Adaptimmune Therapeutics
Fourth Quarter 2024 Conference Call Transcript

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Presenters:

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Adrian Rawcliffe
Chief Executive Officer

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Chief Commercial Officer

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Operator:
Hello, and welcome to the Adaptimmune's Q4 and Full Year 2024 Business Update Conference Call.

As a reminder, all participants are in a listen-only mode. The conference is being recorded. After the presentation, there will be an opportunity to ask questions. To join the question queue, you may press star, and then one on your telephone keypad. Should you need assistance during the conference call, you may signal the Operator by pressing star, and zero.

I would now like to turn the floor over to Juli Miller, Investor Relations for Adaptimmune. Juli, please go ahead.

Juli Miller:
Good morning. Welcome to Adaptimmune's conference call to discuss our full year and fourth quarter 2024 business update.

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 Leadership Team will be available for Q&A.

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

Adrian Rawcliffe:
Thanks, Juli. Thank you, everybody, for joining us on today's call.

I'd like to begin by discussing the TECELRA launch and the fantastic momentum that we've seen building since our approval late last year. This launch, as you know, has been our top priority and we have provided some updated performance metrics in this morning's press release. But I'm going to go into more details on this call so that you can see why we're so excited that our long-range forecast of at least $400 million in combined sarcoma franchise sales seems very achievable given these early success indicators.

Currently, we have 20 authorized treatment centres, or ATCs, available through our network, which you can find on tecelra.com, and that's pretty much updated in real time for the most part. These 20 ATCs represent a full two-thirds of our planned treatment network of approximately 30 sites. So-- we are very much ahead of schedule in setting up these ATCs. When we launched last year, we intended to have the full network established by late 2026. And our Q3 earnings in November and based on enthusiasm from sites and the progress that we've seen up to that point, we accelerated that timeline to the end of this year. Now, having two-thirds of these sites up and running already, we are very much on track to have the full network by the end of the year.

Now on to patients being treated with TECELRA. In Q4 last year, we apheresed three patients, and two of those were invoiced, resulting in Q4 recorded product revenue of $1.2 million. In Q1 2025, as of today, we have apheresed 10 more patients, and we have three additional apheresis scheduled by the end of March for an anticipated total of 13 patients apheresed in Q1 2025. This means we're likely to apheresis more than four times as many patients in Q1 as we did in the prior quarter.

Furthermore, we anticipate that the majority of the 10 patients apheresed in Q1 to date will be invoiced in Q1 with the remainder in Q2. And as such, we anticipate invoicing three to four times as many patients in Q1, i.e., approximately six to eight patients as we did in the prior quarter. But we can see this launch is accelerating rapidly and our KPIs are in line with or indeed exceeding our projections, which is a testament to the team's hard work and to the unmet need of sarcoma patients and the recognition from their treating physicians that T-cell offers a real solution.

And we anticipate the acceleration of these numbers will continue. We have an additional pool of around 20 patients who are biomarker positive, and we expect the majority of these patients to be treated in Q2 and Q3 this year. And behind that, we estimate that approximately 30 patients are in various stages of testing.

Now, we don't have full visibility into all of the MAGE-A4 testing that occurs. But more than 80 patients have completed testing for MAGE-A4 using our sponsored testing program since launch with a positivity rate, which is as expected, around 65%.

On the payer front, we've had tremendous success with reimbursement. Over 70% of commercial and Medicare lives are in plans that already have established policies in place to cover TECELRA. To date, we haven't experienced a single denial, which is a great accomplishment for the team and even greater outcome for patients obviously.

Before we move on to launch performance, I'd be remiss not to discuss manufacturing since this is so important for cell therapies. As you know, an effective, efficient delivery of autologous cell therapies is, in our view, a critical, indeed, a defining characteristic for successful commercialization campaigns. TECELRA manufacturing has exceeded all of our goals and expectations. Although the numbers so far are small, 100% of the released products were manufactured to specification with no manufacturing failures. Our average turnaround time from apheresis to product release has been less than our target of 30 days. We've had no capacity bottlenecks so far. And we have a robust supply of all the key materials, including importantly, vector already in place. We should have no trouble meeting the anticipated accelerating demand in the coming quarters that I referenced earlier.

