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PRESENTATION

Operator

Good day, and thank you for standing by. Welcome to the Galapagos Q3 2023 Financial Results Conference Call. (Operator Instructions) Please be advised that today's conference is being recorded.

I would now like to hand the conference over to your speaker today, Sofie Van Gijsel. Please go ahead.

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

Thank you, operator, and welcome all to the audio webcast of Galapagos Q3 2023 results. I'm Sofie Van Gijsel, Investor Relations representing the reporting team at Galapagos. This recorded webcast is accessible via the Galapagos website home page and will be available for download and replay later on today.

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 environment. 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 will be Dr. Paul Stoffels, CEO and Chairman; Thad Huston, CFO and COO; and Dr. Jeevan Shetty, Head, Clinical Development Oncology. Paul will give an introduction and provide a strategic overview. Thad will then go over the operational and financial results, and Jeevan will discuss our CAR-T programs.

You will see a presentation on screen. We estimate that the prepared remarks will take about 25 minutes. Then we'll open it up to Q&A with Paul, Thad and Jeevan, joined by Michele Manto, Chief Commercial Officer; and Dr. Daniele D'Ambrosio, Head of Immunology.

And with that, I'll now turn it over to Paul.

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

Thank you, Sofie, and thank you all for joining today. I would like to start by taking a moment to remind you of our vision and mission to bring transformational medicines to patients around the world. This drives everything we do at Galapagos.

Over the past year, we have taken key strategic steps in our transformation into an innovative biotech, first, with the implementation of our new operating model and the new approach to research and development to accelerate innovation and strengthen our pipeline; and now with the intended changes related to our Jyseleca business. We reached the critical moment, and we have chosen what we believe is the best option for patients, our people and Jyseleca.

Now let me walk through the key terms of the deal announced on Monday. Galapagos intends to transfer the entire Jyseleca business to

Alfasigma, including the European and U.K. marketing authorization, sales, marketing and all filgotinib development activities as well as approximately 400 employees across our European operations.

Alfasigma is a profitable, privately owned pharmaceutical company in Italy, ranking among the top 5 with revenues over EUR 1.2 billion in 2022. In the contemplated transaction, Galapagos will receive EUR 50 million upfront and is entitled to sales-based milestones of up to EUR 120 million. In addition, Alfasigma will pay royalties in the mid-single to mid-double digits to Galapagos. Galapagos will pay up to EUR 40 million in development costs to Alfasigma before June 2025.

We also announced that we plan to adjust our remaining workforce and streamline our operations to align with the renewed focus on innovation. This is expected to impact approximately 100 positions. This will allow us to focus on innovation and accelerate our pipeline of best-in-class, transformational medicines in our core areas of immunology and oncology.

The completion of the intended transaction is subject to the execution of a definitive agreement and customary conditions, including regulatory approvals and consultations with work councils. With the signing of the letter of intent to transfer the Jyseleca business to Alfasigma, we completed our process of exploring strategic options for Jyseleca, as announced at the half year earnings call in August.

So let's have a look at our pipeline focused on immunology and oncology. For our immunology franchise, Jyseleca is grayed out given by the planned transfer. We are progressing our TYK2 in dermatomyositis and SLE. And we aim to start a patient study with our CD19 CAR-T candidate, '5101, in severe refractory lupus early next year. Meanwhile, we are working on multiple exciting preclinical targets that we are eager to push forward if we see a best-in-class potential.

In oncology, we made good progress with the CD19 CAR-T programs and plan to start the BCMA CAR-T program in multiple myeloma in the coming weeks. Together with our research team, we are working on next-gen CAR-Ts and we are evaluating BD opportunities in this space too.

Today's earnings call, we will focus on important progress that we are making with our oncology programs. We are very pleased that we'll have the opportunity to present 3 posters at ASH in December. The data in the abstract released yesterday underline that our CAR-T programs manufactured at point-of-care are delivering on their promise.

In today's presentation, we will discuss the encouraging data in CLL and NHL observed with our product candidates, '5201 and '5101, as well as the clinical study design of '5301, our third CAR-T program manufactured at point of care. Importantly, we initiated a tech transfer following the agreement with the Boston-based Landmark Bio. This is a key milestone in the geographical expansion of our unique 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 the U.S. to further build our point-of-care manufacturing network. In addition, we continue to strengthen our capabilities in oncology with key hires, amongst others, in the regulatory, clinical, BD and strategic marketing.

