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PRESENTATION

Operator

Good morning, ladies and gentlemen, and welcome to the Adaptimmune Q1 2024 Financial and Business Update conference call.
I would now like to turn the meeting over to Ms. Juli Miller. Please go ahead, Ms. Miller.

Juli Miller, Investor Relations

Good morning, and welcome to our conference call to discuss our first quarter 2024 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, and other members of our management team will be available for Q&A.

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

Adrian Rawcliffe, Chief Executive Officer

Thanks, Juli, and thanks, everyone, for joining us for our Q1 call.

I plan to provide some brief comments before we go into Q&A. The comments are going to be brief because a couple of weeks ago, we held an Investor Day, and we provided a fairly comprehensive update on the regulatory status of afami-cel as we move towards the PDUFA date of August 4. We also talked about how important this is for the field as the first approved engineered TCR T-cell therapy for solid tumor indication.

We also discussed our preparations for the commercial launch of afami-cel in some detail. We said that we'd be ready to do this on approval of afami-cel and that this would be the beginning of a commercial sarcoma franchise that we feel has significant and underappreciated value. In this morning's press release, we provided a further update on the BLA progress, and our Head of Late-Stage Development, Dennis Williams, is here for the Q&A portion of this call.

In short, our interactions with the FDA are progressing as planned and we're looking forward to our late-cycle review meeting in the second half of this month. Thus far, the FDA has not requested an Ad Comm or a REMS program. We look forward to the labeling discussions and also to commercialization in due course, and I'm happy to confirm that our customer-facing commercial and medical affairs team are now fully in place. Cintia Piccina, our Chief Commercial Officer, is here for the Q&A as well.
As I said, we are on track to be ready to launch on approval. We have a focused team starting at six to 10 treatment centres and ramping up to approximately 30 in due course. If you revisit the Investor Day presentation by Dr. Mihaela Druta, which is available on our website, you

will see that the expectations and anticipation for afami-cel within the sarcoma community are very high. I think that sense of anticipation was reinforced by Philip Leider, Patient Advocate and President of the Sarcoma Alliance, who lost his sister to sarcoma, and he very eloquently highlighted the demand for novel therapies in this space.

So, we are scaling our manufacturing to be able to meet what we anticipate to be the launch volumes for afami-cel in the second half of 2024. In summary, all is on track for the launch of afami-cel on approval. That's expected around our PDUFA date in August and is highly anticipated by the sarcoma community. Obviously, we are very eager to get this product into the hands of this community that has worked so hard with us over the last decade to develop medicines for sarcoma.

Behind afami-cel, we are also progressing the development of lete-cel, and I'll point you towards a presentation of the interim data analysis from the pivotal IGNYTE-ESO trial in synovial sarcoma and MRCLS that we previewed at a high level last year. These data look very similar to afami-cel other than, of course, they are in both synovial sarcoma and myxoid round cell liposarcoma and will be presented at a platform presentation at ASCO by Dr. Sandra D'Angelo. This will be an important milestone for people's understanding and the de-risking of this cell therapy as we continue to move towards having a BLA in place in 2025 with anticipated approval for lete-cel in synovial sarcoma and MRCLS in 2026.

You will have seen another press release from us this morning announcing that we've secured up to $125 million in debt financing with Hercules Capital, with the first tranche of $25 million available on closing and an additional $25 million available on afami-cel approval.

In addition, you will have seen that in Q1, we raised approximately $30 million off the ATM based on significant inbound inquiries. We've taken these steps to secure our financial position and have cash runway into late 2025. With this runway, we have the funds necessary to execute on our priorities, the launch of afami-cel followed by lete-cel, and also executing on the other pipeline projects, such as the Phase 2 trial with uza-cel for platinum-resistant ovarian cancer. Gavin Wood, our Chief Financial Officer, is here for the Q&A as well.

With that, I'd like to turn it over to the Operator for questions. Operator?

