

Industry Partners Panel

UCB

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[00:00:03] **Teresa Gasalla:** Hello, good afternoon to you as well. Thank you very much for the opportunity to take part in this webinar. My name is Teresa Gasalla. I work for UCB in Global Clinical Development here in the United States. I was trained in Spain. Just a few brief words about UCB for those who may not be familiar with it: It's a mid-sized biopharmaceutical company headquartered in Brussels. We have about a hundred employees, and we work mainly in the areas of neurology and immunology. Twenty percent of our profits are reinvested in R&D. And right now, the slide that's coming up for this meeting is the one you can see on the screen. We're actively involved in research into MOG-associated disease. I was going to tell you about the Phase 3 clinical trial we have in cosMOG, but first I wanted to say a few words about clinical research and how important it is, because medicine and the development of new drugs really couldn't move forward without participants in clinical research and in clinical trials. It's a process. Everything that's done is very rigorous—how it will be analyzed and all the procedures are laid out in a protocol before starting, and that protocol has to be approved by ethics committees and by regulators. Everything is documented throughout the study, and it's usually audited multiple times.

[00:01:43] And above all, they're done to find out whether the drugs are effective and whether they're safe in a group of people with whatever the disease is. But safety is an extremely important aspect throughout the development of the studies, and it's something that not only the investigator—the doctor who will be there day to day, observing the patient very closely—will be watching very carefully, but also...

[00:02:09] At the sponsor level and by the monitors, who may even come from external groups, all the safety information collected during the study is reviewed continuously. So, in that sense, every possible guarantee is provided, bearing in mind that we're investigating new treatments for the participant. What's the potential benefit? Well, access to a new treatment. And, whatever the disease is, you get fairly close follow-up and monitoring, usually at centers of excellence. But of course you also have to consider the risks: when we're testing a drug, we don't know whether it's going to work or not.

[00:02:58] And sometimes not all the possible side effects are known. So it's very important that, before enrolling, there's always an informed-consent process where the potential participant is given all the relevant information so they can make a decision. And, well, it's a very personal decision.

[00:03:18] There's also a very altruistic side to taking part in a clinical trial. The person may not get a direct, individual benefit, but they're definitely contributing to the benefit of all patients who suffer from that disease, because knowledge is what allows us to move forward. We keep that very much in mind.

[00:03:37] We're studying a drug, rozanolixizumab, which I saw the doctor mention earlier. Basically, what it does is promote the elimination of immunoglobulins, specifically IgG. And we think that, well, among those immunoglobulins are the autoantibodies that cause the disease. It's a medication that's given subcutaneously once a week, and...

[00:04:03] It's a Phase 3 study, meaning the study we do before applying for registration and approval of a medication. And it's positive. We're enrolling adults between 18 and 89 years old with a confirmed diagnosis of MOGAD who have a relapsing form. They must have had at least one relapse in the last 12 months, in addition to the initial event, and a positive antibody test within the previous six months to enter the study.

[00:04:35] But if there isn't a test, it's done during screening, so that's not an issue. And there are three fundamental periods in the study. The first is the screening phase, where we do all the lab work—basically all the tests—to see whether the candidate can be enrolled according to the protocol criteria and whether it's safe for that person.

[00:04:58] Next comes the period we call double-blind, because this study includes a control, which is a placebo. A placebo is a non-active, inert substance, but it's what allows us to know how effective the drug really is and to clearly define its safety—what's happening because we're taking the medication and not due to the natural course of the disease or other factors.

[00:05:22] During the double-blind period, participants stay in the study until they have a relapse. At the moment someone has a relapse that's confirmed by an external committee, they come out of the double-blind phase and enter an open-label treatment period in which everyone receives the drug. Relapses are treated as the physician decides. The investigator—that is, it doesn't depend on them. It's in the study protocol, and of course they can always treat them even if it isn't confirmed afterward.

[00:05:53] This open-label treatment period, in which everyone receives the treatment, lasts at least a year, but there's an extension period that will probably be longer—well, until the drug is available, if everything goes well and we get positive results.

[00:06:13] During the study, there are lots of support measures to make things easier for participants. We have nurses who can go to your home to administer the medication because, as I said, it's given once a week. We can also help with transport and getting to the centers. And honestly, that's what we've been doing.

[00:06:36] We're doing everything we can to tailor it to each person taking part, to make it as easy as possible. We have sites in the United States, in Mexico, in Brazil, in Europe, and in a few places in Asia. And we're basically finishing up enrollment. There's still a little bit of room, so if you're interested, or you know someone who might be interested...

[00:07:01] There's a website for the study, which is cosmogstudy.com. That site is available in many languages, including Spanish, of course. And there's also an organization called OVER where they can help you, or if you want more information, they can refer you to a center that may be participating. In any case, I'd encourage you not only to look at this study, but also to consider—if the opportunity comes up—taking part in clinical research.

[00:07:37] It's really a way to contribute to knowledge and to progress in these diseases. And they're not always clinical trials. They can be natural history studies, biomarker studies—whatever it may be. So, I want to thank all the patients who have taken part in any study, and in this one in particular, and to encourage those who may do so in the future. Thank you very much.