Transcript of the videoconference, September 1st, 2021 – 7.00 pm CEST

MedinCell participants

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Nicolas Gourgues

Good evening. Good evening, everyone. Welcome to this video conference where we will be updating our portfolio following last night's announcement regarding our program mdc-IRM. I'm Nicolas Gourgues tonight I'm replacing David Heuzé, our Head of Communication and usual Presenter, because it's just been a dad. Congratulations to him. With me this evening, we have Christophe Douat our CEO, Joël Richard, our Chief development officer, and Jaime Arango our CFO. Good evening, gentlemen.

Before giving you the floor, Christophe, I remind you that you can ask us questions through the chat module on the right side of your screen. Cristopher, First, I suggest we come back to the news we announced last night about mdc-IRM.

Christophe Douat

Yes Nicolas, thanks a lot. Good evening to all. It's another great day, admitting said. As you saw yesterday, the FDA accepted the filing of Teva for mdc-IRM. You know, it's the last step now before the approval of the product expected in 2022. I'll remind you that Teva even expects launch in 2022.
Speaker 100:02:00

Nicolas Gourgues

Thank you, Christophe. Now, can you remind us what are the characteristics of the product? And tell us a bit, remind us about the Phase 3 study.

Christophe Douat

Yes. So, we have developed formulations for Teva on two products. One month duration and two months duration. The phase 3 that was completed last year showed very strong data. You know, comparing relapses in the treated group versus placebo.

Nicolas Gourgues

Thank you, Christophe, for this update. Now, if you if you don't mind, let's talk about schizophrenia and the markets of schizophrenia globally and in the US.

Christophe Douat

Yes, just as a reminder, you know, schizophrenia is a very significant and bad pathology. It's about one percent of the world population with the dire consequences on the patients. As you know, hallucinations, etc., on the people, you know, their families, their friends, on society, on the health systems that have to cover the cost for treatments and hospitalizations. One number I'd like to mention is that in the US, 20% of hospital beds are related to schizophrenia. So, you can understand that any treatment that improve compliance, such as a long acting injectable, you know, has a lot of value for the payers. If we look at the numbers, we can see that the US market today is 3.7 billion worldwide, 6.1 billion. In the US, it's growing at 14% CAGR, you know, very regular growth. 14% CAGR means it doubles if the trend continues, you know, every five, five to six years. The value of the compliance

that is brought by the long acting injectables is such that the payers, you know, are paying a very significant price for the long acting injectables in the US market, you know, anywhere from 19K t to 25K per year per patient. So significant numbers, significant market, and the significant growth.

Nicolas Gourgues

Thank you, Christophe, for that update. Now Jaime, if you don't mind, let's talk about the metrics of that collaboration with Teva.

Jaime Arango

Absolutely. Thank you very much, Nicolas. So, in the collaboration with Teva, we have, let me remind you, three products under development with Teva. On the financial metrics. So, it's Teva they paid MedinCell to do the formulation of the three products. But in addition to that, Teva is financially developing the three products and will ensure the commercialization of all of them. So, when I say that they're responsible, they are paying for they're assuming all the cost, preclinical and clinical, for the development of the products. Now, for the remuneration for MedinCell consists in two parts. First one are milestones that can reach up to $122 million per product. The bigger chunk of those milestones relates to sales upon the attainment of certain level of sales. MedinCell has already started receiving some of the milestones related to development. So, if we aggregate the three products, milestones can reach up to $366 million. And in addition to that, MedinCell is entitled to royalties mid to high single digit, and that from the first sales that will be generated by the products.

Nicolas Gourgues

Thank you very much for that update.

Christophe Douat

Jaime, I think you forgot to mention something we discussed yesterday because I were trying to find a way to communicate on what does it mean, you know, a market of $3.7 billion. And we checked and we found out that if this $3.7 billion market was a single product today, it would be the 19th product by ranking order of sales in pharma. So, you can understand how significant this is.

Nicolas Gourgues

Thank you, Christophe. Christophe, you again. We wanted in this update to address another point which concerns polymers, one of the main ingredients of our technology.

Christophe Douat

Yes, this is a very important strategic point, Nicolas. As a reminder, you know, the key ingredient in our formulations are our own customized patented polymers, these polymers are what allows us to do better formulations than competition. Subcutaneous injections. You know when most of the products today are intramuscular injections. So very early in the life of the company, we built an alliance with Corbion. The number one manufacturer of bio polymers in the world. It's a Dutch company. It's public on the Euronext. Now, this alliance has evolved the full-blown BV joint venture, which produces all the polymers for partners. This has allowed us to control the quality, to reduce the risk of scaleup, which is a huge risk for small biotech and also to protect the intellectual property related to polymers. Polymers are a very complex material to manufacture. And you can understand that, you know, the quality of the polymer would impact the release of the drug. So, it's absolutely fundamental to control the manufacturing and therefore control the quality and the release of products.

