Company: Kazia Therapeutics Limited
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Start of Transcript

Operator: Thank you for standing by and welcome to Kazia Therapeutics Limited New Asset Investor Conference Call. All participants are in a listen-only mode. There will be a presentation, followed by a question-and-answer session. If you wish to ask a question, you will need to press the star key followed by the number one on your telephone keypad. I would now like to hand the conference over to Doctor James Garner, Kazia CEO. Please go ahead.

Doctor James Garner: Ladies and gentlemen, good morning and good afternoon. Thank you very much indeed for making the time to join this Investor Conference Call. As you've heard, I'm James Garner, I'm a Chief Executive Officer of Kazia Therapeutics.

In the usual way, I'd like to make some introductory remarks here and then we'll open to questions. We do have a lot of attendees so I would encourage anybody with a question to please put your hand up early and get into the queue as quickly as possible.

As you'll be aware, we've announced a worldwide in-licensing transaction with Evotec SE, a leading European drug discovery and development company for EVT801, a small molecule inhibitor, a vascular endothelial growth factor receptor 3, which I will greatly refer to as VEGFR3 for the rest of the call. We intend to develop the drug for multiple solid tumours and our plan is to commence a phase 1 clinical trial, a so-called first-in-human trial, by the end of this year.

I won't take everybody's time by recapitulating all the details of our press release. There is a wealth of information in that release and on the Company website, which incidentally has been rebuilt concurrently with this transaction. However, I did want to take a few minutes to provide some context on the strategic rationale for this transaction. One may reasonably ask why we have chosen to bring in a new drug when we have enjoyed so much success with paxalisib.

The answer in a word is diversification. In general, investors are obliged to assign a substantial risk discount to any company whose fortunes depend on a single asset, no matter how promising that asset may be. Until now, Kazia has presented in the vernacular of portfolio management, a binary risk profile. We succeed or we fail and there are few intermediate outcomes. We've done everything possible to mitigate that reality.

We've carefully de-risked paxalisib in a phase 2 trial and we've deployed a very broad program of studies in other forms of brain cancer and these efforts have been very successful. Nevertheless, we remain vulnerable to the accusation of being a one-trick-pony. Now we have two thoroughbreds in the stable and the difference that makes to Kazia is both subtle and utterly transformative.

We're no longer subject to the all or nothing economics that characterises many drug development companies. On the contrary, we now have a genuine portfolio of first-class drug candidates. That makes us a very different kind of biotech company and one which we hope will have the potential to provide a very much more substantial return to our investors.

The addition of EVT801 to our portfolio also provides scale to our business. To really achieve our potential, we need to develop capabilities, relationships, resources, networks and a reputation and these things exceed the scope of any single drug candidate. Now that we have a genuine diversified portfolio, it provides critical mass to Kazia. It provides a

richer set of opportunities to engage with clinicians, researchers, partners and so this transaction is not merely an addition to the Kazia pipeline, it also propels Kazia itself into a much higher orbit. I want to be absolutely clear that this transaction does not reflect any change in focus for paxalisib. That remains our lead program, currently in a pivotal study for registration and our absolute highest priority.

EVT801 is entirely additive to our business. It's not in any sense a substitution or a back-up. Much of what you hear from us over the coming months will continue to be about paxalisib but we will increasingly be able to weave into that a second storyline for EVT801. Perhaps that's a good moment to make a few comments about EVT801 itself and to begin to explain some of what we saw in the drug.

Over the last few years, we've reviewed perhaps several dozen potential opportunities to expand Kazia's pipeline. Quite simply, none of them met the bar that had been set by paxalisib. EVT801 is the first drug candidate we've seen that met every criteria on our wishlist, and then some. The preclinical work done by the Evotec team is outstanding and the data is extremely exciting. We'll be looking to publish on this in a peer review journal in coming months. For the time being, I'll simply say that this is the first drug we've seen which deserved to stand alongside paxalisib in our portfolio.