The net result of everything we're seeing across our treatment network, our commercial and manufacturing teams, is that we anticipate sales of TECELRA will continue to accelerate in each quarter this year as the pipeline of new patients flows through, as new ATCs come online and as the timelines for each patient moving through the process becomes more efficient and more streamlined.

As of now, we have good visibility of the patients we expect for delivery in April. And although we're not yet in a position to provide formal revenue guidance, we feel very confident that the current consensus analyst forecast of approximately $25 million of sales in 2025 is very achievable. This is a testament to the commercial and CMC capabilities we've thoughtfully and strategically built, and which are now firing on all cylinders. Most importantly, though, it's a testament to the strength of the clinical data as reflected in the approved label, which has provided patients and their treating oncologists with the confidence that TECELRA is the right choice.

Now, we've built this commercial infrastructure not only for TECELRA, the first product in the sarcoma franchise, but also for the next product, Lete-cel, which we expect to be on the market

in 2027. The data we've generated for Lete-cel is as strong as that for TECELRA, and will be the basis for the BLA filing, which is on track for submission later this year.

TECELRA and Lete-cel form the basis of our sarcoma franchise. And as stated previously, we expect to see U.S. peak sales of approximately $400 million. Since Lete-cel will use the same commercial footprint as TECELRA, we will achieve significant operational channel and cost synergies. Put another way, the incremental cost to launch Lete-cel is minor, given that most of the capabilities would already be in place by the time of launch in 2027.

Now, I'm going to elaborate a little more on Lete-cel, and in particular, on the IGNYTE-ESO pivotal data that met its primary endpoint and was presented at CTOS last year. Efficacy is similar to what we saw with afami-cel, which was the basis for approval of TECELRA, and in the 64 patients treated with Lete-cel in the IGNYTE-ESO trial, there is a 42% overall response rate. This also included six complete responses and that's a complete response rate of almost 10% in these advanced metastatic synovial sarcoma and myxoid liposarcoma patients. For these patients with few other options, this is a transformational advance. As I mentioned, these data will serve as the basis for the rolling BLA filing planned to begin later this year.

And I also want to point you to a KOL event we previously hosted, which we've linked in our PR this morning. Dr. Sandra D'Angelo from Memorial Sloan Kettering Cancer Center led after CTOS. Dr. D'Angelo, who has been the lead investigator in our trials framed Lete-cel from the perspective of the provider. She was enthusiastic not only about the data but also about having another future treatment option. She speaks compellingly about her patients who, often in the prime of their lives, receive a devastating diagnosis of synovial sarcoma or myxoid liposarcoma and have limited treatment options. Dr. D'Angelo highlighted Lete-cel's significant improvement over standard of care and described the treatment journey from screening to dosing as streamlined. If you want to understand the transformative nature of these therapies in this space, I encourage you to listen to her presentation, which is on our website.

Lete-cel will expand our sarcoma franchise into NY-ESO expressing synovial sarcoma and myxoid liposarcoma, which we anticipate will more than double the number of treatable patients in the U.S. each year. We estimate that Lete-cel will eventually make up over 60% of our combined sarcoma franchise revenue.

Switching gears a little, last quarter, we shared the key priorities for our restructuring and for the Company going forward. These were: one, to build a successful business with what we anticipate will be two FDA approved products in sarcoma; two, to substantially reduce the need to bring in additional capital before becoming cash flow positive; and three, to achieve our objective to be cash flow breakeven in 2027.

The update for the launch of TECELRA and the progress with Lete-cel demonstrates we are well on track to meet the first of these objectives building our sarcoma business. On the capital reductions and the cash flow breakeven into 2027 objectives, we have two updates for you today.

