Adaptimmune Therapeutics plc(Q4 2020 Earnings)

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Corporate Speakers:

- Juli Miller; Adaptimmune Therapeutics plc; Senior Director of IR
- Adrian Rawcliffe; Adaptimmune Therapeutics plc; CEO, Principal Accounting Officer & Director
- Elliot Norry; Adaptimmune Therapeutics plc; Chief Medical Officer
- Helen Tayton-Martin; Adaptimmune Therapeutics plc; Co-Founder & Chief Business Officer

Participants:

- Charles Butler; ROTH Capital Partners, LLC; Research Division, MD, Senior Equity Analyst & Head of Biotechnology Research
- Kenneth Atkins; Cowen and Company, LLC; Research Division, Research Associate
- Mohit Bansal; Citigroup Inc. Exchange Research; Research Analyst
- Kelsey Goodwin; Guggenheim Securities, LLC; Research Division, Associate
- Nicholas Abbott; Wells Fargo Securities, LLC; Research Division, Director & Associate Analyst
- Mara Goldstein; Mizuho Securities USA LLC; Research Division, MD of Equity Research Department
- John Barrett; SVB Leerink LLC; Research Division, Associate

PRESENTATION

Operator^ Ladies and gentlemen, thank you for standing by, and welcome to the Adaptimmune conference call. With that, I'd like to turn the call over to Juli Miller. Ma'am, you may begin.

Juli Miller^ Good morning, and welcome to Adaptimmune's conference call to discuss our full year and fourth quarter 2020 financial results and business update. I would ask you to please 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 a number of factors, including those outlined in our latest filings with the SEC.

Adrian Rawcliffe, our Chief Executive Officer, is with me for the prepared portion of this call. 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^ Thanks, Juli, and thank you, everyone, for joining us. 3 months ago, during our Investor Day, I made our plans to deliver transformative value for patients and for investors over the course of the next 5 years, our 2-2-5-2 plan.

In concrete terms, this means 2 products on the market targeting MAGE-A4, 2 additional BLAs from our clinical pipeline as well as 5 autologous and 2 allogeneic products entering the clinic in the next 5 years.

All this is based on an integrated cell therapy company with the intent and capabilities to discover, develop and deliver products that are both curative and mainstream.

At the JP Morgan conference last month, we outlined the key catalyst for 2021 and beyond which will be the mile markers on the road to our 2-2-5-2 ambitions. And I'm absolutely delighted every time I say this, we aim to launch our first product next year.

As you know, not many biotechs get to this stage and it is hugely motivating for our research and development teams to know that ADP-A2M4, the treatment they discovered and developed through clinical trials may soon be delivered to transform the lives of people with sarcoma.

The launch is our first building block of our 2-2-5-2 plan, the next key dates when we aim to release data at ASCO and CTOS, and these data will be used to support the registration and approval of ADP-A2M4.

In 2021, beyond our BLA and launch readiness, we will also focus on: Firstly, initiating a Phase 2 trial with our next-generation MAGE-A4 targeted product for people with either esophageal or esophagogastric junction cancers in the first half of this year.

Secondly, treating patients in the ongoing Phase 1 SURPASS trial that also uses our next-generation MAGE-A4 targeted product. We're focused on indications where we've seen signs of efficacy with our MAGE-A4 program, namely lung, head and neck, gastroesophageal and bladder cancer, and we aim to report updated data from the SURPASS trial at ESMO this year.

Thirdly, treating patients in our Phase 1 ADP-A2AFP trial with plans to report data at ILCA. We will also determine the next steps of this product.

And lastly, continuing our research work to bring new products to the clinic, including HLA-independent TCRs, next-generation TILs and next-generation SPEAR T-cells targeting additional HLAs.

Looking back at 2020, you'll find a summary of our key achievements in our press release. I just want to pick up on a few points. When I became CEO, I committed to increasing our focus on speed and quality of execution.

And last year, we demonstrated clear progress by completing enrollment in our SPEARHEAD-1 trial in about 12 months, even with the challenges of the COVID-19 pandemic. Whilst we wait for data from SPEARHEAD-1, we're working towards filing a BLA for ADP-A2M4 for people with synovial sarcoma in the US next year and shortly after that in Europe.

