French company MedinCell and the Bill & Melinda Gates Foundation have signed an agreement for up to an additional $19 million to be granted over four years. It aims to fund preclinical activities and a phase 1 clinical trial for the injectable six-month biodegradable contraceptive (mdc-WWM). The grant is structured in advanced installments to cover the costs that will be incurred by the project. Depending on the options chosen and on the advancement of the program, up to $11.75 million could be raised over the next 12 months including a first tranche of $4.75 million to be paid immediately. The additional $7.25 million may be collected later.

As a reminder, a previous grant of $3.5 million was awarded in November 2017 by the Gates Foundation to fund the formulation research phase. Full results should make it possible to select the candidate formulation.

MedinCell owns all marketing rights of the product worldwide, including the United States where the contraceptive market totaled more than $5 billion in 2018. Long-acting reversible contraceptives (LARC) alone (primarily solid implants and intrauterine devices) represented 28% of this market - more than $1.4 billion - with a 5-year CAGR at 7.8%. The mdc-WWM product could capture a significant share of this LARC market and even expand it easing the adoption of this type of contraception.

In accordance with the Global Access strategy of both partners and to ensure a significant impact on women’s lives, the objective is to make the product widely available. Affordable pricing in emerging economies will help eliminate cost as a barrier to increased availability and voluntary access to the product. High demand among women and girls for long-acting contraceptive options illustrates the potential for market growth and measurably improving maternal, newborn and child health. The Gates Foundation also has a non-exclusive license for non-commercial market in low- and middle-income countries.

mdc-WWM could be the first contraceptive to combine the following essential features to make it a best-in-class product worldwide: progestin molecule (non-MPA), 6-month duration, subcutaneous injection, full biodegradable, affordability.

The Gates Foundation supports the development of products to enhance health outcomes of the world’s most vulnerable populations. An estimated 74 million women fall pregnant unintentionally every year leading to 25 million unsafe abortions and 47,000 maternal deaths. Increasing access to efficient contraceptive solutions, coupled with family planning information and services, aims to reduce unintended pregnancies, deaths from pregnancy and childbirth, abortion rates and lead to fewer infant deaths. It also aims to improve educational and economic opportunities for women, and foster healthier families and communities.

mdc-WWM could indeed address major challenges such as low affordability, weak distribution systems or cultural barriers. Unlike most LARCs such as contraceptive implants, no surgical or specialist intervention will be necessary with MedinCell’s product. After a simple subcutaneous injection a depot is formed, acting as a virtual-pump for up to 6 months, which then disappears completely. Studies have shown that the risk of contraceptive failure in women receiving oral contraceptive or other methods is 17 to 20 times higher than using a long-acting reversible contraceptives (LARC), mainly because of the lack of compliance.

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1. Source: IQVIA
mdc-WWM would be the sixth product based on MedinCell’s technology to enter preclinical development. All products use already approved active ingredients with demonstrated safety and efficacy, significantly increasing the chances of success.

**Human Health Portfolio | September 2019**

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**MedinCell news on the last 12 months (press releases available on invest.medincell.com)**

**mdc-CWM progresses as planned – September 25, 2019**

The General Meeting votes to include the “Raison d’être” of the Company in its articles of association – September 10, 2019

New grant from the Bill & Melinda Gates Foundation to develop a best-in-class long acting injectable product for HIV prevention (PrEP) – September 5, 2019

MedinCell partners to address the untapped financial potential in Animal Health – August 28, 2019

Long-acting injectable antipsychotic receives FDA IND clearance to initiate clinical activities – August 26, 2019

MedinCell receives 7.5 M€ from the European Investment Bank (EIB) – July 23, 2019

Third long-acting injectable antipsychotic using MedinCell’s technology enters preclinical development – July 9, 2019

MedinCell demonstrates in vivo the efficacy of the first injectable combining surgical anesthesia and 3 days opioid free postoperative pain management – March 11, 2019

MedinCell receives 2nd part of the grant from the Bill & Melinda Gates Foundation – January 24, 2019

Successful IPO of MedinCell – October 3, 2018

**About MedinCell**

MedinCell is a clinical stage pharmaceutical company 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 bioreabsorbable. Based in Montpellier, MedinCell currently employs more than 130 people representing over 25 different nationalities.

www.medincell.com

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