First, we are pausing spending on our preclinical programs targeting PRAME and CD70. This decision reduces our forward cash flow demands in the period through 2028 by approximately $75 million to $100 million. This is in addition to the $300 million of forward cash savings over this period we announced at the end of last year as a result of our restructuring.

Secondly, we've engaged TD Cowen to help us explore all strategic options and evaluate every financial opportunity to ensure we achieve our goals and optimize value for our shareholders. This includes potential partnerships or collaborations, strategic combinations, various financial transactions and multiple pipeline monetization opportunities. We won't say much more beyond this, and while we appreciate all your questions, we will only provide an update on the progress of these initiatives when we have something meaningful to discuss. We have a lot of options and financial levers we can pull while we continue to execute our commercial strategy from a position of strength with the early success of the TECELRA launch.

In summary, we have great traction and acceleration on the launch of TECELRA and we'll continue to provide updates on this and the progress of Lete-cel towards a rolling BLA submission later this year. We will continue to effectively manage our costs as we push towards profitability in 2027. And in the context of the current capital markets, we will leave no stone unturned to enable us to achieve our objectives.

With that I'll open the call up for questions. Operator?

Operator:
Ladies and gentlemen, at this time, we'll begin the question-and-answer session. To join the question queue, you may press star, and then one on your telephone keypad. You will hear a tone acknowledging your request. If you are using a speakerphone, we do ask that you please pick up your handset prior to pressing the keys. To withdraw your question, you may press star, and two. We will pause a moment as callers join the question queue.

Our first question today comes from Marc Frahm from TD Cowen. Please go ahead with your question.

Alex:
Hi. This is Alex on for Marc. Thanks so much for taking my question. Just a couple on the TECELRA launch. First, could you comment on the pace of apheresis during Q1, specifically where patient number's higher in March versus January? And then given the cost savings you're working on, how many patients per year do you think you'll need to treat in order to achieve profitability in 2027? Thanks.

Adrian Rawcliffe:
So, I'm going to ask Cintia to comment on the pace of apheresis as we've gone through the last—part of last year and into this year and then I'll take the second question on profitability for the Company as a whole.

Cintia Piccina:
Thank you, Adrian. Thank you so much. Yes, the pace of apheresis has been increasing. As you would imagine, we started to open our ATC network last year so the majority of the apheresis came from the first ATCs that were open. We see that the apheresis to date came from five different ATCs. And as we continue to onboard treatment centres, the pace has been increasing over time. So, we certainly had a greater number of apheresis in February and March than we had in the prior months. So, the pace has been really very exciting.

Adrian Rawcliffe:
On the second question, we deliberately and specifically haven't provided forward revenue guidance through any of the mechanisms that your questions imply. So, I'm not going to actually give you forward guidance on 2027 at that point. But other than to say that by that point, of

course, TECELRA is sort of in its—essentially in its second full year after launch, it's third year after approval. And obviously, Lete-cel will have launched by that point in time, and it's the combination of those two together that get us to operating profitability.

Alex:

Great. Thank you.

Adrian Rawcliffe:

Cheers, Alex.

Operator:

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

Paul:

This is Paul on for Michael. Thanks for taking our questions. Just on the launch as well. Last quarter, I believe you mentioned there had been 15 confirmed double positive patients as of November. Can you just confirm what proportion of those patients are the ones who went on to undergo apheresis this year? And for those who did not, are they still candidates for treatment down the line, or if they dropped out of the treatment journey, do you have any visibility into why?

Adrian Rawcliffe:

Cintia?

Cintia Piccina:

Yes. The majority of the patients that were double positive have already been and starting the journey and the 10 patients that we apheresed so far are part of those. The majority of the others are still in the journey at different stages. We would expect some dropouts. Not all of the patients are going to eventually be treated. We haven't seen a lot of them to date but there could be different reasons why patients could potentially drop out. But what we've been seeing is the majority of them went through apheresis are still waiting to be treated.

