

PRESS RELEASE - April 08, 2024 - 6:00 pm CEST - Montpellier, France - Euronext: MEDCL

# Unitaid Awards Medincell up to \$6 million Extension Grant to Fight Malaria

Global health agency Unitaid has awarded Medincell an extension grant of up to US\$ 6 million over three years to fund the clinical phase 1 activities of long-acting injectable mdc-STM. If proven safe, effective, and acceptable, mdc-STM could have a significant impact on transmission of malaria among vulnerable populations in high-transmission areas.

mdc-STM is an investigational three-month active injectable formulation of ivermectin using Medincell's BEPO® technology to fight malaria transmission. A previous grant of \$6.4 million was awarded in March 2020 by Unitaid to fund the formulation research phase and preclinical activities of the program conducted by Medincell and the project consortium members, IRD, IRSS and CIRDES.

Medincell is committed to the fight against the major global health threats, such as malaria that remains endemic in 85 countries representing 50% of the world's population. According to WHO estimates, 249 million people were infected worldwide in 2022, 94% of them in Africa, leading to 580,000 deaths in the area.

Quiterie de Beauregard, Head of Global Health Development at Medincell, said: "The 2023 WHO's World Malaria Report highlights the significant discrepancies between the objectives outlined in the Global Technical Strategy and the status of malaria indicators. This gap is particularly pronounced in the countries initially identified as high burden, which have seen little to no change in both malaria incidence and mortality rates. In 2022, these nations represented 67% of global cases and 73% of deaths. The report emphasizes the urgent need for additional tools to curb malaria transmission. Ivermectin emerges as a highly promising solution; however, logistical challenges associated with its oral administration may hinder its potential to make a significant epidemiological impact on malaria. At Medincell, bolstered by the support of the IVERMEN community and renewed confidence from Unitaid, we are firmly convinced that a long-acting injectable formulation could overcome these obstacles."

Christophe Douat, Medincell's CEO, added: "We are delighted that our long-acting injectable technology, which has reached the commercial stage following the approval of our first treatment by the US FDA, can address major global health challenges. The renewed support from Unitaid is crucial for advancing this project. It enables us to leverage our internal regulatory development expertise and continue our collaboration with consortium members IRD, IRSS, and CIRDES to conduct further studies. Our 3-month active ivermectin, if proven safe and effective, has the potential to significantly impact populations suffering from malaria."

# About mdc-STM program

Ivermectin, a drug designed to combat parasites, could eliminate mosquitoes upon biting individuals or animals that have been administered it. The individual receiving the injection will not be protected against malaria directly, however the number of mosquitoes will decrease, thus benefiting the whole community by lowering the risk of transmission of malaria, particularly in children. This community-based intervention aims to disrupt the chain of transmission.

Currently in preparation, clinical trials initiation of mdc-STM is planned by the end of 2024. The product is based on BEPO®, a Medincell polymer-based injectable technology that enables the sustained release of ivermectin and has the potential from a single subcutaneous injection to protect people living in malaria-endemic areas throughout the rainy season.

This grant extension is funded through Unitaid's IMPACT project, which aims to develop a long-acting injectable medicine that could both interrupt malaria transmission and be easier to administer and adhere to.

In 2022, Medincell signed a license agreement with The Medicines Patent Pool (MPP) that enables MPP to support the identification of suitable partners needed for the development and distribution of mdc-STM in low- and middle-income countries.

### **About Medincell**

Medincell is a clinical- and commercial-stage biopharmaceutical licensing company developing long-acting injectable drugs in many therapeutic areas. Our innovative treatments aim to guarantee compliance with medical prescriptions, to improve the effectiveness and accessibility of medicines, and to reduce their environmental footprint. They combine active pharmaceutical ingredients with our proprietary BEPO<sup>®</sup> technology which controls the delivery of a drug at a therapeutic level for several days, weeks or months from the subcutaneous or local injection of a simple deposit of a few millimeters, entirely bioresorbable. The first treatment based on BEPO<sup>®</sup> technology, intended for the treatment of schizophrenia, was approved by the FDA in April 2023, and is now distributed in the United States by Teva under the name UZEDY<sup>™</sup> (BEPO<sup>®</sup> technology is licensed to Teva under the name SteadyTeq<sup>™</sup>). We collaborate with leading pharmaceutical companies and foundations to improve global health through new treatment options. Based in Montpellier, Medincell currently employs more than 140 people representing more than 25 different nationalities.

UZEDY™ and SteadyTeq™ are trademarks of Teva Pharmaceuticals

#### www.medincell.com

## **About Unitaid**

Unitaid saves lives by making critical health products available and affordable for people in low- and middle-income countries. We work with partners to identify innovative treatments, tests and tools, help tackle the market barriers that are holding them back and get them to the people who need them most – fast. Since its creation in 2006, Unitaid has facilitated access to more than 100 groundbreaking health products to help address the world's biggest health challenges, including HIV, TB, and malaria; women's and children's health; and pandemic prevention, preparedness and response. Every year, more than 170 million people benefit from the products whose deployment Unitaid has supported.

## unitaid.org

## Contacts

### David Heuzé

Head of Corporate and Financial Communications, and ESG david.heuze@medincell.com / +33 (0)6 83 25 21 86

### **Grace Kim**

Head of US Financial Strategy & IR grace.kim@medincell.com / +1 (646) 991-4023

# Nicolas Mérigeau

Media Relations medincell@newcap.eu / +33 (0)1 44 71 94 94

## Louis-Victor Delouvrier/Alban Dufumier

Investor Relations France medincell@newcap.eu / +33 (0)1 44 71 94 94

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 future 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.

These statements may include, but are not limited to, any statement beginning with, followed by or including words or phrases such as "objective", "believe", "anticipate", "expect", "foresee", "aim", "intend", "may", "anticipate", "estimate", "plan", "project", "will", "may", "potential", "should", "could" and other words and phrases of the same meaning or used in negative form. Forward-looking statements are subject to inherent risks and uncertainties beyond the Company's control that may, if any, cause actual results, performance, or achievements to differ materially from those anticipated or expressed explicitly or implicitly by such forward-looking statements. A list and description of these 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 sell or a solicitation of 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.