MedinCell's partner Teva provides additional information regarding the New Drug Application for mdc-IRM

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> Teva expects a refiling within up to six months followed by probably a six-month review period

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Kåre Schultz, CEO of Teva, spoke today at the Q1 earnings call of Teva. He gave information following the Complete Respond Letter recently issued by the U.S. FDA about the New Drug Application (NDA) for mdc-IRM.

He first said (extract from the earnings call):

"We communicated some weeks ago that we received a CRL on risperidone LAI. So, we will be answering the questions that we got from FDA. We expect that this could cause a delay of a refiling with some up to six months and then probably a six-month review period. We still have strong belief in the concept and in the efficacy. So, we still believe to get this product approved, but there will likely be a delay of up to 12 months on it"

And he added during the Q&A session:

"[about] the CRL, I can't tell you all the details, but I can tell that it has nothing to do with the, you could say efficacy and safety. We have very, very good efficacy data, very good safety data. We are very confident that the principle works very, very well."

"But it's to do with some details around how you could see the whole execution of the clinical trials have been done and some details there which we are confident that we can address and correct and communicate back to FDA within a maximum six months. And then we expect the review time of six months. So, we still have high trust in the fact that we can get the product approved at the end of the day."

About MedinCell

MedinCell is a pharmaceutical company at premarketing stage that develops a portfolio of long-acting injectable products in various therapeutic areas by combining its proprietary BEPO® technology with active ingredients already known and marketed. Through the controlled and extended release of the active pharmaceutical ingredient, MedinCell makes medical treatments more efficient, particularly thanks to improved compliance, i.e. compliance with medical prescriptions, and to a significant reduction in the quantity of medication required as part of a one-off or chronic treatment. The BEPO® technology makes it possible to control and guarantee the regular delivery of a drug at the optimal therapeutic dose for several days, weeks or months starting from the subcutaneous or local injection of a simple deposit of a few millimeters, fully bioresorbable. MedinCell collaborate with tier one pharmaceuticals companies and foundations to improve Global Health through new therapeutic options. Based in Montpellier, MedinCell currently employs more than 140 people representing over 25 different nationalities.
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Any forward-looking statements made by or on behalf of the Company speak only as of the date they are made. Except as required by law, the Company does not undertake any obligation to publicly update these forward-looking statements or to update the reasons why actual results could differ materially from those anticipated by the forward-looking statements, including in the event that new information becomes available. The Company's update of one or more forward-looking statements does not imply that the Company will make any further updates to such forward-looking statements or other forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements.

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