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ADAP - GlaxoSmithKline PLC Exercises Option Over Adaptimmune Therapeutics PLC's SPEAR T-cell Therapy Program Targeting NY-ESO Call

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OVERVIEW:

On 09/07/17, ADAP announced that GSK has exercised its option over NY-ESO SPEAR T-cell program. Further, due to the option exercise and transition to GSK, ADAP will receive up to $61m from GSK between now and transition of program to GSK in 2018, which extends ADAP's funding through to early 2020.

SEPTEMBER 07, 2017 / 12:30PM, ADAP - GlaxoSmithKline PLC Exercises Option Over Adaptimmune Therapeutics PLC's SPEAR T-cell Therapy Program Targeting NY-ESO Call

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Juli P. Miller

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PRESENTATION

Operator

Good day and welcome to the GSK Exercises Option over SPEAR T-cell Therapy Program Targeting NY-ESO Conference Call and Business Update. Today's conference is being recorded. And at this time, I would like to turn the conference over to Ms. Juli Miller. Please go ahead ma'am.

Juli P. Miller

Hi, good morning and welcome to the Adaptimmune's conference call to discuss the news today; the GSK's exercised its option over Adaptimmune's NY-ESO SPEAR T-cell program.

As a reminder, today's conference call will contain forward-looking statements. These statements relate to the future events or the company's financial performance and the listener is cautioned not to rely solely on these forward-looking statements. Such statements are subject to certain risks and uncertainties, which could cause actual results and events to differ materially from any future results expressed in or implied by such statements, especially those inherent in the process of discovering and developing our therapeutic candidates and those set out in our filings with the SEC.

James Noble, our Chief Executive Officer, is with me for the prepared portion of this call. And Adrian Rawcliffe, our Chief Financial Officer; Rafael Amado, our Chief Medical Officer; Helen Tayton-Martin, our Chief Business Officer; and Bill Bertrand, our Chief Operating Officer, will be available for the Q&A after the prepared portion. This call is expected to last approximately 30 minutes.

With that, I will turn the call over to James Noble. James?

James Julian Noble - *Adaptimmune Therapeutics plc - CEO and Director*

Thanks, Juli, and good morning, everyone, and thank you for joining us. Very exciting times in cell therapy.

Today, I am really delighted to announce that GSK has exercised its option of our NY-ESO SPEAR T-cell program. This represents a compelling validation by a major company of the data that we have presented in the solid tumor, namely synovial sarcoma after GSK has carried out extensive and detailed due diligence. The option exercise and these data get powerful support to our conviction that we have a pipeline capable of treating solid tumors. Further, as a result of the option exercise and transition to GSK, Adaptimmune will receive up to $61 million from GSK between now and transition of the program to GSK in 2018, which extends our funding through to early 2020. We have an even longer cash run rate than before

and as we transition away from working on GSK programs, a greater ability to deliver shareholder value by focusing all of our clinical efforts on our wholly-owned assets MAGE-A4, MAGE-A10 and AFP.

I will now go through a more detailed effect of this option exercise. GSK exercised its option over NY-ESO SPEAR T-cell program based on existing data, including the recent results presented at ASCO, which continue to provide strong evidence for a favorable benefit risk profile for this therapy in synovial sarcoma patients. Further, these data provide a compelling proof-of-concept of the potential of our SPEAR T-cell platform with strong initial responses and promising survival in this aggressive and difficult-to-treat cancer. We engineer and test all of our SPEAR T-cells to safety and efficacy using this platform, and we firmly believe that the data we have seen in synovial sarcoma indicate the potential of all of our SPEAR T-cells in solid tumors across multiple targets and indications. And GSK's decision to exercise its option over NY-ESO is, to us, further validation of Adaptimmune's approach.

We are delighted with the successful outcome from our ongoing partnership and look forward to seeing GSK harness its full resources as a global pharmaceutical leader to bring Adaptimmune's NY-ESO SPEAR T-cell therapy to market. Over the coming months, we will transition the NY-ESO program to GSK and there'll be lots of activity between our companies to ensure this transfer is smooth and efficient.