Paul:

Okay. And then perhaps just to follow up. Do you have any visibility into what line of therapy that the patients typically are on who are going into testing? In other words, what proportion of patients who are getting tested could immediately move into treatment if qualified as double positive versus those that are perhaps earlier and being tested in front line and still being treated with other therapies? Thank you.

Cintia Piccina:

The majority of the patients, the large majority of the patients are patients that are being tested with the intent to be treated with TECELRA. So, they have already been exposed to chemotherapies, they could be at different stages of their journey. Over time, we do expect to see testing happening earlier in the treatment journey, and it's something that we'll hopefully be able to support as we grow into the awareness of biomarkers. But to date, the majority of the patients tested are patients that are eligible to start being treated with TECELRA right away.

Paul:

Okay. Thank you.

Jonathan Chang:

Thanks, Paul.

Operator:

Our next question comes from Jonathan Chang from Leerink Partners. Please go ahead with your question.

Jonathan Chang:

Hi guys. Good morning. Thanks for taking my questions. First, on the path to profitability in 2027, can you remind us what the assumptions are and other considerations that feed into that goal?

Adrian Rawcliffe:

Certainly. When we previously announced the restructuring, we talked about the pattern of our spending in 2025, 2026 and 2027. You might recall that we said that we would reduce our spending by about $50 million anticipated in 2025 from the levels in 2024, and then by $70

million to $80 million in each of 2026 and 2027. And that implies the cost base coming down from a little north of $200 million to sort of $130 million, $140 million. We've now subsequently announced that we are pausing the investment in PRAME and 520. And whilst we haven't calendarized that, that has a significant incremental impact in future years on that, reducing that still further.

Against that backdrop, we have the approval and launch of two products. TECELRA, obviously, last year and the sales of that, which we're now really starting to see ramp up and offset that. And then we anticipate the approval of Lete-cel on the basis of the BLA, which we'll complete in the second quarter of next year and which we anticipate the first sales in 2027 on approval in late 2026. So, first recognized sales in 2027. And it's the combination of those two ramping up. And we've not provided specific annual sales guidance for either product or in total but we have said that we anticipate U.S. sales of $400 million in total at peak for our sarcoma franchise. Hopefully, that's helpful.

Jonathan Chang:
Understood. I guess just synthesizing all of that together, did you believe you have sufficient cash today to get to your goal of being profitable in 2027, or does it assume…

Adrian Rawcliffe:
No, we said that last year, that remains the case now. And, the opportunities that we are exploring with the help of TD Cowen to enable us to bridge to that profitability to ensure that we are able to appropriately finance the Company over this time period to get to that goal of profitability in 2027.

Jonathan Chang:
Understood. Maybe just one last question for me then. How are you guys thinking about potential business development opportunities for the Company, for your programs, platform, etc.?

Adrian Rawcliffe:
As you know, we have a pipeline of opportunities preying the CD70 program. We have an ongoing collaboration and partnership with our partner, Galapagos, on uza-cel, and then we have the non-U.S. territories for our sarcoma franchise. All of those are available for partnering.

And we said last year that we were actively exploring and we continue to actively explore partnerships for all of those.

Moving more broadly, we anticipate that we will explore all options to be able to secure the future of the sarcoma franchise and of the Company. We anticipate that the properly financed company is our number one priority. As you've seen, the equity capital markets are challenging.

Now, the good news is that TECELRA is going as well, if not better, than we had envisioned. But that just makes it even more important to have a properly financed company and we are exploring all options. This includes the partnerships that you've mentioned and collaborations, it includes strategic combinations, it includes other financial transactions and the opportunity to monetize parts of our pipeline as well.

So, there's a lot of different levers that we are going to explore and that we are exploring in order to ensure that we can bridge through to that successful sarcoma franchise.

Jonathan Chang:
Got it. Thanks for taking my questions.

Adrian Rawcliffe:
Thanks, Jonathan.

Operator:
Our next question comes from Tony Butler from Rodman & Renshaw. Please go ahead with your question.