I would like to take a moment to highlight the strong fundamentals that we put in place over the last 18 months. We renewed our discovery portfolio and are working hard on accelerating our early-stage pipeline. We continue to broaden our late-stage pipeline, pushing forward our internal programs and scouting for business development opportunities. We are making important progress with our CAR-T programs and are actively expanding our point-of-care footprint with our Cocoon Platform.

With the transfer of Jyseleca, we can further streamline our organization. And to support our innovation, we aim to approximately add 100 expert roles over the course of next year. And we commit to stay disciplined in our use of cash to focus our investments and to maximize them. Summarizing, we have been executing on our company transformation and now have a clear path outlined for value creation.

Now I hand it over to Thad who will provide an operational and financial update.

Thad Huston ***Galapagos NV - CFO & COO***

Thank you, Paul. Let's first go over the key financial year-to-date.

Going to our P&L, we reported a net profit of EUR 54 million in the first 9 months of 2023, in part driven by higher revenue recognition for filgotinib. This is driven by collaboration revenues that increased mainly due to the collaboration agreement with Gilead for the filgotinib development amounting to EUR 186 million in the first 9 months of 2023 compared to EUR 167 million for the same period last year; and by Jyseleca sales coming in at EUR 82 million year-to-date, plus a sales milestone of EUR 1 million and EUR 7 million in royalties for Jyseleca.

We also saw a reduction in total operating costs of EUR 72 million or down 13% versus the prior year, which can be attributed to lower R&D expenses and a reduction of EUR 20 million of SG&A expenses. Additionally, we received higher interest income as a return on our capital in the first 9 months of 2023.

Let's now look at the Jyseleca in-market performance for the quarter. Sales remained flat at EUR 28 million versus the previous quarter. Year-to-date, we booked EUR 82 million in sales, and we are confirming our re-set guidance of EUR 100 million to EUR 120 million.

Now a few words on our cash position and guidance. Our cash and cash equivalents are EUR 3.8 billion at the end of Q3 2023. Our operational cash burn for the first 9 months of 2023 reached EUR 344 million. We confirm our full year cash burn range of EUR 380 million to EUR 420 million. This is explained by an increase in interest income and grants coming in the fourth quarter. Over the full calendar year, we expect approximately 3% return on our outstanding cash balance.

With the intended transfer of Jyseleca announced earlier this week, we will realize significant savings well over EUR 100 million in 2024 and annualized savings of EUR 150 million to EUR 200 million as of 2025. We continue to be disciplined and remain focused on managing our resources effectively.

This brings us to our business development efforts. We are actively pursuing multiple deals in oncology and immunology. Our approach is highly selective, and please be assured that we are laser-focused on partnering and M&A to accelerate our pipeline.

And with this, I will hand it over to Dr. Jeevan Shetty, our Head of Clinical Development in Oncology, to walk us through our CAR-T programs and results.

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

Thank you, Thad. Good morning to you all. Many thanks for your time. My name is Jeevan Shetty. I'm the Head of Oncology here at Galapagos. I'm really very excited to be able to share the significant data review today in a number of really difficult-to-treat cancers. We are sharing data whilst respecting the ASH embargo. Please be assured that more data will be available in San Diego.

I wish to just remind the audience of the key differentiated features of the Galapagos point-of-care platform. Galapagos uses first-principles thinking, focusing on simplification and streamlining of every aspect of the current centralized production we see on the left, weaknesses that actually lead to critically ill patients not getting the life-saving treatment that they need in time.

Our innovative system consists of end-to-end automation, functionally closed systems, a comprehensive real-time monitoring both centrally and remotely through our xCellit platform and 24-hour clinical and manufacturing support. The 7-day vein-to-vein time and fresh-to-fresh cells is really at the heart of our platform. Galapagos aims to make CAR-T therapies globally available to patients not readily served with the current central manufacturing process.

On the top half of the slide, one sees 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, one sees the conditioning regimen being given at day minus 6 to day minus 4. This is given in parallel to the manufacturing of our CAR-T products. This is unique to our system, a testament really to our confidence in our reliable manufacturing process and critical to deliver a 7-day vein-to-vein time. Through our unique platform, Galapagos delivers a life-changing service to patients and a step-change experience for clinicians and providers.