The US and EU regulatory designations, granted based on compelling and durable response data from our Phase 1 trial, will help us with this approval process. We've also started to grow our commercial organization and plan for the launch of a companion diagnostic.

When you compare our Phase 1 data to what can be achieved with available treatment options, ADP-A2M4 has the potential to truly change the lives of people living with synovial sarcoma. And the synovial sarcoma community is incredibly excited about these data.

We confirmed in 2020 that sarcoma is only the beginning for our MAGE-A4 targeted products. Last year, we reported responses from SPEAR T-cells targeting MAGE-A4 in 4 different tumor types, including: melanoma; esophagogastric junction; head and neck; and lung cancers. There are also meaningful tumor reductions in other indications.

We also completed dose escalation in the SURPASS trial with our next-generation ADP-A2M4CD8 product. We're recruiting in the expansion cohort of this trial, and as I said, we plan to report data at ESMO this year.

2020 was also the year where we showed we're building the cell therapy company in the future with our deep preclinical pipeline.

Our research team has made great progress on multiple fronts, including: Identifying the first candidate, mesothelin, to take forward with our HLA-independent TCL platform in co-development with Astellas; products targeting HLAs beyond HLA-A2; and strengthening our toolkit of next-generation options, including a TIL therapy with IL-7 in collaboration with CCIT. This preclinical pipeline supports our ambition to bring 5 new products to the clinic by 2025.

Finally, I want to bring up the progress with our allogeneic platform. We signed a major co-development and co-commercialization agreement with Astellas in 2020 and showed we could generate functional T-cells from stem cells. We also demonstrated these T-cells can kill cancer targets *in vitro*.

Financially, we've confirmed that we are funded into 2023 and equipped to deliver on our ambitions. And with that, I'll open it up for questions. Operator?

QUESTIONS AND ANSWERS

Operator^ (Operator Instructions) Our first question comes from the line of Tony Butler with ROTH Capital.

Charles Butler^ Adrian, I wanted to actually touch on commercial readiness, given that you were moving forward in -- with SPEARHEAD-1. And then I have one follow-up on the clinical program.

Adrian Rawcliffe^ Okay. Thanks, Tony. Thanks for the question. As we're preparing to be able to launch ADP-A2M4 for synovial sarcoma on approval, which we anticipate to be next year.

And clearly, we've been in the process of planning for that for some time. And 2021 is the year where we are committing to both the BLA filing and -- which will happen in 2022 and starting to build the commercial presence.

And I think I've said before, this is a perfectly sized opportunity for a company like Adaptimmune because of the very concentrated nature of the patient and physician treating footprint here.

And we are obviously talking to many of those centers and sites as part of the clinical development. So it's important that we build something that is focused on delivering for the synovial sarcoma community, but also critically scalable for the other indications that will be coming down the pipe in due course, obviously, starting with esophageal and gastroesophageal junction for which we're starting the Phase 2 trial now.

And I think the scope for commercialization for a cell therapy is obviously quite broad. And it covers all of the usual things that you would anticipate for a normal commercialization of a product and the payer and patient and physician research and all of that's been ongoing for a while. And then -- but it also covers, I think, the importance of patient services aspects from our supply chain organization.

And we think about how to develop those from the clinical state, whether we've been operating to date, including for the pivotal trial through to something that is fit-for-purpose for commercial. And we'll have more to say about that and other aspects of it as we go through the year.

It's such a diverse set of stuff that we -- you have to do. I mean, from the large things that I've just mentioned, but all the way through to relatively small things. I mean, just a couple of days ago, we got the generic naming confirmed for ADP-A2M4 for synovial sarcoma, which will be called afamitresgene autoleucel

And it's just accumulation of lots of -- and lots of activity and lots of small and large milestones along the way that's going to ensure that we are able to get there. And I want to just say that I think our ability to do that will be largely based on the fact that we are --

we are specialized in this space, knowledgeable in this space, and we've built the integrated capabilities to enable us to be able to do this.

