Adaptimmune Therapeutics plc (Q1 2022 Earnings)

May 9, 2022

Corporate Speakers:

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

Participants:

- Marc Frahm; Cowen and Company, LLC; Director
- Tony Butler; ROTH Capital Partners, LLC; MD, Senior Equity Analyst & Head of Biotechnology Research
- Unidentified Participant; SVB Securities; Analyst
- Paul Jeng; Guggenheim Securities, LLC; Equity Research Associate
- Nick Abbott; Wells Fargo Securities, LLC; Director & Associate Analyst
- Unidentified Participant; Barclays; Analyst
- Mara Goldstein; Mizuho Securities USA LLC; MD of Equity Research Department

PRESENTATION

Operator: Good morning and thank you for standing by. Welcome to the first quarter 2022 Adaptimmune Earnings Conference Call. (Operator Instructions) Please be advised that today's conference is being recorded.

I would now like to hand the conference over to your speaker today, Juli Miller, Head of Investor Relations. Please go ahead.

Juli Miller: Good morning and welcome to Adaptimmune's Conference Call To Discuss Our First Quarter 2022 Financial Results And Business Updates. I would ask you to review the full text of our forward-looking statements from this morning's press release.

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; and Gavin Wood, our Chief Financial Officer, are here 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: Thank you, Juli, and thank you, everyone, for joining us. Adaptimmune's ambition is to transform the lives of people with cancer by discovering, developing and delivering cell therapies. This is clearly a long-term ambition. But in the short and medium term, we are focused on the delivery of our 2-2-5-2 strategy. And this year, our focus is specifically on 4 clear areas: filed the BLA for afami-cel, continue building our MAGE-A4 franchise, scale up our manufacturing capabilities and progress our allogeneic products towards the clinic.

In the first quarter, we have executed well across all 4 areas. We are making good progress towards the submission of our BLA for our first product of afami-cel for the treatment of synovial sarcoma. At ASCO next month, we will present pooled analysis from patients with synovial sarcoma from across our trials with afami-cel, with a full update on the SPEARHEAD-1 trial planned for CTOS later this year.

Secondly, our MAGE-A4 franchises are expanding with a SURPASS family of clinical trials using our next-generation SPEAR T-cells targeting MAGE-A4. We have continued to recruit steadily in the Phase I SURPASS trial and we are planning a data update at ESMO this year. As a reminder, this is a Phase I trial that has shown responses across a broad range of solid tumors, and we aim to convert these early signals into registrable products.

There have been 2 tumor types identified so far for further progression, esophageal and EGJ as well as ovarian cancer. For esophageal and EGJ cancers, we are recruiting in our Phase II SURPASS-2 trial; and for ovarian cancer, we are planning to initiate an additional Phase II trial SURPASS-3 this year. We are also initiating a combination arm with nivolumab in the Phase I SURPASS trial.

Thirdly, as the only cell therapy company with age autologous programs as well as advanced capabilities in the allo space, we are making progress towards filing an IND for our first wholly owned allogeneic product, tufting MAGE-A4 next year as well as progressing our collaborations with Genentech and with Astellas.

And lastly, we are scaling U.S. manufacturing facilities to deliver cell therapies for our first commercial product and our ongoing and planned clinical trials. And we are nearing the completion of construction for our new dedicated allogeneic manufacturing facility in the U.K., and we'll begin the commissioning process in Q3.

We are constantly developing as a company, building the capabilities required to be an integrated cell therapy company. In our last call, I talked about the external additions to leadership in commercial and quality. Last week, we announced that Jo Brewer has been appointed to the role of Chief Scientific Officer effective May 4.

Jo is an exceptional scientific leader with a strong track record of building successful teams and driving innovation in cell therapy. She has a long history with Adaptimmune

and its predecessor companies, with more than 20 years of experience, specifically in T-cell receptors, TCR T-cells and cell therapies.