I wish to spend a moment on high-risk CLL and Richter's transformation, which is the focus of our first study that I will present. Chronic lymphocytic leukemia is a disease for which there is currently no cure. It is one of the common hematological malignancies in the Western world. The disease progresses from asymptomatic disease to symptomatic and then undergoes transformation to a much, much more aggressive histology.

Richter's transformation is fatal. As you can see, the disease has a dismal prognosis of a median overall survival of only 5 to 8 months. Time is of the essence. With the Galapagos decentralized platform being close to the patients and the 7-day vein-to-vein time, we can address this rapidly progressive disease with speed and with effectiveness.

From an epidemiological perspective, the underserved high-risk CLL population represents 2,100 new patients in the U.S. and 1,800 patients in the EU5. The Richter's transformation population represents a similar patient number with 1,900 patients in the U.S. and 2,000 in the EU5. This is a disease with no effective options, a fatal prognosis. We can finally offer some hope for these patients.

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

I now turn to our important study focusing on high-risk CLL and Richter's transformation, the EUPLAGIA study. The design of our EUPLAGIA study incorporates all the unique components of the Galapagos platform, i.e., concurrent conditioning, seamless CAR-T production and innovative IT and QC technology, ensuring release at the day of harvest and infusion. This is truly transformational.

As you can see, the study population treats patients with relapsed/refractory CLL with more than or equal to 2 prior lines of therapy, CD19-positive CLL patients. Significantly, the trial allows patients with Richter's transformation and also transplant ineligible patients. The study was designed to explore 3 dose levels.

Looking now at the baseline characteristics of the EUPLAGIA study population, we see that they are really consistent with the population of risk of unfavorable outcome, shown here by age and by gender. Furthermore, the advanced nature of the disease in our study is evidenced by, number one, the prior lines of treatment, prior BTK inhibitors and venetoclax and prior allo bone marrow stem cell transplant and also the disease characteristics - number two - TP53 mutation and the high rate of unmutated IGHV that you see.

Turning now to safety. We see a good safety profile with our product. It is well tolerated. There is no Grade 3 CRS. Only 6 patients experienced low-grade CRS, Grade 1 and Grade 2. There were no ICANS reported, no deaths occurred. Most treatment-emergent adverse events were Grade 1 and Grade 2. And most observed Grade 3 and 4 adverse events were of hematological origin and all well managed with standard point-of-care.

I turn now to the efficacy. We have observed excellent efficacy with our drug in patients with relapsed/refractory CLL with or without Richter's transformation. Objective response was assessed as per iwCLL for patients with CLL, and Richter's transformation was observed as per the Lugano classification. 11 out of the 12 patients, including patients responding to the treatment, resulted in an objective response of 92%. 75% of patients reached a complete response as their best response.

A further clear observation is the 83% complete response at dose level 2. This compelling data has transformed our decision on our recommended Phase II dose RP2D of 100 million cells. At the time of analysis, 9 out of 11 patients, 82% of the responders, had an ongoing response. The duration was up to 9 months post infusion, which is the latest available response assessment at the time of the abstract submission. Further follow-up is clearly ongoing.

Focusing on the Richter's transformation subset, 7 of the 12 enrolled patients in the EUPLAGIA study were diagnosed with Richter's transformation. All but 1 patient with Richter's transformation responded to treatment, a rate of 86%. And 5 out of the 6 responding patients achieved a complete response, 83%.

So to conclude, though a small patient number, the efficacy, together with the safety, has excited experts in the field and confirms our desire to accelerate this program to bring this therapy to patients as soon as possible.

The next steps for EUPLAGIA are genuinely exciting. As I alluded to earlier, with the 83% CRR at a rate of dose level 2, the class-leading safety and the ratification by experts, both internally and externally, we will proceed with dose level 2. We will initiate the Phase II expansion cohort for the 2 populations we have described. Critically, we have initiated the tech transfer to the first U.S. site, Landmark Bio, in Boston, as mentioned by Paul. Do remember our poster at ASH on the 9th of December.

Turning now to the NHL program. With our decentralized manufacturing and short vein-to-vein time, we strongly believe accessibility and efficacy of CAR-T therapy can be improved and serve the sickest NHL patients with the most aggressive disease. This has informed our thinking on future NHL subgroups that we will pursue diseases currently underserved by the approved CD19 CAR-T therapies. Additionally, even with approved products available, we identify persistent unmet need in indications where limited CAR-T products are actually available as a result of manufacturing slot shortages through the centralized model that exists.

