Transcript of the videoconference, May 2, 2022 – 7.30 pm CEST

MedinCell participants

Christophe Douat, *CEO*

Jaime Arango, *CFO*

Richard Malamut, *Chief Medical Officer*

David Heuzé, *Head of Communication*

David Heuzé
Hello. Hello, everyone. I am David Heuzé, head of communication at MedinCell. And as you can imagine, I am very happy to be with you today. And with you, Christophe, the CEO of MedinCell, with you, Jaime Arango, you are our CFO. And live with us from the US, Richard Malamut, Dr. Richard Malamut, our Chief Medical Officer. Hi, Richard.
Richard Malamut
Bonjour, David. Hello, David. Hello.

David Heuzé
One person is missing today is Helen, which is the head of alliance at MedinCell. She leads the relation with Teva. But I think too much sport for Helen. And so she cannot be with us today. But Coucou Helen, as we say in French.
So this conference is scheduled to last around 30 minutes. Okay. And as usual, you can send us your questions by using the chat module on the right of your screen. So don't hesitate. Christophe, I believe I will have it. But today, yesterday, no. Friday, we announced that UZEDY, that you can see just behind me, was approved by FDA. So can you explain what is this news and what are the consequences for MedinCell?

Christophe Douat
Very, very exciting times at MedinCell. Very emotional moment. You know, for the first time, our technology will be treating patients on a large scale in the United States. UZEDY is a true game-changer. A product that should become a standard of care in schizophrenia. It has huge benefits. It is in an indication where compliance is critical and long acting injectables help with compliance. Schizophrenia, as you know, has dire consequences when people do not comply with their treatments. Now, of course, the challenge is to sell the product, and we believe we believe we have the best partner to do that. UZEDY is a strategic priority for Teva, and we know that Teva has the right sales force to promote UZEDY. Richard will tell us a bit later on the product, Jaime on the financial potential. Indeed, you know, royalties and potential milestones will arrive in the next few years and royalties, you know, as soon as the next few months. We're talking about dozens of millions. UZEDY validates our technology, the same underlying technology that is under all our future programs. MedinCell is now in a new era among the few companies that have reached this stage. And this is the beginning. Right behind UZEDY, we have two products in Phase three where we expect results in the next 18 months and a full pipeline right behind.

David Heuzé
Thank you. Christophe. Christophe, do we have any news from our partner, Teva? Okay. Do you know what is the current mood, I will say?

Christophe Douat
I think our friends at Teva has as excited as we are. There's lots of emails going back and forth. You know, we have been working with Teva now for nine years. Uh, of nine years of efforts, tenacity, you know, to get this amazing product, to patients. UZEDY is the lead program of what the CEO of Teva unveiled at his last earnings call on February 8th about building a schizophrenia franchise with long acting injectables, and their sales force is in the starting blocks. The product should be ready to go for sale in the next few weeks, and it is the same sales force that has successfully ramped up Austedo, the last blockbuster of Teva, to about a billion in just a few small years. So exciting times, and really looking forward for UZEDY to be the success it deserves.

David Heuzé
Thank you, Christophe. Richard. Richard, you are our Chief Medical Officer, but you were also part of the Teva team that launched the product few years ago, a few years ago. So I can imagine that it is a very emotional moment for you today, Richard.

Richard Malamut

Yeah, it's very exciting to be here at the end. But back to the beginning, I had the opportunity when I was employed by Teva to be part of the team that created the partnership with MedinCell, to develop long-acting formulations of risperidone and other antipsychotics. And as head of psychiatry at Teva, I led the planning around the Phase one study that established safety and confirmed adequate blood levels of UZEDY in humans and which was the first time that MedinCell polymers were injected into human subjects. Now, I left Teva as the story of UZEDY was beginning, but I am thrilled to be back working at MedinCell as Chief Medical Officer at the successful end of the story. When FDA approval was received at the end of last week. I'm now very excited to see favorable outcomes for patients with schizophrenia who will benefit from the use of UZEDY.

David Heuzé
Richard, You're a specialist in the central nervous system, CNS. Can you explain why long acting injectables such as UZEDY can be can play, I would say a major role for patients with schizophrenia?

