# Transcript of the videoconference, December 6, 2022 – 6.30 pm CET

**MedinCell participants**

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Richard Malamut, *Chief Medical Officer*

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*Editor's note: Please note that the transcript of Christophe Douat, Jaime Arango and Nicolas Gourgues is the one translated live. For the original version please see the French transcript available here: https://www.medincell.com/fr/investisseurs/#events_*

**Nicolas Gourgues**
Hello, everybody, and thank you for being with us. for the presentation of the results of the current fiscal year, which is the 1st of April to the 19th of September 2022. I'm Nicolas Gourgues from the communications service at MedinCell. And this evening we have Christopher Douat, President of the company, also Jaime Arango our CFO and on my left, Richard Malamut, who is a medical director. Good evening, Richard.

**Richard Malamut**
Bonjour à tous. Hello all.

**Nicolas Gourgues**
So today we published a press release with our consolidated financial results for the first six months and the press release is available website. Before beginning the presentation of our financial results. I like to remind you that you can ask questions using the chat box on your screen and we will try to answer as many questions as possible at the end of the presentation.
This emission is interpreted simultaneously into English for the first time for our English-speaking friends, and it will last one hour maximum. So 7.30 pm maximum.
Before we come back over the financial, I Suggest we come back over the figures Jaime. We've seen extremely good things for MedinCell recently, the launch of a third phase and we're all waiting for the first product for 2023. But let's talk about figures first. The semester began with a request for additional information from the FDA for our first product. What were the consequences?

**Jaime Arango**
Concretely the delay of ten months more or less with regard to our initial estimates for the launch of marketing with obvious consequences on our financial strategy.
We had planned a safety net in particular, we had been in discussions with the European Investment Bank for a year to defer the repayment schedule of the first loan of 2018 and potentially benefit from additional financing. As you know, we have succeeded. We have signed a new €40 million loan with the EIB. To be quite clear out of the €40 millions of this new loan from the EIB, €23 million will be used to reimburse this first loan and to pay for the interest, so to delay the reimbursement to two years to 2027. Therefore, there is an additional envelope that remains of 17 million Euros net.
7 of which are immediately available, we've already f the conditions and 10 millions of which depend on the approval of the mdc-IRM by the FDA.

**Nicolas Gourgues**
Thank you. Can you tell us about the company's financial situation?

**Jaime Arango**
Yes. We have good cash visibility at least through to the end of the first quarter, 2024. So a few figures. In the September, we have a cash flow of €14.2 million, of which 2.5 million are in non-risky investment. In our forecast for Treasury, we expect to receive more than €29 million in the next six months. So what is this?
You saw last week we announced that we had received from the Bill & Melinda Gates Foundation, $4 million to continue the development of the mdc-WWM project.
And then to these 4 million, we can add the 17 million of the EIB loan, 17 million net as we just said, there are also €4.2 million from the CIR that is the tax credit for research at the beginning of 2021 and 4 million additional dollars that we're expecting in the milestone of Teva upon the approval of mdc-IRM expected in the first half of 2023.
However, we should note that within this forecast we are not including any potential revenue that could come from new partnerships and licensing.

**Nicolas Gourgues**
Thank you. And so, yes, we can talk about this later of the new potential partners. We received a lot of questions about that. So let's come back over the past semester. Can you talk to us about revenue and expenditure?

**Jaime Arango**
So the figures for the periods are as follow the top line, the revenue, we have €7.7 million, which is up, which had been practically doubled, so it's up by 89% as compared to the first semester of the previous financial year. In the 7.7 there are the $3million of Teva to move on to the mdc-TJK phase three. There is also the money received from Bill & Melinda Gates Foundation and also within the scope of new collaborations. And for the time being, these new collaborations process on feasibility studies.
In terms of operating expenses, we spent €19.4 million, which is up 27% for €4.1 million as compared to the previous financial year. But this is normal, and this is something we had anticipated due to the progress of our programs. This 87% increase comes from development. So at the end of the day, our cash consumption related to operations was €10 million. That is in line with our forecasts.