This is the design of our ATALANTA study based on our unique Galapagos platform, a Phase I/II trial in patients with non-Hodgkin lymphoma, consisting of diffuse large B-cell lymphoma, mantle cell lymphoma, marginal zone lymphoma and follicular lymphoma. The study population requires patients with relapsed or refractory disease after 2 or more prior lines of therapy with the inclusion of transplant ineligible patients in addition to primary refractory diffuse large B-cell patients also being included.

With regard to prior lines of therapy, we allow the same patient population as would be eligible for the approved CAR-T products. However, as a consequence of our 7-day vein-to-vein time, our study allows for patients with potentially more aggressive disease to be included in our trial. Here, too, we will appraise 3 dose levels.

Baseline characteristics of the ATALANTA study is typical of the patient population and representative of the heavily pretreated patients in the study. We see encouraging safety data for our product in the ATALANTA study. With ICANS, there were 6 patients who experienced a Grade 1 ICANS and only 1 case of Grade 3 CRS. All others were Grade 1 to Grade 2.

There were 2 deaths in the study. One was with the patient experiencing intra-abdominal hemorrhage. This patient has been previously diagnosed with prior thromboembolic disease and was already on low-molecular-weight heparin. The second was a patient who had urosepsis and had come to this 6 months after infusion.

We observed very encouraging efficacy in our therapy in patients with multiple subtypes of relapsed or refractory disease. In our data set, 13 patients were evaluable for response at the time of analysis and 11 patients responded to treatment, resulting in an objective response of 85%. One can also observe complete response rate of 83% at dose level 2. 69% of our patients reached a complete response as their best response in the all patient population.

This is the data at the time of abstract submission. The study is clearly ongoing, and we'll continue to collect more data with longer follow-up times. We now have the first patient in the ongoing response for over a year, and we will be presenting more of these patients at ASH.

As with EUPLAGIA, the next steps for ATALANTA are similarly exciting. We will expand an indication with the benefit of -- in indications that will benefit from the short vein-to-vein time. We will implement dose level 3. And as mentioned previously by Paul, we will complete the tech transfer to the first U.S. site, Landmark Bio in Boston.

Given the encouraging safety and efficacy we are presented in CLL and NHL using our innovative and reliable platform, we're moving ahead with addressing the unmet need in multiple myeloma in the PAPILIO study. Whilst, of course, there are commercially available BCMA therapies, there is limited access to these products, and this population remains severely underserved.

Here is the study design and the patient population we are proceeding with. We expect our first patient to enroll any time certainly this month. The data from the 26 patients that were enrolled in the EUPLAGIA and the ATALANTA studies that we've shared with you today demonstrate that the point-of-care CAR-T manufacturing with short vein-to-vein time is feasible.

Our CAR-T therapies are administered as fresh products with a median vein-to-vein time of 7 days. We've shown 100% manufacturing

success. All patients that underwent leukapheresis were dosed and they all received fresh CAR-T products. In our trials, the clinical responses were supported by high in vivo expansion of the CAR-T cells and durable persistence post-infusion. This was observed across the dose levels that we tested.

Furthermore, our novel point-of-care manufacturing models and early phenotype of the less-differentiated CAR-T cells is preserved in the CAR-T product. This really strengthens our belief that our manufacturing process contributes to better CAR-T product. And that leads us to believe it is not so much the number of cells that are infused, but more of the quality of the cells. We believe we have a very innovative platform for the future of CAR-T therapies that could serve patients around the world, patients with little time and few options.

Thank you. I hand back to Paul.

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

Thank you, Jeevan. Let's look now at the remainder of 2023. As presented today, we are making excellent progress with '5101 and '5201 in NHL and CLL. And as Jeevan just presented, we reported encouraging safety and efficacy data. At ASH, we'll be able to share more clinical data, including the expansion cohorts Phase I/II results of our NHL study.

Also in oncology, we aim to submit an IND for '5101 in NHL, our CD19 CAR-T candidate, in the first half of 2024. As mentioned, we aim to start the Phase Ib in multiple myeloma with a BCMA CAR-T candidate, '5301, and expect to dose the first patient later in November. We also submitted the clinical trial application in Europe for our CD19 CAR-T candidate, '5101, in refractory SLE and expect the first patient in the first quarter next year.

