

MedinCell receives funding for the second formulation phase of its 6-month injectable contraceptive

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The Bill & Melinda Gates Foundation has made the payment of the second tranche of a grant to fund the second formulation research phase of a best-in-class long acting contraceptive.

This payment is based on promising *in vivo* results that have been obtained during the first 12 months of the project and substantiates the feasibility potential.

The Gates Foundation is supporting MedinCell to develop a product for women most in need in emerging countries.

MedinCell is evaluating ways to extract the product's potential in developed countries, especially in the US where the contraceptive market is worth €4.7bn.

Project highlights

Following positive results of *in vivo* studies, the Bill & Melinda Gates Foundation has confirmed its support to pursue the formulation research of a 6-month active contraceptive. The objective is to enter non-clinical development in 2020 and then clinical development.

MedinCell has been awarded a \$3.5m grant by the Bill & Melinda Gates Foundation to fund the formulation research phase of this program. A first tranche of \$2m was received at the start of the program in November 2017, and the second of \$1.5m has just been received following promising first *in vivo* results.

The product should be the first contraceptive to combine the following essential features that would make it a best-in-class product both in developing and developed countries.

- ✓ Progestin molecule (*non-MPA*)
- ✓ 6-month duration
- ✓ Subcutaneous injection
- ✓ Full bio-resorption
- ✓ Affordability

The Foundation aims at making the product available to most in need women in emerging countries.

The product could indeed address major challenges such as low affordability, weak distribution systems or cultural barriers. Unlike most other Long-Acting Reversible Contraceptives (LARC) such as contraceptive implants, no surgical or specialist intervention will be necessary with the product of MedinCell. After a simple subcutaneous injection, a depot is formed that acts as a virtual-pump up for 6 months and then disappears completely.

Studies have shown that the risk of contraceptive failure for women using oral contraceptive pills or other methods is 17 to 20 times higher than the risk for those using LARCs mostly due to the lack of patient adherence to contraceptive treatments¹.

MedinCell is evaluating ways to leverage the product's potential in developed countries, especially in the US where contraceptive market worth €4.7bn.

In 2017, LARCs represented 30% of the €4.7bn US contraceptive market with 10% 5 years-CAGR (mainly composed of solid implants and intrauterine devices)².

1. Winner, B; Peipert, JF; Zhao, Q; Buckel, C; Madden, T; Allsworth, JE; Secura, GM. (2012), "Effectiveness of Long-Acting Reversible Contraception", *New England Journal of Medicine*, 366 (21): 1998–2007, doi:10.1056/NEJMoa1110855, PMID 22621627

2. Source: IQVIA data in € at constant exchange rates in ex-manufacturer prices

About MedinCell

MedinCell is a 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 bioresorbable. Based in Montpellier, MedinCell currently employs more than 130 people representing over 25 different nationalities.

Glossary

Formulation research

Formulation research is the first stage for all programs. It enables a prototype of the product to be obtained that complies with the targeted specifications, notably the duration of action and the dose of active ingredient to be regularly released. For each product, a new combination of polymers is created, thus making each formulation unique and exclusive.

Non-clinical development

Launched after the development of the prototype, non-clinical development includes a series of studies and operations aimed at confirming the product's viability, testing its safety and establishing the scientific bases and regulatory strategy necessary for all applications for clinical trial approval.

Clinical development

Clinical development includes three major trial phases undertaken on human cohorts:

- Phase I includes healthy volunteers to assess their tolerance to the treatment.
- Phase II is carried with a limited group of sick patients to assess the treatment's efficacy, the drug's optimal dose and any side effects.
- Phase III is undertaken with a large number of sick patients to compare the treatment's efficacy to that of a placebo or standard of care. If successful, this is the final step before the marketing of the product.

NB: as the products developed by MedinCell use active ingredients that are already widely known and marketed, they can be exempt from certain clinical studies.

LARC – Long-Acting Reversible Contraceptive

Methods of birth control that provide effective contraception for an extended period without requiring user action. They include injections, intrauterine devices (IUDs) and subdermal contraceptive implants. They are the most effective reversible methods of contraception because they do not depend on patient compliance. So, their *typical use* failure rates, at less than 1% per year, are about the same as *perfect use* failure rates.

Amy Stoddard, Colleen McNicholas, and Jeffrey F. Peipert, "Efficacy and Safety of Long-Acting Reversible Contraception" (2011)

In Vivo Studies

Tests conducted in non-human living systems to study the activity of a drug candidate.

CAGR (Compound Annual Growth Rate)

CAGR is a useful measure of average growth over multiple time periods.

Contacts

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