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GLPG.AS - Galapagos NV at ASH Meeting & Exposition

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PRESENTATION

Sofie Van Gijsel *- Galapagos NV - Head of IR*

Welcome, everyone, and thank you for joining Galapagos here in San Diego or virtually for our KOL event following yesterday's presentation at ASH of our ongoing Phase I/II EUPLAGIA study in CLL and Richter transformation and our ATALANTA study in NHL.

I would like to remind everyone that we will be making forward-looking statements during today's webcast. These forward-looking statements include remarks concerning future developments of the pipeline and our company and possible changes in the industry and competitive environments. Because these forward-looking statements involve risks and uncertainties, Galapagos' actual results may differ materially from the results expressed or implied in these statements.

Today's speakers for Galapagos will be Dr.Paul A. Stoffels, CEO and Chairman; and Dr. Jeevan Shetty, Head of Clinical Development Oncology.

We are very pleased that we are joined today by 4 key opinion leaders in the field: Professor Davids of the Dana Farber Cancer Institute and Professor Ghia of the University of Milan will discuss the results of the CLL and Richter transformation trial. Professor Anguille of the University of Antwerp, Belgium and Professor Bishop of the University of Chicago will discuss the NHL study.

Paul will kick off today's event with introductory remarks. Then Jeevan will discuss the EUPLAGIA results in CLL and Richter transformation, followed by a KOL discussion. Next, he will talk about ATALANTA results, which will be discussed by Professor Anguille and Professor Bishop. Paul will then present concluding remarks before we open it up to Q&A to the public. To ask questions in the room, please tap on the microphone. (Operator Instructions)

And with that, I would like to hand it over to Paul.

Paul A. Stoffels - *Galapagos NV - CEO,Chairman,Interim Head of R&D*

Thank you, Sofie. First of all, thank you all for being here this morning with us, especially a big thanks to our distinguished key opinion leaders being with us here in the room for the discussion of the results.

It's also a very big day for us. The first time we are public with a number of the data on a big meeting as well as with our CAR-T activities and the instrument which draw a lot of attention yesterday at the meeting for which, of course, we are very proud and very pleased.

Our CAR-T pillar is based on 3 pillars to bring CAR-T to more patients to save lives. And first and foremost, we want to improve patient outcomes by infusing a product containing fit cells with a vein-to-vein time of 7 days. With this, we believe we can deliver an improved efficacy and safety outcome in a patient population that is in urgent need.

The second pillar is our innovative delivery model. By implementing a decentralized CAR-T manufacturing near point-of-care, we've minimized logistic hurdles and maximized the physicians control in the process. This results in an exceptional patient experience and shows our commitment to access for patients globally.

Finally, we are committed to building a portfolio of best-in-class CAR-Ts in hemato-oncology, also in solid tumors, and in immunology through our decentralized manufacturing network.

Here, you see a picture of the Cocoon and the cassette. This -- the Cocoon, we have a very extensive and strong collaboration with Lonza developed over the last 4 years. It is the cassette, which is the end-to-end sterile box where we can generate the CAR-Ts, but it's the environment around it with the Cocoon and the xCellit platform, the digital platform, which manages the whole program, production program, the vein-to-vein administration program, which makes it all happen.

And this allows us to go decentralized where we can control -- the local people can control in the laboratory, in the space, what is going on. But also we, through the network, we can give back up from Leiden, from our team on day-to-day, day-and-night, 24/7 support. And that allows us to be very confident about manufacturing and delivering cells in the 7-day vein-to-vein process.

The collaboration with Lonza is one which was established as an exclusive collaboration on using the Cocoon for point-of-care in the world. And that is a strong collaborative effort to produce as well Cocoons as cartridges and the development around it.

In the whole development of this system, we used the first principle thinking, focusing on simplification and streamlining every aspect of a current centralized production. You see on the left, the weakness that lead to critically ill people, not or delayed getting life-saving treatments while there is involvement of transportation across the ocean for the cell's centralized manufacturing and transportation back to the patient, which takes time, efforts, logistics.

In our innovative system, what we are developing, it consists of end-to-end automation for manufacturing, functionally closed systems, allowing to do quality control during and within the process timing, comprehensive real-time monitoring, both centrally and remotely through our xCellit platform, as I explained before, and 24 clinical and manufacturing -- 24-hour clinical manufacturing support.

We aim to make the CAR-T available globally. We started in Europe, expanding fast now into the U.S., and very soon also in other regions of the world during our clinical trial activities in the next 2, 3 years.

The 7-day vein-to-vein and fresh-to-fresh cells are at the heart of our platform. On the top half of the slide, you will see the seamless and continuous CAR-T production with the innovative QC review through the integrated Galapagos xCellit platform. In the lower half of the slide, you see the conditioning regimen being given at day minus 6 to minus 4 from administration. This is given in parallel to the manufacturing of our CAR-T project -- product, which is unique to our approach, a testament to our confidence in our reliability of manufacturing process and critical to deliver a 7-day vein-to-vein fresh product.

Through our unique platform, Galapagos delivers a life-changing service to patients and a step change experience in clinicians -- to clinicians and providers. Today, only a small portion of patients that are eligible for CAR-T receive a treatment. High-unmet-need cancer patient populations that are not helped today would benefit from CAR-T therapy.

These are patients with fast-progressing cancers and can be helped by quick access and a 7-day vein-to-vein time as well as patients with poor prognosis or with cancers for which no standardized treatment strategy is available.

And as I mentioned before, within the pool of patients that have been found eligible for CAR-T treatment, we see that today only 30% receive a CAR-T product due to barriers being limited manufacturing capacity, complex logistics and restricted access. With our work, we hope to be able to increase the addressable patient population, leveraging the point-of-care model globally.

Here, we show today's pipeline in oncology. We have our ATALANTA study in refractory/relapsed NHL, where we're currently enrolling patients in the Phase II dose expansion while still running a dose escalation cohort to test dose level 3 in patients with DLBCL.

In EUPLAGIA, we are testing our construct GLPG5201 in patients with CLL, relapsed/refractory CLL, and we have just initiated a PAPILIO trial in the first patients screened with the BCMA.

Today's session will focus on the important progress that we are making with our oncology programs. The data in the posters underline that our CAR-T programs manufactured at point-of-care, delivering on their promise. In today's presentation, we'll discuss the encouraging data in CLL and NHL observed with our product candidates. Importantly, we initiated the tech transfer following the agreement with the Boston-based landmark Bio. That's a key milestone in the geographic expansion of our point-of-care production technology and the start of clinical development of our CAR-T programs in the U.S.