Tony Butler:
Good morning, Adrian. This is probably a question for Cintia. If you actually look at the TECELRA map and realizing that the goal of 30 ATC sites, obviously, all of them to date are in the east, in the south and out west. The question is, would the remainder, of course, I assume be in the Midwest, Missouri through I guess Utah, if you think about it, but also importantly given the cost comments that you've made, cost reduction comments that you made, is there a notion or a thought that you in fact may need more sales people, certainly in that midwest region? Thanks very much.

Cintia Piccina:
I can address the question directly. Thank you, Tony. Yes, the distribution of the sites was designed based on the concentration of patients that we see in these cancer centres already. We do expect to see more in the middle of the country, but also the largest concentration, and that's why a lot of the sites are where they are today, there's a higher concentration of patients there too. Our goal with the 30 treatment centres is to be able to provide access in a smoother way to the majority of the patients today.

We currently have a footprint that we announced before of five regions with five key commercial leads and five medical leads in the field. And we are open to exploring opportunities to continue to increase. But at this point, we feel that this is the right number of people that we need to provide the right focus on the treatment centres.

Tony Butler:
Thanks, Cinthia.

Operator:
Our next question comes from Graig Suvannavejh from Mizuho. Please go ahead with your question.

Graig Suvannavejh:
Yes, thanks. Good morning, and thank you for the updates on launch and congrats there. I had two questions relatively brief. Could you just remind us about the commercial strategy? Is it currently right now where your energies are primarily or singularly focused on the U.S.? Or, in other words, can you just remind us what the ex-U.S. strategy is that you would think that you would undertake on your own or is it with a partner? And then any timelines on filing in Europe?

And then secondly, I was just struck, just in the press release just on, I guess, the lack of the financials for the quarter. I realize that the K might come out next week. But that being said, any comments on OpEx, in particular, and kind of thoughts around OpEx trends for 2025, given the restructuring, given the goal of achieving profitability in 2027 relative to the uptake for TECELRA? Thanks.

Adrian Rawcliffe:
Thanks, Graig. I'll take the first question on broader strategies, the commercialization strategies on our sarcoma franchise and then I'll ask Gavin to comment on the costs and the financials.

With respect to the ex-U.S., our view is that it is absolutely—the absolutely critical thing for us to do is establish a commercially viable business around our sarcoma franchise in the United States, and that's the number one priority for us from a product commercialization perspective. It is obvious to us that there is demand outside of the United States, and many people with synovial sarcoma and myxoid liposarcoma who would benefit from TECELRA and from Lete-cel. And we've been clear for a while that we will explore both opportunities to do that ourselves in territories where that is rational and also opportunities to partner where that is rational and where that makes sense too, and we can take advantage of other people's infrastructure, etc.

Nonetheless, the most important thing is that we get the U.S. right and that's really where all of our focus is internally at the moment. And so whilst we are having discussions with third parties about ex-U.S. strategies, our focus is very clearly on the United States.

Gavin, do you want to talk on the financials?

Gavin Wood:
Yes. Thanks, Graig. With regards to no financials in the earnings released today, given the impact of the restructuring on internal teams and the fact that we've got some new areas for the auditors to consider, including revenue and inventory, we just need a little more time to finish the 10-K. Actually, we'll be publishing that on Monday.

With regards to your forward-looking questions around OpEx in 2025, I'll reiterate what we said at the Q call. We think the restructuring will reduce our run rate costs in 2025 by around about $50 million. Today, we've announced that we'll be putting our preclinical programs on hold in PRAME and ADP-520. That will drive incremental savings of roughly $75 million to $100 million over the next four years, an element of that will be in 2025 and we'll be able to update you in more detail on that at the Q1 earnings call.

Operator:
Our next question comes from Yanan Zhu from Wells Fargo. Please go ahead with your question.

Kwan:
Hi. Thanks for taking our questions. This is Kwan on for Yanan. Our question is also around TECELRA launch and ATC. You mentioned that the majority of patients have apheresis so far and from—majority of them came from the first five ATCs. Can you remind us when did those five ATCs become active and do you expect the additional ATCs to onboard patients as efficiently as those five ATCs? Thank you.