Richard Malamut
Yeah, of course. So patients with schizophrenia do respond well to oral antipsychotics when they take them regularly. However, as many as 80% of patients with schizophrenia are not compliant with their medications and suffer severe relapses, which require several weeks of hospitalization to regain control, and on discharge, they will again stop taking their medications, leading to relapse and a repeat of the cycle. A long-acting injectable risperidone such as UZEDY ensures compliance as it is injected by the healthcare provider, rather than relying on patients taking their oral medication. And it is because of this benefit that there has been growth in the use of long-acting injectable antipsychotics by prescribing psychiatrists for their patients with schizophrenia.

David Heuzé
Okay, Richard. Richard, can you tell us why UZEDY could become the treatment of choice for schizophrenia?

Richard Malamut
Yeah. So there are many approved formulations of long-acting injectable risperidone, but UZEDY has four key features that can make it the preferred treatment. First, most existing formulations are given intramuscularly, which leads to a higher level of pain for the patient. UZEDY will be administered subcutaneously by a smaller needle with much less pain on injection. Second, existing formulations often must be reconstituted in the psychiatrist's office, whereas UZEDY will be available in prefilled syringes corresponding to four different oral risperidone doses for each of the monthly and every other monthly formulation. Third, UZEDY will have therapeutic blood levels within 24 hours of injection compared to many of the existing formulations that do not achieve therapeutic blood levels of risperidone on the first injection and require either oral risperidone supplementation or additional titrating injections. And lastly, UZEDY has a positive impact on patients relapses and symptoms. The Phase three study conducted by Teva provided data that demonstrated other differentiating features from existing formulations of long-acting injectable risperidone, such as continued and statistically significant improvement. In both relapse rate and schizophrenia symptoms score beyond the six-month primary endpoint in double blind randomized controlled analysis, there was also a statistically significant improvement in the schizophrenia quality of life scale, which is of high value to people with schizophrenia hoping to resume their normal daily activities.

David Heuzé
Thank you. Thank you, Richard. Jaime, I turn to you now, so the commercialization is going to start now in the US. Can you give us some details about the targeted market?

Jaime Arango
Yeah, absolutely, David. Hello everyone. So these market long-acting injectable schizophrenia, it's a $4.4 billion market in the US back in 2022. It's a market that is growing double-digit 12% on average during the past five years. So it's growing very, very rapidly. And furthermore, Richard Francis, Teva's CEO, mentioned during the investor call last February that he targets this product to reach a 20% market share over time. What that means is that if I take those numbers is that, you know, with the very high market, strong market, over 4 billion growing very rapidly, 20% market share, that means that we see this product as being a potential blockbuster, meaning a product that reaches over $1 billion in sales annually.

David Heuzé
And what does it mean in terms of revenue for MedinCell?

Jaime Arango
Right. So let me step back a little bit and just remind everybody about the deal that this partnership that we have with Teva, it's a multi-product. It's a platform deal that we have with them in which all the costs are covered by Teva. Teva is in charge of developing the products and ensuring the commercialization. In exchange, MedinCell we receive, we can receive up to $122 Million in milestone payments development on commercial, plus there's going to be some royalties, a percentage of sales that we will receive. Mid to high single digit. Now in the short term, what it means is that with this approval and actually we just issued already the invoice to Teva of $4 Million, cash that we should receive in the coming weeks. And then we can wait for the commercial milestones to be reached upon the next four years. That is a total of $105 million. It's not immediately, but in the next coming years as Teva reaches a certain level of sales.

David Heuzé
Okay. And what consequences? Uh, I will say, what is on the cash visibility of the company to date?