In parallel, we continue discussions with multiple centers in Europe and in the U.S. to further build a point-of-care manufacturing network. In addition, we continue to strengthen our capabilities in oncology with key hires, amongst others, in regulatory, clinical, BD and strategic marketing. And we are embarking on setting up a U.S. office to accelerate our activities in the U.S.

With that, it's over to Jeevan to present the story of EUPLAGIA data. After the clinical results, we'll invite Professor Davids and Professor Ghia to talk about the unmet need and their opinion on our data. Jeevan?

Jeevan Shetty - *Galapagos NV - Head of Clinical Development Oncology*

Hi, everybody, and thank you for attending today. I just wish to spend a few moments just talking about high-risk CLL and Richter's transformation. As we know, chronic lymphocytic leukemia is one of the commonest hematological malignancies amongst the -- within the hematology family. And we know that, that disease remains relatively maintained and controlled for a long period of time. And after a period of time, these patients become -- move from becoming asymptomatic to symptomatic and then progressive -- aggressive disease. And really, with that in mind, this is the area that we're really attempting to address with our platform. And we will share with you data on high-risk CLL and also Richter's transformation.

The epidemiology of the disease, as you can see from these slides, is one that appears to be increasing over time. And this underserved patient population, the epidemiology on both sides of the pond East and -- sorry, in the U.S. and also in Europe, is quite consistent. And you can see there that in Richter's transformation, in particular, the unmet need is significant and the disease is fatal with 6 to 8 months median survival.

Here's the design of the -- here's the design of our high-risk CLL Richter's transformation study, the EUPLAGIA study. The design of the study incorporates all of the unique components that Paul talked about with our Galapagos platform. You see it here in action. There's the seamless innovative IT and QC technology, which enables fresh cells in fresh product out and continuous production and expansion of the QC review: The T cell expansion; the transduction sampling; and also the batch release. But the key to the 7-day vein-to-vein time is really the fact that we give concurrent conditioning regimen being given at day minus 6 to day minus 4. And this is all in parallel to the manufacturing of our CAR-T product, and that's really the unique nature.

Looking at the baseline characteristics of the EUPLAGIA study population, you see that this is quite consistent with the population at risk with unvariable outcomes shown here by age and gender and also by the prior lines of therapy as well as the disease characteristics, in particular TP53 mutation and the high rate of unmutated IGHV.

I'll turn to some pretty interesting translational data that we undertook on 13 of the 15 patients that were in the study. Looking at the expansion and the persistence of GLPG5201, we saw robust CAR-T expansion, which was observed in all patients measured by quantitative PCR as the vector copies per microgram of DNA on the y-axis over time on the x. At dose level 1 -- dose level 1 is actually depicted in green and dose level 2 in orange. And the median time to peak expansion, as you can see from this graph, is 14 days regardless of the dose received or whether CLL or Richter's transformation. Follow up is ongoing, and so far, we have 1 evaluable patient with detectable persistent CAR-T cells at month 15.

This is a further important observation. We know that the literature suggests that early phenotype T cells have been shown to correlate with better inpatient expansion and favorable outcomes. And in our study, we see -- we clearly see this.

Comparing the starting material with the final product, we observed that GLPG5201 enriched for early phenotype for both CD4 and CD8 CAR-T cells. Our product may result in higher quality fitter cells. So this fresh process is -- appears to be key to that.

This comes to the piece about whether it's the number of cells. I think Michael Sadelain's quote about it's not the number of cells, but it's the quality of cells. If you have better cells, you can give fewer cells. We assess the T cell phenotype of both the final drug product and the apheresis material in.

Just to go back, we observed this increase in percentage of the early phenotype T cells in both CD4 on the left and CD8 on the right. And the final drug product was compared to the T cells and the apheresis starting material.

Turning to the safety. I think we see a very good safety profile with our drug. It appears to be well tolerated. There were no Grade 3 CRS. Only 7 patients experienced low-grade CRS, Grade 1, Grade 2, and no ICANS reported. No deaths occurred. And most treatment-emergent adverse events were Grade 1, Grade 2. Most observed Grade 3 or 4 adverse events were of a hematological origin, and they're all well managed with standard supportive care.

Turning now to the efficacy. We observed excellent efficacy with our drug in patients with relapsed/refractory CLL with or without Richtertransformation. The objective response was assessed as per rrCLL for patients with CLL, Richter's and RT was assessed as per the Lugano classification.

As you can see here, the objective response, we were able to show that 13 out of 14 patients responded with -- at dose level 2, which is our RP2D. We had a 100% response rate with 8 out of 14 patients responding a complete response of 57%. And 5 out of 8 patients in the dose level 2 reaching a complete response, 63%. We believe this Phase II data is compelling, and it's really informed our choice of RP2D and also our plan to accelerate our regulatory journey forward.

In the RT subset, this was even more prominent with 8 out of 9 patients responding an overall response rate of 89%. And all patients on dose level 2 are also responding. 6 out of 9 patients achieved a complete response, suggesting overall -- a CRR of 67%. At the time of analysis, 77% of responders had an ongoing response. Duration was up to 15 months post infusion. And the last available response rate and assessment is indicated here.

With regard to what we are planning and doing with regard to the next steps, it's very exciting. Dose level 2 has been selected. We're initiating the Phase II expansion study imminently, and the tech transfer has been initiated to the U.S., as Paul discussed to Landmark Bio, and the IND submission is ongoing.

So with that, I'd like to turn to Professor Davids and Professor Ghia to just discuss with them their perception of the data that we've had and the potential impact of the disease. I'll just return back.

QUESTIONS AND ANSWERS

Jeevan Shetty - *Galapagos NV - Head of Clinical Development Oncology*

You've seen the data. I think you're both familiar with the data that's been submitted. We appreciate it's early, but we are very keen to understand what you feel the real unmet need in CLL actually is. Would you be able to give us some insights and thoughts?

Paolo Ghia - *University of Milan - Professor*

Yes. Definitely. I mean the unmet clinical need in CLL is that CAR T cells don't work so far. So that's the major point. We have been an exception in -- among all the B-cell lymphoproliferative disorders because despite the initial enthusiasm, the first original study with CAR-T cells in the world has been done in CLL. And there are 2 patients, 2 individuals all over the world, who achieved a durable remission, one of them actually died during the COVID pandemia. But then all the other patients did not respond or relapse quite early.

So it is still very disappointing for us. I would say that in the CLL field, when we hear about CAR-T cells, it's really show me because nobody believes so much anymore. And indeed, I was compelled by the results. I mean, of course, the numbers are limited. So one has to see how durable the response is, if the results are reproducible in a larger number of patients, but are very promising.