She's worked on all of our clinical autologous programs most recently, has led our allogeneic efforts, building the allogeneic team from scratch, playing a key role in the partnerships with Astellas and with Genentech and with her team taking allogeneic stem cell-derived alpha-beta T-cells from an idea towards clinical reality for us and our partners over the coming years.

And with that, I'd like to hand over to Gavin to provide a financial update. Gavin?

Gavin Wood: Thanks, Ad. With a robust balance sheet with total liquidity at the end of Q1 of $304 million, and I can confirm that this provides a cash runway that extends into early 2024 and enabling us to execute against the focus areas Ad has just laid out.

We have invested significantly over the last few years to build an integrated cell therapy company with a full range of end-to-end capability as well we strongly believe that this is critical for the long-term success of Adaptimmune. Like you, we are acutely aware of the challenges presented by the biotech and wider financial markets. We have a seasoned management team who have weathered difficult markets in the past.

We believe that fundamentally good companies with products that are close to commercialization and with a proven platform, we will achieve fair valuation as the markets rebalance. We have the people and the capabilities to position us well for the long-term success to execute against our mission to transform the lives of people with cancer.

So with that financial update, I'll turn over the call to the operator for Q&A.

QUESTIONS AND ANSWERS

Operator: (Operator Instructions) We have a question from Marc Frahm with Cowen and Company.

Marc Frahm: Maybe just to start off, Ad, you're guiding to the next update from the A2M4CD8 program at ESMO provide some color as to kind of how many patients do you expect to be there? And do you expect more tumor types to kind of reach that go-no-go decision that you've already gotten to with ovarian and esophageal?

Adrian Rawcliffe: So short answer is -- Marc, thanks for the question. Short answer is no, we're not providing any guidance on the numbers of patients. We've said we recruited steadily in that Phase I trial, and we'll update on all of the patients that we have that estimates for at the time that we do the data cut for ESMO. I think the answer to your second question is a bit more nuanced. Obviously, the entire purpose of the Phase I trial is to deliver signals in that. And so clearly, as time goes by, we anticipate that we will

identify additional indications for development, and that's the purpose of the trial, and that's all I'm going to say at this time.

Marc Frahm: Okay. That's helpful. And then maybe on the BLA submission, just on timelines there. I guess you had your pre-BLA meeting in? If not, kind of what the -- what's the need to be done before you can kind of request that and get that part of the process scheduled?

Adrian Rawcliffe: So we haven't had the pre-BLA meeting. What I would say is that the list of things that we have yet to do, we've outlined on the slide that's in our corporate deck. We've got a range of things that we've completed, including the preclinical sections of the filing with the pediatric plans, et cetera. And then on the right-hand side of that slide, which I'll refer you all to, it's got the items that are in progress, many of which relate to the CMC section of the file. I think progress is good on all of those aspects, and we remain on track for the filing this year.

Marc Frahm: Okay. And then the last one, ASGCT, you're presenting on a new next-generation major product with ILS and CCL19. Just can you explain the rationale on that product? And are there particular tumor types or tumor microenvironments that you think that's particularly well suited...

Adrian Rawcliffe: So I'm going to ask Helen Tayton-Martin to take that. Helen?

Helen Tayton-Martin: Thanks, Marc. Good question. Thank you. Yes. So the next general construct you're referring to, is a collaboration program construct from a program with Noile-Immune, where there are 2 additional molecules in the construct alongside the same TCR.

One of them is IL-7, which is there to increase proliferation and survival of the T cells. And the other one is CCL19, which increases basically trafficking to the tumor site of not just the T cells, but broader immune cells as well. So 2 slightly different mechanisms to the CD8 alpha, which is basically increasing potency of CD4 cells.

And in answer to your question in regards to which tumor types, I think that we are taking a view that we're looking at both hot and cold tumors to see whether these 2 mechanisms together had delivered the effect that we hope that they will. So more to come on that as we get closer to opening the study.