Charles Butler^ I did want to follow-up on 2 clinical -- short clinical questions, #1 is, are patients still being dosed with the AFP SPEAR T-cells? That's one.

And number two, on the Phase 2 SURPASS-2 study, which starts the first half of this year -- and SURPASS 1, correct me if I'm wrong, you already have 17 sites, at least according to clinicaltrials.gov, are all those 17 sites going to then switch over to dose for SURPASS-2? How will those be split up? Or will there be new sites that have already been recruited for SURPASS-2?

Adrian Rawcliffe^ Thanks, Tony. I'm going to ask Elliot to answer both of those questions. Please, Elliot.

Elliot Norry^ Yes. So the first question -- thank you, Tony. The first question was around whether we're still dosing patients in the ADP-A2AFP liver cancer directed trial, and the answer is yes.

We're dosing patients in the expansion phase of that trial, and there's an intent to provide an update with respect to patients dosed and direction at the International Liver Cancer Association conference in the third quarter.

With respect to SURPASS sites and SURPASS-2. Many of the sites will -- that are in the SURPASS trial will be engaged in the SURPASS-2 trial as well, but there will be differences as well.

We will be -- we're going to be adding new sites and also expanding geographies as well. I don't think that we've guided specifically to the exact number, but those will be specifically gastrointestinal-focused sites, while the SURPASS trial also includes sites that are focused on a broader range of tumor types.

But we're going to leverage our experience from Phase 1 into Phase 2. Those centers that are enrolling well, we certainly would want to have in Phase 2. And we will have to make that transition for those tumor types from enrolling in the Phase I trial into a Phase 2 trial. That will be the intention once that trial is open, is to enroll the Phase trial.

Operator^ And our next question comes from the line of Kenneth Atkins with Cowen and Company.

Kenneth Atkins^ Could you comment on the breakdown of the enrolled patients in SPEARHEAD-1 between synovial sarcoma and MRCLS? And how many patients in each category do you think you would ultimately need to support licensure in each indication?

Adrian Rawcliffe^ So I'll take that just to say that we haven't guided as to patients in either category and how that allocation split out other than to say that we believe that there will be significantly more synovial sarcoma patients than MRCLS patients.

Kenneth Atkins^ Got it. Okay. And then assuming that ADP-A2M4 is successfully developed for refractory sarcoma, how much of a priority is moving that product into the frontline setting? Do you think ADP-A2M4 has the right profile? Or would you want to explore next-gen product for front line use?

Adrian Rawcliffe^ Elliot, do you want to comment on that?

Elliot Norry^ Sure. So I think that it certainly could be used in a frontline setting, either in sequence with chemotherapy or upfront. It will never be for every patient with sarcoma because of the HLA restriction and the patients' need to express the target, so even if in the frontline setting, it won't be sort of across the board for all patients with the disease type would be those that qualify.

I don't think that we've made sort of a final decision as to -- as we might pursue a first-line setting, whether that would be the first or the second-generation product. I would -- I think that we would have to sort of evaluate closer to the time of us really implementing the studies that would support that.

Operator^ And our next question comes from the line of Mohit Bansal with Citigroup.

Mohit Bansal^ Congrats on the progress. One question I have is regarding the use of AKT inhibitor. You have talked about that on your R&D Day. Could you please help us understand the rationale there, what it does and how it actually improves the manufacturing aspect of the TCR manufacturing?

And the other second part related to that is that you are using that in your CD8, the second-generation program at this point. Would we be able to see any comparative data in a clinical setting that -- I mean, use of AKT inhibitor is actually doing something to these patients, either in terms of responses or durability? Any color there?

Adrian Rawcliffe^ Sorry, just coming off mute. So as you say, we use the AKT inhibitor in the manufacturing process. So I just want to be clear that the comparison, that there's no AKT inhibitor in the final product that's administered to patients.

So I just want to make that clear. And then I was wondering, Helen, do you want to talk about use of the AKT from a mechanistic perspective and what it does?

Helen Tayton-Martin^ Sure. Just coming off mute. Sorry about that. I think that there are -- the use of kinase inhibitors and the impact on T-cells has sort of been known for some time, and bluntly, I think the -- probably a number of dimensions to the mechanism that sort of simply said, I think it increases the -- seems to increase the overall potency of the cells, and there's probably a number of pathways involved in that.