And in particular, what I was concerned is not RT. So Richter transformation is definitely an unmet clinical need, but we have, in particular, patients who are relapsing after the best drug that we have. So BTK inhibitors, BCL2 inhibitors. So the story is not over in CLL. We have these patients sooner or later will relapse and therefore, having another option is definitely welcome.

Matthew S. Davids - *Dana Farber Cancer Institute - Professor*

I fully agree with what Paolo said. We have a couple of great mechanisms to target CLL -- BTK inhibition, BCL2 inhibition, but we're finding more and more patients in our clinic who have started to exhaust these options. We had pirtobrutinib FDA approved last week, which probably benefits patients for a median of another 16, 17 months. So it just kind of kicks the can down the road a little bit.

I think, initially, there have been a lot of excitement for pirtobrutinib. I think it's a good drug, but it's certainly not going to provide very long-term benefit for these patients. Paolo and I have been collaborating on CAR-T studies for a while now. We worked on the ZUMA-8 study together with the brexu-cel product and then looking at the liso-cel data together.

This really feels different from the start. And I think all the data to me are looking like they're lining up. With the ZUMA-8 study, we didn't see very much CAR-T cell expansion early on. So we had concerns that we would not see clinical benefit, and that's what happened.

Here, it's very different. All of the patients are having robust expansion of the CAR-T cells. I think this live process where you don't have to freeze cells and ship them and then ship them back, particularly in CLL, I think, is going to be important because the sort of the more fragile nature of the cells, the immune suppression in the disease, et cetera. So I'm also very encouraged by the early efficacy data. Again, you need to see more numbers. But from what we're seeing so far, everything is lining up for a very effective product.

Paolo Ghia - *University of Milan - Professor*

Yes. I mean, if I can add on that, we talked about efficacy and the promising results, but it's really, from a technical point of view, I think it's really a game changer because especially in CLL, CLL cells are more fragile. The T cells are more energized than in other lymphomas. That's the real key issue in CLL immunosuppression. So the less you handle the T cells, the less you manage the T cells, so you don't freeze and thaw, you don't keep them for a month in expansion, I think that's beneficial.

Otherwise, we are really -- as you also showed with the data, I mean, we are really exhausting even further the cells. And therefore, that's probably an explanation why we do see such a difference because the technique -- from a technical point of view, it's complete different approach. And I think it's even more beneficial in CLL, the problem in other diseases.

Matthew S. Davids - *Dana Farber Cancer Institute - Professor*

Yes. The other thing I would add is that the CLL disease itself is immunosuppressive. And I think their results are particularly impressive in the sense that the patients they were treating had very high disease burdens. So you can imagine, as this product maybe gets moved into an earlier line or in a setting where the patients are more debulked and they have less CLL disease around it, it maybe even more effective due to better immune function.

Jeevan Shetty - *Galapagos NV - Head of Clinical Development Oncology*

Okay. And with regard to the actual platform itself, the practicalities of the decentralized model, do you see any barriers to that in terms of the real-world practice? Or do you see that as being something that is relatively easily incorporated?

Matthew S. Davids - *Dana Farber Cancer Institute - Professor*

I think that's going to depend. Obviously, center to center is going to be different. I know at Dana Farber, we have a long-standing experience with CAR-T cells. And we've, for a while, been looking for a product to partner with at a point-of-care kind of manufacturing. And this is really one that looks very straightforward to work with. So we're enthusiastic to work with this group. I think there's going to be centers, obviously, that can't do this. So having partners of manufacturing nearby makes a lot of sense sort of that decentralized model. But I think for larger academic centers, it's going to be great to have this in our center to be able to have some control over the process, but also to have the support from the company with the expertise.

Jeevan Shetty - *Galapagos NV - Head of Clinical Development Oncology*

Thank you very much.

Paolo Ghia - *University of Milan - Professor*

Yes. I think that I might envision really a decentralized approach. I mean in each hospital, at least a large hospital, in Italy, we don't have community doctors. When we speak about hematological disorders or patients with hematological disorder, they have access to hematologists that is working in a hospital, not on -- so I see that decentralization, and I'm very favorable because of the tradition.

I've been for many years and I am still a President of the ERIC, the European Research Initiative on CLL, that is really creating a network of hospital-based units where all patients can have access to the most advanced prognostic and diagnostic techniques. So immunoglobulin gene analysis, minimal residual disease assessment, TP53 assessment that 10 years ago, everybody said that it was complicated, was difficult, it's not something that every laboratory can be done -- can do. And therefore, we show that indeed if through the correct education, you can actually have everything done everywhere. And I think and I envision the same approach with your Cocoon.

Jeevan Shetty - *Galapagos NV - Head of Clinical Development Oncology*

Sure. And just based on the data that -- I think you alluded to this, Matt, the potential to move to earlier lines of therapy, is that something you could comment on?

Matthew S. Davids - *Dana Farber Cancer Institute - Professor*

Yes. As I said, I think from a scientific point of view, it makes a lot of sense to go into earlier lines. I think as you start to approach frontline and CLL, the bar does get very high because we do have such well-tolerated therapies. So I think maybe frontline use, probably not so much, even in high-risk patients because those patients will typically start with a very effective and well-tolerated therapy.

But that being said, most patients, at least in the U.S., are being treated with covalent BTK inhibitors, and they'll typically be on them for a few years, but then when they progress, those patients do have high-risk disease. And we have other options available like venetoclax, for example. But if they have high-risk genomics and they've already progressed on their frontline therapy with a covalent BTK inhibitor, I personally would feel very comfortable having a CAR-T product in that patient if it's relatively safe and effective. Especially, I think for our younger patients who have a long time horizon, having the potential for cure with immunologic therapy is really appealing.

Paolo Ghia - *University of Milan - Professor*

Yes, definitely also because we didn't speak enough about the safety profile. So at the moment, the safety profile looks quite nice. I mean no neurological toxicity and Grade 1 and 2 cytokine release. So that makes it really affordable, as you mentioned, especially for young people. So it's -- you try. If it works, good, you have a long remission.

So it might be even in frontline. I don't know, someone who says, yes, let's take our chance and have it. Maybe I have to spend a couple of weeks in the hospital, but you don't die. So the issue in our disease, in particular, because we have a lot of comorbid patients is that you don't want therapies that are bringing in too many safety issues. And this seems not to be the case.

We will see. In particular, again, you are treating patients who already received a number of lines of therapies. So they are definitely more fragile. So maybe the safety profile will look even better when you move it to earlier lines.

