Adaptimmune Therapeutics
FDA Approval of TECELRA Announcement Transcript

Date: **Friday, August 2nd, 2024**

Time: **8:00 AM ET / 5:00 AM PT**

Presenters:

Dan Od-Cohen
Investor Relations

Adrian Rawcliffe
Chief Executive Officer

Cintia Piccina
Chief Commercial Officer

Dr. Elliot Norry
Chief Medical Officer

Dennis Williams
Senior Vice President, Late-Stage Development

John Lunger
Chief Patient Supply Officer

Operator:
Hello and welcome to the Adaptimmune Therapeutics conference call to review its recent approval of TECELRA.

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

I would now like to turn the conference over to Dan Od-Cohen, Investor Relations for Adaptimmune. Dan, please go ahead.

Dan Od-Cohen:
Thank you, Operator. Hello and welcome to our conference call to discuss the recent announcement regarding approval of TECELRA by U.S. FDA.

I would ask you to review the full text of our forward-looking statements from our 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. Ad?

Adrian Rawcliffe:
Thanks, Dan, and thank you everyone for joining us. Yesterday, we received notification that afami-cel, now TECELRA, has received accelerated approval from the FDA. This is a watershed day for Adaptimmune, for the cell therapy field, but most importantly, for the sarcoma community, and in particular, for people with synovial sarcoma.

TECELRA is Adaptimmune's first commercial cell therapy product. It's also the first engineered cell therapy product approved by the FDA for a solid tumor cancer, and it's the first new treatment option for synovial sarcoma in well over a decade.

© 2024 Adaptimmune Therapeutics

We're honoured to be joined on this journey by the patients, the caregivers, the clinical investigators and the teams who participated in the SPEARHEAD-1 trial and also by our partners and the ultra-dedicated colleagues here at Adaptimmune who have worked tirelessly with endless determination to bring TECELRA through a decade of groundbreaking R&D to this point of approval.

People with synovial sarcoma are frequently afflicted with the disease as young adults. They suddenly face a diagnosis for a rare, devastating cancer before they turn 30. Adaptimmune has developed a novel, cutting-edge, clinically impactful onetime infusion treatment option, TECELRA. Today is the day we redefine how this cancer can be treated, and we are extraordinarily proud of this achievement.

TECELRA is positioned to make a significant impact to the lives of people with synovial sarcoma. We are already in process of onboarding sarcoma centres of excellence at authorized TECELRA treatment centres. We aim to onboard 30 ATCs over time, and we believe this will allow us to supply TECELRA to every eligible U.S. patient.

Following market access research and discussion with payers, TECELRA will launch at the list price of $727,000. We've stood up a patient support program we call Adaptimmune Assist, which aims to provide end-to-end support ensuring a seamless, personalized experience throughout the treatment journey. And you know we've built Adaptimmune from the ground up as a fully integrated cell therapy company, complete with our in-house manufacturing. We manufactured every single dose of afami-cel for the SPEARHEAD-1 clinical trial in our manufacturing facility here at Philadelphia's Navy Yard over the five years of the trial. And we've recently bolstered our manufacturing capabilities and we stand ready to deliver all ordered doses of commercial TECELRA.

Beyond TECELRA, we are dedicated to advance our clinical pipeline to bring cell therapies to more people who need them. We're planning to progress lete-cel, the next product in our sarcoma franchise, with a rolling BLA submission to the FDA next year. We're also developing our next-generation cell therapy uza-cel in ovarian cancer in a potentially registrational SURPASS-3 trial.

© 2024 Adaptimmune Therapeutics

Adaptimmune was founded on the conviction that cell therapy would revolutionize the treatment of cancer. This has been demonstrated in the hematological cancer space and TECELRA's approvement is a significant milestone in our journey to expand cell therapy into solid tumors.

With that, I and the members of the leadership team here are happy to take any questions.

Operator:
Thank you. We will now begin the question-and-answer session. To join the question queue you may press *, then one, on your telephone keypad. You will hear a tone acknowledging your request. If you are using a speaker phone, please pick up your handset before pressing any keys. To withdraw your question, please press *, then two.

The first question is from Marc Frahm with TD Cowen. Please go ahead.

Marc Frahm:
Hi. Thanks for taking my questions and congratulations on getting the first approval, a big accomplishment for any company, particularly in the space of cell therapies.