Cintia Piccina:
Thank you. Yes, I can address that question. Those five ATCs were active last year throughout the launch and we do expect now the ATCs that have been activated this year to bring additional patients. In fact, 85% of the ATCs of the 20 that are already in our website have identified at least one patient, the majority of them multiple patients. And so that's going to continue to grow as we onboard and activate more ATCs.

Kwan:
Got it. Thank you for that. Can you remind us what percentage of the patients that the first 20 ATCs cover and how about the next 10? Thank you.

Cintia Piccina:
What's happening today is that the patients are—and it's going to continue to happen, to a certain extent, the patients can be tested anywhere. They are being tested locally. And then when that patient is a biomarker positive patient for both biomarkers, then they end up getting referred to the treatment centres that are active already. It's hard to calculate the number of patients per ATC, because that referral pattern is being established as we activate those ATCs. But certainly, the proximity to the patients and the proximity to where the referral sites are is going to make it easier for patients to get to the treatment centres, the more treatment centres we have.

Does that answer your question?

Kwan:
Yes. That's helpful. Thank you so much.

Cintia Piccina:
Great. No, thank you.

Operator:
Our next question comes from George Farmer from Scotiabank. Please go ahead with your question.

George Farmer:
Hi, good morning. Thanks for taking my questions. First one is on your ex-U.S. efforts, I know this was touched on earlier. But are you actively engaging in the process of filing in the EU or is that on hold? And realistically, when do you think this drug could be available or cell therapy could be available in Europe?

And my second question relates to PRAME and CD70. Can you talk about any level of outside interest in these programs and do you think that those programs could be monetized in any way in the near future? Thanks.

(Multiple speakers 33:01)

Adrian Rawcliffe:
Sorry. I was going to say we haven't provided timelines for the ex-U.S. filing, etc. But, I would like to ask Dennis to comment on the regulatory position and development position there, particularly for the EU.

Dr. Dennis Williams:
Yes, thanks. We have—for TECELRA, we are part of the prime scheme in Europe for this program. We have all the things that you would typically do, preapproval in advance of marketing applications. We have an agreed pediatric investigational plan. We have open drug designation.

For a variety of strategic reasons, to make a stronger application, we're more likely to go in with the full trial results, meaning Cohorts 1, 2, and 3 of the SPEARHEAD-1 trial. As you know, right, we're looking to conclude our confirmatory evidence later this year. We're going to report out the results of Cohorts 2 and 3 in the third quarter. And, when we have the totality of data that's independent of the launch activities in Europe, that's really the strategy we would go in with a marketing application in Europe if the decision was to pursue that.

Adrian Rawcliffe:
Thanks, Dennis. And with respect to your other question, I mean, on PRAME and CD70, I mean, both of those programs target what generally regarded in the industry as a very high value, large opportunity targets and they are already of interest to a range of pharma companies and other large and small biotechs who have programs in this space. And so, we continue to believe that—and we have ongoing discussions that those are likely to be valuable programs for us.

However, I will refer to my comments in the scripted portion of this call that we are exploring all opportunities for—in order to be able to enable us to be successful with our sarcoma franchise that includes those partnerships. It includes other collaborations, strategic combinations, other financial transactions and monetization opportunities as well. And we have a lot of those levers that we can pull and we will give updates when we have something tangible to talk about.

George Farmer:
Okay. Thanks, Adrian.

Adrian Rawcliffe:
Thanks, George.

Operator:
Our next question comes from Arthur He from H.C. Wainwright. Please go ahead with your question.

Arthur He:

Hey, good morning and the team. Thanks for taking my question. I apologize if this question has been addressed before. Could you give us more colour on the patient number that has been identified by (inaudible 36:34) during—so far during this year?

Adrian Rawcliffe:

Maybe I'll ask Cintia to comment on that. Yes.