PRESENTATION

Jeevan Shetty - *Galapagos NV - Head of Clinical Development Oncology*

Okay. Thank you very much. We'll move on to the ATALANTA study, which is our relapsed/refractory, NHL study or maybe just start actually based on the technology. Here is the epidemiology for non-Hodgkin's lymphoma. Clearly, it's a subset of many different subtypes, follicular lymphoma, marginal zone, mantle cell and primary CNS and Burkitt's, which are all represented in our program. And with regard to the incidence and then the potentially CAR-T-eligible population, we can see that this is a representation, as things stand at the moment.

The -- this is the design of our study, which is quite similar to what you've seen before and really has all of the unique components of the Galapagos platform with regard to what we do with a leukapheresis and in terms of the T cell selection as well as the expansion and the continuous monitoring. And in addition to that, you can all see the conditioning that runs between minus day 6.

So that really allows a 7-day vein-to-vein time. You can see that the key eligibility criteria are not controversially consistent with what we have seen in the studies that are running at this point in time. Unusual, though, is the fact that we included transplant ineligible patients.

With regard to the baseline characteristics, we think this represents the aggressive patient population who have significant unmet need and are in need of therapy. This is clearly just the Phase I, Phase II data. As we expand, we will make -- we will determine the kind of inclusion/exclusion criteria to a greater extent.

Turning now to the expansion and persistence. It's important to note that we're actually seeing something very similar to what we actually saw in the CLL study. We have the same set up here with the y-axis and the x-axis in terms of -- over time. And the green represents dose level 1, orange

representing dose level 2. And what we see here is this robust CAR-T expansion that was observed across all dose levels as measured by quantitative PCR with vector copies per microgram of DNA on the y-axis.

And with the Phase I study on the left and the Phase II part of the study on the right. For Phase I dose levels, you can see this rapid expansion and then this persistence. We believe, based on what we've seen, this consistency is as a consequence of the process. Clearly, we need to follow up over a longer period of time.

And then the other component, which is about the product characteristics. With the enrichment of the frequency of the early phenotype CAR-T cells, both for CD4 and CD8, compared to the starting material, we see a very consistent elevation in the benign early phenotypes. And we believe this fits in with the fresh cell 7-day vein-to-vein time approach result in fitter cells.

Turning now to the safety profile. What we were able to see is that there was only one case of Grade 3 CRS and one case of Grade 3 ICANS. There were 2 deaths in the study. Remember, these patients have got very aggressive disease. The first was a patient with a double hit diffuse large B-cell lymphoma with significant comorbidities and developed a thromboembolic disease for which he was anticoagulated and succumbed to a bleed. And the second was a patient who developed infections that were ongoing and died 6 months after the infusion.

What we see here in terms of efficacy is very encouraging. 12 out of the 14 patients responded across the whole population in Phase I, with 11 out of 14 patients reaching a complete response, a CRR rate of 79%, and in dose level 2, a CRR of 86%.

In Phase II, we saw something similar. 7 out of 9 patients were efficacy evaluable. 6 out of those 7 patients had -- relates to an overall response rate of 86%, with 4 out of 7 patients achieving a complete response. Clearly, early patient -- small patient numbers, but compelling nonetheless.

Median duration of response was not reached. The median time on the study was 8.6 months with a range of 2.8 to 15. 8 out of 12 patients responded in Phase I, and 6 patients responded in Phase II with ongoing response. And in Phase I, 4 patients progressed after the initial response.

Again, very exciting period for the ATALANTA study. We're planning on expanding into the indications that we talked about with regard to NHL unmet need indications. And we've implemented dose level 3. And there's a completion of tech transfer to the first U.S. site with Landmark Bio that is ongoing.

So maybe at this point, I turn to Professor Bishop and Professor Anguille. Just to comment on your thoughts on the data that you've seen so far with regard to the total population and maybe the subpopulations.

QUESTIONS AND ANSWERS

Sébastien Anguille - *University of Antwerp - Professor*

Yes. Maybe I'll say first thank you. From my experience with also the commercially available CAR-T efficacy data, they really remind me about the best-in-class CAR-T cell therapies that we are now currently using. So I think from an efficacy point of view, these are indeed, as you are -- were telling, compelling data, even although the numbers of patients are quite small.

I think from an efficacy point of view, it's convincing. And from a safety point of view, from the real world experience, we are now having with these point-of-care manufactured CAR-T cells, it's actually easy to handle. We are not afraid of CRS. It's something we expect. We want CRS because it proves that your immune system is acting against the lymphoma. And it's usually very manageable, and we can handle it. So I don't think it's -- these are big problems at the moment.

Jeevan Shetty - *Galapagos NV - Head of Clinical Development Oncology*

Thank you. Professor Bishop?

Michael R. Bishop - *University of Chicago - Professor*

Yes, I just want to echo those. When I try to think about we're all looking for what's the next -- what's going to be best in class. And I think that's very good. And so it's either better efficacy, less toxicity, but what has entered into the equation now is logistics. And I agree, these are -- the efficacy is extremely promising. And we're seeing what's particularly -- when the first CARs were approved, they just set a really kind of a naive bar of overall response. We want complete responses. There are not partial responders going long term. And a signal of that success is CR is at 6 months. So you were seeing those swimmer plots, and those are very impressive. And so there's a strong signal. We need to see it now beyond that, but that's a good signal.

The safety is, I think we'd agree, best in class in that regard. And then logistically, the 7 days means a lot, I mean, when we're sitting around waiting for commercial CAR-T cell products. And just biologically, what we're seeing phenotype-wise, that is a big difference. And as a matter of fact, it is actually being demonstrated that the subsets of T cells that you were seeing here are the ones that lead to the greatest success. So you put that all together, and these results are extremely promising.

Jeevan Shetty - *Galapagos NV - Head of Clinical Development Oncology*

Yes. Great. And with regard to that 7 day vein-to-vein time, those aggressive patient subtypes, do you think the Cocoon platform is something that's going to help?

Michael R. Bishop - *University of Chicago - Professor*

Well, the answer is yes. So -- and the reason is so when we think about it. So we're seeing a variety of disease here, but let's focus on diffuse large B-cell lymphoma. So 2/3 of patients are going to do great with our available therapies. 1/3, though, unfortunately, are going to recur, and 75% of those are going to recur early.

So when you look, and as a participant on BELINDA and also ZUMA-7, you think about it, how soon can you get the patient there to be treated? And do they need it right away? But when you're waiting, and particularly what we saw in BELINDA, but even with ZUMA-7, you're still having a minimum of 21 days. And think about the logistics of trying to get a slot, getting their cells shipped and everything else, that's a critical time for the -- for our patient population.