Maybe just first, can you just kind of remind us the timeline from here to actually being able to recognize revenue. Obviously, there's a whole multi-step process to actually getting to an infusion. But then also, have you had any ability to maybe warehouse some patients getting cells already harvested that you can now with the approval in hand convert over to the commercial process? Or does everybody have to start completely from scratch for that entire process?

Adrian Rawcliffe:
Actually, what I'll do is I'll ask Cintia to talk about the patient journey, and then I'll come back to what that means for revenue recognition at the end. Cintia, our Chief Commercial Officer, here.

Cintia Piccina:
Thank you for the question. That's exactly what we are doing right now. So in the process of onboarding the sites, we do expect patients to start to be tested right now and go through their journey starting immediately, so it will take some time until we get the revenue recognition. We know that there's a lot of anticipation and excitement. As soon as the treatment sites get onboarded, we'll be able to see the orders coming through.

© 2024 Adaptimmune Therapeutics

Adrian Rawcliffe:

The impact of that is that we anticipate first commercial sales in Q4 this year, and those will obviously be modest because it's the front end of the curve and we'll see increasing sales as we move into 2025.

Marc Frahm:

Very helpful. Then just in terms of disclosures, as you kind of onboard and get towards that 30 ATCs actually active, able to administer commercial therapy, what's kind of the disclosure strategy there? Do you plan on disclosing when the first centre is fully authorized? Not until you get to the next earnings? What's the plan there?

Adrian Rawcliffe:

Yes. I'll ask Cintia to comment on what we're going to see in terms of as we onboard centres starting immediately with the centres that are in process. Then I'll wrap up now with the discussion that we will have more to say about what we're going to be doing from a metrics perspective in our Q2 call in about a week's time.

Cintia, do you want to talk about the immediate centres?

Cintia Piccina:

Yes. We are in the process of onboarding the 6 to 10 treatment sites that we are planning to have fully activated in the next few months. We have a locator tool that will be available in our website, so that information will be public immediately. We already have a few sites that are going to be up and available at that locator tool. Hopefully, you're going to be able to see that even today publicly. As more sites get in that onboarding process, they will be visible, so then patients can look it up and be able to reach out to them as well.

One important thing to keep in mind is that the testing was approved also at the same time that TECELRA was approved, and they are available as well. The patients don't need to go to a treatment centre to be tested. They can get tested anywhere, and the testing is already available, so that journey can start right away.

Marc Frahm:

Great. Thank you and congrats again.

© 2024 Adaptimmune Therapeutics

Adrian Rawcliffe:

Thanks, Marc. Cheers.

Operator:

The next question is from Michael Schmidt with Guggenheim. Please go ahead.

Michael Schmidt:

Hey guys, good morning and congrats from me as well. Great, great accomplishment.

Adrian Rawcliffe:

Thanks.

Michael Schmidt:

Just a quick housekeeping question. So there are some minor differences in response rate and duration of response in the label versus the Lancet article. Could you just comment on any differences there in the analysis perhaps?

Adrian Rawcliffe:

Certainly. I'm going to ask Dennis Williams, head of our Late-Stage and who led the development and approval of TECELRA to comment on that. Dennis?

Dennis Williams:

Yes, sure. During the FDA review of this application, they requested some additional analysis, including independent review analyses. Those analyses resulted in actually a higher response rate because some additional patients were identified as having response by independent review. Additionally, that analysis identified some patients that were determined now to be complete responses when previously they were determined to be partial responses.

With these additional responders, it did affect the median duration of response because some of these patients, the response durations were not greater than six months, but the responses were very consistent to the Lancet article where the proportion of patients that have responses 12 months or longer is 39%. And you can see what's in the prescribing information that these responses were quite durable with some patients ongoing in response out to Year 3 at the data cut.

© 2024 Adaptimmune Therapeutics

Michael Schmidt:

Okay. Great. Super helpful. Thanks for that. Then yes, thinking about sort of the early launch, do you have a sense of how many patients are seen in these initial 6 to 10 ATCs? And related to that, generally, how would you characterize physician awareness of the therapy, perhaps outside of your clinical trial sites? How quickly do you anticipate NCCN guideline inclusion, for example, do you expect it to be a driver for uptake next year? Thanks.

Cintia Piccina:

Okay. Let me address your questions. I'll start with the last one. From an NCCN perspective, we have approval. We will wait to see and hope to have it revised as soon as possible, so we're looking forward to that.

With the treatment sites that we are onboarding, the majority of them have been clinical trial sites, so they have been working with afami-cel from the beginning of the clinical program and are now in the process of getting ready to make it available on the commercial setting as well. So in terms of awareness and understanding how the patients need to be tested and treated, it's very high.