**Nicolas Gourgues**
So all of this is aligned with our forecasts. So in the press release we just published, maybe you haven't had time to read it. You're talking about adaptation of our investment plan. What does that mean? Can you tell us a bit more about it?

**Jaime Arango**
Of course. So after the delay of the launch of mdc-IRM, and given the situation on the financial markets, we adapted things to maintain healthy financial status and to maintain the development dynamics in our portfolio. So concretely, this means financing the company whilst protecting the interests of its shareholders. That is what we've done with the European Investment Bank.
We also had to adapt our investments and to increase our chances of creating value in the short term. So here are a few examples. We have intensified efforts to quickly engage the right partner for our animal health Program, and we've also decided that at this stage we will not invest, no longer invest alone in the mdc-TTG. We will look for a partner if the results of the current study are encouraging. Meanwhile, we're continuing to develop our portfolio with two internal programs, and we are going to continue our activities so that three programs can be ready for clinical development in 2023. Among these two are funded respectively by the Gates Foundation and UNITAID.

**Nicolas Gourgues**
Thank you. Hi. So a very dynamic portfolio. Christophe, do you want to comment on anything that Jaime just said?

**Christophe Douat**
Yes, thank you, Jaime. It was very clear and indeed this loan from the EIB is an extraordinary event for the company. Biotech has just experienced its most serious financial crisis on the stock exchange. The value has been divided by two.
And then we have also had this answer from the FDA, and this loan is helping us to close that gap.
As Teva said on the 3rd of November and Rick will explain why we are very optimistic about the approval of mdc-IRM and above its potential. So follow this page.

**Nicolas Gourgues**
So, Christophe, you talk about Teva, Teva said that it had made a new application for marketing in September.
Although you're expecting it, it is a very important piece of news.

**Christophe Douat**
Of course, because it is the first product that will be marketed in America with MedinCell's technology. And it's an amazing product. So which is very differentiating and it's a wonderful testimony of our technology and its power.
This approval is a validation of this technology. So it's a key step that will necessarily speed up the business development. And we can see the premises of this. And in addition to that, it is increasing the validation of all of the pipeline. So it is a key step which makes us think that 2023 would be a great year.

**Nicolas Gourgues**
Yes, indeed. And we've prepared ourselves for this new step. Richard, let me turn to you. You're very familiar with the regulatory process in the United States.
What will happen now for you for mdc-IRM?

**Richard Malamut**
So thank you. So just as a reminder, the CRL was filed, was received by Teva in April of last year and we can confirm that the CRL, the complete response letter was focused on data derived from the Phase 3 study that demonstrated efficacy of long-acting injectable risperidone for the treatment of schizophrenia. We know that the complete response letter did not address any concerns with MedinCell's technology, the polymer, or its manufacturing, which is good news for MedinCell.
So now we've learned that Teva has addressed the concerns raised by the FDA and has refiled the NDA on or earlier than November 3rd, which is good news.
So what happens next? So the FDA will receive the NDA resubmission. They'll review it and assess it for the suitability for review and provide Teva with that notification. In approximately a month after they receive it that it will be reviewed.
In that notification, they'll also provide Teva with a date by which they'll have to provide a response. That's called the PDUFA date. So we know that Teva will be hearing back from the FDA no later than first week in May. But I should add, based on what we know about the complete response letter and the complexity of the resubmission it's entirely possible that Teva could receive news from the FDA much earlier than that, and we look forward to that.
And the last thing I would say is that because of what we know was in the CRL and the data that had to be addressed, we're optimistic that the FDA will provide Teva with a favorable response on this review.

**Nicolas Gourgues**
Thank you, Richard. Yes, indeed. We're all optimistic around this table about the FDA's response. So we're going to stay on Teva, the other good news of this quarter is Teva has decided to launch a phase three clinical study for the mdc-TJK.

