ying Huang - *BofA Merrill Lynch, Research Division - Director in Equity Research*

First one on the Chinese drug administration approval process for fruquintinib in third-line colorectal cancer. Can you just tell us, besides the API and also the manufacturing plant in Suzhou, what else is the Chinese side agency looking at before the final approval? What other procedures or gating factors are here? And then, secondly, can you provide a little bit clarity on TATTON B data? I suppose we're expecting maybe some presentation or publication by AstraZeneca in the second half, so we can see the data, even though, they plan to start the trial soon. And then, maybe lastly on the guidance, if we follow your guidance, you're expecting a pretty significant drop in the second half for revenue. Is that completely due to the accounting change for the so-called, Two-Invoice System?

Christian Hogg - *Hutchison China MediTech Limited - CEO & Executive Director*

Thanks, Ying, thanks. Yes, good questions. So your first question on the CNDA process for third-line colorectal cancer. I mean, it's incorporated everything. It's been a massive, massive program of analytical work on the API and the drug product, both clinical supply as well as now the product of our GMP inspections to the commercial supply. There have been deep technical reviews of all the clinical data, the stats, the pharmacology, the talks, the CMC by the CDE. The CFDI, the inspection unit has done deep clinical data inspections at a handful of the 28 sites that we conducted the study in, sending their inspectors to these sites. And literally, going down, picking -- each site of the 28 sites, we did probably 20 patients per site, roughly. So the inspectors would go into these sites, they would pick maybe 5 of the patients and they would go down and study absolutely every piece of documentation around that patient, from the start of when they first visited the hospital to the end of their treatment and follow-up. So it's been an amazing process. It's totally occupied us as a company for the last 12 months. I can't see small biotech companies being able to manage and navigate this process, it's enormous. But yes, we're almost there, it's almost complete. All the work's done from our side now. So now, it's really, the ball is in the court of the regulatory authorities to assess everything and make their decision. I know -- I think, we're very hopeful that should be concluded in the next month or 2 or 3 months probably. TATTON B, publishing more data. I think you're probably -- you're talking about what's the PFS -- more mature PFS data from TATTON B. I quite like for the data to be presented. Ultimately, it's AstraZeneca that, kind of, holds the control of that. It's positive. I mean that -- the PFS data is pretty encouraging and particularly in patients that have not been through multiple rounds of chemotherapy. Real true target patient populations, patients that have been first-line treat EGFR mutation-positive patients treated with Iressa/Tarceva failed, then go on to the Tagrisso/Savo combination. Those patients' PFS is very encouraging. Patients that have been on 5 or 6 lines of chemo and

EGFR inhibitors, they tend to have much short PFS, because they're much sicker patients, but I can't guarantee or tell you when they're going to publish it. But I would imagine, it would be in due course of the -- maybe ASCO next year or maybe before that if they decide. But we're pushing for it. But hopefully, they'll decide to do that, maybe Asma might, I don't know. But they are definitely at the moment focused on the -- getting ready for these -- the next phase of development of these Tagrisso combinations. And these studies, these Phase II -- they'll start off as Phase II studies, because we haven't had the full regulatory dialogue yet. But these Phase II studies will be designed in a manner, they're like our Exon 14 study, it may start as a Phase II, but subject to regulatory discussion there would be a great hope that they would be turned into regulatory studies along the way. On the guidance, I think what you mean is, because we've done very well on the -- I think you're talking about the Commercial Platform. Because we've done very well in the Commercial Platform in the first half, why haven't we taken our guidance up on the Commercial Platform? If that's the basis of your question, it's a good question because based on that, you would assume that you would take your guidance up pretty significantly having over delivered by so much in the first half. The reason we haven't done it is because of the uncertainty around the RMB-U. S. dollar exchange rate, which is being driven to some extent by all of this trade war rhetoric between the U.S. and China. You've seen the RMB weaken pretty significantly over the last couple of months to the tune of, sort of, 6%, 7% -- 5%, 6%, 7% just in a month. So I think with that uncertainty, if -- because obviously, all of our profits and revenues are in local currency -- Chinese local currency. If the local currency devalues because of all of these external factors then that would put pressure on our reported results in U.S. dollars. So I think the reason we didn't change it is because we felt that, that was an uncertainty, and there's no point in changing it to change it back because the RMB has weakened over the second half of the year. That was the reason we didn't change it. But I think the basic fact is, the first half has been terrific and all being equal, foreign exchange and all of that, then certainly we would do better in -- is in -- than our guidance. I hope that answers your question.