Finally, we are actively pursuing multiple business development opportunities and remain very focused on executing multiple deals. Our transformation continues, and we have a clear path forward for value creation for all stakeholders. We are accelerating our early-stage pipeline, building on our new discovery portfolio based on best-in-class targets for best-in-class medicines. While we push forward internal programs, we are in active BD discussions with the aim to expand our innovative pipeline very soon.

And we are streamlining our organization with the aim to implement a focused, rightsized organization. While we are very well capitalized, we commit to staying disciplined in our use of cash to focus our investments to maximize value. We delivered on our commitment to take action and firmly believe that we are executing on our strategy, unlocking value for shareholders.

Thank you all for your support and interest in Galapagos. Let's now open the line for Q&A.

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

Thank you, Paul. That concludes the presentation portion of today's audio conference call. I would now like to ask the operator to open up the line for Q&A.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) We will now take the first question. It comes from the line of Xian Deng from UBS.

Xian Deng ***UBS Investment Bank, Research Division - Analyst***

Just one on BD, please. Apologies if I have missed it. So just wondering if you could elaborate a bit more in terms of the area of interest in terms of BD because you mentioned oncology. I'm also just wondering, like are you sort of focusing on CAR-T? Or are you -- would you also be interested in other modalities? For example, ADCs, we're seeing some major deals recently, et cetera.

Second one, if I may. Given you are starting the CAR-T trial in lupus next year, I mean, on one side, generally also it will mean that the

patient would have a higher bar for safety compared to oncology patients. But at the same time, like CRS, I kind of think to be linked to high tumor burden, which is probably missing in autoimmune patients. So just wondering, longer term, what do you think about the safety profile for autoimmune, please?

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

Yes. First of all, on BD deals, we continue to focus on solving high unmet medical needs, focusing on global deals, late preclinical, early clinical, but also mid-stage. If there are good opportunities, we will go for either M&A or L&A for mid-stage asset, which could accelerate time to resolve and time to the market and time to value creation.

With regard to modalities, we started with small molecules only in Galapagos. And with CAR-T, we brought the second modality in. With that, biologics made the entrance. And our scientists today are using the CAR-T, but also antibodies, and we are looking at bispecifics. So we don't stay on the CAR-T small molecules. We look at the best modality to solve the severe disease. And today, we think, to us and to our partners, we can handle multiple modalities as needed.

Your question on CD19 and autoimmune disease, lupus, you're right, it is a different -- it's not an as urgent, let's say, type of disease. But still, safety is important. We still are in discussion with the regulators on starting our first study, and that will guide us on what they expect.

But what's important for us, we think, is that we have the platform, which we'll put in place in the oncology space in now 3 CAR-Ts, and with all the hematologists who treat the patients, including who treat the patients with autoimmune disease because it's a CAR-T kind of transplant. And that's where we think we have the gateway to market. We have a platform where we can introduce it on a global basis once we have our oncology in place.

And that's where we see it as leveraging our platform, but also going for access worldwide. And we are convinced that the platform, it shows a very good safety in oncology. And we are pretty sure -- or hopefully, we can confirm that the same safety will be observed in patients with lupus and autoimmune disease.

Operator

We will now take the next question from the line of Dane Leone from Raymond James.

Dane Vincent Leone ***Raymond James & Associates, Inc., Research Division - MD & Biotechnology Analyst***

Congratulations on all the progress. Kind of one larger question for me, if I can. So the early data that you've shared on your CAR-T programs is obviously very encouraging from the response rates and emerging durability and safety profile. But I think in the minds of many investors, to give Galapagos more credit for these programs and what the value of these programs could be over the longer term, the question is really, can these results be reproduced in larger cohorts and at more clinical sites? And not necessarily doubting the clinical outcomes, but more, can the manufacturing success rate hold up in a truly decentralized manner?

So I guess 2 parts to this. One, can you clarify a little bit more of what we'll see from the additional patients that were not in the abstract of the 2 ongoing studies? Is there kind of a size of the patient population that we'll see? And/or will they be more than one site contributing patients that have manufactured the product and been treated? And then secondly, looking later into 2024, do you think we'll start to see some of those data sets come out of true multicenter outcomes, manufacturing outcomes for the Cocoon system?