Nicolas Gourgues

Thank you for that update. Before handing over to Joël to continue on the update of the portfolio, Christophe maybe a sum up of that amazing news that we announced last night.

Christophe Douat

Yes, month after month mdc-IRM is moving forward. This is the last step now before the expected approval in 2022 and the launch of the product. Huge news for MedinCell. I know very, very few companies have reached this stage. We are among the happy few. This technology, the underlying BEPO technology for mdc-IRM, is the same as all other products. And therefore, you know, this evolution, favorable evolution of mdc-IRM benefits all our other programs. Joël.

Joël Richard

Yes, you are. You're right, Christophe. This is exactly the same technology our proprietary technology based on our block PEG-PLA copolymer. And I would say about, the know-how developed, and the data obtained during the

development of IRM will enable us to accelerate the development of the other products of the pipeline and derisk or development projects.

Nicolas Gourgues

Thank you, Joël. Let's talk about other programs now and the two other one we have in partnership with Teva.

Joël Richard

Yes, for sure. We have actually exciting news on our portfolio of projects. And first, I would like to remind you of the excellent news regarding IRM and the expected commercialization in 2022. The step that we have gone through yesterday is really remarkable step for the project and for MedinCell and believe me, in drug development, this is a major one, and we would like to have it very often, of course. Now, I would say about for the over two projects in partnership with Teva, which are mdc-TJK and mdc-ANG. Actually, we are expecting news from Teva on the next steps for these projects before the end of the year.

Nicolas Gourgues

Thank you very much Joël for that update on our programs in partnership with Teva. Now let's talk about our third product in clinical mdc-CWM.

Joël Richard

Yes, so CWM is a project that we have in partnership with AIC in Canada. And actually, I would like to mention that AIC is going to follow now the recommendation from the FDA as regards to the safety of phase 2 study. And actually, this phase 2 study will be a reschedule in 2022. And AIC has confirmed that this will not have any impact on the timelines of the project. As you know, this is an open babel study which is not on the critical path for the registration. And the recruitment will be much simpler than the phase 2, since actually they are less exclusion criteria. So, for the time being, AIC is preparing the phase 3 for efficacy and safety. And so, this is a randomized study with a control. And actually, AIC is expecting the agreement from FDA on the protocol for the phase 3 and IND by the end of 2021. And as you know, there will be two phase 3, which is absolutely necessary in the treatment of pain, according to the recommendations from FDA as well.

Christophe Douat

Maybe Joël, I'll spend a few seconds reminding you of what mdc-CWM is. It's about reducing pain, inflammation after large surgeries, especially orthopedic surgeries. The first indication is total knee surgery. It's one million surgeries a year in the US. The most painful surgeries of all, about 20% of patients, you know, become addicted to the prescription opioids, you know, with the consequences we know. Remember before the pandemic, this was the priority of the FDA. The current products in that field, you know, treat the pain, but for a very small period of time, maximum three days, this product here intends to treat pain, you know, for four weeks and inflammation for a month. So, it's really a change of paradigm.

Nicolas Gourgues

Thank you very much to both of you for the update for that project. Now let's move on with two of the projects supported by the Gates Foundation and by UNITAID, Joël.

Joël Richard

Yes, sure, so we have a collaboration with the Gates Foundation on a contraception project. This is a six-month formulation. So, our technology makes it possible to get to this release period. And we have also another collaboration on the prevention of malaria with United. And both projects are actually on time and progressing as per plan.

Nicolas Gourgues

Thank you. Thank you, Joël. Finally, there is three programs left, three internal programs mdc-GRT, mdc-KPT and mdc-TTG.