But it's certainly something that we and others have seen and are using. And I think it's been a relatively straightforward adjustment to sort of making our process for a potential increase in the potency of the cell product that we make.

I don't think we -- we probably won't go into more details on that. I think we've published on quite a bit of this or we've certainly put it into posters. And John may also have commentary on the years with which we brought that into our process.

Mohit Bansal^ Do you think it could help you in the -- from the patent point of view? Can you patent it, this particular part of the manufacturing that you are using AKT inhibitors in there?

Adrian Rawcliffe^ We haven't commented on our patenting strategy as regards to our manufacturing process with this aspect of our manufacturing process.

Operator^ And our next question comes from the line of Michael Schmidt with Guggenheim.

Kelsey Goodwin^ This is Kelsey on for Michael. I guess, first question in the SURPASS trial. What efficacy signal, I guess, would you need to see in order to kind of make that go/no go decision? And how many patients in a given indication, would you feel comfortable basing that on?

And then separately, if I could, maybe bigger picture. Maybe could you just remind us of your strategy for developing HLA-independent T-cell receptors, and maybe to what extent that might broaden the opportunity for your platform kind of longer term.

Adrian Rawcliffe^ Certainly. Thanks, Kelsey. So I'm going to ask Elliot to comment on the signals in SURPASS, just to say that the focus areas for SURPASS are obviously lung, bladder, head and neck, and gastroesophageal.

That doesn't mean we'll only recruit patients in those settings, but that's what we're focusing the trial on. And we plan on putting data out at ESMO on the first set of patients in the expansion cohort. Elliot, do you want to comment on that? And then we'll move to the other question on TILs.

Elliot Norry^ Sure. So thank you. With respect to what efficacy signal would we look to see to drive a go/no go decision to a later-stage development program, there's nuance here. It's not a specific -- I can't quote you a specific cutoff with a specific number of patients where we would say, if we see this, we will go and if we don't, we will not. There are several parameters. And we like to think of it along the lines of when we see it, we'll know that we're seeing it.

And I think that you could use the example of synovial sarcoma as a great example, where we saw a 44% response rate in the Phase 1 study, which is clearly advantageous as compared to the other treatments available for second-line treatment.

The we've typically used a threshold of a 30% response rate with a 6-month duration of response as a guidepost, but not as a definitive marker. And the reason that I say that is that there are other factors beyond just response rate.

And it really depends on each tumor type as well. And you can use the gastroesophageal cancer example as -- to look at that, where these patients have very limited treatment options and very short -- very short time of survival.

Even with -- after first-line treatment, I think that with the data that was published at ESMO last year showed that even in best circumstances, the median overall survival was approximately 15 months in this patient population with first-line treatment.

So coming in at a later line of treatment, it's obviously going to be -- the expected survival is less than that. So if you determine that a patient -- if we're able to show that there's 25% response rate, but some of those are durable or that we really improved the quality of life in patients with prolonged stable disease, those are things that need to be factored in as well. And you start to look at progression-free survival as well as just overall response rate to look at the benefit of a treatment.

So if you look at the gastroesophageal scenario, we saw the 3 patients out of 3, with the first -- with the -- in the first 6 -- 3 out of the first 6 patients in the Phase 2, the SURPASS trial had esophagogastric junction or esophageal cancer, and all 3 demonstrated meaningful anti-tumor response.

Well, that was enough for us to say that we ought to be planning a Phase 2 trial, especially when some of those patients have been treated with lower cell doses than we had seen previously.

So I think that, again, it takes nuance. We have some guideposts and -- that we're going to work around that, but we're really looking for relatively clear indications of advantage over current treatment.

You shouldn't have to squint at it to say, maybe that's going to be advantageous, maybe it's not, you're going to need 500 patients to show a very narrow marginal difference. It has to be visible.

Adrian Rawcliffe^ Right. Thanks, Elliot. And on the HiT question, which was sort of how it works and how it works to expand the applicability of our platform. Maybe I'll ask Helen to touch on that.