QUESTION AND ANSWER SESSION

Operator

Thank you. We will now take questions from the telephone lines. If you have a question, please press star, one, on your device's keypad. You may cancel your question at any time by pressing star, two. Please press star, one, at this time, if you have a question. There will be a brief pause while participants register for questions. We thank you for your patience.

Our first question is from Jonathan Chang from Leerink Partners. Please go ahead.

Jonathan Chang, Leerink Partners

Hi, guys. Thanks for taking my questions. First question, can you talk about the impact of the debt agreement announced today on your cash runway guidance? I'm just trying to better understand what's assumed in the current guidance.

Adrian Rawcliffe

So, Gavin?

Gavin Wood, Chief Financial Officer

Yes hi, Jonathan. A number of things have changed since we last gave guidance at the start of the year. Clearly, we had the termination of the Genentech agreement, and we're still working through the terms of that termination agreement. We've made significant progress on afami-cel and the development of the broader sarcoma franchise. As Ad's just mentioned, we've raised money under the ATM, and we've also executed a new debt facility with Hercules. Putting all those moving pieces together, we thought it prudent in bringing our cash runway by about a quarter to late 2025.

Jonathan Chang, Leerink Partners

Got it. What assumptions are there for how much of the debt is being drawn down?

Gavin Wood, Chief Financial Officer

We drew down $25 million at close, and there's $25 million available at the PDUFA date.

Jonathan Chang, Leerink Partners

Got it. Then, second question, just can you help set expectations for the upcoming ASCO IGNYTE-ESO presentation? Thank you.

Adrian Rawcliffe, Chief Executive Officer

Dennis, do you want to take that?

Dennis Williams, Head of Late-Stage Development

Yes, sure. For the ASCO presentation, we're going to be presenting results on the interim analysis of the pivotal IGNYTE-ESO trial. This is 45 patients in that trial followed for at least six months. It's evenly comprised of patients with synovial sarcoma and myxoid round cell liposarcoma. So, we'll present the efficacy data and safety data that were available at that interim analysis.

Jonathan Chang, Leerink Partners

Got it. Thanks for taking my questions.

Adrian Rawcliffe, Chief Executive Officer

Cheers, Jonathan.

Operator

Thank you. The following question is from Marc Frahm from TD Cowen. Please go ahead.

Marc Frahm, TD Cowen

Hi, thanks for taking the questions. Maybe first, nice that you're giving details along the way of the FDA review, and you have a late-cycle review meeting coming up. Can you kind of review what your disclosure strategy is going to be around some of the information that may be conveyed or gleaned by you guys at that meeting?

Adrian Rawcliffe, Chief Executive Officer

So, why don't I take a stab at that? We're actually running pretty hard towards the late-cycle review meeting and the discussions on labeling that we anticipate and on post-marketing commitments. We're going to be focused on that in the run up to the PDUFA date. I think if there's anything material that comes out from that, we will be disclosing. Otherwise, we're pushing hard for the discussions with the agency and getting to PDUFA and then being able to launch.

Marc Frahm, TD Cowen

Okay. As you get into the labeling decisions, I mean, what do you view as the kind of major kind of questions that need to be answered about indication statements and things to include or not include in the label?

Dennis Williams, Head of Late-Stage Development

Hi, this is Dennis Williams. I think it's like I mentioned at the Investor Day, some of this really comes down to individual sort of wording that goes in the label. Like, for example, I'll give the—to follow up on the example I gave at Investor Day, how we manage cytokine release syndrome, right? We'll be talking about how that information should be structured in the label, how we give tocilizumab, or how we would recommend that product and for what grade CRS.

Sometimes it's really about the finer points of how the words are in the label. We have had no discussions to date with the FDA around the indication statement, and we feel very confident that the indication statement we proposed is more or less, like a few words, is what we're going to end up with at the end of this review.

Marc Frahm, TD Cowen

Okay, thanks. Very helpful.

Adrian Rawcliffe, Chief Executive Officer

Thanks, Marc.