To be clear, EVT801 is not a brain cancer drug and we don't see this merely as an adjunct to paxalisib. It is an entirely new and distinct program and it has potential applications in many solid tumours. The fundamental mechanism of the drug is to modify the formation of new blood vessels and lymphatic vessels around the tumour. That's well understood and well validated science but of course the titan in this class is Avastin bevacizumab, a drug worth US$7 billion in annual sales, some 15 years after its launch.

But EVT801 brings something new to that story. It's one of the first drugs that is able to very selectively inhibit the formation of lymphatic vessels by specifically targeting the receptor the VEGFR3. We expect that specificity to counter many of the problems of drug resistance seen with other drugs in this class and to result in a much more favourable side effect profile.

We also see very high potential for immunotherapy combination and this is something we intend to explore right from the outset in the phase 1 study. Just as paxalisib brought something new, brain penetration, to a well proven class of drugs, PI3K inhibitors, so EVT801 brings something new, the VEGFR3 specificity to the very well proven class of drugs, angiogenesis inhibitors.

In addition to the licensing deal, we've also entered into a Master Services Agreement with Evotec, whereby we will engage with them for certain tasks in the ongoing development of the drug, under Kazia's overarching direction. Evotec's business is to help other companies develop their drug candidates and they are exceptionally good at it. Kazia's business is to design and oversee development programs, but we don't have substantial in-house resources to execute them.

So, this is in a sense a perfect match and additionally, it gives us ongoing access to a brilliant team of scientists, who have been living and breathing EVT801 for the last several years. This is a very novel partnership; it is ground-breaking in its own way as the drug itself and we think it provides a terrific framework in which to take the drug forward.

I'll just say two more things in conclusion and then we can open for questions. First, I want to emphasise that this has always been the vision for Kazia. When we set out to build the Company some four or five years ago, we always envisaged a portfolio of assets at different stages of development. Our first drug, paxalisib, was so rich in potential and promise that it's kept us busy for the last few years. But we never lost sight of those founding ambitions. Everything we've done to date, including the whirlwind of licensing transactions in the last few months, is entirely consistent with our - with what we set out to do at the beginning of everything.

Second, there will be those who had begun to think of us as a brain cancer company and who are now surprised and perhaps even confronted by the fact that we've become something very much larger. I can appreciate this may be disorientating but in reality, despite this period of rapid evolution, our Company remains the same in the only respects that matter. We want to take the very best drug candidates we can find, develop them in the most innovative and imaginative way that we can in order to make the biggest difference we can in the lives of patients with cancer.

That was our goal with paxalisib, that's our goal with EVT801. That hasn't changed and that will not change. This is chapter two in the Kazia story and we're grateful as always for the support and engagement of each and every one of our investors as this remarkable journey continues to unfold. I'll now open for questions.

Operator: Thank you. If you wish to ask a question, please press star one on your telephone and wait for your name to be announced. If you wish to cancel your request, please press star two. If you're on a speakerphone, please pick up your handset to ask your question. Your first question comes from Sean Lee from HC Wainwright. Please go ahead.

Sean Lee: (HC Wainwright, Analyst) Good morning James, thanks for taking my questions. My first question is on the upcoming clinical study as you mentioned. You guys expect to explore the combination of EVT801 together with the immuno-oncology therapies. I was wondering, what's the rationale behind using them in combination? Are there are any ones that you're looking - any one specifically that you're looking to combine EVT801 with and are you looking to form additional development partnerships to codevelop these drugs?

Doctor James Garner: Thank you, Sean and good afternoon, it's great to talk to you. In terms of the phase 1 study, I think we're still nailing down the study design. It will undoubtedly have a monotherapy element as most first-in-human studies do, but we are also very keen to explore immunotherapy combination. The basis for this interest is actually very data driven.