Ying Huang - *BofA Merrill Lynch, Research Division - Director in Equity Research*

Yes. Just a follow-up, one is on the TATTON trial protocol. Did Astra figure out the dosing regimen? Because there was some overlapping toxicity between the different molecules.

Christian Hogg - *Hutchison China MediTech Limited - CEO & Executive Director*

Yes. that's a -- Yes, it's a good question. So there has been great progress in that area. We were doing 2 things, the first thing is we were looking at a weight-based algorithm of 600 milligrams QD for patients over 50 kilos and 300 milligrams for patients under 50 kilos. I think AstraZeneca is now at a point that they feel very comfortable with that weight-based algorithm. And In fact, for the first study that will kickoff, which will be the savolitinib plus Tagrisso -- post-Tagrisso failure. So either in second line or third line, we'll go without weight-based algorithm, and we're just charging ahead with that. But separately, we have been enrolling patients into TATTON C, 300 milligram QD dose. And we're building a data set there and it looks encouraging. So where we end up -- I think as we built all this data set, it's just about, sort of, pulling as much information together so that when we do go talk to the -- or when Astra goes and talk to the U.S. FDA about the regulatory pathway, they've got all of the answers to all the questions that the U.S. FDA might ask them. But I think at the end of the day, they're quite happy with the weight-based algorithm as a sort of a starting point. And as we get more of this 300-milligram QD data playing out, that will probably just give us even more comfort about -- that treating patients under 50 kilos with 300 milligrams is more than enough and help us in any dialogue with the U.S. FDA.

Ying Huang - *BofA Merrill Lynch, Research Division - Director in Equity Research*

Great. Just lastly, I presume you did not include any potential revenue from fruquintinib in milestone into the guidance, right?

Christian Hogg - *Hutchison China MediTech Limited - CEO & Executive Director*

Well, there's already in the guidance. There's already a $15 million, well it's actually $14.5 million because of exchange rate milestone for approval on fruquintinib. So in our guidance for the Innovation Platform, we have $50 million to -- sorry USD 40 million to USD 50 million of revenue. Of that, about $15 million of it is that approval milestone. So it's in there.

Operator

The next question comes from the line of Tom Shrader calling in from BTIG.

Thomas Shrader

Fruquintinib, can you talk a little bit about reimbursement? Is that a high priority? I know there are price caps in China, did they make it not worth pursuing? Just how that would rollout? And maybe some sense of time line if you would.

Christian Hogg - *Hutchison China MediTech Limited - CEO & Executive Director*

Yes. So the way it works in China is that we will launch out-of-pocket. So patients will pay out-of-pocket. And so the price will be probably on the slightly higher side where we would want to be. But that said, we would then engage immediately or actually Lilly and Chi-Med together, would engage in discussion around inclusion in a national drug reimbursement list and catalog and talk to the regulatory authorities around how can we get on to that list as quickly as possible. Now the good thing is, the Chinese government has made a lot of progress in recent years in adding targeted therapies in oncology drugs to the national drug reimbursement list. And so, we expect that -- hopefully, that process to go quite quickly. Historically, those reviews of that list have been actually every 5 years, and now they've changed to every 2 years, and now there's even talk of it changing every year. So I think for sure, we'll launch out-of-pocket and then, we will engage pretty much immediately or as quickly as possible on negotiation around trying to get onto the national reimbursement list. It's still a bit early to be able to know what getting on that list means. You would assume that getting on the reimbursement list would mean a broader patient population would have access to your drug, and that's true, it is. But there are caps and there are limits as to how much reimbursement is actually given. So we will have to watch closely what's going on in the market with some of the cancer drugs that have been put on the list last year, last July. We should start to see data as far as what that's done for those businesses. And spreading the use of these drugs and then we'll be able to assess our own views on what we want to do basically. But all is basically on track, in that sense.

Thomas Shrader

And just to clarify the caps are total reimbursement or a price cap?