Joël Richard

Yes, sure. So, we have these three internal projects which are in preclinical development at the present time. For TTG we are a little bit more progressed, and I would like to really focus on another excellent news, actually, since we are launching a phase 2 of proof of efficacy in prophylaxis of COVID 19 in Europe, including France, with, oral administration and continuous dosing of a one months to simulate a long-acting formulation, which is actually what we are we are going to develop. So, this is a clinical trial with a very a rigorous design with control, with placebo, randomized, double blinding and multi centric. Just to say that this is a real study, a way of let's say, high reference in the field of prophylaxis of COVID 19 and actually there is, I would say no means to put these results that will be obtained in doubt. So, this is exactly what we want to develop right now. So, the dossier, the regulatory

dossier has been filed in France, our first last week. And will be also filed in other European countries beginning of September. And the protocol will be available on clinicaltrials.gov site in the next weeks. The results are expected in the next months. And actually, our objective for this phase 2 are threefold. I would say first we would like to confirm the efficacy in prophylaxis, in controlled conditions and under conditions that cannot be in doubt, I would say. And so, this is a I would say very controlled by the placebo, the randomization, double blinding. That will really provide confidence into the results that we will get. Second point is to define and optimize the development plan for the long-acting injectable formulation, which is our goal. And the third point is that in the present context, where the regulatory agencies are not so favorable regarding ivermectin, we would like to convince them to prioritize this approach and accelerate the processes for regulatory approval.

Christophe Douat

Yeah, Joël, I think I will I would like to interrupt you for a couple of seconds and paid tribute. to Professor Jacques Descotes, Jacques was a professor emeritus, well-known toxicologist. He has been working with MedinCell for 10 years and he contributed significantly to our Ivermectin Covid program. By, you know, making a full review of ivermectin safety, a landmark study that is now used worldwide. And also, by helping us, you know, look at all the scientific data and clinical data and all the work we've done in the last year and a half. So, thank you, Jacques.

Joël Richard

Yeah, I just would like to add that regarding this project, based on the strong phase 2 results that we will get, we have selected also a long-acting injectable formulation, which is ready to go to regulatory and clinical development.

Nicolas Gourgues

Thank you, both of you, for that update. So that's the complete update of our portfolio for you. Now, let's look a bit further. Let's see what is expecting in a year from now. You can see on your screen the portfolio in the year. Maybe Joël you want to say a few words about it.

Joël Richard

Yes, sure. So, as you can see, the pipeline is really progressing very well and very efficiently. And what is really impressive is that in 2022, we would have one product on the market based on our technology. Six of our products in clinical development with the major progress of these projects towards filing of a product. So, we have excellent perspectives on the outcome. And I would also say that we have new programs that have been initiated in early development. And a part significant part actually of my teams are working today on new projects in proof of feasibility step.

Nicolas Gourgues

Thank you very much Joël. Before moving on to the question we received, maybe Christophe you want to add a few words to sum up of that presentation.

Christophe Douat

Yes. Thanks, Nicolas. Thank you, Joël, for the comprehensive explanations. First, we are seeing a formidable franchise in long acting in Anti psychotics being build, you know, with our lead program mdc-IRM and potentially two more following the first one. This is an extremely important program for MedinCell, which validates the technology, BEPO is used in all our programs and any, favorable evolution of the lead program is of course, benefiting, and derisking the others. These steps are increasing dramatically, the visibility, the credibility of MedinCell and that should allow us to execute new partnerships in the next few years. And of course, you know, if you summarize if I summarize again, the coming news flow before the end of the year, you know, potential news on the two of the programs with Teva at the start of phase 3, and then mdc-CWM and the start of our phase 2 with oral ivermectin.

Nicolas Gourgues

Thank you. Thank you, Christophe. Let's move on to the question we received, the first one we received by email a bit before this conference. Are you aware of the PR of Jessen issued today, about six months injectable of paliperidone done? Is it intramuscular? Christophe?

Christophe Douat

Yes, of course. We are fully aware of this. Yes, it is intramuscular. And the only thing I can tell you is that we fully trust our partner.

Nicolas Gourgues

My mic was off. Let's move on to the question we received from the Chat, on the right side of your screen. Bertrand is asking us, is there any PDUFA date for mdc-IRM application? Or if confidential, any guideline for the usual review length under 505B2?

Joël Richard

Yes. Sure. So, I would say that typical review time is expected to be about 12 months, so we're expecting approval in 2022.

Christophe Douat

As a reminder, not only approval, but, you know, Teva expects the launch in 2022.

Nicolas Gourgues

Thank you Joël and Christophe. Next question. Who is going to manufacture the products I think we're referring to mdc-IRM, Teva or MedinCell, Joël?

Joël Richard

Yes, the product will be manufactured by Teva.

Nicolas Gourgues

OK, thank you, that was very easy to answer. Next question, when will the phase 3 data on your LAI schizophrenia be published? And what do you believe peak sales in the US could be? Christophe maybe.

Christophe Douat

Well, we can't comment on the peak sales, I gave numbers on the market potential, its growth. It will depend, of course, on the on the ramp up and the market share that Teva will obtain. You can check on Teva's website. They are planning to disclose further data on the phase 3 on mdc-IRM as soon as October and will publish as well in peer reviewed journals.

