Adaptimmune Therapeutics

Q1 Financial and Business Update Transcript

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Presenters:

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OPERATOR:

Hello and welcome to Adaptimmune's First Quarter Call and Business Update.

I would now turn the call over to Juli Miller. Juli, please go ahead.

JULI MILLER:

Good morning and welcome to Adaptimmune's conference call to discuss our first quarter 2023 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, is 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 it over to Adrian Rawcliffe. Adrian?

ADRIAN RAWCLIFFE:

Thank you, Juli, and thanks to everyone for joining the call. My comments today will be brief, and we can go directly to questions.

We started 2023 at pace, and it promises to be a year of change for Adaptimmune. We completed the prioritization and restructuring in Q1, cutting costs whilst remaining focused on our priorities. We have the afami-cel BLA, the CD8 program in ovarian, bladder and head and neck cancers, PRAME and our allogeneic platform, a strong pipeline of cell therapies for a wide range of solid tumours.

Adding to that strength, we announced that we entered into a strategic combination with TCR2. We are two companies that have spent our entire histories focused on solid tumours with experienced teams, with advanced strong clinical pipelines with significant value-creating near-term catalysts. Add to that, the compatibility of our technology platforms, including an innovative next-generation toolbox and a cash runway into 2026, and taken together it's clear that this combination will create a preeminent cell therapy company to treat solid tumours.

We expect the transaction to close in Q2 2023, subject, of course, to shareholder approval at the end of this month. Both companies are very actively planning for integration, and we will update further once the transaction is closed.

We are also on track to have a commercial product, afami-cel, which would be the first engineered T-cell product on the market for the treatment of a solid tumour. We announced that we have completed Part 2 of the BLA submission in Q1, and Part 3 is in progress for completion in mid-2023.

Afami-cel is an incredibly exciting drug and the need for new marketed treatments for synovial sarcoma is compelling. Recently, we had the privilege of hosting a young woman, who is surviving synovial sarcoma at an internal meeting. Hearing her personal account of misdiagnosis, harsh treatments and her pleas for new and innovative therapies are inspiration for all of us here and highlights further how important afami-cel is for this patient population. She also described the loss of young lives from this cancer and the experiences of her peers in the sarcoma community. We hope to share stories like hers in the future and continue to raise awareness for synovial sarcoma and high unmet need in this cancer.

Continuing with the afami-cel news, we will present updated overall survival analysis for afami-cel in June at ASCO. It's clear that this is a powerful treatment for this rare and deadly cancer.

Beyond afami-cel, we remain focused on developing our MAGE-A4 franchise with our next-gen CD8 therapy and progressing more products to market. To that end, we are initiating the Phase II SURPASS-3 trial in combination with nivolumab for platinum-resistant ovarian cancer. This trial has the potential to become registrational and is supported by RMAT designation with the FDA. We are also initiating additional cohorts in the Phase I SURPASS trial in combination with pembrolizumab to treat patients in earlier-line settings for head and neck, and urothelial cancer.

Last year, we announced we have PRAME back from GSK, and we believe this is another powerful target for solid tumours, with increasing validation across the industry. We are progressing PRAME to be IND-ready by the end of this year and plan to initiate trials next year.

We also announced in Q1 that we are in the process of transitioning lete-cel back, and we will receive approximately $37 million from GSK in relation to the transition of the ongoing clinical trial. We anticipate lete-cel data in synovial sarcoma and MRCLS later this year, and we'll evaluate this opportunity accordingly.

In closing, this has been a significant first quarter for us and will undoubtedly prove to be a year of change as we move towards our first BLA and marketed product.

Behind that, we have an unparalleled pipeline of cell therapies for solid tumours, and we'll continue to prioritize development in a thoughtful, data-driven fashion. I look forward to reporting out on future progress.

With that, I'll turn the call over to Q&A. Operator?

OPERATOR:

Thank you. We will now begin the question and answer session. (Operator instructions).