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

Yes. First, on additional patients, at ASH, we'll present data for 15 patients for up to 15 months durability; for ATALANTA, 23 patients up to 15 months durability. And I think the most important addition to that data set will be durability and further confirmation in a slightly larger data set of patients. So that's what we will show there.

With regard to the feasibility of expanding this, just to remind you, the system we produce, the Cocoon system is a standardized system, which is very independent of handling, of local handling. It is the -- everything is standardized from A to Z. It's a sterile system from when the cells go in to when the cells come out -- not come out, but the cells are pumped into the bag which goes to the patient. And it is a

very standardized system with very standardized reagents and processes. And so there's little which we think will interfere with scaling it out in a larger way.

What we have been thinking more recently also is, can we be in the hospital or close to the hospital to make sure that GMP requirements are respected? But at the same time, we see in Europe already that one of our centers is serving multiple hospitals. And so we think that with a decentralized network with highly controlled quality systems and a good GMP environment with a standardized Cocoon in there will show little variability.

The variability ultimately is mainly depending on the ingoing cells from the patients. And that is the one thing you cannot standardize. And as we use very advanced -- as we deploy the system in areas where very advanced patients go in, that's where some variability could happen on the ingoing cells. If you have really a late-stage patient with very bad cells and you still want to make the CAR-T therapy, that is where the variability could be, but not in the operations. We think we have that very well under control.

Dane Vincent Leone ***Raymond James & Associates, Inc., Research Division - MD & Biotechnology Analyst***

And would Landmark Bio be that concept of a center that would service a number of hospitals in the U.S.?

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

Yes, that's correct. That is for the Boston area. We think that as long as we are with 1, 2 hours from a hospital, we will be able to do it fresh, vein-to-vein without too much issues. Our position of more than 1, 2 hours will make it work, and that's all possible in Boston. And probably in the major U.S. cities, we would be able to operate like that.

Operator

We will now take the next question from the line of Brian Abrahams from RBC Capital Markets.

Joe Johoon Kim ***RBC Capital Markets, Research Division - Associate***

This is Joe on for Brian. Congrats on all the progress. So I guess a similar question to what was just asked. So yes, we saw from the ASH abstract, I guess, there might have been some low yield issues. So just wondering what led to this issue and if there's something that you were able to resolve.

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

Jeevan, can you take this one?

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

Yes. Thank you for your question. The issue -- what we've observed with regard to the low yield is, as Paul just mentioned, this is a very patient-driven component, characteristics. Even in the few patients that didn't achieve the dose level as intended by the protocol, what we actually observed were the patients actually continued to have a very good response. And we also saw good expansion and good -- a very positive phenotype of the cells in actual fact.

So therefore, the -- whilst the reason for this low yield might be the disease itself, it doesn't appear to have an impact on the outcome and it may -- and the efficacy. And so therefore, this worked. We're doing a very deep analysis with a very robust transformational plan and program that's running in parallel to the program.

Operator

We will now take the next question from the line of Jason Gerberry from Bank of America.

Jason Matthew Gerberry ***BofA Securities, Research Division - MD in US Equity Research***

Just 2 for me. As you advance your CAR-T programs in '24, I'm just wondering about the scope of R&D and CMC investments and how that sort of fits with kind of the outlay of operating spend this year. I imagine there's some cost shifting post the Jyseleca update, just maybe it's a shift in the composition of your operating spend more towards R&D. So just maybe if you can just talk about how the cost of the CAR-T program starts to scale directionally in the next few years.

And then can you just remind us, so Gilead will have standard opt-in right here on the CAR-T program, I assume, up through the readout of the pivotal Phase II, if you get there. So Gilead obviously has more advanced marketed products and partnerships in these respective spaces. So how do you ensure, with that kind of dynamic, best efforts if Gilead were to opt-in towards your programs?

Thad Huston ***Galapagos NV - CFO & COO***

Thanks for the question. It's clear that with the transfer of Jyseleca to Alfasigma, it does significantly improve our cash burn and allows us more flexibility to invest in broadening our portfolio. Part of the guidance that we gave about saving roughly EUR 150 million to EUR 200 million is assuming that we're also increasing our investments in oncology, particularly in the CAR-T expansion. We're adding resources - the 100 positions that Paul mentioned - largely in those areas to help us build out regulatory, CMC, clinical capabilities to help us broaden our CAR-T network in the U.S. and in Europe. So we've been actively doing that and continuing to add. And roughly, that 100 heads will be over the next 1 year, 1.5 years roughly increasing our spend.