Christian Hogg - *Hutchison China MediTech Limited - CEO & Executive Director*

No. It's not price cap, it's total reimbursement. So for example, if you're a patient on bevacizumab. Bevacizumab still in China is, even after negotiation of a price reduction of around 30-odd percent to get onto the reimbursement list, bevacizumab is still around USD 4,000 a cycle, so it's a lot of money. And so, patients are not going to get an open-ended endless supply of bevacizumab paid for by the Chinese government or the reimbursement scheme or their national medical insurance scheme. What they'll do depending on their status, depending on their sort of position within the reimbursement scheme, and that depends on how much that company that employs them has put into the scheme and et cetera, is they'll be given a -- an annual cap of funds that can be used for reimbursement of drugs for these patients. It also depends how much they use last year versus this year et cetera. And so, you may find there's a cap of USD 10,000 or USD 15,000 for a particular patient. And so, that would be able to allow them to be treated for 3 or 4 cycles, but then beyond that, they'd have to pay themselves. Then the next year, they probably get another pool of money that they would be able to access. So I think that's more likely to be the status. The pricing is -- frankly, the pricing today in China is set by the company. Now, if you set it too high, you're never going to get on the national reimbursement (inaudible). But likewise, if you are not intending to get a national reimbursement, then pricing is at your discretion.

Thomas Shrader

Okay, on epitinib. It seems like interest has increased in that drug on your side. I think there were some worries that Tagrisso had very good blood-brain barrier penetration, what's changed?

Christian Hogg - *Hutchison China MediTech Limited - CEO & Executive Director*

Actually, the reason for more of a highlight in this presentation on epitinib is we've always had faith in epitinib. It's a terrific drug that -- a drug candidate that clearly delivers benefit intracranial to patients, so we've always felt strongly. But the reason we highlighted a bit more in this presentation is because we've been working really hard on this Phase III protocol with the regulatory authorities, with CDE as well as with our principal investigators and it is really complex. I mean you've got a changing EGFR landscape, you've got a very complex patient population for brain METs. As I said earlier, some of them are progressing quite quickly, some of them are progressing very slowly, so the design of this protocol, it's taken a lot of effort and I just wanted to -- I felt that if we just came and said what we said last time, well, we're working on and hoping to try and start this study at the end of the year, there would be a little understanding of the scale of effort that is going into this, and it's material . We are very hopeful on epitinib, but we've got to get sign right or else it will be a fruitless effort.

Thomas Shrader

Okay. And then finally savo. This Exon 14-skipping mutation you've started to talk about, can you give us a sense of the size of that market? And is it constant with the west and China? Or is this a mutation you see a lot in China? Or in the U.S.? Just -- what's the opportunity here?

Christian Hogg - *Hutchison China MediTech Limited - CEO & Executive Director*

Yes I -- maybe I'll let Weiguo answer that question. Weiguo, you're on the line, right?

Weiguo Su - *Hutchison China MediTech Limited - Chief Scientific Officer, Executive VP & Executive Director*

Yes. I am. Sure. Well, basically, there are -- I'm thinking in terms of incidents for this particular molecular driver, it's similar to maybe a bit higher than RAS1. So typically, it's around, I will say, 2% to 3% of the nonsmall cell lung cancer. The difference though is that it is -- it can also be detected in squamous as well. So basically, in terms of the patient population size, it's not that big. It's somewhere between RAS1 mutation or RAS1 fusion and ALK. So it's in their range but in addition to Exon 14, as a matter of fact, there is also pure amplification as well. That's why you see 6% there, but what we are targeting is this for this particular trial is the Exon 14-skipping, which is about 3% and then, there could be another 3% in MET amplification, which will get on to in the future. So in the first-line setting, monotherapy targeting these genetic alterations could be a total of about 5% to 6%, which is similar to ALK fusion.

Operator

We have no further questions in the queue. So I'll hand back to your hosts for any concluding remarks.

Christian Hogg - *Hutchison China MediTech Limited - CEO & Executive Director*

Okay, thanks. Yes, no concluding remarks other than to say thanks for joining the call, and we're really looking forward to the second half. I think it'll be a big second half for us and look forward to seeing you all in person along the way. Thanks very much.

Operator

Thank you for joining today's conference. You may now disconnect your lines.