The first question comes from Marc Frahm of TD Cowen. Please go ahead.

MARC FRAHM:

Thanks for taking my questions and congrats on the progress.

Adrian, you made the update of Part 2 being in of the BLA. On the Part 3 there, do you now have everything you need in-house and it's a question of packaging it all appropriately and submitting it? Or is there still a lot of data points that you need to gather for that portion?

ADRIAN RAWCLIFFE:

There's still a lot of work going on to complete the BLA on time. I'll ask Dennis, who is leading that program, to comment a bit further.

DR. DENNIS WILLIAMS:

Hi. As Adrian said, I mean, we're in the final stages of method validation and some of the other activities related to the dossier preparation, but we continue to look forward towards our goal, and we're excited to have two-thirds of the application already down at the FDA.

MARC FRAHM:

Okay. That's helpful. Then maybe just on the pipeline, the MAGE-A4 CD8 program, any data presentations we should be looking forward to, maybe in the second half of the year?

ADRIAN RAWCLIFFE:

We've said that we will provide an update on the monotherapy cohort in late-line patients and the patients that we've dosed in combination with nivolumab at and as appropriate at a congress later on this year.

MARC FRAHM:

Great. Thanks.

ADRIAN RAWCLIFFE:

Cheers Marc.

OPERATOR:

Our next question comes from Tony Butler of EF Hutton. Please go ahead.

TONY BUTLER:

Thanks very much. Adrian, I just wanted to discuss some of the trials with checkpoint inhibitors. I want to make sure that—is Adaptimmune paying for the checkpoint inhibitor? That's point one. And number two is, is the notion here that the combinations—let's be clear, the combinations may evolve greater activity, but I guess in the absence of a total control arm, how do you actually separate the two when you're simply, if you will, doing a Phase II study or at least a study that's exploring the combination? How do you think through that if you were to move to a regulatory trial? Thank you.

ADRIAN RAWCLIFFE:

The short answer on the question of who's paying for the checkpoint inhibitors, the answer is that Adaptimmune is currently paying for the checkpoint inhibitors. Then on the question of the trial design, I think we focused on the SURPASS-3 trials since that's the one that is a Phase II trial progressing particularly towards registration. I'll ask Dennis to comment on that trial design and how we consider that in platinum-resistant ovarian cancer.

DR. DENNIS WILLIAMS:

Sure. In SURPASS-3, it's a randomized trial, in that there's a monotherapy arm and then there's another combination arm with nivolumab. Both arms are compared against historical response rates for non-platinum-based chemotherapy in platinum-resistant disease.

Your point is well taken, but in the checkpoint inhibitor space, both as monotherapy and in combination with chemotherapy in platinum-resistant disease, the efficacy is very well described. So for us, it will be very obvious that if the combination arm shows something, it will allow us to compare that against the monotherapy arm to make some inferences if we see perhaps greater depth and durability. But we certainly will be able to determine that that's not solely due to the checkpoint alone because, as we know, checkpoints alone don't have appreciable activity in that disease.

We feel very confident that we will be able—the results of that trial will be quite interpretable.

TONY BUTLER:

If I could just ask one follow-up, Dennis, on this topic? Thank you very much for the commentary, but the other is, do you limit the number of previous therapies that a patient may undergo, in part because it seems that at least the response rates in a number of tumours were better when it was, I think, two or

less, at least for monotherapy. I'm just curious how you may balance that in combination also with a checkpoint inhibitor? Thank you.

DR. DENNIS WILLIAMS:

Yes. For SURPASS-3, we do limit the number of prior lines of treatment.

The data we presented about baseline characteristics and how they related to response, among them being the number of lines of prior therapy, that's across the basket experience we have in the Phase I SURPASS trial. Of course, some of those prior lines of therapies differs notably depending on which cancer that patient has.