Operator: Our next question comes from Tony Butler with ROTH Capital.

Tony Butler: Two brief questions. One, I just want to again refer Adrian to Slide 12, speak directly to the vector release from I want to understand you -- if I'm correct, you're also building your own vector manufacturing, but you're going to continue to use Miltenyi's vector, if that's correct. What are the steps that -- that would strike me as being of the lift, a much more, let's say, heavy-weighted item that needs to be checked off. And I'm just curious if you could speak to the nuances there.

Second question is around SURPASS. And to -- I guess, to what end, is there a desire perhaps to consider or is there a consideration for a tumor agnostic indication for MAGE-A4?

Adrian Rawcliffe: Okay. So I'm going to ask -- I'm going to say something I ask John to answer the first question, which is I'd just point out that Miltenyi Biotech is our supplier for vector for afami-cel for all other products, we make our own vector. John, do you want to comment on the deliveries around the BLA?

John Lunger: Yes, sure. Thanks, Tony. This is John. So antigen is in their new commercial facility. They're early day -- early days, actually. They're quite advanced in the commissioning of that facility. So we expect by Q3 to have material from that facility that we'll use for our own drug product, PPQs in Q3.

And you're also right on that we have our own facility as well for SURPASS and for future products. We will use that for the viral vector. (inaudible) To the opportunity for a tumor agnostic indication arising out of the SURPASS trial, I'm going to ask Elliot Norry, our Chief Medical Officer, to comment on that.

Elliot Norry: I think that from the standpoint of a tumor-agnostic approach, it certainly makes sense. Our belief is that the basis for efficacy is the target, not the tumor type. That being said and with -- in conversations with experts and regulatory advice, one needs to establish that the drug would generally be approvable in one or more tumor types initially and then can approach a more tumor-agnostic approach. So I think that we certainly have our eye on the ability to approach this from a tumor-agnostic standpoint, Tony.

But we're also simultaneously looking at how do we demonstrate in each specific tumor type what would warrant an indication so that we can sort of move along those paths simultaneously. The trials that are designed to look individually at one tumor type and then another trial to look at another tumor type are not exclusive of a tumor-agnostic indication. They can be pursued simultaneously.

Operator: We have a question from Jonathan Chang with SVB Securities.

Unidentified Participant: This is (inaudible) on for Jonathan. I just wanted to ask on SURPASS-3, just what steps need to take place between now and trial initiation? And if there is just any other detail you can provide on that trial and the plan there?

Adrian Rawcliffe: Elliot, do you want to take that?

Elliot Norry: Sure. Jonathan, for the SURPASS-3 trial, it's really no different than what it takes to get other trials up and running. We have learned over time that it really is worth our while to get the protocol and the questions that we're specifically answering with the study really hammered out upfront. So the steps that are ongoing, really not sort of remaining, but ongoing are seeking KOL advice, finalizing protocol, getting ready to

submit the protocol to regulatory authorities and study sites, and we're on track to initiate that study this year.

Unidentified Participant: Great. Then also just wanted to ask, as you're starting the checkpoint inhibitor combination for the CD8 strategy, just curious if there are certain indications that you think might be more warranted for combination versus monotherapy approach?

Elliot Norry: Yes. So the combination can be used with any of the indications in the SURPASS trial. So it's not being introduced for 1 or 2 specific indications. We actually think that the mechanism of action should be applicable to all of the tumor types. And it's really there to help the T cells. And we know that we bring both our own T cells and other T cells into the tumor based on translational studies, and that cross tumor types.

So if that's the case, then the checkpoint inhibitors really should have a chance of working across tumor types. Obviously, checkpoint inhibitors have had a range of efficacy in those tumor types. So -- it's possible that it behaves differently from tumor type to tumor type, but we think that there's reason to pursue it in all of them.