Operator

Thank you. The following question is from Tony Butler from Rodman & Renshaw. Please go ahead.

Tony Butler, Rodman & Renshaw

Yes, good morning. I'm very respectful of the focus on afami-cel and to a lesser extent on lete-cel, but I wanted to ask about uza-cel and whether or not, at least in the calendar year, there was any anticipation of a follow-up on SURPASS-3 either in ovarian or in the Phase 1 with bladder, etc? Thanks very much.

Adrian Rawcliffe, Chief Executive Officer

So, why don't I cover that with what we're thinking about for uza-cel? With SURPASS-3 in platinum-resistant ovarian cancer, that's designed with the potential to end up as a registrational trial, and therefore, we won't be putting out any data on that until we have at least enrolled all of the patients in that trial. There are interim reads for futility analysis, but we won't be communicating the data until we've at least enrolled all of the patients in that trial, which we anticipate being a 2025 event, full enrollment of that trial.

So, with respect to the other indications, we've now focused down onto ovarian cancer in SURPASS-3 and the two other indications in head and neck and bladder. The objective is to gather data in a Phase 1 setting in a range of patients, potentially in combination with checkpoint inhibitors as well. What we've said there is we anticipate giving an update on the basis of the data that we've gathered at the tail end of this year about how we anticipate moving forward with those, which would include the data themselves.

Tony Butler, Rodman & Renshaw

Thanks very much.

Adrian Rawcliffe, Chief Executive Officer

Cheers, Tony.

Operator

Thank you. The following question is from Graig Suvannavejh from Mizuho Securities. Please go ahead.

Graig Suvannavejh, Mizuho Securities

Good morning. Thanks for taking my question, and congrats on all the progress. I just wanted to go back to the FDA review process, and in particular, also in light of the great analyst event, or Investor Day, you had down in Philly, I'm just curious if there have been any other perhaps progress or maybe any additional inspections by FDA on the manufacturing facilities. Do you expect any other visits prior to approval? I just wanted to get a better handle on how things were shaping up there as it relates to CMC manufacturing in your facilities.

Dennis Williams, Head of Late-Stage Development

Hi, this is Dennis Williams again. So, yes, I think at this point, all the inspections are expected to be completed, right? Both manufacturing facilities that we utilize—so our own manufacturing for afami-cel drug product, the Lentiviral manufacturing facility that for the vector that supplies for drug products has been inspected that's had a good outcome, and all the clinical trial sites that were inspected also are completed. They all had a very good outcome. As I mentioned during Investor Day, the Navy Yard facility here from a GCP standpoint was also inspected. At this point, we think all the inspections are complete. I guess there's always a scenario where another clinical site could be inspected, but at this point, I think at this stage in the review, the inspections are completed.

Graig Suvannavejh, Mizuho Securities

Okay, thank you for that clarity. Just with regards to earlier comments that the Company made about not anticipating, or not expecting, perhaps, an Ad Comm or a REMS program, maybe just on the latter with regards to a REMS, just from a calendar perspective, is this something that a discussion would naturally have happened by now, or is it still part of a potential discussion between now and the PDUFA? Thank you.

Dennis Williams, Head of Late-Stage Development

Yes, sure. We did not submit a REMS in this BLA application. We've had discussions with the FDA during the review, and I think at the time I had this discussion at Investor Day, the FDA review was ongoing and there was no decision about a REMS at that time. They certainly had not asked for one at that time. You're correct that had a REMS been requested that that time would have elapsed already. That would have occurred within a few weeks of that mid cycle meeting. I can just say, in general, the conversations we've had with the FDA, we don't anticipate a REMS for this product.

Graig Suvannavejh, Mizuho Securities

Okay, thank you. Maybe the last question, if I could, just if you could remind us all, assuming an on-time approval, how we should be thinking about the shape of the uptake curve, particularly from a revenue perspective?

