-Adaptimmune Therapeutics plc (Q2 2021 Earnings)

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Corporate Speakers:

- Juli Miller; Adaptimmune Therapeutics plc; Senior Director of IR
- Adrian Rawcliffe; Adaptimmune Therapeutics plc; CEO, Principal Accounting Officer & Director
- Helen Tayton-Martin; Adaptimmune Therapeutics plc; Co-Founder & Chief Business Officer
- Elliot Norry; Adaptimmune Therapeutics plc; Chief Medical Officer
- John Lunger; Adaptimmune Therapeutics plc; Chief Patient Supply Officer

Participants:

- Tony Butler; Roth Capital; Analyst
- Marc Frahm; Cowen and Company, LLC; Director
- Unidentified Participant; Guggenheim; Analyst
- Jonathan Chang; SVB Leerink; Analyst
- Mara Goldstein; Mizuho Securities USA LLC; MD of Equity Research Department

PRESENTATION

Operator: Good day and thank you for standing by. Welcome to the Adaptimmune Second Quarter Earnings Conference Call. (Operator Instructions) Please be advised that today's conference is being recorded.

I would now like to turn the conference over to Juli Miller, Investor Relations. Please go ahead.

Juli Miller: Hello, and welcome to Adaptimmune's conference call to discuss our second quarter 2021 financial results and business updates. Please review our forward-looking statements from this afternoon's press release as we anticipate making projections during this call, and actual results could differ materially due to several factors, including those outlined in our latest filings with the SEC. Adrian Rawcliffe, our Chief Executive Officer, is with me for the prepared portion of the call. Other members of our management team will be available for Q&A.

With that, I'll turn the call over to Adrian Rawcliffe. Ad?

Adrian Rawcliffe: Thanks, Juli, and thanks, everyone, for joining us. So last year, we set out our 2252 strategy for the next 5 years. And at the beginning of this year, we identified the milestones in 2021 to start to deliver that strategy. From a clinical perspective, these milestones were: one, to present initial data from our pivotal SPEARHEAD-1 trial with afami-cel at ASCO with a fuller data set to follow at CTOS.

Two, present data from our AFP trial at ILCA and three, present data from our SURPASS trial with our Next-gen program targeting MAGE-A4 at ESMO. I'm pleased to say that in Q2, we delivered our first of these with excellent data afami-cel at ASCO, and we're positioned to deliver on the next 2 in Q3 at ILCA and ESMO as anticipated. I want to say a little bit about each of these milestones in turn.

As you can see from the press release, we had a busy Q2. In June, we presented initial data from our pivotal SPEARHEAD-1 trial at ASCO. With a disease control rate of approximately 85%, an overall response rate of approximately 40% and very encouraging initial durability. These data demonstrate that afami-cel has life-changing potential for people with synovial sarcoma and MRCLS. We plan to update data from this trial at CTOS later this year. And we're working hard to file our BLA next year and achieve the first element of our 2252 strategy to have a product on the market targeting MAGE-A4.

We're preparing for a successful commercial launch working with key industry leaders, Agilent for companion diagnostic, Miltenyi for our viral vector supply as well as developing our in-house capabilities to support commercial delivery for.afami-cel.

For the second and third clinical milestones this year, we are on track to update in Q3 on our AFP and SURPASS programs at ILCA and ESMO, respectively. At ILCA, on September 5, Dr. Bruno Sangro will present data from our AFP Phase I trial. He will present data on 13 patients who have been treated in cohort 3 and expansion. 11 of whom have had at least 1 post-baseline scan. We'll issue a full press release around these data, and we'll update regarding this program going forward. At ESMO, we presented an update from the SURPASS trial with our next-gen program targeting MAGE-A4.

You'll remember that last year, we reported data at SITC from 6 patients in the dose escalation cohort of this trial with 2 confirmed responses in patients with EGJ and head and neck cancer as well as tumor reductions in 3 other patients with esophageal, ovarian and EGJ cancers.

As I said in the Q1 call in May, enrollment in the first half of 2021 in this trial has gone very well. As of the data cut for the ESMO presentations, we've treated 25 patients in this trial, and 23 of these patients have at least 1 post-baseline scan. And we are very much looking forward to sharing this data update as planned at ESMO. The poster will be available online on September 16. Again, we'll issue a full press release and provide an update on the future for the development of this therapy. A couple of other updates on this program.