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

Paul Jeng: This is Paul on for Michael. Just one more from us on the BLA filing. You previously mentioned the method validation for potency assays as part of the orphan process, which has caused some issues for other health care therapies during the process. So maybe just your thoughts on similarities or differences from others on potency assays and your confidence in line with the FDA there?

Adrian Rawcliffe: So I'll ask John to cover that one. John?

John Lunger: Yes. So on the potency assay, we're validating the same potency IC for our drug product that we use in the clinic. So we feel pretty confident about being able to successfully complete that validation. Obviously, we have the MAGE-A4 target to test against, which is a little different than what some of the other companies, particularly the toll companies have had to face. So for those 2 reasons, I think we're in good shape from a potency assay perspective.

Paul Jeng: Okay. Great. And then just secondly, really quickly on the ASCO data. So will this update for primarily the updated analysis in patients for whom we've already seen data? Or will there be any new patients from cohort in the update at ASCO?

John Lunger: Yes. So the -- what will be different about the ASCO evaluation presentation will be that we're combining data from the Phase I study and the Phase II study in patients with sarcoma. So it will be a larger data set, which will allow us to look at contributing factors to efficacy in a more robust fashion.

Paul Jeng: But specifically, to your point, there aren't any new patients that are significant new patients in that data set -- significant numbers?

John Lunger: Yes. I mean it's a pooled data set which makes it larger. Yes.

Operator: We have a question from Nick Abbott with Wells Fargo.

Nick Abbott: I have a question on the TIL. And that is obviously used the impact from to control IL-7 makes sense. My question is -- what are the levels of IL-7 that you expect to reproduce? And are these sufficient to support other T-cell populations on the hopeful assumption that 2 induced antigen spreading? And then I have a follow-up.

Adrian Rawcliffe: Okay. So we'll get back to you on the levels of IL-7 produced, and we have the presentation at ASGCT that I think will deal with that. What's your follow-up?

Nick Abbott: Well, it's kind of another one from But do you think you'll be able to measure the level of IL-7 in patients? And could it correlate to quality for of a better term is you can interpret the data from TIL is reflective of varying levels of T cells able to effectively target the tumor. So hopefully, better still quality products might produce more IL-7, but I don't know if you expect to be able to measure that in patients.

Elliot Norry: Yes. So Tony -- sorry, sorry, Nick. -- sorry. Wanted to -- let me just try and address that First of all, we can measure IL-7 in patients. But what's really important is the IL-7 in the tumor. And the way that the construct is made is that it's -- the IL-7 production is actually triggered by T-cell activity.

So the action will actually be inside the tumor. And there are ways that we can assess that with post-treatment tumor biopsies and systemic measurements of IL-7 will be a part of it. And there'll be other translational ways to look at activation of T cells and other markers that we'll use to assess the impact of IL-7 in addition to the efficacy itself.

Operator: And we have a question from Peter Lawson with Barclays.

Unidentified Participant: This is (inaudible) on for Peter Lawson. Just briefly on the pre-BLA meeting. I believe you mentioned you had set up a date for that, but could we expect an update when you have it, particularly around the manufacturing and release testing? And is there any sense of timing for when that may happen over the next few months here?

And then secondly, if you could talk a little bit about how you're thinking about preparing for the launch now ahead of that filing and what the next steps are there? And then just third, just quickly as well on the nivo cohort. Are you expecting to just have this in Phase I? Or are you already planning to incorporate this into your Phase II SURPASS 2 and SURPASS 3? And what might that look like there?

Adrian Rawcliffe: So first question -- first question around the pre-BLA meeting. So typically, that will happen a few months ahead of the file. So we anticipate that later this year. We will update on the progress on that and on all of the milestones that we've outlined between now and the BLA. With respect to -- well, your second question was with respect to launch? What was the question there?

Unidentified Participant: Yes, correct. The launch -- and when might you expect to do that or released in 2023?