Adrian Rawcliffe, Chief Executive Officer

Why don't I touch on that? What we've basically guided to is that we've not given guidance on the specific numbers of patients that we anticipate coming through in the early

part of the launch. What we have said is that it's important to understand that because this is an autologous product that's manufactured, it needs to be screened for targets and then manufactured and then returned to patients. Whatever you think that uptake curve looks like, it's essentially frame shifted by, and we're guiding to, about a quarter from—so the first revenues from afami-cel would—the first patients would not be dosed, treated, and the first revenue is recognized until Q4 this year, even though we anticipate approval and we anticipate starting to enroll patients from the PDUFA date in August.

Graig Suvannavejh, Mizuho Securities

Great, thank you.

Adrian Rawcliffe, Chief Executive Officer

Thank you.

Operator

Thank you. The following question is from Michael Schmidt from Guggenheim. Please go ahead.

Paul Jeng, Guggenheim

Hi, this is Paul on for Michael. Thanks for taking our question. So, on the afami-cel launch, you've talked about targeting about six to 10 sites for that early launch. But looking beyond this year, what's your current thinking on strategy for scaling up to all 30 ATCs across the country, and how many of those centres have had experience with afami-cel in the clinical trial setting?

Adrian Rawcliffe, Chief Executive Officer

I'll ask Cintia to talk to that. Cintia?

Cintia Piccina, Chief Commercial Officer

Thank you. Yes, as Adrian said, we are targeting about six to 10 sites during the launch period, meaning the first quarter after launch, and we are already starting to engage beyond those with the expectation to have up to the 30 sites available about 18 months after launch. Out of these 30 sites in total, 16 of them, which will be the priority sites, have clinical experience with afami-cel, and some additional sites that are part of the 30 also have experienced with lete-cel. So, all of our 30 ATCs in the future—all of our clinical sites from lete-cel and afami-cel will be part of those 30. Again, we know that those sites see the majority of the synovial sarcoma patients in the country.

Paul Jeng, Guggenheim

Great, thanks for that. Maybe just a follow-up as you look ahead to the launch. Can you give a sense of what kind of metrics you're planning to sort of disclose in the early months to give a sense of how that launch is progressing? This has been an area of focus for the Amtagvi launch for Iovance, so just curious if we can expect updates on the number of patients identified versus infused, or if you're likely to provide more qualitative updates in the early months. Thank you.

Adrian Rawcliffe, Chief Executive Officer

We plan on updating that at our next Q call.

Paul Jeng, Guggenheim

Gotcha. Thanks so much.

Adrian Rawcliffe, Chief Executive Officer

No problem, thank you.

Operator

Thank you. The following question is from Arthur He from H.C. Wainwright. Please go ahead.

Arthur He, H.C. Wainwright

Hi, Ad and team, this is Arthur from H.C. Wainwright. Thanks for taking my questions. I guess I just had a broad picture question. As we see the cell therapy industry moving to the autoimmune disease area, could you help educate us to the potential from your platform aiming for the autoimmune disease? I know you guys are laser-focused on the launch, but I'm just curious on the potential there. Thanks.

Adrian Rawcliffe, Chief Executive Officer

Sure. As you've said, we are laser-focused on the launch. If you dig into the history of the Company long enough, we have explored the opportunity to develop TCR-targeted therapies for autoimmune disease, mostly focused on Treg programs. But I think in the short term, our focus is on,

obviously, the launch of afami-cel and the sarcoma franchise. But also, in between that and the very long-term future in autoimmune and maybe other indications, just the massive unmet need that can be addressed with TCR T-cell therapies in the oncology space.

If you look at the rest of our pipeline, you'll see that over the coming years, we will very quickly move from a sarcoma-only franchise with two products and $400 million of sales into much larger patient populations. There's an opportunity with uza-cel in, obviously, ovarian, bladder, and head and neck cancers; and then beyond that with PRAME, given the recent interesting data with that target, and with CD-70, both of which are in the late preclinical pipeline, and the opportunity there to address over a hundred thousand patients that are currently dying from their indications with the right target and the right HLA type.

