# Transcript of the videoconference, April 23, 2020 – 3 pm CEST

## MedinCell participants

Christophe Douat, *CEO*

Jaime Arango, *CFO*

## Christophe Douat

Hello, I am Chris Douat, the CEO of MedinCell.

Welcome to this videoconference, which is targeting our shareholders but also open to the public. I would like to welcome in particular all our new shareholders which have joined us recently.

First, I hope all of you and your families are well in this Covid epidemic. I am right now in our facility in Jacou, nearby Montpellier, South of France. Our facility was a former Renault garage, which was modified to get our open space and labs.

This is where our 140 employees, 25 nationalities, work every day and develop all the products we work on. We have a spectacular density of PhDs, Masters, engineers, pharmacists, Doctors.

I am here today with Jaime Arango, our CFO, and Jaime is obviously in another room due to the confinement, which we have implemented with this crisis.

We usually hold these calls twice a year, but we decided to organize this one first to let you know how we are going through the crisis, second to give you an update on the portfolio and third to, of course, to talk about our Covid-19 initiative.

Some of you may be new shareholders, so I will go back a bit into details on what we do and how it works. We have communicated a PR this morning, raising the main points.

This is the first time we do video, instead of straight calls, so you can see the nice haircut I did myself because of the crisis, the confinement. You will be able to see Jaime too in a minute.

I will go through the most important point, you are able to give your questions through the chat on your screen, you can already write questions now, you can also like the questions that others have asked, and we will answer by priority the ones with the most likes.

We will of course moderate the questions, to avoid an inappropriate use of the system.

This video conference is planned to last 45 minutes and we will try to answer as many questions as we can.

First I would like to remind you about MedinCell and its vision. Great companies always have two things: a vision and values.

At MedinCell our folding vision is twofold. First it is a vision of a humanist pharma, a company which will deploy its technology in every indication where we can make a difference, but also for all the populations in the world. Second it is also a humanist company, since all our employees are shareholders which unleashes energy, autonomy and initiative. As we do it usually, I will start giving you an update on products, as you see we have very good news given the Covid context.

But first I will just tell you, or remind you, what BEPO® is about. So what we do at MedinCell, it's what called long-acting injectables. We inject a liquid which will form a depot under the skin, and this depot will degrade and as it degrades it will diffuse the drug for an intended period of times, sometimes weeks, sometimes month. The main value of a long-acting injectable is bringing additional compliance to patients, in some cases it is also use in local treatment to administered the drug where it is needed and third since we transform the peaks and throughs of pill administration in smoother release of drug we can sometime improve efficacy and reduce side effects.

When we started MedinCell, we chose BEPO®, because it had known components which are already approved in pharmaceuticals. It is also a very robust technology that can allow us to do top notch drug releases. It has the capabilities to be deployed massively at low cost.

Our current portfolio comprises 3 clinical stage products, and 8 in pre-IND candidates. All use API, drugs, that have already been approved, which means that the chances of success of our product is much higher than when you develop a new drug. Second because those drugs are known, their efficacy, toxicity are known, we can benefit from accelerated regulatory pathways, and this pathway is called 505b2 in the US.

What we call a candidate product is a formulation which we have validated in vitro and in vivo in terms of duration, dose, stability and it is a product that can enter regulatory development.

So we have 3 products in clinical trials. 2 of them are done and developed and financed by our partner Teva. And the great news is that despite the Covid context, Teva have not communicated any change in development. I remain you that the current expectation on our Phase 3 program in schizophrenia is to get interim data in the second half of 2020 and approval from the FDA could be obtained based on this interim data.

Schizophrenia is a disease that hits 1% of the population, with really significant consequences. It is said that 20% of hospital beds in the US are correlated directly or indirectly to schizophrenia. So at a time where hospital capacity of course is questioned, having a product, where we can provide a better treatment, have better compliance of course can have a big impact on the Health System. And despite the Covid context, let's not forget about all the pathologies out there, where patients need care and in particular hospital care. This phase 3 should be the last phase before commercialization.