In the platinum-resistant space, since platinum-based therapy is quite effective until they become resistant, we do allow a number of prior platinum treatments. We would expect patients to have received bevacizumab unless they were otherwise unable to receive that. We would also expect patients to have received a prior PARP if that was indicated. But we do intend to have a more homogenous Phase II population and among that to limit the number of prior lines in this trial.

TONY BUTLER:

Thanks very much.

ADRIAN RAWCLIFFE:

Thanks, Tony.

OPERATOR:

Our next question comes from Mara Goldstein of Mizuho. Please go ahead.

SUPAWAT THONGTHIP:

Thank you for taking our question. This is Supawat for Mara. Two small ones first. When are you going to get that $37 million payment from GSK? It says on the release that there will be a vote on the 30th. Is that TCR's or is that Adaptimmune's vote?

ADRIAN RAWCLIFFE:

I will comment on the vote, and I will ask Helen to comment on the payments received from GSK. The votes on the 30th are both the TCR2 and the Adaptimmune votes, happening on the same day. Subject, of course, to that vote, we plan to close the transaction very shortly thereafter. Helen?

DR. HELEN TAYTON-MARTIN:

Yes. Thanks for the question. This is Helen Tayton-Martin.

In relation to the money, the income from the GSK transition, the majority of that will be in line with the transition of the programs which is anticipated—the lete-cel program, which is anticipated during the course of 2023. There is some very small amount which will come in 2024, but we haven't disclosed it. It will come in stages, basically, but the majority of it will be during this year and hence it being built into our runway and production.

SUPAWAT THONGTHIP:

Got it. Then just a follow-up on afami-cel's launch. I was wondering if there's anything you can share regarding the payer discussion? How is that going? Any colour on the pricing strategy would be helpful. Thank you.

ADRIAN RAWCLIFFE:

I think the discussions with payers are going well at this point in time. We are obviously a year or so away from launch and we will have more to say on pricing strategy as we approach approval.

SUPAWAT THONGTHIP:

Got it. Thank you so much.

OPERATOR:

Our next question comes from Michael Schmidt of Guggenheim. Please go ahead.

PAUL:

This is Paul on for Michael. Thanks for taking our questions.

My first one is on PRAME. As you look towards a future Phase I, how are you currently thinking about expression thresholds for PRAME and potentially enriching for certain tumours up front versus sort of a broader signal-finding approach?

Then maybe just to read through from the recent PRAME updates across the landscape, it seems like some of the responses have mostly been in particular tumour types in the melanoma, ovarian. As you're moving towards the IND, what gives you confidence in the broader opportunity, and are there any sort of particular indications in focus for you?

ADRIAN RAWCLIFFE:

I will ask Jo Brewer to comment on that and our thinking as regards PRAME expression, our TCR and what indications we are considering.

DR. JO BREWER:

Thanks, Ad. It's a great question and I think we're really excited about having PRAME back in our hands because it's a fantastic target, and we are very excited about the opportunity that this will give us.

You're right, we'll likely look at more than one indication. We are making informed decisions about our clinical strategy at the moment. We're still deciding exactly where we will go. There are obviously synergies in ovarian with our other trials as we're working with the right people in that area, but there are these great expression profiles in other tumour types as well, and PRAME is a large opportunity for us. So I think we will use some of our learnings from MAGE-A4, most definitely. We'll look at working with sites that we know well. We're still in the preclinical phase here, getting ready for IND and obviously we're discussing those right now.

I think in terms of PRAME out there, it's obviously a well-validated target. There's been some great data recently from Immatics and we're very mindful of that. Our TCR is engineered as you would expect, so we have a higher-affinity engineered TCR, where we've been optimizing the TCR for binding and function, and so we're quite confident that this is going to give an edge with our PRAME product. We're also looking at our next-gen opportunities with PRAME as well. Based on work that we've done with the MAGE-A4 program, we're transferring that across to PRAME and so we will be looking to make the most of PRAME as a target with products coming forward.