The SURPASS trial was initially in a wide range of MAGE-A4 expressing tumors, but was subsequently amended to recruiting 4 focus indications: lung, bladder, head and neck and gastroesophageal cancers, where we have seen antitumor activity and responses with our MAGE-A4 targeted therapies previously.

Based on emerging data in several patients with ovarian cancer treated in the SURPASS trial, we will add ovarian cancer back to the list of focus indications. So going forward,

the SURPASS trial will continue to enroll patients with lung, bladder, head and neck, gastroesophageal and ovarian cancer.

In addition, our SURPASS 2 trial which is the Phase II trial with the next-gen product targeting MAGE-A4 for patients with esophageal and EGJ cancers is on track to initiate as planned in Q3. We've designed a protocol to account for the evolving standard of care in this setting and identify a patient population that is most likely to benefit from this type of therapy.

We are committed to identify more indications for late-phase development with the 2252 goal of having an additional MAG-4 marketed product in the next 5 years. Our clinical data, our translational learnings as well as our preclinical pipeline including our industry-leading allogeneic program, move us closer every day to our goal of cell therapy products that are both curative and mainstream.

And with that, I'd like to turn it over to the operator for questions.

QUESTIONS AND ANSWERS

Operator: (Operator Instructions) And our first question comes from Tony Butler with Roth Capital.

Tony Butler: There are 2 -- 1 of the 2 parts. Adrian, you mentioned the companion diagnostic development with Agilent. And I'm assuming that you're going to see CLIA validation. So the question is, can you provide some information around the number of patients that you may need to see to provide to the FDA? And importantly, Will that cause any delay? Or do you think it will cause any delay in the BLA filing based on SPEARHEAD 1? And part B of that question, would you use this particular validated based on diagnostic in SURPASS 2 in esophageal cancer and EGJ

Question two, is around the program that you have with Astellas. And I recall that 1 of the -- I believe it was 1 of the hit programs. Astellas had taken, if you will, an ownership or joint venture in, they've also taken a second program. And I wondered if you would speak to that and if you don't want to reveal the program fine, but how far along are the development of both?

Adrian Rawcliffe: Thanks, Tony. So we have not provided details on the development pathway for the companion diagnostic. I can confirm that there won't be any delay to -- we don't anticipate any delay to the BLA file on the basis of that. Could you repeat the question on the SURPASS 2 trial?

Tony Butler: Yes, so you're going to use that companion diagnostic in the SURPASS II trial, and therefore, that trial may actually be somewhat delayed in enrolling even though you said it's going to be in Q3.

Adrian Rawcliffe: So the answer is no, we're not using that diagnostic in that trial, and we don't anticipate that, that will be delayed in enrolling. With respect to the Astellas collaboration, I'm going to ask Helen to comment on the status of those programs.

Helen Tayton-Martin: So thanks for the question, Tony. Can I just repeat it back to you? I think you were double checking -- On the second program, the first 1 we named Mesabi as a target for 1 of our HLA independent or HiT TCRs, and we are codeveloping that onetogether. The second 1 is -- has been selected but is not named and won't be named foreseeable. -- if that's the question.

Tony Butler: It is, Helen, thank you. The issue was how far along has that progressed since they have decided to take that program under their wings as well.

Helen Tayton-Martin: I wouldn't be at liberty to say exactly how far it's progressed, but it is moving along the time lines that we anticipated for selecting the target. So I think early basically, but not that far behind the mesothelin program.

Operator: Our next question comes from Marc Frahm with Cowen & Company.

Marc Frahm: Congrats on getting all these patients in and ready for presentation. maybe, Adrian, your comment about adding a focus on ovarian within SURPASS. Just to be clear, is that based on -- I think you had a little bit of -- you have some tumor shrinkage and 1 ovarian patient as of the last update it based off that? Or is it really that you've seen more in additional patients that have happened subsequent to that update?

Adrian Rawcliffe: We are going to comment on any of the data that is in the SURPASS trial, pending the ESMO data release. I think that question will be much better answered when we can all look at the same amount of data and have that discussion there.

Marc Frahm: Okay. And may get a similar answer here, but on this one. But can you give us a flavor you gave that kind of patient numbers, but can you give a flavor of kind of the spread of tumors that are going to be in there? And are -- should we be thinking about any of these tumor types starting to get to that kind of high single-digit type of threshold you've historically talked about, but useful for kind of establishing proof of concept or futility, if that were the case?