**Richard Malamut**
So the long-acting injectable olanzapine is the follow up to the long-acting injectable risperidone. Also for the treatment of schizophrenia, but it's complementary to risperidone. So first of all, both products will provide the same benefit in terms of ensuring compliance and preventing hospitalization and relapse of patients with schizophrenia when they don't take their medicine. But risperidone is used for more typical schizophrenia patients, while olanzapine is reserved for the use in patients who have more severe symptoms and or do not respond to typical therapy.
So it will be used in a more severe group of patients. The other advantage over existing long-acting injectable olanzapine is that the current formulation requires the physician after injection to monitor the patient in the clinic for at least 3 hours for the signs of neuropsychiatric symptoms. This is a burden for the patient, for the physician and their office. And Kåre Schultz has said that based on the MedinCell technology the new product, there is a potential to eliminate that need to monitor patients in the clinic.
This should improve the utility and the utilization of the product and have it available for more patients with schizophrenia.

**Nicolas Gourgues**
Thank you, Richard. So, Christophe, if we listen to what Richard's just said, this product could have a tremendous amount of potential.

**Christophe Douat**
Yes, tremendous. And even more than the first one for those who were not with us in our September conference, I can remind you of the context. So risperidone and olanzapine have been two wonderful blockbusters in the pharmaceutical world.
Both have in the oral format achieved more than 5 billion of sales per year. So it's among the 20 first product of Pharmaceutics at the time. The sales went down when the generic medicines came on the scene after the patent fell. That was Johnson Johnson and Eli Lilly, two wonderful pharmaceutical companies and both companies follow the same strategy to preserve their franchise. They made long action injectables with new patents and maintaining the prices, their treatments that are today sold for about 20 and $25,000 per year in the United States. Janssen succeeded, they replaced the 5 billion franchise of a franchise of more than 4 billion today, which is growing on average by 15% per year. So a tremendous success. But with the first generation products and it is that franchise that Teva will be attacking with mdc-IRM, a very differentiating product which we know the advantages, and which were demonstrated in the clinical results of phase three.
So olanzapine, the context is different, and it failed, Richard explained clearly why. because the patients had to stay for 3 hours with a doctor close to an emergency service. And so it was a commercial failure. So we can see that thanks to our technology, Teva think that they can do away with this constraint and by doing so they could build a franchise that is equivalent parallel to that of Janssen sur olanzapine in a market where there is no competitor, whether of that name. So a very, very large potential.

**Nicolas Gourgues**
Thank you, Christophe, for these clarifications. Richard, let me come back to you. Do we know a bit more about this new phase three. Could it be led more quickly by Teva?

**Richard Malamut**
Has not yet released the details of their study protocol. We anticipate that they will release all the details just prior to first patient enrolled in their Phase three study, which should occur sometime very early in 2023 and once that has happened, we look forward to speaking to all of you again and going through more of the details of the study and the implications on the development plan and timelines.

**Nicolas Gourgues**
Thank you, Richard. So, yes, we will communicate more about that as soon as we know more. Richard, we're staying with you. During this semester, you announced another phase three. It was a few weeks ago with this time our Canadian partner AIC. Can you tell us about that project?