Adrian Rawcliffe: Okay. So I'll ask -- Chief Commercial Officer, to just touch on that, Cintia.

Cintia Piccina: Thank you, Adrian. So we're planning to submit by the end of the year, and so hopefully be able to launch by the end of next year. The launch preparation is going great. We're leveraging a lot of the expertise that we already have the sites from a clinical perspective, from a clean operations perspective. And putting the team together to really have a launch that will be very focused on the centers of excellence. It is an ultra-rare disease, and we have the opportunity to also be extremely customer-centered as we are very focused on cell therapies alone. So really very agile and focused and leveraging our expertise for the launch.

Adrian Rawcliffe: And with respect to nivolumab in the Phase I trial and its potential use outside of that Phase I trial, I'll ask Elliot to comment on that.

Elliot Norry: Yes. So the use of nivolumab is really based on the fact that it's given every 4 weeks, which fits very well with the way that the current trial is organized. And we plan to test it in Phase I. I mean I think that that's really the nature of the arm of this trial. If we see that there are important efficacy advantages to it, then we certainly could advance that into a later-stage trial, just like we look for other signals. But we think that this is an important combination to explore.

Operator: We have a question from Mara Goldstein with Mizuho.

Mara Goldstein: Firstly, I'm wondering if you can maybe outline for us sort of where you are in terms of target identification with the Genentech program? And how we should think about that for 2022 and 2023? And the second, just on the SURPASS-2 and 3 programs. And what should we think about in terms of what would be considered sort of the bar for signal for those programs?

Adrian Rawcliffe: So I'll ask Helen Tayton-Martin to talk about the status of the Genentech program, and then I'll come back and touch on the (inaudible) Helen?

Helen Tayton-Martin: So in terms of the Genentech collaboration, the initial targets were already selected at the time of the deals, and they're not closed and unlikely to be disclosed in the near term. So targets nominated, and we're pleased with that. The

collaboration is moving forward the expected plan. I think it's different to the autologous system because here you have a gene-edited stem cell line that we start with.

So obviously, the focus is there and then constructs drop into that. So work is moving forward according to the plan. I think we're really pleased with the collaboration. I think more to come. Milestones will really probably be around the anniversary payments and also research payments that become due and we'll update on those in due course.

Adrian Rawcliffe: Thanks, Helen. And with respect to the level of signal, I think there's a general answer in a specific answer. The general answer which we've given quite a lot is with the you anticipate that at least 3 out of 10 patients show significant efficacy in the response in order to identify that that's sufficient efficacy to be thinking about taking that forward.

Obviously, with individual types, as Elliot referred to earlier, there are specific patient populations that exist within specific treatment paradigm, the bar for efficacy may be will vary across the tumor types that we're studying and that's one of the things that we're taking into consideration as we go into SURPASS-2 and SURPASS-3. But for SURPASS-1 in terms of signal 3 out of 10 responses with reasonable durability in what is inherently a very late end stage patient population.

Operator: And I have no other questions in the queue. I'd like to turn the call back to Adrian Rawcliffe for any closing remarks.

Adrian Rawcliffe: Thanks. As I conclude the call, I want to just refer back to our ambition to transform the lives of people with cancer by designing and delivering cell therapies, which, as I opened where there's not a short-term ambition, but we do have short-term deliverables against that. We have chosen to go after a difficult to treat solid tumors.

And we are about -- in that context, we're about to submit the BI for our first product. We have shown significant responses across multiple indications with our first next-gen product, and I look forward to updating that at ESMO. More broadly, we are developing the manufacturing capabilities to deliver the commercial product and products for our clinical trial, and we are well underway to finalize construction for our first allogeneic manufacturing facility.

Overall, I believe we are in a strong position to deliver against the ambition both for people with cancer and for investors. Thank you for listening.

And with that, we'll close the call.

Operator: This concludes today's conference call. Thank you for participating. You may now disconnect.