Nicolas Gourgues

Thank you. Next question maybe for you Jaime. When do we expect, or do you expect the next milestone payment from Teva?

Jaime Arango

Right. So, if we're talking about-IRM. Let me remind you that for the last fiscal year that ended on the 31st of March of 2021, we registered it some sales related to milestone. Milestone that corresponds to the positive phase 3 results of mdc-IRM that was published in the beginning of the year, and we registered for five million dollars. The next milestone that we will receive for this project, I cannot disclose the amount, but it will be upon the approval of the product. And from then on, we will reach, we will touch milestones upon the commercial milestones that I described earlier on. Now, when we regard, when we look at the other projects we're expecting, milestones for the other products like TJK, ANG, move forward. We will be able to register and to account for these for this milestone payments.

Nicolas Gourgues

Thank you. Thank you, Jaime. Next question regarding mdc-CWM. Oliver saying on clinical trials.gov and AIC websites, we see that the safety phase 3 is on standby. Is this a strategic choice made in partnership with the FDA? In a favorable scenario, when could we have the final results of phase 3 of efficacy and safety for this program, Joël?

Joël Richard

Yes, sure. So, FDA has asked for further data regarding both safety and efficacy obtained in controlled study on the blinding conditions, and this is the reason why actually the strategy has been adjusted and decision has been made by AIC to first get to this phase 3 under controlled conditions to get these additional safety and efficacy data, and then to come back later on, on the safety study, which is the open Label one. So exactly, there is a lot of communication between the FDA and the AIC, and this is the best way now to develop their product.

Nicolas Gourgues

Thank you. Thank you, Joël. Next question, can you share details of mdc-TJK like the genetic molecule being used and route of administration? Christophe, maybe.

Christophe Douat

No, we cannot. There will be information on clinicaltrials.gov, you know, once and if, you know, phase 3 starts.

Nicolas Gourgues

Thank you, Christophe, I think that the last question that we received today about the mdc-TTG program. As per the communications from today, a phase 2 study is in the pipe. Will you take help from a partner or will MedinCell continue this program alone?

Christophe Douat

Well, that's one of the objectives of this phase 3 is that with, you know, rigorous phase 2 sorry, with rigorous data, you know, and favorable results, you know, it is obvious that this will raise interest for partners, you know, given the context.

Nicolas Gourgues

Thank you. Christophe. We just received a new question. At this stage still about mdc-TTG, at this stage, could you say they are indeed proof, preclinical, or confidence that ivermectin can heal COVID 19, Christophe?

Christophe Douat

You know, this program is the consequence of a year and a half for work from our scientists, teams. We've pretty much talked to every principal investigator in the world that's conducting, you know, trials on ivermectin, looked at the data. And, you know, scrutinize tall the favorable signs and even more any sign that could be a, you know, not favorable. We are doing a weekly watch on all the papers that are being published on Ivermectin. We organized even an international workshop a year ago. Yes. The all the signals in prophylaxis are extremely encouraging. Actually, you know, have higher statistical significance, than ivermectin in early treatment even and there is also you know, scientific foundations from people such as Jean-Pierre Changeux at Institut Pasteur, you know, supporting the mode of action. So, you know, there's a lot of data out there. But there is a need for an extremely rigorous, randomized, double blind, placebo-controlled study. And This is what we are doing.

Nicolas Gourgues

Thank you very much Christophe. I think someone's asking us to show again the slide, where you show stand one year from now. So, I'm going to put it back on screen, maybe, Joël, you can comment it again, just to be sure. So, we all have the same information about the portfolio, the targeted portfolio in one year.

Joël Richard

Yes, sure. So, as already mentioned. So actually, we are going to see tremendous progress of our portfolio in the next 12 to 18 months. And actually, as you can see here, we have a situation which is very impressive since we could get to a situation where we would have one product on the market based on our technology. Six other products in clinical development, with a major progress towards filing of projects and NDA application. So actually, we have excellent perspective for the year to come. I would say and we have also new projects coming which are initiated in early development and a significant part of my teams all working on these new projects in early development and proof of feasibility. So, these are excellent news for the next year to come. And I think we are all proud of this situation.

Nicolas Gourgues

Yes, we are. Thank you Joël. There is no more question for tonight, so I think that it we're going to wrap it up now. Thank you. Thank you to Christophe, Joël and Jaime for being with me today in the studio for that update. And I guess we'll talk to you soon when we have more news. Bye.