**Richard Malamut**
As a reminder, AIC is our partner developing an intra articular in the knee joint formulation of Celecoxib. Celecoxib is a non-steroidal anti-inflammatory medication for pain associated with osteoarthritis. In this instance, the formulation is injected in the knee at the time of total knee replacement, which is a very painful surgery. So in the treatment of pain after surgery after knee replacement surgery, the desire is to create analgesia for at least three days after surgery without the use of opioids.
If you can achieve this, the belief is that it will limit the risk of opioid addiction after knee replacement surgery. Current formulations, current medications approved to treat pain after surgery don't last as long as three days. The AIC product went through phase two testing in which not only was demonstrable analgesic at three days versus placebo, but similar analgesia was demonstrated at one week, two weeks and even six weeks after surgery, which is well beyond what existing products can do.
This would be a tremendous game changer for patients. It should allow for early rehabilitation, early functional return of function, and should be as important limit the use of opioid after surgery. So the study itself is a 150-patient study, 75 patients receiving the intra articular celecoxib, 75 patients receiving placebo. They'll be monitored in the hospital for three days after surgery to look at their immediate pain after surgery to that three-day time point.
They'll then be discharged and receive and use an electronic diary to record their pain scores frequently over the next three months. Time points will include one week, two weeks, six weeks, and the primary end point for the study will be at two weeks after surgery. And I should add that this study has initiated, and the first patient was enrolled earlier last month, which is a major milestone for the start of any Phase three study.
And we look forward to continued recruitment and data that we hope to receive after analysis of the three-month data sometime third, fourth quarter next year.

**Nicolas Gourgues**
Thank you, Richard, for these details. And what will happen if the results are good at the end of next year?

**Richard Malamut**

So this study was designed as a registration study. Now, once the data is analyzed, AIC will be able to assess whether the study met its end points to impact enough to qualify as a registration study. Either way, the FDA requires two confirmatory studies for approval. So either AIC will need to conduct a second Phase three study. If this study not only is very positive, but meets power needs to qualify as a registration study.
Or if the study is positive, it doesn't meet those requirements. AIC would need to conduct two studies in parallel, but it wouldn't impact the timelines. Whichever scenario occurs, it would either be one study, or two study conduct conducted in parallel.

**Nicolas Gourgues**
Thank you, Richard on the clarifications of the feature of this project with AIC. Once again, a product with a tremendous amount of potential.
Christophe before we move on to the questions and answers, would you like to say anything else about the past semester?

**Christophe Douat**
Well, we've had some good clarification on the complete response letter, a timeline for the approval that we're waiting for. Of course, this ten-month waiting time was very frustrating.
But we're all extremely optimistic about the approval, as is the president of Teva, as he said himself on the 3rd of November.
What we see now is that during this period we haven't been wasting time. The pipeline continued to progress because we have two projects which will be in phase three in 2023, and these are major events when we go into phase 3 study. We have three products which should also reach a step where they're ready to go into clinical development, also major steps; to new products in formulation as Jaime mentioned earlier on which at the time being stay confidential in terms of therapeutic indications. But we will speak in more detail about this in the coming months. The potential of licensing and products where we think that we've achieved important steps so that we can trigger this licensing.
And thanks to this this exposure, we were in a conference with Jaime just three or four weeks ago where people now know that MedinCell is behind Uzedy™ the nickname of this product based on risperidone.
And this increasing exposure and increasing credibility means that we expect an increase in the number of partnerships and I can say that we're waiting for this impatiently and that we're ready to go.

**Nicolas Gourgues**
Thank you, Christophe, for these very positive words on the future of that company. So now let's move on to the questions we've received. So I'm going to ask a few questions that we received ahead of time. Christophe I am turning to you to begin. The first question concerns the TTG program, where do we stand on this program?

**Christophe Douat**
So in September we were expecting the final results of the study, which will be finalized in the coming weeks. We are a few weeks late so it would be during the first quarter. As Jaime announced in the scenario with encouraging results, we consider that now it would be essential for this program to find the right partner, to continue development and to go to the market. It's very important to back ourselves up in the context. Meanwhile, the Covid situation has evolved. We know that COVID is lasting. We can see the new variants.
You can see the news in France with people obliged to wear masks again and the cases that are going upwards. But this pandemic has become endemic, and it has become, you know, part of our everyday life. And the regulatory processes have been standardized with the processes of acceleration. But we know that we still, still need more effective protection tools in order to protect against infection.
And in particular for certain segments of the population, such as immuno deficiency.
So this study will bring an answer according to the best standards of the industry double blind study with a double placebo controlled and an independent committee controlled DSM-B in Europe. And therefore this study will bring the necessary elements on the potential of ivermectin in prophylaxis against Covid. So we need to follow this, and it will be happening in 2023.