And all of a sudden, feasibility-wise, other than insurance approval, that may be potentially a 2- to 7-day delay. But we can still actually collect the patient's cells and have them, say, ready to go or have it as soon as we get the go. And all of a sudden, now we're able to treat a patient within 7 days. And actually, you could even envision them getting their conditioning regimen while you're generating the cells. I mean that will be a game changer, right?

Sébastien Anguille - *University of Antwerp - Professor*

Yes. Just to jump in. That's actually what's happening now because a lot of people talk about vein-to-vein time, manufacturing time, which is indeed longer with the centralized manufacturing. But here, what is more important to me is actually the time from patient identification to actual infusion. And that can even happen in maybe 10 days.

I had identified a patient. Even the same week, I can do the apheresis. The next day, I start the lymphodepletion. And 1 week after the apheresis, the cells are refused. So that's really what we are speeding up the entire process.

And with decentralized manufacturing, it's not only the manufacturing time, which is 3 weeks nowadays with Yescarta, for example, but it's about having your patient, identifying him and getting him through the actual infusion, it can last sometimes several months.

Michael R. Bishop - *University of Chicago - Professor*

Right. We refer to it as brain to vein. You think about if a patient is eligible and getting him it into it.

Jeevan Shetty - *Galapagos NV - Head of Clinical Development Oncology*

Do you feel that in terms of the commercial therapies, I think, Sébastien, you talked about 3 weeks now. Have you seen like a decrease in that from origin, I mean? And do you see that continuing to improve?

Sébastien Anguille - *University of Antwerp - Professor*

Yes. So it has decreased. In the beginning, it was longer. It was more than a month. Now it's usually quite standard, 28 -- 21 days 18, 21 days or 3 weeks. But I think it will stay with that because, of course, here, you have a fresh product. So it's fresh out and fresh in, which is different with the other models.

Michael R. Bishop - *University of Chicago - Professor*

In the United States, I would relatively agree with that. I think with the axi-cel product, it's very consistent. The other product, not so much. And again, it's a longer time. So when you look at those median times, I think Kite/Gilead did a very good job, but they can't go any faster because they're set in their manufacturing process.

And so -- and even if they could get a short incubation time, you're still going to have this logistical problem of getting it, shipping it, cryopreservation. So here having it, and you don't have to worry about waiting to coordinate between the company and getting a slot and then finding out when your apheresis time you go again, the identification and moving forward logistically is going to be quite significant.

Sébastien Anguille - *University of Antwerp - Professor*

Yes. But it's -- I think it's not only about logistics, it's also about the physician or the hematologist, the treating hematologist, who is more in charge now. We have control over the process or more control because we also have direct links with our manufacturing units. So that's also something that is really important.

Michael R. Bishop - *University of Chicago - Professor*

Yes, agree.

Jeevan Shetty - *Galapagos NV - Head of Clinical Development Oncology*

And Sébastien, I think you're unique in this group of being the only person who's actually recruiting patients and using this platform. Any kind of practical pragmatic insights that you want to share?

Sébastien Anguille - *University of Antwerp - Professor*

Yes. For me, it's what I told. It gives us a lot of flexibility. So let's say that I have several patients that are eligible for CAR T. I can select the one that I think is one that is in the highest need where we can wait. And I just -- I can plan the apheresis in the same week. And the next week, the cells are

infused. So it's really easy also to use because a lot of hospitals and especially those that do stem cell transplantation have experience with cell therapy. So it's not something that we are not familiar with.

And even this entire model for our cell manipulation technologies, it's quite intuitive. It's easy to handle, easy to use. And especially with the support we are now receiving, it's -- yes, it's a very fluid or a very easy-to-use model actually.

Jeevan Shetty - *Galapagos NV - Head of Clinical Development Oncology*

Good. Thank you. And just maybe a last question before I hand over to Paul. Just with -- based on the data that you've seen in the platform, I mean, do you think this is a game changer?

Matthew S. Davids - *Dana Farber Cancer Institute - Professor*

Certainly, it looks like it has that potential. I mean, I do want to see more numbers and longer follow-up. But yes, I think it has potential.

Paolo Ghia - *University of Milan - Professor*

Yes. In terms of CLL, it can be game changer from 2 different aspects. One, as I said, the technological one, definitely, having there in your hospital or very close by, you can really plan it as another drug, I mean, like an infusion drug. I mean do you have any how to order it to the pharmacy a couple of days and then you get it. So it's exactly in the time frame that goes well for the patients and the doctors.

For us, it can be also a game changer because it's effective. So there's two times a game changer, and that's what I'm looking forward because, really, I think I have a strong background in the laboratory. I keep my career working in the lab, and I know how bad it is to freeze and thaw the cells. So I really think that can be really the key thing.

Jeevan Shetty - *Galapagos NV - Head of Clinical Development Oncology*

Professor Bishop?

Michael R. Bishop - *University of Chicago - Professor*

Yes. I think this can be quite significant and impactful on our patients. And so that's actually what gets me most excited is that we are now going to have this option. And again, it's both quality and logistics.

Sébastien Anguille - *University of Antwerp - Professor*

I agree. I think it's game changing at the individual level, the patient level. I included or recruited the first patient in ATALANTA-1. It's now almost 2 years ago. Patient is still in complete remission, whereas he was on death row actually, he had no treatment options left. So on an individual level, it can be game changing, but I also think -- from another perspective, this model is also extrapolatable to other diseases, other types of cancer.

We are now going to start PAPILIO-1 trial in myeloma, which is fairly similar. The process is similar. Only the target CAR-T is different, but the entire process is the same. And even this Tuesday, we are going to do the apheresis of the first patient in this trial. So this model is extrapolatable to other diseases and hopefully in the future also to solid tumors.

Jeevan Shetty - *Galapagos NV - Head of Clinical Development Oncology*

Perfect. Thank you very much. Paul, maybe over to you.

PRESENTATION

Paul A. Stoffels - *Galapagos NV - CEO,Chairman,Interim Head of R&D*

Well, just for me to thank Professor Davids, Professor Ghia, Professor Anguille, Professor Bishop for their contribution here in the discussion. Think the teams of Galapagos and previous CellPoint have worked very, very hard for many years on getting this to this point.

Also including here the teams at Lonza which were very collaborative in making this happen. It has been a collaboration -- extensive collaboration to get this CAR-T instrument, which can make it at point-of-care really function and now us being able to decentralize and implement, resulting in the 7-day vein-to-vein.

It's very important for fit cells, fresh cells to be able to administer as we demonstrate now in small numbers. As the high manufacturing success rate is key because, yes, if you deplete the patient during the manufacturing process, you need to be able to deliver. And so far so good. We have been very constant in delivering. And the ability to use fresh cells goes together with the results.