We also have onboarded our commercial and medical affair field teams, so they have been already engaging with sites beyond the clinical sites to communicate all the information that they need to know about testing and also about TECELRA. So, the awareness is very good on the treatment sites and will increase over time now with the approval.

Michael Schmidt:

Great. Thanks. Maybe just one more, just following up on the prior question. I know the manufacturing time itself is very short for afami-cel. How long would you estimate it would take from a patient initially receiving the test, the antigen test, to actually being able to recognize sales for that patient? Is it a few weeks? Three months? How would you estimate that?

Adrian Rawcliffe:

We're basically encouraging people to think about three months from approval to first registration, first recognition of revenue, so that will put it into Q4 this year.

Michael Schmidt:

Super helpful. Thanks so much and congrats again.

© 2024 Adaptimmune Therapeutics

Adrian Rawcliffe:
Thanks, Michael.

Operator:
The next question is from Tony Butler with Rodman & Renshaw. Please go ahead.

Tony Butler:
Good morning. Thank you. First of all, again, much like the others, congratulations Adrian to you and the team. Two questions. Cintia, one is, roughly how long does it take to onboard a site? The second question is, with the commercial team available today, what do they actually do today given that the 6 to 10 sites are currently being onboarded? Thank you.

Cintia Piccina:
The field teams are very engaged in not only helping to onboard the sites, because this is part of what they work closely with the sites that will become treatment sites, but also engaging with other centres of excellence in sarcoma to make them aware of the availability of biomarkers that are now actionable in synovial sarcoma, and also educating them on the clinical profile of afami-cel so then we can identify patients beyond the treatment sites, have these patients tested and then referred to the treatment sites.

The onboarding process that we put together is fairly simple. We started this onboarding already a few months ago and there are activities that are on our side and some activities that are on the sites' side, so it depends a little bit on each site. We are very close to have sites fully activated, and we will already have a few sites that are in the final stages of just now that we've got approval being received in the final activation. Their names will be already up in the locator tool very soon, so then patients will know where to go if they want to go directly to a treatment site. As we have more ATCs that are going to be getting closer to that point, their names will also be available there.

Tony Butler:
Thank you.

Adrian Rawcliffe:
Thanks, Tony.

© 2024 Adaptimmune Therapeutics

Operator:
The next question is from Jonathan Chang with Leerink Partners. Please go ahead.

Jonathan Chang:
Hi guys. Congrats on the approval and thanks for taking my questions.. First question, how should we be thinking about the TECELRA early launch? What could that look like? I know you guys have given your thoughts on peak sales. How should we be thinking about the early ramp? And then second question, do you guys have updated cash runway guidance post the announcement today and the recent Galapagos deal? Thank you.

Adrian Rawcliffe:
On the launch dynamics, I think we've sort of talked about the number of centres we have up and running. When we talk in Q2, at the Q2 call about a week from now, we'll talk a little bit more about how we're thinking about some of the metrics that we're going to be tracking. So I'd encourage you to wait for that.

With respect to earnings guidance, runway guidance, etc., we'll also cover that in the Q2 call. Obviously, since the last Q, we've not only taken on board the debt deal with Hercules Capital; we've also done the deal with Galapagos and we will update appropriately at the Q2 call.

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

Adrian Rawcliffe:
Thanks, Jonathan.

Operator:
The next question is from Graig Suvannavejh with Mizuho. Please go ahead.

Sam Lee:
Hi. This is Sam Lee on for Graig. Congrats again on the approval and thank you for taking the questions.

© 2024 Adaptimmune Therapeutics

Maybe just one quick one on my end. How should we be thinking, I guess, about gross to net and price increases, if you had any guidance there? And then also, maybe any updates on timelines for Europe for afami-cel as well?

Adrian Rawcliffe:
I'll take the European one, and then I'll ask Cintia to comment on thinking on gross to net, etc..

With respect to Europe, I think over time, we are committed to bring the benefits of cell therapy, TECELRA and the rest of our pipeline to as many patients as possible, but for the moment, our focus is on the U.S. commercialization and launch and will be for some time. That's the singular focus of this organization at this point in time and in the coming months.

Cintia, do you want to comment on gross to net?

Cintia Piccina:
Yes. From gross to net, we expect that it would be similar to other cell therapies. We're not contracting at this point in time, so just regular and traditional discounts, so probably about between 8% to 10%.

Sam Lee:
Got it. Thank you so much and congrats again.