Helen Tayton-Martin^ Yes. Thanks, Ad. Very happy to talk about the HLA-independent TCR platform, the HiT platform. It is exactly sort of what it says it is. It's actually a T-cell receptor that can bind an epitope on a cell surface protein.

So the target protein, the whole protein could be the same as a CAR or an antibody, but it's actually a TCR that's binding to a specific peptide or specific epitope on that cell surface protein.

So there are 2 aspects of that. One is that there is no HLA restriction. So we don't have to screen out the -- for HLA for the treatment of patients with an HLA-targeted T-cell therapy. So that obviously increases the number of patients by removing a specific criteria that segments our population with HLA-restricted T-cell receptors.

The other aspect of this, which is very exciting for us is this is a functional T-cell receptor. It functions and behaves like our other optimized T-cell receptors. And we also have the ability to test that for specificity and sensitivity, affinity, really leveraging all of the capabilities we've built up over many years to safely bring T-cell receptors through to the clinic.

So very excited that we've got a T-cell receptor platform that can broadly increase the number of patients that we can access with a T-cell receptor that combines to a cell surface protein, and that broadens out the patient pool for specific targets. And mesothelin, I think, is a validated target now. We're very excited about that program with our collaborator, Astellas, in which we are co-developing.

And we also mentioned another one that we've started to bring through targeting GPC3, which is a hepatic-cancer-specific target. And obviously, for us, it will be very important to continue to bring and validate this platform alongside the HLA-dependent programs that we have like MAGE-A4 and AFP to increase the numbers of targeted products that we can bring through. I hope that's a useful overview of the platform and its applicability.

Operator^ Our next question comes from the line of Nick Abbott with Wells Fargo.

Nicholas Abbott^ Ad, can you provide some additional guidance on when in 2022, you plan to file on the SPEARHEAD-1 data?

Adrian Rawcliffe^ Short answer to that is no, we haven't provided additional guidance, and we won't -- there's a whole swathe of moving parts, as you can imagine, that affect the timing of that. And we'll update as we have more certainty as to the specific filing time frame.

I would -- I'd just mention, we've got the RMAT designation, and therefore, the opportunity to have a rapid -- more rapid approval on that.

Nicholas Abbott^ Right. The goal is to file and launch in 2022.

Adrian Rawcliffe^ That is certainly our goal.

Nicholas Abbott^ Yes. So in preparation for the filing, obviously, this would be the first TCR engineered product to be reviewed. And clearly, there's no established par. So how confident are you have alignment with the agency on CMC, given the issues that have delayed filing or approval of other cell therapy products?

Adrian Rawcliffe^ So I think the challenges that have been faced by people who have sought to bring cell therapies to the market are significant. And nobody should ever think that this is easy. We do it because it's hard. But I think we do have some advantages for us in thinking about this.

Number one, we have the advantage that others have taken, not exactly the same product, so not a TCR, but an autologous cell therapy, autologous cell therapies in the hematological space. And I think there were likely to be at least 4 of those approved by the time we get there, 4 or 5 of those approved by the time we get there.

And then secondly, I think there's the opportunity to learn from the experience in TILs and the first TIL product is likely to have been approved there. So there are precedents for this. And obviously, in the interactions with the agencies, we -- they get to see that, and we get the benefit of that in terms of understanding their evolving thinking over in this space.

I think the second thing that I'd point out is that we have RMAT designation in the US and PRIME designation in the EU. And that gives us, I think, the opportunity to have enhanced interactions with the regulators in both of those jurisdictions and to ensure that insofar as possible, there is alignment there.

Now you will never find anybody at this company tell you what the regulators think, that's going to be for them speak to. But at the same time, we are having what we believe is constructive discussions with both of those. And I think we are -- we certainly believe that we understand what we need to do.

Then lastly, I'd say that we are using, from a CMC perspective, same facilities and the same process in the Phase 2 that we will use for launch. And I think our processes and our assays, et cetera, are in an appropriate place relative to where we want to be for our BLA goals.