Initially, it was like a concept and idea. But as you have seen, the expansion curves in -- both in the CLL and the NHL, it is, like, yes, the transaction and the first growth is done in the incubator. The patient is the real incubator where the cells grow. And most likely, that has its effect on its safety and its efficacy, all to be further scientifically evaluated and confirmed. And then the rapid robust expansion observed in vivo, as I said, is key to the success, and the preserved early phenotype was a theoretical idea, but it looks like it works out in practice.

So with this, I think we had a good start. The team said the advisers also, the key opinion leaders here said, it has -- we have to now see it work on a larger scale. We are committed to build it out first in Europe and the U.S. and do the next pivotal studies over -- starting in the course of next year. And hopefully, then we can -- this product -- project -- product and also the production can be distributed across the entire world. There is no limitation to where this can go because transportation is out of -- it's all local. And we, as a company, will set up to be able to support and make a huge difference, bring CAR-Ts to many patients and make a lot of difference in the world.

So with that, thank you, and we'll go and have the floor open for questions. So Sofie, if you can moderate the questions. Thank you.

QUESTIONS AND ANSWERS

Sofie Van Gijsel - *Galapagos NV - Head of IR*

Yes, Phil go ahead, please. Thank you.

Philip M. Nadeau - *TD Cowen, Research Division - MD & Senior Research Analyst*

Phil Nadeau from Cowen. Two questions from us. First, on the CLL poster yesterday, there was a mention of 3 patients who had to have dose level 1 because they didn't have adequate cells for dose level 2. We're just curious what happened with those patients? Was it a manufacturing issue or variability just in the patients themselves? And then second question on the regulatory process. Can you give us some understanding of what the FDA looks for to validate a point-of-care manufacturing paradigm for cell therapy?

Sofie Van Gijsel - *Galapagos NV - Head of IR*

Would you like to make a start, Jeevan?

Jeevan Shetty - *Galapagos NV - Head of Clinical Development Oncology*

Yes. So I can make a start to the first part of the question. The recollection that I have is all patients received treatment. Yes, it was lower than the dose that we expected. But this goes back to that translational data, whereby quantity is not as relevant as quality because we actually ended up seeing responses in those patients that got a lower dose of treatment. So in a sense, this is something that we need to continue to observe.

And yes, there is an element of this, which is really about what is your starting material. So the starting material -- the patient's starting material really determines a lot. This is what we're discovering. So this is something that we need to continue to interrogate, but it goes back to that T-cell while we continue to see responses in those patients as well. With regard to the regulatory point, maybe, Paul?

Paul A. Stoffels - *Galapagos NV - CEO,Chairman,Interim Head of R&D*

Yes. In the regulatory, the way we will implement a model is that we will take full end-to-end responsibility for the manufacturing in on-site. So -- and that will follow normal regulatory requirements: GMP; fully validation of the product; an NDA with an approval; and then for us, being able to standardize and implement the manufacturing across these centers in a very consistent way. And that's where the team is working on the -- as you can see, it's almost a fully automated model. And at this moment, there's still a lot of work ongoing on the standardization and the automation of the quality release.

That all can be captured in the electronic data systems and be centrally released by us as the final approval of the release. So we will use industry -- pharmaceutical industry-grade standards to do this entire process, but we'll have to pioneer and do this in a decentralized way.

We think that the benefit risk, which we address here by being able to do a decentralized with fresh cells requires a lot of attention, and we will work together with the FDA. So far, so good. We're doing this in Europe in 3 countries, 5 hospitals and expanding. We are in very close connection with the regulators over this with the local - in the countries, but also centrally with EMA. And we have initiated a discussion with the FDA. But there, we couldn't submit IND before we had the first manufacturing site on the ground and data produced from that.

That's ongoing. And in the first half of the year, we'll be able to submit an IND and start working in the U.S. Our teams are in discussion with the FDA, but submitting the IND will require our first manufacturing site up and running. And that will be one in Boston, which is currently being validated.

Sofie Van Gijsel - *Galapagos NV - Head of IR*

Yes, we'll have a next question from Pete from Citi.

Peter Verdult - *Citigroup Inc., Research Division - MD*

Pete Verdult, Citi. Just a few topics. I hope you don't mind given that we've got 4 KOLs in front of us. But just sorry to harbor on the point. So the data that's been presented, was that done over the 5 hospitals that you mentioned, Paul? Or is that okay?

So in terms of reproducibility, how many times have you done this process? I suppose just being at the poster board yesterday, I mean I'm just earwigging, hearing what everyone else is saying, but the -- I mean there's a healthy dose of skepticism that the FDA is going to be relaxed about this decentralized process. So just how do you sort of push back to the pushback?

Paul A. Stoffels - *Galapagos NV - CEO,Chairman,Interim Head of R&D*

Well, I'm not relaxed at all. I've been 30 years in the business, I've been dealing with the FDA for a long time. We will meet -- we'll need to meet the standards, need to meet the quality, and we are not going to undershoot. We're going to overshoot with what we do. So that is -- yes, the -- I think the -- and Ruiz can respond, but we probably have done more than 100 runs laboratory-wise in ourselves. Ruiz, why don't you answer this -- the quick question on manufacturing?

Ruiz Astigarraga - *Galapagos NV - Head of Manufacturing Cell Therapy*

My name is Ruiz. I'm the head of manufacturing at Galapagos. We have actually performed more than 300 runs in -- overall, including our central facility in Leiden, where we have a vast experience in healthy donor production. That helped us to increase the understanding of the process and also how comparable the process can be across different sites.

Comparability is at the core of our work as we have a consistency by design approach. By standardizing, automating and making everything digital, we are able to really have all the sites performing under comparable conditions, and that's also what the FDA is expecting from us, and we are ready to present the data to support our first IND with comparable sites also between U.S. and Europe.

Paul A. Stoffels - *Galapagos NV - CEO,Chairman,Interim Head of R&D*

Everything is standardizable, except, of course, the apheresis from the patient. And that's the biggest variable. Like you hear in CLL, for example, the variability of that and the viability of CLL is very well known that it's not that easy, but it has been shown that with our process, we can do it, and with the fresh cells. So more to learn. We have to do this times 10, times 100, but I think a good start for where we are today.

Peter Verdult - *Citigroup Inc., Research Division - MD*

And Paul, is the plan just to have 1 U.S. site next year? Or how many are you looking for?

Paul A. Stoffels - *Galapagos NV - CEO,Chairman,Interim Head of R&D*

No, no, no. We are -- first one will be started up as we speak. It's ongoing. We have already 2 others in view, which we are contracting with, and probably at least 5 in the first year. But if not, we try to shoot for 10 to have a good presence in the U.S. for the clinical trial as well as in Europe to run our clinical trial in the European context.

