Additional US$ 4 million received for next development steps of MedinCell's 6-month active injectable bioresorbable subcutaneous contraceptive

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MedinCell has received an additional US$ 4 million payment from the Bill & Melinda Gates Foundation

This amount is intended to finance the next steps of MedinCell’s program mdc-WWM in readiness to initiate the first clinical trial end of 2023

It follows US$ 11.8 million already received as part of the two successive grants for a total of up to US$ 22.5 million from the Bill & Melinda Gates Foundation to finance the development of the program up to phase 1 completion

The Gates Foundation has a non-exclusive license on the product for the purposes of achieving Global Access in the target low- and middle-income countries, whilst MedinCell owns all marketing rights worldwide

Based on MedinCell’s BEPO® technology, mdc-WWM could be the first contraceptive product to combine the following essential features to make it a best-in-class product worldwide: progestin molecule, 6-month duration, subcutaneous and self-injectable product, full bio-resorption, affordability.

The US$ 4 million payment intended to finance the upcoming technical and regulatory activities is part of two successive grants representing up to US$ 22.5 million awarded by the Bill & Melinda Gates Foundation to MedinCell to finance the formulation, the preclinical activities, and a clinical Phase 1 study of mdc-WWM. (cf. press release of November 28, 2019).

Helen Martin, Head of Alliances at MedinCell said: “Yearly, around 111 million women fall pregnant unintentionally leading to 35 million unsafe abortions and 299,000 maternal deaths in low- and middle-income countries, according to the Guttmacher Institute. Supported by our collaboration with the Bill and Melinda Gates Foundation, our mission is to facilitate full access to an affordable and sustainable contraceptive solution for women across the world. Favorable results of preclinical studies have confirmed the potential of the investigational product. We now prepare the initiation of the first clinical study, which will be performed in the U.S.”

Unlike Long-Acting Reversible Contraceptives (LARCs: implants and intrauterine devices), no surgical or specialist intervention will be necessary with MedinCell’s product. After a simple subcutaneous injection, a deposit 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.

Christophe Douat, CEO at MedinCell said: “We are committed to improving health outcomes for people in both developed and low- and middle-income countries through affordable innovative therapeutic options. This program originally initiated by MedinCell and now supported by the Gates Foundation illustrates that we can combine commercial and nonprofit goals from early development stage with the right partnership.”

MedinCell owns all marketing rights of the product worldwide, including the United States where the contraceptive market totaled US$4.9 billion in 2021. LARCs alone represented 26% of this market, i.e. more than US$1.3 billion. The mdc-WWM product could capture a significant share of this 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 the cost barrier, increase availability and voluntary access to the product. High demand for longer-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 distribution mainly destined to low-and middle-income countries.

The US$ 4 million payment received from the Bill & Melinda Gates Foundation was already included in the company’s financial forecast anticipating a cash visibility until at least end of Q1 2024.

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 150 people representing over 30 different nationalities.

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This press release contains forward-looking statements, including statements regarding Company’s expectations for (i) the timing, progress and outcome of its clinical trials; (ii) the clinical benefits and competitive positioning of its product candidates; (iii) its ability to obtain regulatory approvals, commence commercial production and achieve market penetration and sales; (iv) its ability to obtain funding; and (v) prospective financial matters regarding our product portfolio; (v) its future partnering arrangements; (vi) its future capital needs, capital expenditure plans and ability to obtain funding; and (vii) prospective financial matters regarding our business. Although the Company believes that its expectations are based on reasonable assumptions, any statements other than statements of historical facts that may be contained in this press release relating to future events are forward-looking statements and subject to change without notice. Factors beyond the Company’s control and the Company’s financial capabilities risks, contingencies and uncertainties can be found in the documents filed by the Company with the Autorité des Marchés Financiers (the “AMF”) pursuant to its regulatory obligations, including the Company’s registration document, registered with the AMF on September 4, 2018, under number I. 18-062 (the “Registration Document”), as well as in the documents and reports to be published subsequently by the Company. In particular, readers’ attention is drawn to the section entitled “Facteurs de Risques” on page 26 of the Registration Document.

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. This press release is for information purposes only. The information contained herein does not constitute an offer to buy or subscribe for the Company’s shares in any jurisdiction, in particular in France. Similarly, this press release does not constitute investment advice and should not be treated as such. It is not related to the investment objectives, financial situation, or specific needs of any recipient. It should not deprive the recipients of the opportunity to exercise their own judgment. All opinions expressed in this document are subject to change without notice. The distribution of this press release may be subject to legal restrictions in certain jurisdictions. Persons who come to know about this press release are encouraged to inquire about, and required to comply with, these restrictions.