One of the things that's been very interesting in the preclinical data is that administering EVT801 produces clear changes in the T-cell population in an around the tumour. It has a very clear effect on the tumour immune microenvironment. The exact mechanism for this is not entirely clear but it's something that has been seen with other agents with related mechanisms. It does seem very consistent and reproduceable, so this drug potentially has the effect of, if you like, rendering cold tumours hot. It causes an infiltration of active immune cells and equally dials down some of those suppressive myeloid type cells.

So, this is something we're really keen to understand. The exact combination or combinations that we look at and exactly the population we put this in is something we're still fine tuning. We probably lean more towards PD1 combinations than CTL-A4 combinations, so in other words, pembrolizumab, nivolumab, atezolizumab, more than [say adalimumab]. But I think that that's - it's fair to say this is something we're still fine tuning, so we're really looking to see if this very consistent preclinical signal is replicated in the human context, and I think that will be quite exciting data if it is.

Sean Lee: (HC Wainwright, Analyst) Thanks, James, that was helpful. My last question is on the upcoming phase 1 studies. You mentioned - are there any specific indications that you guys are looking to? Because I know in the preclinical work, this was looking to liver cells - liver tumour cells, I think and there has been previous work in lung cancer cells, as well. Any thoughts on that?

Doctor James Garner: Sean, this is again something we're still fine tuning, almost as we speak. The potential applicability of the drug is broad and the general approach for first-in-human cancer studies is to deploy the drug in a population of patients with advanced solid tumours. We tend to go quite broad in these studies, partly for practical reasons and partly to give us the broadest reach of patients.

What we will likely do in the study, however, is to also focus on a couple of expansion cohorts, looking at particular tumour types. A couple that we've already flagged to people are [planocellular] carcinoma, liver cancer and renal cell

carcinomic kidney cancer. The reason for these is that these are both tumours which are associated with quite a high level of VEGFR3 expression. So, they provide a very good place to look for proof of mechanism for a drug like this. It's a very good opportunity for us to really see how the drug works in the human context.

They may or may not be the right commercial indications, and to be honest, it's not clear exactly how much difference the level of VEGFR3 expression is going to make in terms of defining the population [here]. We found with paxalisib, for instance, that at least in primary brain cancer, PI3K activation is not a particularly strong marker of response. The drug seems to work quite well in "PI3K" wild-type patients, so we may find the same here. But it's a good place to look for these pharmacodynamic markers and to really test out the mechanism.

Sean Lee: (WC Wainwright, Analyst) Yes, thank you. That's all I have.

Doctor James Garner: Thank you, Sean.

Operator: Thank you. Your next question comes from Rebecca Harding from [Twinings] Asset Management. Please go ahead.

Rebecca Harding: (Twinings Asset Management, Analyst) Thank you and congratulations, James on what looks like a really interesting transaction. I guess two questions for me. One was just looking at share price reaction with Nasdaq overnight, it's obviously off slightly, so was just wondering if you could make some comments on that. Then the follow up question for me is about news flow and how you see that panning out for this new asset over the next say six to 12 months.

Doctor James Garner: Thanks, Rebecca, thank you so much. First of all, on the first question you raised, clearly, we always prefer to see the share price go up each day rather than otherwise. However, this is a complex story; this is something that's going to take a little while for investors to get to grips with. This has really added something very substantial to the Company and that's more than a 12-hour process for the market to digest and value and interpret. So, I think there's no real surprise that there was perhaps a hesitant initial reaction.

Our focus has always been on building long-term shareholder value in Kazia. We've never been really focused on just the day-to-day ups and downs that the rollercoaster of life in a biotech company. We've really been about building sustainable value in the business; our share price has quadrupled in the last 12 months and that's really the kind of trajectory we want to stay on. I think - as I often say to people, this is a long-term gain and we're in it for the long-term.

So, no surprises there I think and no concerns. I think over the coming few weeks we'll be working really hard to put the story in front of investors as broadly as we can to really explain what we're doing and why and to really [socialise] this news with the market.