Paolo Ghia - *University of Milan - Professor*

Actually, I want to reconnect also to the first question, meaning that the surprises should not come from the fact that the patient -- 3 patients did not get to DL2, but the fact that all 3 patients have DL1, that they expanded. So that's the -- I think what is also the beauty of the system that, again, we were used to inject a lot of cells because we were expanding a lot of cells in vitro. And then those cells did not expand, and they were dying only.

Instead it's very nice what you said. So the patient is the incubator, the real incubator. So you just have to shoot some cells and probably they will expand because they are so live and so not manipulated that I think that's the key. We will see with data, of course, but that's what is attracting me as an investigator.

Paul A. Stoffels - *Galapagos NV - CEO,Chairman,Interim Head of R&D*

Thank you to describe this. The key innovation is probably that, having very high memory content, very fit cells getting into patient, and the patient is the incubator, much better incubator than the Cocoon to keep the cells for a long time.

Paolo Ghia - *University of Milan - Professor*

Especially because the cells will be specific against the target, and we know you can put one cell and that theoretically, it should expand and become...

Peter Verdult - *Citigroup Inc., Research Division - MD*

And then just rounding out to the 4 docs, but just 2 questions for you. As it stands today, just that whole bispecific cell therapy story. I mean we're seeing it playing out in myeloma, but how -- I'm not asking you to crystal ball gaze, but how are you thinking about it in CLL and DLBCL? And then just topically with the FDA's recent review of T-cell malignancies. Just any views on that?

Matthew S. Davids - *Dana Farber Cancer Institute - Professor*

Yes. So very, very early in CLL, 20 or so patients treated. There is some activity with bispecific antibodies. So it's early, but I think that is a potential competitor. I think that certainly with bispecific antibodies, though, you still have the challenge where the cells are not being sort of manipulated at all. They're just staying in an immunosuppressed host. So you're relying on generating that initial immune response in that context. So there may be some advantages to engineering the cells outside the body and then reintroducing them that I think CAR-T can provide.

Michael R. Bishop - *University of Chicago - Professor*

Yes, I'd just like to address that. Again, when bispecifics can show the complete response rates that CAR-T cells, then they become a competitor. And I think that's -- it's fair. They're probably going to be moved more in the front line. So what do we do after they relapse from that? So I think that's the intention.

Coming back, in fact, made to address the T-cell lymphoma issue, it is important and I'm glad. Every time we do CAR-T cell therapy, we do -- that's why it's very, very important we report all SAEs. But putting it into the context, I mean, when patients go through CAR-T cell therapy, there's an inherent of approximately 5% mortality rate, be it from whatever infection, cytokine release syndrome, neurotoxicity, et cetera and including secondary malignancies. But when we look at this incidence of T cell lymphoma and initially what was reported to the FDA, it was 0.15%, and that's among the SAEs.

So if you put it in the context of how many CAR-T cells performed, the incidence becomes less than 0.1%. Now that's a significant 0.1%. And again, the studies are being done to understand what the biology is, whether there actually is an insertional mutation resulting in this proliferation, but I think we have to study it hard. But would that prevent me from moving forward and presenting this potentially curative option to my patients? The answer is no.

Sofie Van Gijsel - *Galapagos NV - Head of IR*

Yes, questions from Brian from RBC.

Brian Corey Abrahams - *RBC Capital Markets, Research Division - Senior Biotechnology Analyst*

Maybe 2 questions. First, for the CLL experts. I'm curious, how much data do we have on the correlation between T cell expansion versus anergy to response and to duration of response with some of the older CAR-Ts? Just to be able to project what we might see here over time given some of the technical advantages of this process.

And then for the NHL experts, do you envision using this broadly in most of your patients or just in certain patients where the shorter vein-to-vein time would be a potential advantage? And what would you want to see in terms of long-term data to use this ahead of the more established centralized cell therapies?

Matthew S. Davids - *Dana Farber Cancer Institute - Professor*

Maybe I can start and just briefly mention an interesting finding from the ZUMA-8 study, which I presented at the ASH meeting last year, actually, which was that there were about 15 patients and very -- generally very poor expansion of T cells in these patients with brexu-cel. But there were 3 patients treated with low disease burden, where there was some expansion of the T cells, and those were the patients who had the best response. So to me, that was pretty suggestive. And actually, I encouraged the company to pursue that signal, which they didn't. But that would have been very promising, I thought. I don't know if you want to speak to liso-cel yet.

Paolo Ghia - *University of Milan - Professor*

The -- I think we don't know much in CLL about that. I mean we are trying to translate too many -- too much information from other lymphomas, and it's a completely different thing. The -- again, even the strategies to -- for CAR-T cells in CLL is like changing the ratio between CD4 and CD8. Do we know if that is relevant or not? We don't know.

The phenotype, they are anergic starting with. So that's, again, to answer the bispecific question. With the bispecific, we are trying to stimulate cells that are not so able to be stimulated. And in fact, in CLL, again, another big failure is anti-PD-1 and anti-PDL1 that revolutionized most of cancers, solid and blood cancer, not in CLL, they don't work because the cells that are sitting there are probably not responsive. The CLL cells are inducing them into an anergic state.

So we probably need to take the cells out to give a stronger antigen recognition capacity because probably the anergy that is present in CLL patient is really impairing an immune response against the tumor. So we don't -- probably don't have so many cells and so specific against the leukemia. So we needed to manipulate them, put an anti-tumor, anti-leukemia antibody. And then with a short time, probably they can recover a little bit outside the body. And then when they are injected, they find their target and they can be stimulated. So this has to be proven.

Sébastien Anguille - *University of Antwerp - Professor*

Maybe I'll take the question regarding which model to choose or which CAR-T to choose because we're now doing both. We are doing commercial Axi-cel and also participating to this trial. For me, from -- of course, from an ethical perspective, when you have a commercial or regular CAR-T patient, normally, that's superior over getting into a Phase I or II clinical trial.

So when the patient fulfills the criteria for receiving Axi-cel, he or she will receive Axi-cel. Unless, for example, it's a rapidly progressive patient where we think that maybe this model where you can go faster can be better. So -- but the advantage here of this study is in lymphomas. We are also having a lot of NHL types, or this trial is getting into NHL types where Axi-cel is not available.