**Nicolas Gourgues**
Jaime let me turn to you now. We have a number of questions. We already received a number of them. Recall the agreement between MedinCell and Teva, the royalties, the milestones, etc. Can you remind us how all of this is working?

**Jaime Arango**
Yes, of course. So case of this Teva contract. It is a standard contract of licensing with milestones and royalties, milestones that can reach more than $120 million. These milestones are split into two. The first is the development milestones, and then there are the marketing milestones. So we can take as an example mdc-IRM project. So the last development milestone that we're expecting, the $4 million that I talked to you about, which MedinCell will be receiving upon the FDA approval. So from that point on, there are 100 or so millions of dollars of marketing milestones, plus the royalties. So the marketing milestones, what are these? We won't receive them immediately. So we have to wait for Teva to achieve a certain level of yearly sales.
In Order to trigger the payment to the milestones. So there are a number of stages that Teva has to reach. But what's very important is that normally, In the different scenarios that we're working, the peak sales of Uzedy™ we can work on certain hypotheses, but we can hope that the product achieves peak sales after four or five years, which gives us trust in the future. As we've already said, that after these five years we will be able to receive these hundred of millions of dollars. And why is it important? I'm talking about Four or Five years. And let's come back to what we said on the European Investment Bank. We have the first goal of this negotiation with the EIB, which was to delay the reimbursement of the 2018 loan. So if we can gain that in the coming days, we will should be able to pay off this debt of €20 million at the end of 2027. And at the end of 2027, we will give the time to Uzedy™ and Teva to gain market share and for us to receive more milestones and more royalties to pay off that debt. So the financial engineering is related to the market share of Uzedy™.

**Christophe Douat**
And if the dollar remains strong, it will be extremely favorable for our company.

**Jaime Arango**

Absolutely, yes.

**Nicolas Gourgues**
Thank you, Jaime. Fred is also asking is it the same type of agreement for the new therapeutic indications of mdc-IRM, because Teva decided to launch mdc-IRM for new indications. Is it the same type of agreement?

**Jaime Arango**
Well, that's a very good question. But we're talking about a product. So whether it whatever the therapeutic indications, this will not trigger milestones. However.
The sales created for these new indications will enter into the calculation of royalties mid to high single digit.

**Nicolas Gourgues**
So they will add. And if the program goes through to the end, it will be added to the first indication of mdc-IRM. Thank you very much Jaime for these clarifications and continue with you. We've just received a question. You've answered it partially, but maybe we can add to this. Why did we borrow 40 million euros when we were expecting milestones and royalties from Teva for IRM?

**Jaime Arango**
So this is what we said about the safety net that we've started to plan.
So mcd-IRM has been delayed in its launch. We were expecting the launch to be done mid 2022 and it will actually be in the first semester of 2020. Meanwhile, we've been using up cash cashflow and therefore we had to close this gap in the lack of income from mdc-IRM.
So we mustn't stay in a situation where the cash flow is too low. And we found a very good compromise here with a solution that makes our shareholders happy, and this gives us a safety net to continue to progress on the different projects that we have in the pipeline.

**Nicolas Gourgues**
Thank you, Jaime. Christophe, I think this question is for you still about Teva and still about Uzedy™ We are asked if there is a registration plan in the rest of the world by Teva, MedinCell or somebody else?

**Christophe Douat**
Well, quite obviously this product is very important for Teva. We know that it's one of the main products that they have in their product pipeline and It's quite obvious that Teva will look towards other regions of the world to market it. Because Teva is planning to market it in other regions of the world under the NDA regime. And will also assess the opportunities within Europe and the EMEA regime. Now that it is derisked in the States.

**Nicolas Gourgues**
Thank you, Christophe for these clarifications. So, Christophe, another question for you. Can you tell us a bit more about these new contacts, partnerships in which you've engaged recently? And we've announced new collaborations very early stage. But can you tell us more about that, can we have clarified, the therapeutic areas in which we're working?