I think it's still early days for the PRAME space, and we intend to be in there doing the best that we can and hopefully bringing forward some great products.

PAUL:

Great. Maybe just a follow-up on lete-cel. Just wanted to get your updated views on that program and how you might expect that program transfer in the third quarter to perhaps impact your OpEx? Then for that data later this year, is there a particular response rate threshold you're hoping to see to support a potential commercialization decision? Thank you.

ADRIAN RAWCLIFFE:

I think implicit in your question is the correct consideration that we're making, which is, as I've touched on before, we view lete-cel's return as essentially a free option on what has the potential to be quite a late-stage product, given that the NY-ESO trial was designed to support, at least in part, registration.

We look forward to getting those data back in-house, and it will be very much tail end of this year. We will make rigorous data driven decisions. I think the standard for activity in this space has been set by afami-cel with response rate approaching 40%, but I think if we look historically at what we've said about the required response rates in this space, I think if we're not at 30-odd percent in the space, I think it will be challenging to think about development. That's been our historic benchmark; that probably ends up being a future benchmark at this point in time for that particular asset, too.

PAUL:

Great. Thanks so much.

ADRIAN RAWCLIFFE:

Thank you.

OPERATOR:

Our next question comes from Jonathan Cheng of SVB Securities. Please go ahead.

DYLAN DRAKES:

Hey, guys. This Dylan Drakes on for Jonathan. Thanks for taking my question. First of all, I just want to ask, how you guys are thinking about strategic priorities for your pipeline programs following the merger, particularly when you think about your approach to ovarian cancer and how you plan to address any overlapping MAGE or mesothelin patient populations?

ADRIAN RAWCLIFFE:

Let me say, please, say a little about that. Obviously, we're limited in what we can say because we have yet to conclude the transaction, and at the moment TCR2 and Adaptimmune are continuing as independent companies. The best way of thinking about our focus at the moment is that we're focused on our priorities for Adaptimmune as a company, which I went through afami-cel, BLA, CD8, PRAME and our allogeneic platform.

However, clearly, as we bring this pipeline together, we will need to address two angles. One is how do you develop these programs in a synergistic fashion, a synergistic and efficient fashion. There's pros to, there’s benefits to the fact that we have both assets in ovarian, in terms of execution, clinical execution and experience in the ovarian space. There's also considerations like overlap between the antigens that we need to think about how one would deal with. All of that is driven by data and I think we are looking forward to the data that has been accumulated by TCR2 of Gavo-cel in combination with nivolumab. We look forward to making data-driven decisions on the entire portfolio as we go through this year and into next year.

We are very clear that we will need to be thoughtful and rigorous about the prioritization across the portfolio in order to develop the best medicines out of what is the best pipeline with the broadest range of targets and the deepest base of assets in the cell therapy industry at this point in time.

DYLAN DRAKES:

Following-up on that, I suppose, how do you see the allogeneic pipeline progressing, and how do you guys think about prioritizing both allogeneic and autologous programs in the future?

ADRIAN RAWCLIFFE:

So I'm going to touch on that just very briefly, and then I'm going to invite Jo to comment as she is leading the allogeneic platform work. I think one of the things that's become clear in the industry, and in fact, I think this is why there's a resurgence of interest in the autologous space, is that it's been clear to us for a long time that the allogeneic promise is definitely there. The idea of an off-the-shelf cell therapy product is incredibly attractive.

It's also quite a long way away. I think the next decade is, particularly in the solid tumour space, is the decade of autologous solid cell therapies. I think you can see in the investments that people are making in the CAR-T space why I think this is becoming an industry perspective.

Now, it's unfortunate that some of that is because of the inevitable challenges that have arisen as you try to develop a new modality, i.e., allogeneic T cells. That means that there's now I think, going to be quite a gap. Autologous is not simply a bridge to allogeneic. There will be different products and the allogeneic products will be, I think, quite a way behind the autologous products, particularly in the solid tumour space. As such, our focus is on developing our autologous pipeline of products which have near-term potential, near and medium-term potential, to benefit thousands of patients who have deadly cancers.