Adrian Rawcliffe: You're correct, you're going to get the same answer as for the previous question, but I do admire your persistence on this. We haven't guided and we're not going to guide. I think it's best it's only a month away, everybody can look at the data set when we put it out there at ESMO, and we can talk about it from an informed perspective at that point.

Marc Frahm: Okay. And then maybe turning to the planned BLA. You're continuing to enroll a second cohort of patients in the -- in SPEARHEAD-1. Will the filing just have the first cohort that we've already kind of seen the response rate data plus the couple of

incremental patients? Or do you expect that filing to have the complete trial, including some of these patients who are enrolled into the second cohort?

Elliot Norry: Hi Mark, it's Elliott. The plan is to file the BLA based on the data in Cohort 1..

Operator: Our next question comes from Michael Schmidt with Guggenheim.

Unidentified Participant: This is Kelsey on for Michael. I just had 2 quick ones. Could you just provide some color on where you stand with the launch prep and commercial readiness? And then the second one, we saw in the press release that the radiation sub-study was officially closed. Maybe just a little bit of color there on why it stopped. And that's it for me. Thank you.

Adrian Rawcliffe: Thanks, Kate. I will ask Elliot to touch on the radiation sub-study. And Helen, do you want to just pick up on where we are with commercial readiness and prep?

Helen Tayton-Martin: Yes, sure. I'll kick off with the answer to that one. I mean I think we're in reasonably good shape. We've been planning for this for quite some time. We've had internal folks focused on the key things around market access, marketing, broad commercial planning and now we're beginning to turn our attention to the to dig deeper and also obviously into the outward customer-facing roles.

So as you would imagine, we're working very closely with KOLs, et cetera, and then getting feedback and beginning to sort of map out all kinds of materials pathways and roles on that side. And then I know that Don could quite easily comment on the prep that's going on to put our commercial manufacturing and our operations technical operations in place ready for for a different level of delivery of products to complement what we do on the clinical side. So yes, we're -- that will say more in due course, I'm sure, but at that -- at this stage, I think we're pleased with how it's tracking.

Adrian Rawcliffe: John, do you want to pick up on the CMC aspects of this?

John Lunger: Sure. We've said before that our commercial launch will come out of the same facility here in Philadelphia that we've been using for the clinical trials and we had the capacity that we need for that launch. So supply wise, we're in good shape, and then we're obviously going through all of the activities that you need to prepare for the BLA filing, the process characterization work and those type of things, which is proceeding well.

Adrian Rawcliffe: Elliot, do you want to touch on radiation subsidy?

Elliot Norry: Yes, sure. So we decided to end enrollment in the radiation substudy for, really for multiple reasons. This is -- was a single-center substudy of the Phase I afami-celmulti-tumor study and really the only part that was remaining open. The study was

significantly affected from an enrollment standpoint by the COVID pandemic and really presented a very challenging enrollment scenario with the single center and also with expanding into other centers.

And when we look back at the trial design as well based on how it had been organized, it was really unlikely to provide sufficient answers as it relates to differentiating the addition of low-dose radiation to cell therapy. So while there's still I think scientific promise to the idea of using low-dose radiation to improve T cell trafficking, and we'll sort of retain the option to reintroduce that at a later time if it makes sense, this study really did not make good sense for us to continue to enroll. The real focus is for those same tumor types that are expressing MAGE-A4, to really be put into the CD8 alpha program and continue to enroll SURPASS.

Operator: Our next question comes from Jonathan Chang with SVB Leerink.

Jonathan Chang: A question, what do you see as the go-no-go bar for advancing the next MAGE-A4 program into late-stage development for the different indications beyond the Phase I SURPASS study?

Adrian Rawcliffe: So maybe I'll take a stab at that. So the -- I think I don't want to get into speculation about individual tumor types. I think we'll let the data speak for itself at ESMO. But I think I'd just refer everybody to the discussions that we've had previously about what efficacy in cell therapy in very late-stage population such as those that we are studying in this Phase I trial would look like. And I think we've consistently said that 3 out of 10 patients responding with benefit to patients of 6 months, give or take, would be -- would probably be the ballpark that we're looking to see.