**Christophe Douat**
I Give a few ideas without necessarily revealing the partnerships, or the therapeutic indications because we have a confidentiality agreement. And in addition, in the first feasibility stages, there's a lot of attrition. So we don't want to raise hopes until we get into the formulation phase. This year we signed a number of feasibility studies.
In which we call, the central nervous system sector, sector that we're very familiar with. And we have a specialist with us, and also on diabetes for projects with potential, it will have a major impact on the health.
What we've been seeing in recent months and paradoxically the complete response letter actually did a bit of advertising for us and in pharmaceuticals it's an event which is quite common as we explained it is, about two thirds of psychiatric program go through that stage. But nevertheless, it puts a spotlight on the company, and it shows that we are on the eve of approval.
And we now are in touch with pharmaceutical companies which in the past looking at MedinCell with a little distain. But now we're being taken seriously because the product has completed phase three. Teva and Kåre Schultz said are absolutely amazing, phenomenal.
And we see our teams in the development Talking at levels that we have, talking at levels that we never seen before. So all of this now has to actually come into to life. So projects take time, but it does look like the company has a bright future.

**Nicolas Gourgues**
Thank you, Christophe. Richard. I'm going to turn to you now. I guess the question is and we've already had it, but maybe, maybe repeat it, how much time do we need to finish the phase three of the mdc-CWM project with Canadian AIC? And can you recall us if this phase is successful, what next for this product?

**Richard Malamut**
Sure. So, yeah, so the phase three will gather, recruiting now, will have its primary analysis complete by third quarter of next year. We may be able to disclose results into early fourth quarter and at that point, AIC will make an assessment of the data, the strength of the data, and whether the data qualifies to be a registration study for filing with the FDA.
Either way, the positive results will trigger a second Phase three study the FDA requires two confirmatory studies for approval. If the study is positive but doesn't qualify as a registration study, then AIC would need to conduct two phase three studies. But these would be done in parallel, so there would be no impact on the timelines to approval.

**Nicolas Gourgues**
So Christophe, I would like you to remind that you have to speak in French because we translate simultaneously in French and English.

**Christophe Douat**
Yes of course this is something we're discussing with Richard as well, is that this study that's underway that's just beginning will be essential and will bring us elements that can also facilitate partnerships around that project. And that the later Phase three studies could be led by partners because this project, as Rick explained on IRM, and that's really a shift in paradigm in a field which is extremely active now. And once again, a partner can bring power throughout development and guarantee a future marketing.

**Richard Malamut**
So yeah, and if I could add the one thing. This, just as with the phase three results in long-acting injectable Risperidone added credibility and support for MedinCell's technology as a subcutaneous formulation. So too will positive results in an intra articular study also lend the same sort of support and, credibility and belief in success with future intra articular products using the MedinCell technology.

**Nicolas Gourgues**
Thank you. That will bring more credibility in another field of application for our technology. Let's move on to another question regarding in partnership with Bill and Melinda Gates of mdc-WWM. And we're asking questions for developing countries where MedinCell retains the rights for marketing. Do you have an idea about the size of the market Europe, the States, etc.?

**Christophe Douat**
Yes, this is a project that we began as an internal MedinCell project, it is a MedinCell project to start with. And the foundation has been funding so far in order to Own the rights for humanitarian applications.
In the States, the contraception market represents about 5 billion. So a lot is oral contraception, but one third, about 1.5 billion is what we call long action
Contraceptives intrauterine. And so this product will also be a shift in paradigm because we're talking about a six-month injectable bioresorbable self-injectable subcutaneous and ready to use. So a product that does not exist on the market with a new generation contraceptive. So this is an exceptional product which in addition in the complex environment of birth control in the United States could have an important role to play. So a real commercial potential for that product. However, it will take time because we're talking about a six-month injection. Therefore, each test takes six months or more, and with clinical trials you have to repeat the injections. Therefore it is a program that will take time to develop. But which will also consolidate its anti-competition position with regard to future generics. And so it will have a long life ahead of it.