And I'd say, we have not got some of the challenges that some other types of therapies have, for example, the potency assay as it relates to a TIL therapy, which is obviously quite different to the discussions that we've had.

So this isn't easy. And there are, as I said, there are a number of moving parts. But because we've sort of been focused on this, because of our -- the capabilities and the insight that we've built up over a long period of time and a lot of interactions with the

regulators, I think we're confident that we've got the process and the requirements gripped.

Nicholas Abbott^ All right. And then you recently listed the Phase 2 esophagogastric trial, which I believe you have -- you consider as potentially registration enabling, and like SPEARHEAD-1 plans to enroll 45 patients. So can you explain how you got to that number?

And then also, I know this is being studied in other tumors, but clearly, perhaps a unique concern here is for on-target off-tumor toxicity. What do you need to do to assure the regulators that this is not an issue? How many patients do you need really to treat in order to ensure them it's not an issue?

Adrian Rawcliffe^ So, Elliot, do you want to speak to the thinking around the SURPASS-2 trial design a little bit and in terms of what we've said publicly, and then -- and how we're thinking about the toxicity or the safety profile that will be required to register products in the space? Elliot, I think you're on mute.

Elliot Norry^ Sorry about that. I'll start over. The -- I don't think that we've guided with respect to the powering and statistical methodology for the trial. I will say that it is designed very similarly to SPEARHEAD-1.

So while the statistical considerations are not exactly the same, the study is powered to demonstrate benefit as compared to what would be the sort of historical control as it relates to line of treatment. So I don't want to provide specific numbers around that at this juncture.

With respect to the off-tumor on-target toxicity, it's important to remember that the T-cell receptor is the same as the first generation T-cell receptor.

And we have -- it's not a huge amount of experience as compared to like a diabetes or cardiovascular trial, but we have a pretty good accumulating experience of patients that we've treated with a MAGE-A4-directed T-cell receptor at this point and really have not seen any indication of off-tumor expression of MAGE-A4 or off-target reactivity of the TCR against other tissues.

So look, I think that ultimately, the benefit/risk ratio is what will drive the day. As we're able to further demonstrate the benefit of the T-cell receptor, in this patient population or in others, it will have to come with a safety profile that is acceptable.

And the safety information that we put out along with the 6 patients that were reported at SITC showed that at least in early days, that the safety profile for the second-generation product is very similar to the first generation product. Now you can't compare 6 patients to over 70 patients, but that will come with time.

And we -- at this point, it's our anticipation that if the drug is more potent, then we may see some of the more common toxicities associated with the potency of the product like cytokine release syndrome. That has not been the case to date, but we'll have to see that over time. But I think we're feeling reasonably confident around the specificity of the T-cell receptor in that we haven't seen off-tumor or off-target toxicity to date with MAGE-A4.

Nicholas Abbott^ Great. And then -- that's very comprehensive. And would you expect to communicate to us data from this trial as it's going along or only when it's complete?

Elliot Norry^ I wouldn't want to promise to provide data should we think of this, as you said, is potentially registrational. So if we were to make the decision that this trial would be a registrational trial, then we would be unlikely to provide patient data along the way.

If it were to be determined to the contrary, then we would -- I would certainly -- we would reserve the right to provide interim data along the course of the trial if that were helpful from a communication standpoint.

So I think we just -- I can't -- in general, for registrational trials, we would not do that. But if it turns out to not be a registrational trial, then we certainly could.

Operator^ And our next question comes from the line of Mara Goldstein with Mizuho.

Mara Goldstein^ Great. I have 2 questions. The first just is on the SPEARHEAD-1. And can you just clarify for us the scope of what you anticipate for the preliminary update in June versus the full update later in the year?

And then secondarily, I'm just curious about the status of the TIL program. It certainly appears within your pipeline chart advanced from a preclinical perspective. And I know it appears in your corporate deck, almost as a crossover in the graphics that you have between the cure versus mainstream therapy. So can you talk a little bit about what's going on in that program?

Adrian Rawcliffe^ Certainly. Thanks, Mara. So I'm going to ask Elliot to talk about the updates of what's likely to be happening at ASCO and CTOS. And then I'm going to ask Helen to talk about the IL-7 TIL program.