Then, I think the evolution of the allogeneic platform will then determine two things. One, the extent to which there is a direct overlap or the extent to which there is complementarity between these platforms in due course. We're very pleased that we have a foot in both camps, in particular with the allogeneic platform with our partner, Genentech.

But we see a very, very significant solid business in the autologous space in solid tumours before there's any allogeneic players out there, including our own.

Jo, anything that you'd like to add to that?

DR. JO BREWER:

I think you covered that pretty well, Ad. As I said, we are still really committed to the allogeneic platform, and we are making progress there. It's one of those working through unknown unknowns, what comes up in these programs. There are new challenges that need to be solved and the team has been working very hard on this for a long time now, and we've made a huge amount of progress, but we have to react to the ever changing landscape around us as well.

The regulatory bar for allogeneic program is very different to autologous, and the way that the autologous programs are progressing in terms of business model and ability to supply patients is also making that bar higher for allogeneic products as well. It's becoming—we're getting better at supplying and treating patients with autologous products, which means that the allogeneic products have to try much harder to be improvements on that.

So, we're still completely convinced that, that is the long-term future, and we're keeping all of that in mind, so we're still putting a huge amount of effort into our allogeneic platform because we do see that as our long-term play for the future, and that's why we're very happy to be partnered with Genentech who view it in a similar way to ourselves in that this is a long-term play for good gains at the end of it.

We've not been talking about it much recently because we're just carrying on. It’s great, but right now there’s transformative data within the autologous space and we're committed to that as well. We're making a valid business with strong data in treating patients. Allo will come in time, but for now there's important work to be done in autologous as well and important products that we can bring forward.

DYLAN DRAKES:

Great. Thank you. I appreciate that.

OPERATOR:

Our next question comes from Peter Lawson of Barclays. Please go ahead.

ALEX:

Good morning. This is Alex on for Peter. Thank you for taking our questions.

Just another question on the PRAME program. I was wondering if you could clarify just the timing of the IND, if that's mid-'23, and then when would you be in a position to start a Phase I study here?

Then kind of related, in terms of manufacturing for the PRAME program, are there any synergies in terms of being able to leverage your current manufacturing footprint or know-how processes for manufacturing for that program? Thank you.

ADRIAN RAWCLIFFE:

I will comment briefly, and then I'll ask John Lunger, Chief Patient Supply Officer, to comment on the manufacturing approach for the PRAME program.

I think you might be confusing our BLA timing of mid-2023 with the discussion that we've had on PRAME where we said we would be IND-ready in 2023, with the clinical trial to follow shortly thereafter. We anticipate being in the clinic with PRAME in 2024.

John, would you like to talk about the manufacturing for PRAME?

JOHN LUNGER:

Yes. Thanks, Ad. Hi. Absolutely, we're leveraging our capabilities that we've built in manufacturing. It's definitely one of the advantages of building the integrated capabilities that we have. As soon as PRAME began to come back, we started to look at our network. We have the ability to make the lentiviral vector that we would need in our facility that's in the U.K., and we have the capacity for cell product in the Navy Yard. So the flexibility that, that's enabled us to react is fantastic, and we'll certainly leverage that.

ADRIAN RAWCLIFFE:

Okay.

OPERATOR:

This concludes the question-and-answer session. I would like to turn the conference back over to Adrian Rawcliffe for any closing remarks.

ADRIAN RAWCLIFFE:

Thanks everyone for your time today. We've been very pleased to share our progress with you, and we look forward to updating later on in 2023 after we have concluded our transaction with TCR2. In the meantime, please feel free to reach out with any questions. Thank you again for your time. Bye.

OPERATOR:

This concludes today's conference call. You may disconnect your lines. Thank you for participating, and have a pleasant day.