In terms of news flow, I think there's some really - this really adds a whole new layer to what is already a dense slate of news flow with paxalisib. We have a lot of activity going on with the paxalisib program; as we touched on before, seven clinical trials in progress. As we've seen in the last few months, potentially things that are a little bit wild card like partnering transactions which obviously are a little bit more difficult to foreshadow but which can be quite transformative when they occur.

We have all that work going on as has been the case up till now. In addition, there will be some key landmarks for EVT801 and the big-ticket item here is going to be taking this drug into human trials. We've said we want to do that by the end of calendar '21. I think we're - it's a relatively ambitious goal, given that it's mid-April now but we're pretty confident we can do that. As soon as this drug starts to get into human trials, I think that's really going to open up a whole new vista in terms of the Company's activities. It's a time when drugs [tundra] start to really attract a lot of attention from investors and partners and so on and we think that will be the case here.

So, that's really the big-ticket item. In the meantime, obviously we'll be reporting activities like some publication of existing data and some work like that that prepares us for that phase 1 program. In the meantime, obviously also we'll be providing updates about the structure of the phase 1 trial, our plans, the outputs and so on.

Rebecca Harding: (Twinings Asset Management, Analyst) Thank you and just a final question, if I may regarding the phase 1 trial planned, it looks as though you're considering doing those in France. What's the rationale behind choosing that location in particular?

Doctor James Garner: Yes, it's a little bit of new territory for us as Kazia because up till now, almost all of our clinical trial activity has been US-based and to be clear, I think the development of EVT801 will also include a very substantial US component. But we're planning to start in France for a couple of reasons. One is that there are some excellent centres there that really have tremendous experience with this class of drugs, one in particular in Toulouse that we're in very advanced discussions with.

We also plan to do some very sophisticated biomarker analysis in this study. It's going to be a very sophisticated study in terms of its pharmacodynamic measures, in terms of its assessment of the activity of the drug. That work requires proximity to Evotec's own laboratories, which is where we'll be doing some of these very detailed analyses. So, just the practical realities of wanting to ship samples around and things like that really means that we want to be close to Evotec's laboratories. That also drives [us]. That won't be a consideration for future studies, it's really just right here at the beginning where we want to really measure these pharmacodynamic measures. But it does lead us towards staying in Europe at least for the beginning.

Then the final consideration is that to start the drug in the US, we'll need to open an IND, an investigational new drug application; essentially, approval from the FDA to conduct clinical studies. That will take us a little bit of time and it's work we'll be doing in parallel. But in the interests of opening the study rapidly, we think we can open it quicker in Europe at this stage than we can in the US. So, for all those reasons, our focus is on starting in France but we expect the program will fairly quickly broaden out to encompass other countries.

Rebecca Harding: (Twinings Asset Managing, Analyst) Makes sense. Okay, thank you very much, James and congratulations.

Doctor James Garner: Thanks Rebecca, thank you very much.

Operator: Thank you. Once again, if you wish to ask a question, please press star one on your telephone and wait for your name to be announced. We will pause to allow participants to join the queue. We are showing no further questions at this time. I will now hand back to James.

Doctor James Garner: Thank you, Amanda and thank you everybody for making the time to join this morning. I'd just maybe say in conclusion that this is a step into a much bigger world for Kazia and not a step that has occurred in isolation. We've seen over the last few months our first commercial partnership for paxalisib with our transaction with Simcere, now in a new addition to the pipeline. This has been a dramatic period for our Company and one which I think puts us in very good shape for the months and even the years ahead.

So, it's an exciting time for all of us in Kazia. Once again, we're really grateful for your support and engagement and we'll have a lot of exciting news to share with you as the year progresses. Thank you very much.

Operator: Thank you. That does conclude our conference for today. Thank you for participating, you may now disconnect.

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