I would also like to emphasize that GSK's commitment to SPEAR T-cell therapy goes well beyond NY-ESO. And you may recall that under the agreement we signed 3 years ago, GSK has the ability to select up to 5 Adaptimmune programs, the first being the NY-ESO SPEAR T-cell therapy program and the second being PRAME, which GSK nominated in January of this year, 2017. By exercising its option of NY-ESO, GSK gains the right to nominate up to 2 additional targets, following completion of the transition against which Adaptimmune will develop SPEAR T-cells. Notably, GSK cannot nominate targets in Adaptimmune's current pipeline, including any of MAGE-A10, MAGE-A4 and AFP programs or the numerous undisclosed preclinical programs, on which work is already underway.

Adaptimmune has no clinical development obligations with respect to NY-ESO after the transition is complete. And as per the additional targets, including PRAME and the 2 additional targets that GSK has the right to nominate, Adaptimmune would only conduct preclinical testings of these targets and will deliver IND-ready packages to GSK.

In financial terms, we have previously indicated that the first target program, NY-ESO, will provide development milestones of up to $500 million for Adaptimmune and the second target program, PRAME, will provide Adaptimmune with development milestones of up to $300 million. GSK also now has the potential to nominate 2 additional targets. And if this occurs, Adaptimmune could receive up to $325 million in development milestones for each of those 2 additional programs. Adaptimmune would also receive tiered-sales milestones and mid-single to low-double-digit royalties on worldwide net sales of each product.

As previously announced, following our fundraisings in March and April of this year, we had previously guided that we will fund it until late 2019. As a result of the option exercise and the transition to GSK, Adaptimmune will receive up to $61 million from GSK between now and the transition of the program to GSK in 2018. This extends our ability to fund the business through to early 2020 and provides us with a clear runway to deliver clinical data from our ongoing trials of each of our wholly-owned assets. The transfer of the NY-ESO program to GSK is an important transition for Adaptimmune. It enables us to shift our entire clinical development focus to our wholly-owned clinical stage assets, targeting MAGE-A10, MAGE-A4 and AFP. We are pleased to say that we are identifying and enrolling antigen-positive patients in these trials.

We are on track to obtain initial data from all 3 wholly-owned assets in up to 8 tumor indications by the end of 2018. These are exciting times for Adaptimmune and for cell therapy as a whole.

We demonstrate the results in the solid tumor, which will further validate about GSK's option exercise over NY-ESO. We remain committed to our patients, and we will work diligently with GSK to ensure the NY-ESO is transitioned smoothly. This transition is a critical inflection point for Adaptimmune, enabling us to fully focus on our wholly-owned clinical stage assets, and we are funded and on track to deliver data from those programs in up to 8 tumor types by the end of 2018. We are the leaders in the TCR T-cell space, and our goal remains to be first to market with an engineered TCR T-cell therapy in solid tumors. We are well positioned to achieve this objective.

With that, I'd like to open the call up for the questions. Operator?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) We will now take our first question from Mr. Eric Schmidt from Cowen & Co.

Eric Thomas Schmidt - *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*

James, I guess, I was looking for a little bit more color on why the ovarian and non-small cell ongoing studies are being stopped as opposed to transfer to GSK? Should we mean -- should we take that to mean that you are not seeing much yet from the data or you haven't enrolled enough patients to see anything? Or what's the discussion in the background there?

James Julian Noble - *Adaptimmune Therapeutics plc - CEO and Director*

So as we pointed out, we've gone through in our press release study by study, which are going ahead and which are not going ahead. Obviously, we have very limited ability to discuss what GSK's plans are, obviously you've talked to GSK about it. But the essence is that on the lung cancer study, obviously, if patients were enrolled, they will continue to be treated, and that has apprized all of the studies by the way, whatever we are doing with them. But they want to start a new lung cancer study of -- it's not to say that anything is going wrong with the study at all. So it actually, essentially where studies are at relatively early stage, I think GSK will take them over and start their own studies where they -- further down the track that obviously, we get to finish them off, Cohort 2 in the sarcoma studies. So I wouldn't read anything into that at all.

Eric Thomas Schmidt - *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*

Okay. And then in terms of the impetus for this decision, I think, it's coming a little bit earlier than we had excepted. Do you think that's because GSK is very keen to nominate these 2 additional targets? And if so, when might we expect that to happen?