But on the Gilead side, I mean it's clear that Gilead has been a great partner. We see they have opt-in rights to any of our programs after pivotal. And so, yes, they ultimately could choose to partner with us on that. We need to establish the clinical network and get to that point and then we'll ultimately see whether Gilead opts in at that time.

Jason Matthew Gerberry ***BofA Securities, Research Division - MD in US Equity Research***

Yes. Sorry, how would that ensure that your program gets prioritized versus sort of maybe minimizing the competitive threat to the existing businesses that they're in?

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

Let me answer this one. The first one, Richter's transformation and CLL -- resistant CLL -- double refractory CLL, Gilead doesn't have the indication at this moment in their portfolio. So that's complementary. At the same time, setting up a decentralized network for CAR-T provides more access not just in the U.S., but it could also bring it to much wider in the world. And again, there could be a significant complementarity with what Gilead is doing.

And for us, being able to build on the Gilead expertise both in marketing and sales, but also especially in the reimbursement and dealing with this type of products in the U.S. could accelerate for us the roll-out. And as long as we can make sure that we can produce all CAR-Ts locally in the network, mostly close to the hospitals, we -- absolutely, we welcome how we can work together with Gilead to accelerate access to patients and accelerate the reimbursement that we can get access.

Operator

We will now take the next question from Sebastiaan van der Schoot from Van Lanschot Kempen.

Sebastiaan van der Schoot ***Kempen & Co. N.V., Research Division - Analyst***

Congrats on the progress. The first one is on the dose level. You are now moving to the dose level 3. I am assuming that you use the same production process for each of the different dose cohorts and then insert the predefined dose. Can you maybe elaborate in what percentage of patients you get to that dose level 3 in the non-Hodgkin lymphoma? And I was wondering also with the data that you have generated so far in CLL, whether you can expand on how many different clinical sites have patients been treated at?

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

On the dose level 3, we are still preparing to introduce that based on the outcome of the first 2 dose levels, and that's a discussion with the investigators. So the commitment is there to do that. I can't give yet a percentage on how much we can -- in how many patients we can achieve that dose level 3. And I don't have the production -- the detailed production data on the others to derive it from that.

And on the CLL, at the moment, it's done in one big center where a lot of patients are flowing in from different other centers.

Sebastiaan van der Schoot ***Kempen & Co. N.V., Research Division - Analyst***

Okay. And then on the non-Hodgkin lymphoma data set, is that generated in different hospitals?

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

Yes, that's in 5 different hospitals in 5 different sites in Europe.

Sebastiaan van der Schoot ***Kempen & Co. N.V., Research Division - Analyst***

And then those 3 patients that did not have a high-enough dose, were those at different centers? Or was that one single center?

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

I can't answer that on the spot.

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

Those patients were on different centers. We just want to point out that those patients, to the point that we made earlier on, we're able to actually deliver good efficacy as well because of the in vivo expansion and cell viability still being good at the dose that was achieved. So we are interrogating that data in more detail. It will be available in coming conferences.

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

Let me add to it. As I discussed in previous meetings, what we see in our clinical trials is that because of the short life expectancy of the very aggressive late-stage NHL patients, that is the patients are in very high -- highly pretreated, but at the same time in very bad condition. And so that made the incoming material very variable. And that's probably why it's across centers, but that's probably why it's difficult to reach the higher dose levels.

Operator

We will now take the next question from the line of Phil Nadeau from Cowen.

Unidentified Analyst

This is Alex on for Phil. Congrats on the progress thus far. Just wondering if you could comment on the few patients in the abstract with vein-to-vein time greater than 7 days. Any factors that may have led to the longer time here? Any ongoing efforts to kind of optimize this process and further reduce the average vein-to-vein time?

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

So if I -- the question about the beyond 7-day vein-to-vein time, across the board -- and again, at ASH, you see that 7-day vein-to-vein time is achieved quite consistently. And the patients in the abstract, there were -- I think you're referring to CLL. And in CLL, it was related to the yield from the patients.

But I reiterate the point I made previously, which is that we continue to have good efficacy, in vivo expansion and the increase in the cell viability of those patients as well. So it was related to the -- what we were able to get from the patient rather than anything specific to the actual -- the process itself.