Second product, Teva is developing with BEPO® is another antipsychotic, which is now in Phase 1.

The third program in clinical is a product to deal with pain and inflammation, post-op pain and inflammation, to reduce the impact orthopedic surgeries. We develop this program with our Canadian partner AIC. The first indication is total knee surgery and when I tell you that total knee surgery is the surgery where patients use the most opioid of any surgery and that 15% of them become addict, you can understand that a product which will impact potentially pain and therefore opioid consumption will have an impact. The opioid crisis was the priority of the FDA until a few month ago. The great news is that the phase 2 trial is now completed, and our partner expects favorable results that will allow him to launch a phase 3 before year end, without going through a phase 2b. This strategy will be validated with the FDA this summer. For strategic and competition reasons the results from the trial will be kept confidential for now.

The other 8 programs are either at formulation stage or preclinical, the last important facts of the last few weeks are the validation of the candidate formulation for a 6-month contraceptive with the Bill & Melinda Gates Foundation. We have received 3,5 million dollars two years ago to finance the formulation stage, and the Gates Foundation committed to another 19 million last December.

We are also working on another program, with another foundation, Unitaid, and it is about developing a anti malaria treatment to break the vector of malaria. Unitaid gave us a grant of 6.4 million dollars, less than a month ago. Coincidently it is very interesting to notice that the API we use on this program is ivermectin, the same we'll discuss a bit later on our initiative on Covid.

I should remain you that this product is not a product against Covid, it is antimalaria, the two of them, despite using the same API will be different, will have a different clinical trials and different goals.

Last we started a few weeks ago the activities to develop the anti-HIV product, with the support of the Gates Foundation again. This is quite interesting because what we will do here is attempted to develop a product in prophylaxis, so prevention of patients, with the same strategy as we intend to use on Covid.

It has been shown that when patients or people take a low dose of antiretroviral on regular basis, they are protected infection, against HIV.

Now let's talk about what we call at MedinCell the third path. And what we intend to do on Covid-19. Before I talk about it, I would like to precise that contrary to what has been written in a publication in Thailand, this program is a MedinCell program, it is not done today in collaboration with the Gates Foundation or Unitaid.

Today most companies and efforts toward Covid-19 look at either treatments or vaccines. Historically, vaccines development has taken many years, sometimes over 10 years and sometimes without success, there is still no vaccine on HIV, plus this is made difficult because virus can have mutants.

There is a third way, the third way is prevention. It is about administering patients a drug which will protect them against infection. Now you understand that, when you have such drug, if the patient stops taking it, then he takes the risk of becoming infected and so having a long-acting injectable which will deliver the drug for month would be a great tool in prevention. It would, you know, bring a tool to protect populations that are at risk, health care workers, elder people, maybe populations at large maybe in the developing world. A tool that would allow, you know before vaccines come, to reduce the impact of confinement, social and economic impact. So great potential for this third path.

As you have seen, the API, the first API we are working on is ivermectin. Ivermectin is known, safe API, it was discovered about 40 years ago in Japan. The two people that successfully develop it to fight against river blindness in Africa received the medicine Nobel prize in 2015. And some early studies are showing that it may be effective against Covid, to treat hospitalized patients which already have Covid. They are many others clinical trial coming, the last one that came out, came out last week, things are moving extremely fast right now and this last study from scientists from the university of Utah and the Brigham Women's Hospital of Harvard is giving interesting hints about the potential of a single treatment of ivermectin in reducing mortality of people with Covid. Since we knew this molecule extremely well, it is compatible with BEPO®, we can do formulation that last for month. We decided a few weeks ago to start this initiative and we decided recently to make it public because many questions were asked to MedinCell as ivermectin became a potential API for Covid. Just two weeks ago, the university of Monash in Australia showed that it can kill Covid cells in less 48 hours, in lab experiment. Now what we intend to do is not treatment of patients, it's prevention. So, using a long-acting injectable to protect populations. It could, eventually, have a major impact in treating the pandemic, and next ways of Covid. I cannot today give you an agenda, and the timing of future development. Our objective of course is to go as fast as we can, there is a lot at stake here. We have relationship with many companies and foundations who may become extremely useful in joining effort at some point. I like to remind you that we are already in a capacity to produce at GMP quality levels massive amounts of polymers, thanks to our joint venture in the field.