Jaime Arango

Yeah. Just before talking about cash visibility. So you understand the teams are ready. The sales reps are ready. Marketing is already ongoing. The market share will be gained gradually. For that, I mentioned the milestones, the commercial milestones that we will receive. But on a quarterly basis, we will start receiving royalties, A percentage of sales I mentioned mid to high single digit cannot give you contractually the details, but somewhere between 5 and 9%. If we take the average, then we're not going to be that far off. But what it means is that we will start then receiving these royalties as of the next quarter if Teva starts the commercialization.
Now, in terms of cash visibility, yes, this approval confirms the cash visibility that we have been communicating constantly during the past few months, and that is that the visibility brings us at least until the end of Q1 2024, we will receive the four million from Teva, this milestone plus the approval then allows us to withdraw the third tranche of the loan that we have with the European Investment Bank that of €10 million that we signed back in November 2022 plus there might be some other opportunities to increase the visibility as some potential licensing deals could come over. But I will let Christophe talk about that later on.

David Heuzé
So this is a new era for MedinCell. Christophe A new era, financially speaking. What does it mean, new era for MedinCell?

Jaime Arango
Yeah, absolutely. It's a new era. Why is that? It's because the company changed its profile. Now we are a commercial company. We have a first product on the market. The perception of risk will be reduced. We're not only on the research and development, but now two products in phase three, but now one product being commercialized. It's great. And you know, in the future, the creation, the value creation will come from the different products as they advance in the pipeline. I mentioned the two in Phase three, but also there are some other products in the pipeline that will generate value for the company in the future.

David Heuzé
Thank you, Jaime. We have a question for you, but I will ask you later. Christophe. Before we answer the question, we received some questions. New era. What does it mean from your point of view? From an answer?

Christophe Douat
Well, first, as I said at the beginning, you know, our technology is going to treat the first its first patients on a large scale. This is our mission. You know, the DNA of the company is to treat patients. We will get our first commercial revenue like Jaime explained very well, UZEDY is also a validation of the technology, the same technology that is, you know, under all our products, everything is going to accelerate. We are ready. We have a great, amazing team, a team that has shown its resilience these last few months, a team where every single person is a shareholder aligned with all our investors. And I'm waiting, of course, for the next approvals.

David Heuzé
We are waiting for that. So we receive a few questions.
So first question about the future. So congratulations to the team. Thank you. Well deserved. Does this incredible news pave the way for new partnerships with Major pharmaceutical company Christophe?

Christophe Douat
Well, of course, you know, we saw we've seen an acceleration in discussions with the data from phase three, which is which was spectacular. The CRL gave us additional visibility, and now the approval, you know, is the final validation. So we are seeing increased discussions. We have early-stage collaborations, which we'll talk about if they are successful. So yes, we expect more and more partnerships.

David Heuzé
Thank you. Next question about our partner, about Corbion. Could you come back on the company which is manufacturing your products?

Christophe Douat
Corbion has been an amazing partner. You know, we've worked together for 15 years now. Corbion is the company that allowed us to scale up the polymers, you know, from lab scale to clinical stage and to commercial stage. We work with polymers, you know, at research and clinical stage coming from the same production lines from the future commercial polymer; it's a huge advantage. Corbion is the largest manufacturer of Biopolymers. The alliance has become a full-blown joint venture. That has allowed us to control very tightly, you know, the quality of what we do. What we do is amazingly complex. You know, we have to convince authorities that each formulation is identical and can work on all patients and deliver the right amount of drug, you know, for weeks in each formulation. Is the equivalent of one grain of rice of our patented polymers, which are manufactured in Corbion's factories. So thank you. Corbion.

David Heuzé
Thank you. Christophe. Next question. Greetings, MedinCell team. Congrats again on this amazing achievement. So the question now is, can we expect Teva sales efforts on UZEDY to be beneficial to mdc-TJK? So the olanzapine product currently in phase three in the US could it accelerate its sales ramp-up in the future, assuming successful phase three results and NDA sure. Are UZEDY and TJK sales channels similar? Christophe.

Christophe Douat
The answer is yes. They are targeting the same prescribers, although they are very complementary products. You know, risperidone is first intention treatment, a standard of care in schizophrenia. Olanzapine targets the most severe patients. So yes, they will go through the same channel. And we've all learned, you know, from our experience with

UZEDY and we hope we won't get this again because this is a major product, you know, one that is even bigger than UZEDY. And I want this one to come as early as possible.