Now obviously, that does vary depending on individual settings and tumor types and -- but I think we need to understand the data a little bit more before we can discuss that and look forward to doing so from ESMO onwards.

Jonathan Chang: Got it. And maybe a similar question in the same vein. -- what do you see as the go-no-go bar for picking a particular indication to be a focused indication in the ongoing SURPASS study?

Adrian Rawcliffe: But that one is a bit more -- a bit simpler in that we selected those indications some time ago, the 4 that we had previously. And obviously, I'm not going to comment on the rationale behind putting ovarian in. As I commented earlier, we'll talk about that when we get down to ESMO.

But more generally, you might recall that we had an analysis of all of the patients that we've treated with MAGE-A4 targeting therapies in the -- both the dose escalation portions of the SURPASS study and then also the Phase I trial for afami-cel that recruited a number of non-sarcoma patients, you may recall. And the indications that we selected as focused indications, then lung, bladder, gastroesophageal and head and neck were

indications where we had seen either confirmed responses or very substantial antitumor activity in the case of bladder or urothelial cancer.

We didn't have any responses there, but we have seen very significant antitumor activity. And really was a way of focusing down that trial from the sort of 10 indications that it was routinely expressed MAGE-A4 down to something a bit more manageable in to try to get to patient numbers where we could make development decisions.

Operator: Our next question comes from Mara Gladstone with Mizuho.

Mara Goldstein: It's Mara Goldstein. Just 2 questions. On SURPASS-2, you spoke to in your prepared comments about making some modifications to sort of conform to evolving standard of care. And I'm wondering if you can just speak to that at this point in time? And then the second is, I'm just curious, we've heard from a couple of companies within the cell therapy space around vector supply constraints, and you also kind of alluded to a little bit around sort of supply management. Maybe you could speak to specifically as it relates to you guys and what you're doing?

Adrian Rawcliffe: Certainly. Thanks, Mara. So I'm going to ask Elliot to talk about the SURPASS 2 study and the standard of care, evolution there. And then I'll ask John to pick up the discussion on our strategy around vector supply.

Elliot Norry: Hi Mara, Just very briefly, the standard of care for really the gastroesophageal cancer has evolved from being a chemotherapy approach in first line followed by PD-1 inhibitor in most scenarios. There are some other drugs that play in, in specific settings. But those drugs are now being used fairly commonly as a combination first-line approach, which does 2 things.

I mean, first of all, it improves the standard of care for those patients, but it also opens up the space for second-line therapy in many patients in that the patients don't just receive -- they don't receive first chemotherapy progress then PD-1 inhibitor, then progress, then be open to third-line treatment.

They're really compressing those 2 treatments still into first line. That being said, there's still tremendous unmet need in this population and that the response rate and duration of response with those -- with that combination, although better and an advancement for patients, there's still quite a long way to go to help this really devastating tumor type. -- the patients with that disease -- those diseases.

Mara Goldstein: So the modifications you'll expect to make will be essentially to move sort of closer to a second-line therapy? Is that what I'm understanding?

Elliot Norry: The study does allow for the drug to be used in second line behind combination chemotherapy -- We've made some other changes with respect to patient selection and whatnot based on what we've learned in the Phase I program, but that's the most significant change.

Mara Goldstein: All right.

John Lunger: Yes. And on the vector, you probably recall back in 2017, we made the decision to pursue a vector strategy that had 2 main elements One was an external partner that could work with us through commercial. And Ad mentioned Miltenyi earlier, which we've used work with Miltenyi for the vector supply for our SPEARHEAD trial in other trials. So that's the material that we'll use going into commercial. But secondly, we decided to also develop the internal capabilities. So we have done that, and we're supplying our other trials with material produced internally from our facility that's in the cell and gene therapy Catapult Center in the U.K. So we've kind of executed on the plan to have 2 sources of vector available to us, 1 internal and 1 external.

Operator: And there are no other questions in the queue. I'd like to turn it back to Adrian Rawcliffe for closing remarks.

Adrian Rawcliffe: Thank you, everyone, for your questions and your continued support for the company. We look forward to updating everyone on the data in September and keeping you up to date with continued progress. With that, we'll close the call. Thanks a lot.

Operator: This concludes today's conference call. Thank you for participating. You may now disconnect. Everyone, have a great day.