Adrian Rawcliffe:
Thanks, Sam.

Operator:
The next question is from George Farmer with Scotiabank. Please go ahead.

George Farmer:
Hi. Good morning. My congratulations as well.

Adrian Rawcliffe:
Thanks, George.

© 2024 Adaptimmune Therapeutics

George Farmer:
I was wondering, is it possible to prospectively identify patients prior to being eligible for therapy? Does MAGE-A4 expression change over time and the like, just to get them ready for treatment when they ultimately will need it?

Adrian Rawcliffe:
Cintia.

Cintia Piccina:
We don't know for sure if the MAGE-A4 expression changes over time. We don't have any data to support that, but we do support and emphasize the ability to treat patients early in their journey, so they can plan for a treatment plan that is the most appropriate for the patient.

We have the companion diagnostic from Agilent that just got approved today, so from a commercial test that is going to be available, that is IHC based, it got approved today and it will be broadly available as we speak, so that journey can start.

Adrian Rawcliffe:
Do you want to say anything about HLA testing as well?

Cintia Piccina:
HLA testing is more broadly available. We do have a companion diagnostic that also got approved yesterday—last night, in fact. But the HLA typing, that doesn't change over time. That's something that is a characteristic of the patient.

George Farmer:
Great. With regard to price, what went into the thinking about the appropriate price for this therapy?

Cintia Piccina:
We determined the price of TECELRA based on the clinical value that it brings to patients that have a rare type of tumor and with a very high unmet need. We provide the very strong clinical efficacy with a single dose, and that's also very different than traditional therapies, in particular in the synovial space where there has been no innovation in the past several years.

© 2024 Adaptimmune Therapeutics

George Farmer:

Okay. Great. Thanks again and congratulations.

Adrian Rawcliffe:

Thanks, George.

Operator:

The next question is from Arthur He with H.C. Wainwright. Please go ahead.

Yu He:

Hey Ad and team, congrats. I have two questions. Regarding the FDA's requirement for the confirmatory evidence to convert these to a full approval, is there any additional information you can provide to us? Is there Cohort 2 data or is this the requirement?

Adrian Rawcliffe:

Dennis, do you want to talk to that?

Dennis Williams:

Yes, sure. Like we have previously communicated, the confirmatory evidence plan really is around the ongoing SPEARHEAD-1 trial. We have both Cohort 2 data, and we actually have a Cohort 3 as well. Essentially, those cohorts are nearly identical and they're both treating the synovial sarcoma patient population. Essentially, those two groups pooled comprise the confirmatory evidence, which we will submit to the FDA next year to complete that obligation and convert this application to regular approval.

Yu He:

Great. Thanks, Dennis. My second question is regarding the label expansion for the afami-cel. Could you give us some status update on the SPEARHEAD-3 study and when can we expect the data?

Dennis Williams:

SPEARHEAD-3 is early in its development, the pediatric trial. That trial is currently recruiting, and we do not expect full data for that for some time. We certainly could give further updates on that.

© 2024 Adaptimmune Therapeutics

But ultimately, if that data shows that we see the very similar efficacy in the pediatric population of synovial sarcoma, we would look to extend the indication statement down to that age range.

Yu He:
Very helpful. Thanks again and taking my questions, and congrats.

Adrian Rawcliffe:
Cheers, Arthur.

Operator:
Next question is from Ted Tenthoff with Piper Sandler. Please go ahead.

Ted Tenthoff:
Great. Thank you very much and congratulations. Great day for patients.

Adrian Rawcliffe:
Thanks, Ted.

Ted Tenthoff:
A lot of the questions have been answered—yes, absolutely. I wanted to ask about CMC and manufacturing. I know this has been an intense focus for the company. Was there anything in there in terms of release backs or anything like that, that we should be aware of or that came as a surprise? What do you guys envision as potential out of spec? Thank you.

Adrian Rawcliffe:
I'm going to ask John Lunger, our Chief Patient Supply Officer, to take you through that. John?

John Lunger:
Yes. Thanks for asking. On the specifications, no surprises there. The specifications for the drug product, they're consistent with what we measured against in the SPEARHEAD-1 trial. Really, there's nothing that we have at the moment that tells us that our out-of-spec rate should be markedly different, if at all, from what we saw in SPEARHEAD-1, which was about 90%.

© 2024 Adaptimmune Therapeutics

Ted Tenthoff:
Great. Thank you.

Adrian Rawcliffe:
Cheers, Ted.