James Julian Noble - *Adaptimmune Therapeutics plc - CEO and Director*

Obviously, we can't really tell you what GSK's strategic reason is, but it is much earlier than they needed to exercise. As I have pointed out many times in our investor conferences, we could have woken up any morning and found out that they exercised the option. They did have the opportunity to exercise it. So it obviously fits that strategic direction to take it on the side. You will obviously be aware of many announcements that GSK has made this year about which programs they're continuing and discontinuing and this must fit into that. And in addition, I think very important to their decision, they'll take any and you'll talk to them. It means that they will take over the pivotal study in synovial sarcoma, but you have to talk to them individually. It is earlier than we had expected and you had expected, but as I say, they could nominate any time. I think, it's a great commitment for them, I mean, they will have to -- this is a serious amount of resource they will be putting into this. And they really want to capitalize on the in-house Cell and Gene Therapy expertise, of which they do have a great deal. So I think this fits into that pretty well.

Eric Thomas Schmidt - *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*

Could you -- one last question, James. Could you give us an update on the number of targets that you now have internally, I guess, validated via your platform that they could choose from?

James Julian Noble - *Adaptimmune Therapeutics plc - CEO and Director*

Well, that's a difficult question, actually, because we have -- it changes everyday with the odds. So there will be -- there will be a number of targets that they can choose from. But as I say, it won't -- the targets they get to choose from won't come from anything that we have started work on and that's been the same from the beginning of the agreement. They've never been able to nominate targets if we have started a program on them. So they can't nominate MAGE-A4, MAGE-A10 or AFP. They can't nominate any of the other -- it's actually quite longer, such things that we work on already, I think, we are working on 10 programs or so preclinically. But after that, obviously, at some point, they will come to us and nominate things. They don't have to be on our list. They can nominate -- it could be -- they could provide their end target or find a target from somewhere else. They can just simply nominate. It just can't come out of the pool of things, which we are working on.

Operator

We will now take our next question from Peter Lawson from SunTrust Robinson Humphrey.

Max Lewin - *SunTrust Robinson Humphrey, Inc., Research Division - Associate*

Max Lewin in for Peter Lawson. I was wondering if the next data we should expect from your wholly-owned programs is that MAGE-A10 or MAGE-A4 trial, and is that going to be in second half '17? And then the follow-up question to that would be, is that going to be at a conference or would we expect that to be the top lined in a press release?

James Julian Noble - *Adaptimmune Therapeutics plc - CEO and Director*

We've done -- we're on track. We are enrolling patients. I think, it really -- we're not going to provide patient-by-patient data, obviously, unless we have to because there is a tragedy, but if we're not going to

[Audio Gap]

so it really depends on the speed and number of patients. I think it's unlikely to be at a conference in my opinion, because I think once we move from one-dose level, for example, to the next dose level, we've treated several patients for an acceptable time, we will have to announce something. So, I think, it will be coming in first half of next year.

Operator

We will now take our next question from Reni Benjamin from Raymond James.

Reni John Benjamin - *Raymond James & Associates, Inc., Research Division - Senior Biotechnology Analyst*

Congratulations on the exclusive licensing agreement. A couple of questions. Can you talk to us a little bit about this transition period, maybe what are the gating factors involved in this transition period? And when I initially read the press release and from your comments, it seems like the $61 million is all but guaranteed. But then, in the press release, you mentioned development milestones and an option payments is included in that $61 million. And so I guess my question is what if they don't opt for the other 2 programs or do they have to opt for the other 2 programs, which is why you know that the $61 million definitely will be coming in?

James Julian Noble - *Adaptimmune Therapeutics plc - CEO and Director*

Actually, the way the payments work is that we will get GBP 30 million for the option payment, which gives them -- which is actually -- roughly $38 million. So unfortunately, the milestones are technically in pounds, but it's roughly $38 million. It relates entirely to the option fee and the rest

relates to development milestones, but those development milestones were effectively getting it transitioned across to GSK. They're all -- because obviously, there are lots of things to do. I mean, at the moment, the vector is not manufactured -- we hold the IND, we hold all of the contracts with the hospitals. We have the contract with pharma (inaudible), we have the contract with the vector manufacturer with PCT for the cell manufacturer. And we have to make sure that all of that is transitioned, but there is no -- it's not as though we have to achieve sort of 70% response rate in some cancer. They are not that type of development milestone, they are actually related to the transition over to the next several months. We obviously have a lot of obligations to do, to make a smooth transition -- it's actually quite complicated because there are a lot of hospitals involved and there are a lot of third parties apprized involved, all of which have to be effectively transferred to GSK prior to the IND. So it's not -- and the exact amount only really depends -- we should get almost all of that amount if the transition happens. The exact amount can't be determined. It slightly depends on how many patients we recruit in continuing -- in continuing cohorts. So it's pretty much there. It's just -- if the transition happens, you can assume it's roughly that amount of money.