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

And to be in detail there, 2 patients had a slight delay with -- from 8 to 9 -- 8 and 9 days. One patient, in one case, we had to do a restart because of an issue in the manufacturing. And so that is why there's variability in delay. Yes?

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

And the important point would be that all patients were treated within 14 days, and that is incredibly competitive of what is already out there. But most of the patients were 7 days.

Operator

We will now take the next question from the line of Jacob Mekhael from KBC Securities.

Jacob Mekhael ***KBC Securities NV, Research Division - Financial Analyst***

I have 2, if I may. My first one is, how do you look at the expansion of CD19 CAR-T into other autoimmune diseases beyond lupus? Would you consider a basket trial set-up, for example, to capture a number of indications in one go?

And my second question is, can you perhaps share some feedback on the process of setting up new sites in the U.S.? And how many do you expect to have up and running by the end of 2024, let's say?

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

Yes. Well, we are considering additional activities beyond SLE and looking actively at other indications. We are not very much favoring a bucket study because all of these diseases have their own evaluation criteria, both on the inclusion side, but also on the progress and the success side. And with a bucket study in that area, most likely, we will not advance very quickly to good conclusions and moving later on into Phase II/III.

So we will consider other indications, but do it in a very, let's say, organized way that the indication -- the early data leads to conclusions on what we can do for it. So that's the way we approach this. And we're starting with SLE, but are considering several other indications going forward.

Thad Huston ***Galapagos NV - CFO & COO***

Yes. We haven't disclosed the number of U.S. sites that we're going to set up for '24 at this time. We are actively working with a number of different additional sites beyond Landmark Bio, and we'll provide updates in the future.

Operator

(Operator Instructions) We will now take the next question from the line of Brian Balchin from Jefferies.

Brian Balchin ***Jefferies LLC, Research Division - Equity Analyst***

Can you just help us with the latest timing on when you expect to have an asset on the market? Is it still '26, '27? I think that's what you last said on the first half call, likely CD19 CAR-T, I think it was, despite the delayed time lines assuming...

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

Yes, that's what we assumed before. Yes. And it's kind of -- yes, the review. Yes.

Brian Balchin ***Jefferies LLC, Research Division - Equity Analyst***

Got it. Yes, that's on a BTD, right?

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

Sorry?

Brian Balchin ***Jefferies LLC, Research Division - Equity Analyst***

On a breakthrough...

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

Breakthrough designation, yes. We think with the encouraging data we have, we hope to be able to recruit in an accelerated way more patients into the pivotal, and it still lands us with '26, '27. That is the current time line which we're still looking for.

Brian Balchin ***Jefferies LLC, Research Division - Equity Analyst***

Got it. And just the second one, just on T-Charge manufacturing from Novartis, PHE885. I think that is 10 days door-to-door, showed good data at ASCO, because yours is 7 days. But just curious to know how you're thinking about that as a competitor to your GLPG5301.

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

Yes, T-Charge is a different process where you produce fast then freeze and do the quality control and the quality release in the next so many days. And that results in a 10 day -- I don't know exactly how many days, but approximately 10 days.

What we do is we keep the cells in fresh condition in the incubator. We produce fast because, in fact, the production is in the first few days. But then you have to keep them in the incubator fresh to do the quality release and the quality work. And then you can release at day 7, which also fits the 7-day prep time a patient needs in order to receive the cells. So that's why the process is tailored to keeping it fresh, making sure they can do the quality while the cells are in fresh situation, but then also fit exactly the prep time for patients, the depletion time.

What we also do is we make sure that it's very well organized for the physicians and the staff in the hospital because the 7-day vein-to-vein is always organized that there's no work in the weekend, not for the staff, only machines, not for the physicians. Anybody has to do anything in the weekend. It's all organized in a way that it's work -- facilitating the work in the hospital and the labs and the best possible way to bring fresh cells to patients. So T-Charge is a short process, but it's not fresh vein-to-vein.

Operator

There are no further questions at this time. I would now like to turn the conference back to Sofie Van Gijsel for closing remarks.

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

Thank you, operator. That's all for today's call. Please feel free to reach out to the IR team if you still have questions. Our next financial results call will be our full year 2023 results on February 23, 2024.

Thank you all for participating, and have a great rest of your day.

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

Thank you all for joining.

Thad Huston ***Galapagos NV - CFO & COO***

Thank you. Bye now.

Operator

That concludes our conference for today. Thank you for participating. You may now disconnect.