In case of success the impact of such a product could huge for world populations and it is our responsibility at MedinCell to do every single thing we can to participate in the world effort against the virus and succeed.

Now let's talk about how MedinCell is going through the crisis, through the unprecedented crisis. MedinCell's management has gone through crisis before, in 2001, 2008 and others. We know that when you go through a storm you have to take the sails down and wait until the storm goes. We don't know how long it will last or how strong it will be. So early in the crisis we have taken measures for the safety of our employees by stopping travelling and putting most people in home-office. We even have taken the initiative to deliver their desk chairs home so that they can work appropriate conditions. The lab keeps working, of course with all precautions necessary to move our strategic programs forward.

I will now let Jaime maybe show us his hair cut and tell us about finance.

**Jaime Arango**

Thank you, Christophe. So, you took my idea of the razor. Thank you very much for this and thank you everyone for joining us in this videoconference.

As Christophe mentioned, we have managed to adapt ourselves very rapidly. We have very early on, revised our spending, line by line, in order to ensure the continuity of all our strategic activities and put on hold those that we could. We have also put in place the partial activity scheme, over here in France for a part of our teams.

This allows the company to preserve a good financial visibility, that we estimate today that can go over a year, regardless of the scenario we look at, one of those scenarios including a return to normal activity.

But, with the uncertainty surrounding different factors like how the current crisis will evolve, how the financial markets appetite will be in the coming months, or the impact of the crisis on our partners, we are working very actively on additional tools, like the Government guaranteed loans or getting the access to the last tranche of the 5M€ we could get with the agreement we have with the European Investment Bank.

We have therefore protected the company and preserved our strategic programs, but we remain very vigilant.

Let me remind you that our fiscal year closes on March 31st. Our annual financial results will be presented in June. For that purpose, we will organize a new shareholder meeting then.

I propose that we now go to the Q&A section.

Christophe.

**Christophe Douat**

Thanks a lot Jaime.

Indeed we will now go through the questions and answers and the first question I have is the following: "How will you manage the potential toxicity of ivermectin?"

Let's, I will make three points. First, ivermectin is a known drug which has been used to treat over 30 million people over the years. It is even on the list of essential medicine of the WHO. There is a lot of information of its low toxicity at current dosage, and even some analysis of potential toxicity above current dosage. We choose ivermectin with Unitaid to break the malaria vector because of this low toxicity profile. It is in the lowest category of toxicity at FDA. Of course, some of the studies that you see, especially this Australian study are using high concentrations because it is an invitro experiment, it is quite hard, or impossible to extrapolate to acute treatment doses. The current trials that

we see are using usual approved doses and seems to have an impact like in the Utah-Harvard study however we are not working on treatment here, pills can do the job. We will be, and we are working on prophylaxis, prevention and we expect doses to be much lower. One of our early objectives is to define of course the right dose.

Next question: " I understand that you are not able to communicate a schedule for the specific injectable ivermectin program. But maybe you want to share information with similar programs as to how fast they have been brought to market in the past? »

You know it is difficult because there is no similar program. Our ivermectin program should go way faster than everything we've done in the past. First because we have already you know promising formulations in the lab which need to be fine-tuned, but we know the API well. Second, we expect to have in the next few months trials, data, trial start and data that will show efficacy for prevention and if we do, we can of course piggyback on those data for the long-acting injectable. And third, given the situation all the regulatory systems have put in place accelerated programs. What I can tell you, is that we have adapted processes at MedinCell to optimize a parameter which is often under optimized in the pharma industry: time. Time is of the essence here, so we have to really change the way we work and include time early on in our design.