Reni John Benjamin - *Raymond James & Associates, Inc., Research Division - Senior Biotechnology Analyst*

Got it. Okay, thanks for the clarification. And just maybe the flip side of the argument, what kind of expense savings might we see or will kind of this -- and those entire savings be plowed back into the company's own proprietary programs?

James Julian Noble - *Adaptimmune Therapeutics plc - CEO and Director*

Yes, that's interesting. There will be savings, so part of the cash runway extension to 2020 is savings and part of it is -- part of it is the payments, but we are plowing everything we can back into our own programs. So we're not -- in fact, the transition happens at quite a neat time for us because it's just when we expect the MAGE-A10, MAGE-A4 and AFP programs to expand significantly once we got through the initial safety cohorts.

Reni John Benjamin - *Raymond James & Associates, Inc., Research Division - Senior Biotechnology Analyst*

Got it. Okay. And then just one final one. You'd mentioned the transition period is also dictated probably by the enrollments into the synovial sarcoma studies and Myxoid/round cell. Can you give us, maybe, a status update as to how that enrollment is going and kind of when you think that will conclude? And I know you mentioned that this will take several -- in the coming months, but maybe in your prepared remarks, you mentioned some time in 2018. Do you have any additional sort of color as to when in 2018 you think this will be complete?

James Julian Noble - *Adaptimmune Therapeutics plc - CEO and Director*

I don't think I can because it depends on a lot of third parties and how quickly they can transfer the supply agreements to GSK. It's not dependent on achieving numbers of patients in cohorts. It's just that at some point, the transfer will happen, at which point a number of patients will have been treated, and therefore, there will be a payment per patient on some of the cohorts. That's all it is. It's not -- there are no significant obstacles to the transition happening, but there is a tremendous amount of work. This is -- it's not contingent upon some success milestone. It's contingent on a whole series of things, where GSK can satisfactorily take over the program. But they can't take on the IND as they haven't got a deal with PCT, for example, someone else to make the cells. So it's things like that.

Operator

Our next question comes from Tony Butler from Guggenheim Partners.

Charles Anthony Butler - *Guggenheim Securities, LLC, Research Division - MD & Senior Equity Analyst*

James, two questions. One is on manufacturing post the transition. What -- does GSK have any rights to your manufacturing -- physical manufacturing facilities? And how will that actually occur post transition? And the reason I ask is all this capacity constraints. And then the second question is

during the transition, I would argue and you may disagree and that would be fine that GSK could be quite needy for a number of resources from your team. So how do you ensure that the programs that you have are continuing to move forward and yet you are also satisfying the GSK in the transition period because I would think it's a little tricky?

James Julian Noble - *Adaptimmune Therapeutics plc - CEO and Director*

(inaudible). So no, we are -- we are well staffed up. I mean, essentially, we're well staffed to cope with both. There is a large amount -- there are a large number of reports and things like that we produce to GSK obviously to make sure paperwork transition happens satisfactorily, but that is all well planned out of a hugely detailed transition plan with agreed inputs from both sides. And of course, just to be clear, I mean, GSK is extremely experienced in this area and has got a lot of very good people and they, of course, have been on the steering committees and the manufacturing committees, the [approaching team] committees, they have been on all of those, so from day 1. So they have a tremendous -- first of all, they got a tremendously good team and secondly, they got a tremendous experience on this particular program. So moving to your first question on the manufacturing. I like you are sitting in The Navy Yard in Philadelphia, where our pilot plant is being built, and I am delighted to say it's going very well. So we should be able to manufacture cells, not the vector, but with the cells of patients in due course. GSK doesn't have any rights to come at Navy Yard at all, and we won't be manufacturing cells for them, so the capacity here is entirely for our own programs.

Operator

Our next question comes from Michael Schmidt from Leerink Partners.

Wei Ji Chang - *Leerink Partners LLC, Research Division - Associate*

Hi, this is Jonathan Chang stepping in for Michael. Congrats on the GSK option exercise. First, can you provide any additional color on how this exercise will impact development timelines of the NY-ESO program? And when should we expect that pivotal study initiation on synovial sarcoma?