Operator:
The next question is from Yanan Zhu with Wells Fargo Securities. Please go ahead.

Kuan-Hung Lin:
Hi. Congrats on the approval. This is Kuan-Hung for Yanan. Two quick questions from us. First is on the box warning of CRS. When you engage with physicians, is this a concern of physicians? Any colour you have from the physicians? Second is on the enrollment in Cohort 2 and 3 of SPEARHEAD-1. Can you share with us the enrollment status and when we may see the data? Thank you.

Adrian Rawcliffe:
Certainly. I will ask Elliot Norry, our Chief Medical Officer, to comment on physicians' reactions to the black box warnings, and then Dennis to comment on the status of SPEARHEAD-1, the other cohorts in SPEARHEAD-1. Elliot?

Elliot Norry:
Hi. As it relates to cytokine release syndrome in the black box warning, the physicians that are going to be treating patients with TECELRA are very well versed in identifying and managing cytokine release syndrome. The means by which to treat it are good, particularly with IL-6 inhibitors. I don't think that it represents any hesitation from the standpoint of a treating physician as it relates to using this product.

Dennis Williams:
Yes, hi. This is Dennis Williams again. For Cohorts 2 and 3, Cohort 2 has been completely recruited and all the patients have been treated and they're currently in follow-up. Similarly for Cohort 3, we expect recruitment to close; the last patient treated this summer. But essentially that cohort is also nearly finalized in its treatment journey.

© 2024 Adaptimmune Therapeutics

Since the response to afami-cel, the duration of response could be quite long, what we have agreed with the FDA is to take a data cut 15 months after the last patient is treated in Cohort 3. So we expect that data cut to occur mid next year, at which point we would present the data, and then we would subsequently file with the FDA, as I mentioned earlier, to convert the application from accelerated to regular approval.

Kuan-Hung Lin:
Got it. Thank you so much for the colour.

Adrian Rawcliffe:
Thanks, Kuan.

Operator:
The next question is from Peter Lawson with Barclays. Please go ahead.

Alex:
Good morning. This is Alex on for Peter at Barclays. Thank you for taking the question and congrats on the approval. I was curious if there was any updated or new thinking around potential expansion opportunities into earlier lines, other HLA types or other sarcomas for afami-cel or a next-gen product?

Adrian Rawcliffe:
I think the short answer is that I think there's a lot of potential over time to expand the use of our sarcoma franchise products, so that's TECELRA and potentially lete-cel in a couple of years' time geographically, as we've talked about already on this call, in terms of line of therapy, potentially in terms of other MAGE-A4 expressing sarcomas. The opportunities are significant. However, what I do want to say is that our focus at this point in time is very much on delivering TECELRA for patients with synovial sarcoma who really need it and that's going to be the focus over the short period of time.

Furthermore, the sales projections that we've made for our sarcoma franchise, I want to be really clear. All of the expansion opportunities is in addition to the sarcoma franchise opportunity that we see at about $400 million peaks out in the United States in the launch indications only. So I

© 2024 Adaptimmune Therapeutics

think whilst there are lots of opportunities to go forward, our focus in the short term, as I'm sure you would expect, is on let's deliver TECELRA to patients who need it.

Alex:
Yes. Makes sense. Thank you. Then maybe just another quick one on lete-cel, on the BLA. Anything you can say in terms of timing here of when you could initiate that rolling BLA, and if there are any other sort of complexities or differences from afami-cel that we should keep in mind with respect to the BLA. Thank you.

Adrian Rawcliffe:
I think at a very high level, the differences are that lete-cel has a different supply chain. It's a third-party supply chain and will require a companion diagnostic specific for its target NY-ESO as opposed to the target for TECELRA, MAGE-A4. Those two things are likely to be amongst the gating items for us initiating a rolling BLA, which we're working on, as you can imagine, at full speed. We anticipate that rolling BLA starting in 2025, and that's what we've said.

Okay.

Operator:
This concludes the question-and-answer session. I'd like to turn the conference back over to Adrian Rawcliffe any closing remarks.

Adrian Rawcliffe:
Thank you everyone for joining us on the call today and thank you for your questions, but I think most of all, thank you for your support. There's a lot of familiar faces on this call and I think thank you for your support over the years to deliver this groundbreaking cell therapy.

Now, as I said in response to repeatedly questions over the past half an hour, we turn our attention to making TECELRA, the first engineered cell therapy approved for solid tumor available to people with synovial sarcoma. Thank you very much. Have a good day.

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

© 2024 Adaptimmune Therapeutics