"What is your deal with Teva? When will the first product be on market? »

So our deal with Teva is classic milestones and royalty deal. It was about developing three antipsychotics. So one is at the end of phase 3, the second is in phase 1, the third one is in preclinical. Teva has responsibility for developing the product post-formulation and commercialization, and I will let Jaime describe the financial metrics.

**Jaime Arango**

So, as Christophe mentioned, this is a classical biotech-pharma deal in the sense that we are receiving milestones and royalties. So, in the development of this products, MedinCell will receive up to 122 million dollars in milestones, milestones in development and also in commercialization for each product. So that would be up to 366 million dollars for the three products. And in addition to that MedinCell will receive high single digit royalties from the first sales of the product.

**Christophe Douat**

Thank you Jaime. About the timing to go to market we are not, we don't communicate on this. But we know that when a product is at the end of phase 3, then the next step is to get approval and then commercialize. Next question.

"Can tou give more detail about your pain program in clinical Phase 2? When will it be on market?"

So this one is about releasing an anti-inflammatory drug in the place of surgery to reduce pain and inflammation. The endpoints, or some of the endpoints on the current phase 2 are pain and opioid consumption. The results are expected, phase 2 is just completed and our partner expect very favorable results that should allow him to go straight into Phase 3 by the end of the year and expects to talk to FDA in the meantime. Next question.

"In the press, there are articles linking nicotine, covid-19 and ivermectin. What do you think about this? Do you think the doses of ivermectin required to treat Covid-19 could be toxic to humans? »

I'll talk about the first question first. Yes, actually this, the paper coming out on nicotine are quite interesting and go in the same direction as our program. There is more and more data that is showing that the percentage of smokers in Covid patients that are hospitalized is way lower than in the normal population and that nicotine could have a protective impact. There is a paper that just came out two days ago, from some French scientists, one of them at Institut Pasteur was the promoter of the nicotinic receptor and he has shown in the past that ivermectin had an impact on this nicotinic receptor. So we are learning two extremely interesting things here. First that prevention may be possible if actually nicotine protects people. But nicotine is not seen as the best alternative by many people, especially because of its addiction power. And second, ivermectin may have the same impact, because of its impact on the nicotinic receptor. The next question was about the toxicity of ivermectin. I think I did answer this.

And the last one is : "Can we have more detail about the press release on wwm program with the gates. Thank you »

So, this program we started about 2 years ago. It is about developing a 6-month bioresorbable self-injectable, sub cut contraceptive, which would be not only a great product for humanitarian purposes but also a best-in-class product for the developed world. So, the first tranche of the project a-was about finding a lead formulation to go to preclinical.

And we just reached this stage, and the press release that we did yesterday. And the first financing from the Gates Foundation for that first step was 3,5 million dollars. And in December, the Foundation gave us another grant of up to 19.5 million dollars over three years ; 19 million sorry, over three years to go to clinical.

In the agreement with the Foundation, the Foundation has all rights for humanitarian purposes and MedinCell has kept all rights for commercial rights worldwide, especially in the US where it is a 5 billion dollars market contraception, with about a third of it on long-acting devices or products.

I think this was the last question. As a conclusion I would like to first thank you for attending this call. As you can see, all our programs are moving according to plan. Of course, we are monitoring the situation of the Covid-19 context carefully, especially on the US side where all hospitals, you know, are focusing on Covid.

I would like to thank in particular the 140 employees of MedinCell, which have done their upmost to go through the crisis, sometime in difficult family conditions, and sometimes far from their families and which have allowed us to keep all our strategic activities going forward. I would like to thank, our current shareholders which have sent us a lot of support and messages and the new ones which are joining us. We will do all our efforts and put all our energy trying to move Covid initiative, the third path, forward. I would like also to wish you a safe next few months and tell our new shareholders in particular that I hope they will see how a formidable company MedinCell us. Thank you.