James Julian Noble - *Adaptimmune Therapeutics plc - CEO and Director*

So in the sense that the synovial sarcoma pivotal study won't start this year, there is in effect as GSK moves the program internally, but I can't comment on exactly when they'll start. I mean, obviously, they can answer that question. They do have a very extensive team on this. As I said just a minute ago, they've been participating in this program for a very long time. The breakthrough status and prime status still carry on through the transition to them. So they have every incentive to work diligently. They're hardly going to have spent all this money exercising the option and getting teams ready to transition just to sit on the asset. So I'm very confident that they've got an excellent team, which will push things forward. But in terms of exact timing, the only thing I can say is they can't start this year because of the transition mechanism. This maybe sounds pivotal, but after that, it is up to GSK.

Wei Ji Chang - *Leerink Partners LLC, Research Division - Associate*

Great. And then you previously talked about a single-arm study being sufficient for regulatory submission in synovial sarcoma. Can you provide more color on the regulatory path forward in synovial sarcoma? And how does the GSK option exercise impact this?

James Julian Noble - *Adaptimmune Therapeutics plc - CEO and Director*

Though GSK has been party to all of the regulatory discussions we've had with the FDA from day 1 and from us and has been heavily involved in the design of the trial. So they -- that the single-arm nature of the trial has been talked about a great length and it's not as though someone just walked into the door and just to exercised their option the asset, they have been involved, they have been very, very heavily involved in this and though they've obviously got detail, I mean, they have patient-by-patient data on every single cohort and every single program. So they -- it's up

to GSK whether they want to change the design of the pivotal study. But as I said, they have been heavily involved in everything to-date. So we just have to see where it goes.

Operator

(Operator Instructions) We will now take our next question from Ying Huang from Bank of America Merrill Lynch.

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

Maybe, James to start, the first one on the pivotal plans for ESO run by GSK. It sounds like they will go with sarcoma first. But can you elaborate whether GSK will move into pivotal development for NY-ESO run in myeloma? And then secondly, can you give us an update on your end-to-end manufacturing time for the NY-ESO T-cell program now?

James Julian Noble - *Adaptimmune Therapeutics plc - CEO and Director*

So on the pivotal sarcoma, as I just mentioned, that will transition to -- we will not start the pivotal study. So GSK will be running that pivotal study, and they will run it on their own time course. They clearly are interested in other trials going along. Of course, we have a combination study in multiple myeloma. I think, that's the one you referred to. That study is enrolling right now. And obviously, GSK will be -- would be putting -- we'll be talking to them directly about that study with us involved as well as to exactly what plans they have. We will be -- in fact, we will be updating on the myeloma study at ASH later this year [with that data], the original cohort. In terms of -- in terms of the other plans, I think, you do need to refer to GSK, but I am sure that they will want to maximize the opportunity for an asset across different cancers, but exactly which ones and how they will do, we've -- we are leaving it to them to explain. Sorry, I obviously what they -- there I missed one of your questions. So the end-to-end manufacturing, the vein-to-vein manufacturing is between 28 and 35 days, as it has been for some time.

Operator

Mr. Noble, we have no further questions. So at this point, I'd like to turn the call back to you for any additional or closing remarks you may have. Thank you.

James Julian Noble - *Adaptimmune Therapeutics plc - CEO and Director*

Well, thanks, everybody, for listening. To me, it's a very, very exciting days. We set out this company many years ago to develop therapies, and we now have evidence that one of the world's leading pharmaceutical companies wants to invest very significant resource into pushing forward a successful program in a solid tumor and investing in other tumor types as well. I do think, I'd say, it's another real shot in the arm for cell therapy. We've had 2 or 3 fantastic things happening in the last 2 weeks with Kite and Novartis, in particular, being stellar examples of where cell therapy is getting to in terms of excitement. And I think, this is another demonstration, a major company with enormous resources and enormous choices about where to invest the money has chosen to invest in a cell therapy program and, obviously, is looking forward to building a franchise in that area with its PRAME, TCR and it's -- the target after that. So I think it's a great day for cell therapy, and I hope it's a great day for patients and certainly for us. It's a transformational moment because we now have an even longer runway, and we can invest our resources into our own programs with -- all of our resources into the MAGE-A4, MAGE-A10 and AFP programs as we want to. So thank you very much.

Operator

Thank you. And once again , ladies and gentlemen, that will now conclude today's conference call. Thank you very much for your participation today. You may now disconnect.

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