So, Elliot, do you want to touch on SPEARHEAD first?

Elliot Norry^ Sure. So good question. First of all, I want to just say that the update at ASCO is based on the information being accepted by ASCO. And you raised, I think, the point of this being a registrational trial, how is it that we're presenting interim data.

The reason for, we believe, that's being allowed is that all the patients will have been dosed by the time this information would come out. So it would have no effect on the

recruitment and enrollment of the trial. But it is ultimately up to ASCO as to whether they will allow the presentation of data in an interim fashion.

So if we were to present it, it would be based on a data cut that will be ultimately, approximately 6 months prior to the final data cut for the trial. So the level of durability of response across the whole population will be less robust than the final information.

We'll also have to provide some interpretation along the lines of patients who have been treated but have not yet completed their series of assessments, as to whether they represent responses or stable disease or there are some patients who have stable disease at one juncture, who then go on to have a response.

So we'll have to interpret it with some clarity as it relates to who's been dosed, who's had the right number of assessments to make a determination around efficacy. And then, of course, there will be safety information as well.

We will provide duration of response information as is available at the time of the data cut, but just recognize that, for example, if the data cut is sometime in let's say, March, then a patient treated in February, we won't be able to provide real meaningful duration of response information. So I hope that clarifies what we expect to present at ASCO.

Later in the year, we would anticipate providing the data that would essentially be similar to what we would present to agencies for registration. The study is set to read out 6 months after the last patient is dosed, provided that patient remains on study. So if you go 6 months from -- we've said that we plan to finish dosing in this study by the end of the first quarter.

So that data cut would be around the end of the third quarter. And then we would be able to provide information at the CTOS conference that uses that data. So that will be a more complete look at the data that will also be shared with regulatory authorities for the purpose of registration.

Adrian Rawcliffe^ Thanks, Elliot. And, Helen?

Helen Tayton-Martin^ Yes, sure. Great question. It's a pleasure to talk about the TIL program that we have on our pipeline. So we have executed a collaboration with CCIT in Denmark, which is the Center for Cancer Immune Therapy, which is a leading center for TIL trials in Europe, a group that we've known for some time.

There are 2 aspects to this. I think the TIL strategy feeds into 2 things. It feeds into our integrated cell therapy capabilities, which we believe really enable us to sort of read across and apply in a relatively straightforward way, the same sorts of approaches from the science through to the CMC optimization, execution of the clinical programs, regulatory interactions, et cetera, as we do with our SPEAR T-cells. We can apply an awful lot of those capabilities to TILs.

And we have a TIL IL-7 program. It currently is preclinical, but expecting to move quite quickly towards the clinical stage in collaboration with the CCIT, where we're bringing in our own second-generation capabilities and expertise and knowledge from the SPEAR T-cells into a second-generation TIL product, which we think will improve the proliferation and penetration of TILs in other solid tumors because I think that there's great promise with tolls. And we believe that there's more promise in other tumor indications to be had.

So TILs don't require HLA restriction testing, they don't require target testing. So it's another one of our strategies that enables us to reach more patients without segmenting for HLA type or target type. And it adds and complements our in-house capabilities in cell therapy broadly, in T-cell therapy broadly.

So hopefully, that gives a bit more color to where the TIL IL-7 program fits within our overall strategy of bringing further products. It's in the 5 of our 2-2-5-2. So hopefully, that helps.

Mara Goldstein^ And do you have a sense of which indications would be prioritized?

Helen Tayton-Martin^ We do, but we're not commenting on that at this point, I'm afraid.

Operator^ And our next question comes from the line of Jonathan Chang with SVB Leerink.

John Barrett^ This is John Barrett on for Jonathan. I realize it's still early in the year, but for the second-gen MAGE-A4 program, can you talk about the current status of the SURPASS study? Any color on the progress of that study since the last update and help set expectations for the data readout at ESMO, including any potential or hopeful number of patients or a breakdown of what tumor types you expect?

Adrian Rawcliffe^ Thanks, John. So you asked for color on the study. It's a very colorful study. It was enrolling a basket of patients, 9 -- across 9 different tumor types. As you know, we've focused it down onto 4 different tumor types.