**Nicolas Gourgues**
Thank you, Christophe for the clarification. So I'm going to ask you the question, Christophe, and maybe Richard can add to this. The question is, can you collect biomarkers on the in the ivermectin study? I'm not sure if we're talking about for the study, for mdc-TTG or mdc-STM the two studies that use ivermectin, to have a clear idea of the mechanisms anti-inflammatory mechanism and this would enrich the knowledge on the properties of this kill.

**Christophe Douat**
Rick go ahead.

**Richard Malamut**
I mean of course. So yeah. So the if we're talking about the ivermectin for the treatment of exposure to Covid, the study is complete. So no additional tests can be added, of course, but there are different types of biomarkers and there were some clinical biomarkers and predictive biomarkers that were included in the study. For instance, we know that the variant of COVID is important in assessing the effect of any treatment for COVID.
And so we carefully collected the type of variant in the study. And we the first part of the study included patients mostly affected with B.A. 1.1. And the second part of the study included mostly patients with BA 5. So we'll do that comparison. We'll make similar comparisons for demographics, comorbidities that we know can worsen disease, severity of symptoms, hospitalizations and so on. So while not we wouldn't we didn't collect true inflammatory biomarkers with the study, we will still have some clinical biomarkers that will be quite interesting to interpret.

**Nicolas Gourgues**
Thank you, Richard, for this clarification.
Christophe, I'm turning to you for this question. We've announced that we should have three new products that are entering clinical phase next year. One of them is mdc-GRT. And the question is MedinCell now planning to develop it alone and if so, to what stage?

**Christophe Douat**
So as a reminder, mdc-GRT, is a long action version of the anti-rejection medication for Transplant.
Today between 20 or 30% of the organs transplanted or transplanted in patients that have rejected the organs due to a lack of observance. And so one of the interests of this product, which can be multiplied by a potential reduction of the toxicology of this drug, and we know that for people who are familiar with people who have been transplanted, is that it creates renal toxicity but also it creates 20% of induced diabetes. So there are hypotheses, scientific hypotheses, which say that with a subcutaneous version, and we go around the digestive system and the hepatic system, and by reducing the dose, we might have an effective impact, so a major project.
And with a drug which, and Rick can maybe add some information about this, which has inherent toxicity. Therefore it's important to achieve this phase 1 stage Which shows that is safe. Rick you can.

**Richard Malamut**
Yeah, so absolutely. So the safety concerns of tacrolimus are real. Patients often discontinue their therapy because of the development of high blood sugars and diabetes potassium changes and renal dysfunction among others. So being able to maintain patients on their medication with, by mitigating the safety tolerability complaints will provide overall benefit on preventing organ

rejection. But even beyond that, the fact is that patients who take tacrolimus are not always like, all patients are not always compliant with their medications every day.
And for many medications, if you miss your drug, you missed your dose for a day, maybe two. There's no real impact or harm caused. But for a drug like tacrolimus, which is very dependent on having adequate blood levels to prevent organ rejection, missing doses were being noncompliant with your drug can have a severe impact by lowering the amount of tacrolimus in your blood and increasing the chances of the very serious organ rejection.
So having a long-acting formulation, apart from improving safety tolerability by maintaining patients' blood levels of tacrolimus and limiting the chance of noncompliance will have a huge impact on these patients lives.

**Nicolas Gourgues**
Thank you, Richard. Once again, a project that can have a very good impact. So this brings us to the end of the questions. Christophe, maybe you can take the floor for a few last words.

**Christophe Douat**
So thank you for being with us again this evening.
As you can see the company is moving ahead, the entire team is behind me. So that 2023 will be a great year. I wish all of you excellent, great holidays and thank you for your patience and see you very soon in 2023.

**Nicolas Gourgues**
And thank you to all of you for having been with us for this conference and see you soon.