David Heuzé
Thank you. Thank you, Christophe. Jaime, the next question is for you. Well done to everyone. Are you planning a capital increase in the short term?

Jaime Arango
Right. So as I talked in the past, in a few minutes ago, it's a new era. We've mentioned that. And it's a new era being, you know, derisking the company. And we will always be looking to finance the company either through different grants or non-dilutive financing. But of course, we will look; we're always monitoring the capital markets, and we will do what is best for MedinCell and its shareholders on the basis that if we were to refinance the company, it's basically to refuel, to fuel the pipeline of the company to be able to bring more products in the pipeline to advance some others even further. And that's how we will create value. So we will look into all the different options that will arise to us.

David Heuzé
Thank you, Jaime. Next question. I don't know maybe Richard can address it. Or maybe you Christophe. Do you expect initial scripts to come from newly diagnosed patients or will it come from patients currently on orals or even other LAI formulations? Christophe?

Christophe Douat
You know, there's probably three segments. You know, Teva will probably look at. Of course, you know, the prime target is patients that are switching from oral to long acting injectables every year. There's about 15,000 of them, you know, every year in the US. And then, of course, there are patients that are already using long-acting injectables that may look at UZEDY, you know, as a better product, you know, small needle, subcu injection. But it may take a bit longer to switch them over. And of course, then, you know, they might be also the opportunity to treat patients earlier in the disease, you know, first-episode patients. And since we know that UZEDY is a very easy product to use, you can be a prescriber can switch easily from oral to injectable. And we know that the earlier patients with schizophrenia are treated, you know, the less cognitive irreversible, irreversible damage. You know, they have to, to sustain.

David Heuzé
Yeah. I don't know if Richard. Richard, you want to add something?

Richard Malamut
Well, I think just to add one other thing is that you know, while we, of course, would love it if psychiatrists would use UZEDY or long acting injectable first, it is likely that patients will be on orals to gain control before switching to a long-acting injectable. But we do know that patients who are on long-acting injectable antipsychotics do have lower costs related to hospitalizations, which should be of interest to payers in the United States to perhaps allow for earlier adoption of a long-acting injectable over orals in these in these patients.
David Heuzé
Thank you, Richard. The last question. Starting by congratulations, but not about UZEDY, but about another program which is WWM, a program we developed with the support of the Bill and Melinda Gates Foundation. So the question is simple Will Bill Gates, so the foundation continues to fund projects in the future. So projects.

Christophe Douat
Well, we hope they will. We've been able to go further than anybody else on their, you know, prime objective to develop a six-month contraceptive for humanitarian purposes. You know, there have been a great partner and we hope we can help them with their humanitarian goals.

David Heuzé
Jaime, I think we already received a grant for up to 25.

Jaime Arango
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David Heuzé
$23 million. Yes. Okay.

Jaime Arango
Yeah, absolutely. So in this partnership with the Bill and Melinda Gates Foundation, they are supporting us with this grant that can go up to $23 million to bring the product up until the end of a phase one in exchange of the rights for humanitarian purposes in the low and middle-income countries. But MedinCell keeps all the commercial rights everywhere in the world.

David Heuzé
Thank you, Jaime. So thank you all. No more questions. Thank you. Christophe. I leave you the floor for the last word.

Christophe Douat
Yes, Thank you, David. You know, it's an amazing event for the company. Thank you to all of you. You know, for trusting the team and trusting MedinCell. You know, we look forward to the next milestones and more products getting approval. We have major news coming in the next 18 months. I would like to pay tribute to an Anh Nguyen or chairman. Anh has been also my mentor for all those years and was, you know, added the vision to move MedinCell in the direction

where it has. I would like to thank all our former employees for their contribution to MedinCell, and all the existing employees who have shown incredible resilience in these last few months. Thank you to all. Thank you too, you know, our investors and maybe future investors that are attending the call today. And I say à bientôt.

David Heuzé
A bientôt. next video conference will be on June the 13th. 13th. Okay. For the annual results. So I hope you will be with us. Thank you, Christophe. Thank you, Jaime. Thank you, Richard. And thank you, everybody. Bye.