I do just want to be really clear about that. That doesn't mean we're only going to have patients in those 4 tumor types, which are lung, bladder, head and neck, and gastroesophageal cancers. But that in our recruitment, we are focusing on those centers that are recruiting those patients. But we will have others.

Recruitment is going well. We had a -- last year, we had a biphasic recruitment driven off the COVID pandemic increase in cases and decrease in people being recruited into early stage oncology and cell therapy trials in the second and third quarter, but we've reestablished and rebuilt the pipeline, as we talked about in the fourth quarter of last year. And I think the recruitment and dosing of those patients is going well as we're headed into 2021.

We have not explicitly -- not commented on numbers of patients, but all of these patients are being recruited in the expansion cohort of that trial, and we will update at ESMO on all of the patients that we have dosed and have access to.

I think the objective of that is to be able to gather a sufficient cohort of patients to say meaningful things about the development of that therapy going forward. And beyond that, we aren't commenting until we put out the data.

John Barrett^ Got it. Makes sense. And quickly on SPEARHEAD-2, could you talk about the process of that study? And just conceptually, is this still viewed as a learning type of study that you might eventually move forward with the second-gen? And what is the bar for success of that trial?

Adrian Rawcliffe^ Elliot, do you want to talk to those points?

Elliot Norry^ Yes. So thank you. I don't -- we haven't really guided as to sort of numbers of patients screened, enrolled, dosed, et cetera. The study is open and enrolling. We do still look at it as a -- I mean, every study should be looked at as a learning opportunity.

But this one in particular is the first scenario in which we'll be combining the MAGE-A4-directed TCR program with PD-1 inhibitor. So based on the sort of natural potential synergy of those products, we'll certainly be paying attention.

The -- I don't want to say that we wouldn't take the combination of those 2 products in head and neck cancer forward if we were to see the right kind of responses. And again, I would comment on -- I'll go back to the go/no go comments that I made before. But I also do think that this is -- the learning here is really more about the potential of this type of combination across programs.

And the benefits, we'll certainly see how the patients do from a response and toxicity standpoint, that will be really important. But there will also be important translational information about what happens to upregulation or downregulation of certain genes that control cancer growth, T-cell exhaustion, tumor microenvironment, et cetera.

So I think that the -- it is a learning trial, as you've indicated. But it does have the potential to really demonstrate the advantage of this combination with T-cell therapy for solid tumors.

I want to add that the way that we've organized and designed the trial also is an example of how cell therapy could fit into a first-line sequence with approved therapy that is that one leukapheresis and obtained cells prior to treatment. So no impact of the treatment on the bone marrow that would be -- that would produce the cells that we would use to manufacture.

The patient gets their first-line treatment while the manufacturing is ongoing so that the product is ready at the time that they're no longer either seeing continued benefit or

additional benefit from the first-line treatment, and it provides an opportunity to use cell therapy right in sequence with another treatment.

And that's a paradigm that is -- it's not simple to organize from a patient standpoint, but we feel this is, again, our first toe in the water as it relates to that as well.

Operator^ Thank you. And this does conclude today's question-and-answer session, and I would like to turn the conference back over to Adrian Rawcliffe for any further remarks.

Adrian Rawcliffe^ Thanks. Thanks everyone, for joining us. I want to, before we close the call, acknowledge the incredibly hard work and commitment of everybody here at Adaptimmune, who, despite the challenges of the COVID-19 pandemic over the last year, have remained focused on our mission and our vision and delivery of the results that we've just put out in the press release and everything that we accomplished last year.

I also want to thank our investors who continue to have confidence in the opportunity presented by Adaptimmune.

I think we're all here, looking forward to 2021. And I'm looking forward to being able to update you all on the key mile markers on the road to delivering that 2-2-5-2 in strategy that I talked about at the beginning of this call, and ultimately, the opportunity to create significant value for people with cancer and for the company. And with that, thank you, and speak soon.

Operator^ Ladies and gentlemen, thank you for participating in today's conference. This does conclude the program, and you may all disconnect. Everyone, have a great day.