Cintia Piccina:

Yes, I can address that. In addition to the 10 patients that have been apheresed, we do have line of sight for about 20 other patients that are double positive and are going to be getting into the journey moving forward. We see a lot of excitement from the sites with the launch and now the availability of this new option for patients in an area that has not had any innovation. So, we see excitement in sites becoming treatment centres but also with the other centres of excellence in identifying and testing patients.

Arthur He:

Thank you, Cintia. And just a quick follow-up. To date, what's the roughly conversion rate from the double positive patient to get the apheresis?

Cintia Piccina:

It's more a matter of time than percentage. And so each patient has a very different journey. It can take different timings for them to be able to get through insurance approval, schedule apheresis and go through the process. It’s just too very low numbers at this time for us to be able to calculate any very specific statistics. But the majority of them are going through the journey over time.

Arthur He:

Thank you. Very helpful. Thanks for taking my question.

Cintia Piccina:

Thank you.

Operator:
Our next question comes from Michael Kim from Zacks Small Cap Research. Please go ahead with your question.

Michael Kim:
Hey everyone. Good morning. Thanks for taking my question. First, just curious to get your perspective on the incremental $75 million to $100 million of savings related to pausing on PRAME and CD70, just in terms of how these incremental savings impact the anticipated timeline for reaching an inflection in operating profitability?

Gavin Wood:
Yes. Thanks, Michel. Clearly, those incremental savings will help accelerate that time to profitability. But there are a number of other variables involved in that, including successful launch of TECELRA and the acceleration and ramping that we're already seeing, though, of course, we're four or five months into this. The launch of Lete-cel would be an important part of that as well.

So a number of variables. But continuing to focus on our cost base and being judgmental about where we put our assets to work will clearly help in expediting that voyage to profitability.

Michael Kim:
Got it. Okay. And then I appreciate the commentary on Lete-cel in terms of initiating the BLA later this year with an anticipated approval in '26, which I think would represent a meaningfully shorter timeline with respect to the process for TECELRA. Just curious to get your thoughts on where you might be able to leverage your experience with TECELRA to drive synergies or efficiencies and then what sort of timeline are you building in for FDA approval once you complete the BLA? Thanks.

Adrian Rawcliffe:
Thanks, Michel. I'm going to ask Dennis to talk about how the learnings from TECELRA have built into our plans for Lete-cel and the path to approval. And then maybe I'll ask Cintia to talk about how we anticipate the launch of Lete-cel in the context of a fully established commercial organization and treatment network that we've established with TECELRA.

Dennis, do you want to go first?

Dr. Dennis Williams:
Yes, sure. Thanks, Ad. There are a lot of learnings that we have from the TECELRA BLA review and approval that we've already incorporated into the planning of the Lete-cel BLA as we prepare it. They could be on the clinical side, just the CNC side things at the FDA going through that process. But essentially the same patient population that they would expect to see as far as planning around the companion diagnostics and having contemporaneous approvals. So all those learnings will be applied.

Now to your question about the FDA review period. We have breakthrough therapy designation for both indications for Lete-cel, both for synovial sarcoma and more recently that we received for myxoid/round cell liposarcoma. That application, that breakthrough therapy designation, was based on the results of the IGNYTE-ESO, right? The FDA has already seen some of the data from this pivotal trial. But as you know, these designations grant a lot of avenues to expedite development. Among them is the rolling review, which we intend to pursue that and we'll start that process at the end of the year. We would also be eligible for a priority review and a priority review for this application would essentially be eight months.

This is some of the timings that go into the plan where we would expect approval at the end of next year.

And then, Cintia, I think you're going to have some additional comments about the launch activities.

Cintia Piccina:
Yes, thank you Dennis. From a commercial perspective, as you would imagine, there's a lot of synergies. Initially, targeted therapy in sarcoma is something new. Testing patients is something that is being established right now for TECELRA and that's going to be established when we bring Lete-cel on board. It's going to be a different target but the paradigm of testing patients for sarcoma is going to be established. The ATC network is going to be available and a lot easier to just pick up on Lete-cel. Commercial platform is in place in terms of ordering and all of the chain of custody, chain of identity process is all established already.