We see this in terms of horizons, short-term sarcoma, longer-term, broaden that out, making cell therapies potentially curative and mainstream across a broad range of tumors, and then taking cell therapies into other spaces where patients can benefit in other non-oncology indications in the long-term.

Arthur He, H.C. Wainwright

That's it, thanks for the colour.

Operator

Thank you. Our last question is from Peter Lawson from Barclays. Please go ahead. Mr. Lawson, your line is open. You may proceed with your question.

Peter Lawson, Barclays
Great, thank you so much. Thanks for taking my question and thanks for the update. I wonder if you could talk around the turnaround time, kind of time it would take between kind of approval, booking the initial revenues, I guess we just think about the turnaround time, your end, also the turnaround time with the hospitals and the patients, and just any variables that we should be thinking about?

Adrian Rawcliffe, Chief Executive Officer

Cintia, do you want to talk to that?

Cintia Piccina, Chief Commercial Officer

Yes, absolutely. When we think about the turnaround time from the patient journey perspective, we need to consider that the patients, when they are identified, the first step is that they need to be tested for HLA and MAGE-A4, which is a process that can take a few days. Then, we go through the apheresis process, scheduling apheresis. When we receive the apheresis material, from a manufacturing turnaround time, then that would be of about 30 days, and then shipping it back to the sites. That's why at launch, the companion diagnostic test will be approved at the same time—that's our expectation, at the same time that afami-cel is approved. We would expect to see, as Adrian mentioned before, first patients dosed during the fourth quarter of the year.

Peter Lawson, Barclays

Gotcha, okay. Thank you. Then, after the patient's identified and the apheresis, what's the general timeline you expect around that? I imagine there's a fair amount of variability.

John Lunger, Chief Patient Supply Officer

Yes. Hi, this is John. I'm leading manufacturing. So, the turnaround time from—typical time from the collection of the apheresis material until the release of the product to send it back to the site tends to range between four and six weeks.

Peter Lawson, Barclays

Okay, and are there things that we should be thinking about the front-end and the back-end that are outside your control, and kind of the sense you get how long it takes patients to kind of get through that funnel from being identified by diagnostic test for HLA, and then, the other end, once it gets to the hospital and actually gets infused?

Cintia Piccina, Chief Commercial Officer

Yes, so a couple of things to consider before will be patient identification, the testing, then, depending on where these patients are, they will have to be referred to a treatment center. That can take a few days. Reimbursement is also something that will be checked at that very early part of the journey. Then, from apheresis all the way back to infusion, it's mostly straightforward. We could have potentially the patient condition getting worse, or other things that are out of control, but then it's mostly a little bit more straightforward.

Peter Lawson, Barclays

Gotcha, okay. Just, I guess, a final question just around the SURPASS data. I guess it's later this year we get head,

neck and bladder. Just the expectations around the number of patients we should see and kind of what you regard as a positive coming out with those data sets?

Adrian Rawcliffe, Chief Executive Officer

Elliot?

Elliot Norry, Chief Medical Officer

Yes, thanks. We haven't guided to specific numbers that we would anticipate as it relates to patient dosing. We have said that we anticipate having sufficient data to make directional decisions regarding both of those indications by the end of the year.

Peter Lawson, Barclays

Great. Thanks so much.

Adrian Rawcliffe, Chief Executive Officer

Thanks, Peter.

Operator

Thank you. We have no further questions registered at this time. I would now like to turn the meeting over to Mr. Rawcliffe.

Adrian Rawcliffe, Chief Executive Officer

Thank you, everybody, for your time today. Thank you for your questions. We look forward to seeing those of you at ASCO who are attending and look forward to updating you as we move towards approval and launch of afami-cel later on this year. Thanks a lot. Take care.

Operator

Thank you. The conference has now ended. Please disconnect your lines at this time, and we thank you for your participation.