Let's, for instance, say, primary CNS lymphoma, where there's a high unmet need. So actually, in this ATALANTA trial, we showed, I think, that this works, that is CAR-T is highly efficacious also in the indications for Axi-cel. But now we are moving into the other lymphoma types, follicular lymphoma, primary CNS lymphoma, maybe in the future also Burkitt lymphoma, and that's the exciting part here, I think.

Michael R. Bishop - *University of Chicago - Professor*

And I just want to follow up on that because it's an interesting question. We sit on a lot of ad boards and particularly where this early necessity for these more aggressive patients. And the other option in this would be an allogeneic CAR T cell off the shelf. And it's very funny. Just recently, my peers, they said, well, if I could get this immediate access, I'd be willing to accept a lower outcome when we set the bar, like I say, for a complete response rate. And the reason is because if they can't get a CAR, they're going to die, right?

So -- but in this situation, I mean, we're seeing very, very promising data in terms of response. And so if the data holds true and if I have this available, why would I want to wait 28 days or 21 days? So would I apply it to all of my patients in the future because you're talking about where right now, we'll be doing the, really, Phase I, Phase II of this, but if it became approved, this -- and again, I didn't have to ship cells off, I didn't have to do the cryopreservation, et cetera. It's kind of, to me, a no-brainer.

Paolo Ghia - *University of Milan - Professor*

And as I said, I was speaking with them a few days ago. And I said, it depends how many Cocoons you can give to my hospital. That's the only limitation.

Sébastien Anguille - *University of Antwerp - Professor*

Maybe if I can just add, it's something, it's maybe intuition. But for example, if we like have like an older patient that is quite maybe frailer, more frail, in my opinion, the toxicity, although the safety data need to be more mature, need to mature a little bit more, but from a neurotoxicity perspective, for example, there is a difference with this product versus Axi-cel, where you can sometimes see severe Grade 3 neurotoxicity, which, in my hands, I haven't seen this with this product. So maybe that's something in the future that will also guide us.

Sofie Van Gijsel - *Galapagos NV - Head of IR*

Thanks so much. If that's okay, we'll take a question from Jacob Mekhael of KBC Securities who joined virtually. So that's one for Paul I think. Your pipeline chart includes next-generation CAR-Ts. Will those be internally developed? Or could they come from licensing or M&A?

Paul Stoffels

Yes, both. We have a very strong capability led by John, John Mellors, and our internal team in Pittsburgh working on next-generation CAR-T, but we are very open to look at all possible outside options here. They're not invented here. It's not our thing. We will use the best possible option, which we can bring for next-gen CAR-T to patients. And John is very active also with his whole team on looking externally what is evolving, including going -- what we're looking at in China, Europe and the U.S. So yes.

Sofie Van Gijsel - *Galapagos NV - Head of IR*

Thank you. And then maybe a second question, how fast do you expect to complete the expansion cohorts and progress to the pivotal trial?

Paul A. Stoffels - *Galapagos NV - CEO,Chairman,Interim Head of R&D*

I think for CLL, we are determined to start the clinical study in the course of next year, pending the IND submission, the validation of the sites in the U.S. and being able to start it. It's a very attractive trial because we solve a real medical problem. So it's up to us now operationally to handle it all. But in the course of the first half of the year and get the sites and the IND in and then make sure we start in the second half of the year the clinical trial in an extensive way. Yes. Europe, U.S.

Sofie Van Gijsel - *Galapagos NV - Head of IR*

Thank you. More questions from the room, perhaps?

Daina Michelle Graybosch - *Leerink Partners LLC, Research Division - Senior MD of Immuno-Oncology and Senior Research Analyst*

Daina Graybosch from Leerink Partners. A question for the doctors using this. So you save the logistics of cryopreservation, but what does it take in terms of space and people to actually do the Cocoon on site? So you're trading off one logistics to the other, and I wonder if you could talk about the trade-offs of both those things.

Sébastien Anguille - *University of Antwerp - Professor*

Yes. So we have really a really small GMP cell manufacturing unit, which I think you can count the cell manipulation technologists on one hand. They are also doing other things in the hospital. They are doing a stem cell work and things like that. So it's -- from a personnel point of view, it's something that is -- you don't need a lot of people actually to run this.

And also from a space perspective, we have several clean rooms. We have 6 clean rooms, I think. But of course, you can envision that you can put a lot of clean rooms in -- a lot of Cocoons in 1 clean room also. So even from a space perspective or room perspective, it's not that you need big or large infrastructure.

Paul A. Stoffels - *Galapagos NV - CEO,Chairman,Interim Head of R&D*

But we, ourself, are doing an extensive exercise to be able to communicate to the centers what it takes. We know what it takes today in clinical trials, but it could be very efficiently organized in small clean rooms. And actually, at the moment, there are 3 people needed with 3 different types of capabilities to be available. But of course, in clinical trials, you don't do 3, 4, 5 Cocoons at the same time. It's one. And so at the moment, the number of people to run it per product is still high. But if you can get to efficiencies with many Cocoons and an organized lab, we'll be back with much more information on how that could function. It is exactly the same question the centers who collaborate with us ask. And we have to work out as we speak now to build it out. But high interest, I can tell.

Daina Michelle Graybosch - *Leerink Partners LLC, Research Division - Senior MD of Immuno-Oncology and Senior Research Analyst*

And then one more question, another regulatory one, perhaps more specific. When you -- when the companies of 2-day manufacturing have presented their results, they often say the actual vein-to-vein time is limited by the quality testing. And I wonder what you're doing in terms of quality testing in these trials thus far that you can get to 7 days? And do you have to have new solutions to keep it there as you move forward?

Paul A. Stoffels - *Galapagos NV - CEO,Chairman,Interim Head of R&D*

Yes, we have existing solutions, which make it happen today. We are further optimizing it. The fact that we use a sterile incubator end to end with no manual handling allows to start quality release testing during the process. And that is -- that's one of the key features. There is no manual handling of the cells. It's a totally closed system end to end. And that allows after the transfection start doing evaluation.

More to follow, more information to follow on this. It works today. We're working with the regulators to make sure we can standardize it on the global level. And we are also further automating each of the different quality release tests, quality control tests to make them also, I would say, that no human -- human error proof, yes? So that it's all foolproof, yes, foolproof. Foolproof, foolproof. Yes, so that's all ongoing. But so far, so good.

Well, thank you very, very much for the crowd here in the room coming to listen to us for your presence at some of you at the meetings yesterday, it was really encouraging for our entire team to have this type of motivation from the key opinion leaders. Showing the results is a big day for us, but a lot of work to do. And hopefully, next ASH, we'll be able report even much more data and hopefully very far advanced with the clinical trial.

So thank you very much, and have an enjoyable stay in San Diego, and good learnings at the meeting. So thank you.