And we do have a small commercial team but really, we're very proud of the team that is in the field across both medical and commercial. They're very experienced in working with the sites. And the customer overlap with Lete-cel it's 100%. So we're going to leverage exactly the same network and commercial footprint, medical footprint that we have in place at this time. So a lot of synergies with Lete-cel.

Michael Kim:
Great. Very helpful. Thanks for taking my questions.

Cintia Piccina:
Thank you.

Operator:
Once again, if you would like to ask a question, please press star, and then one. To withdraw your questions, you may press star, and two.

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

Peter Lawson:
Great. Thanks for the updates and taking the questions. Just on the ATCs that are actively infusing patients, how many have infused more than one patient and what percentage of those ATCs are actively infusing? And then just your confidence level around kind of whether it's meeting or exceeding that target of 30 centres by year end?

Cintia Piccina:
I can address that. As I mentioned before, about five ATCs have been the ones responsible for the patients that have been apheresed so far. We do have ATCs that infused more than one patient. And the pace in which the ATCs are enrolling patients and having patients apheresed is exactly as what we would expect. The pace of onboarding ATCs has actually been a little faster than what we expected based on prior experiences. And I attribute that really to the excitement of the sarcoma specialists to be able to offer this new treatment option for their patients.

And also, the fact we learned a lot from the prior cell therapy programs. We had a lot of conversations with our treatment centres to make sure that we implemented an onboarding process that was as simple as it could possibly be. And having a team that is very focused and customized to meet the needs of these customers in a way that the process is as simple as it can be and it can be expedited and we can troubleshoot very specifically as needed.

Peter Lawson:
Great. Thank you. And then are there any capacity constraints or manufacturing bottlenecks that could potentially limit the patient infusions you need to kind of hit the 2025s and also that 2027 profitability number?

Cintia Piccina:
We have not seen any capacity limitations so far, not on our manufacturing side, not on the site side as well in terms of apheresis beds, and maybe John can comment on this as well. But we—our capacity is enough to reach all of our goals.

But John, you want to comment on it?

John Lunger:
Yes, sure. Thanks, indeed. Absolutely. I think some of the challenges that we've perhaps seen in other CAR-T launches that we've learned from have put us in a position where we don't have capacity constraints. Adrian mentioned that we've been exceeding our targets of the 30 day time from the apheresis collection to release. And he also mentioned that while it's a small number, we've had 100% success rate thus far with our commercial, which is, of course, both of those are different than what you've seen in other CAR-T.

So it just gives us continued confidence that we've set this up right for a successful launch and ultimately on the way to Lete-cel as well.

Peter Lawson:
Got you. Thank you. I know it's hard to kind of break out individual components, but for that cost savings from PRAME, CD70 and headcount reduction, what proportion of that is kind of folded into the commercial rollout versus extending the cash runway?

Gavin Wood:

Peter, I think you're right when you say it's difficult to break those components at the moment. We'll certainly give further update at the Q1 earnings update. But we are absolutely focused on successful commercial launch and applying resources appropriately to support what's been so far a very successful launch into TECELRA.

Peter Lawson:

Great. Thank you so much. Good luck going forward.

Adrian Rawcliffe:

Thanks, Peter.

Operator:

Ladies and gentlemen, with that we'll be concluding today's question-and-answer session. I'd like to turn the floor back over to Adrian Rawcliffe for closing remarks.

Adrian Rawcliffe:

Thanks. And thank you, everybody for your questions. As I think we've demonstrated, we have great traction and acceleration on the launch of TECELRA. And I'm really looking forward to being able to update you on that as we move through the year and also on the progress towards the BLA for Lete-cel. We will continue to manage the cost base. We will continue to push forward through to profitability in 2027 and we will leave no stone unturned to enable us to achieve that from a financing perspective.

And with that, I'll close the call. Thank you all for your questions and your interest.

Operator:

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