

PRESS RELEASE - April 22, 2025 - 6:00pm CEST - Montpellier, France - Euronext: MEDCL

Medincell and iM4TB Initiate Development of a Long-Acting Injectable Version of Macozinone, a Promising Investigational Tuberculosis Treatment

iM4TB, through its participation in ERA4TB – a European Union’s Horizon 2020 research and innovation program – is supporting initial development of a long-acting injectable (LAI) version of Macozinone, a potential new therapy for tuberculosis (TB)

LAI Macozinone could help address some of the biggest challenges in TB treatment: facilitating access, improving patient adherence even after symptoms subside, and lowering the risk of drug resistance

TB remains one of the deadliest diseases in history, still causes over 1.2 million deaths every year

iM4TB, Innovation Medicines for Tuberculosis, is a Swiss non-profit foundation dedicated to accelerating affordable TB treatments, backed by world-class partners like the Gates Foundation, and active in global collaborations especially in ERA4TB alongside leading organizations such as GSK, J&J, Evotec, TB Alliance, Universidad Carlos III de Madrid and the Pasteur Institute

Prof. Stewart Cole, Chairman of the Board of iM4TB, said: “Long-acting injectable antiretroviral formulations have simplified, and radically improved HIV-AIDS treatment and we are confident that this will also be the case with TB. Being highly potent due to its ideal physicochemical properties, Macozinone is a perfect candidate for the LAI approach. We are thrilled to partner with Medincell and to harness their groundbreaking technology in the fight against the world’s leading killer.”

Quiterie de Beauregard, Head of Global Health Development of Medincell, said: “As with other infectious diseases, long-acting injectables could represent a true breakthrough in TB care. They have the potential to ease the burden on public health systems by reducing the need for daily supervision and expanding access to treatment in underserved communities. Perhaps most important, adherence to treatment should limit the incidence of drug resistance which is a major problem with current treatments for TB.”

Christophe Douat, CEO of Medincell, said: “Facilitating access and adherence to treatment through innovation is a key pillar of global health. In a world facing increasing health challenges, Medincell remains fully committed to developing therapeutic solutions that can benefit as many people as possible. In partnership with iM4TB, we are honored to join a consortium as dedicated as ERA4TB, which brings together many leading players in global health.”

Macozinone is a novel and promising treatment under development to combat tuberculosis

Backed by the iM4TB, Macozinone was initially discovered through major European research programs and has since progressed to phase 2 clinical trials. Preclinical studies show that it may be particularly effective when combined with other TB treatments (such as bedaquiline and pyrazinamide) offering hope for faster, more effective therapeutic options.

Unlike current regimens, which require patients to take daily pills for several months, a long-acting injectable (LAI) formulation could significantly reduce dosing frequency and help patients stay on treatment even after symptoms have subsided and when the risk of transmission is still high.

Moreover, LAIs could help lower the risk of drug resistance, a major issue in TB treatment today. Traditional TB therapy involves long courses of multiple antibiotics, and missed doses can lead to antimicrobial resistance, a condition in which bacteria evolve to withstand the drugs meant to kill them. Each year, approximately 500,000 people are infected with multidrug-resistant TB, underscoring the urgent need for innovative treatment options such as Macozinone.

iM4TB strengthens global fight against tuberculosis through ERA4TB consortium

The Innovative Medicines for Tuberculosis Foundation (iM4TB), a Swiss non-profit foundation based at the EPFL Innovation Park in Lausanne, plays a pivotal role in accelerating the development of faster, more effective treatments for tuberculosis. Founded in 2013 and chaired by world-renowned microbiologist Professor Sir Stewart

Cole, iM4TB works to bridge the gap between scientific discovery and market availability of affordable TB therapies. The foundation has received support from prestigious organizations such as the Gates Foundation and is under the patronage of Nobel Laureate Professor Françoise Barré-Sinoussi.

As part of its ongoing mission, iM4TB is a key member of the ERA4TB (European Regimen Accelerator for Tuberculosis) consortium, a seven-year €200 million public-private partnership under the Innovative Health Initiative within the H2020 EU program. iM4TB leads the Preclinical Development Work Package within ERA4TB, contributing its expertise to accelerate promising candidates such as Macozinone. ERA4TB brings together more than thirty leading academic, clinical, and pharmaceutical partners, including GSK, J&J, Evotec, TB Alliance, Gates Foundation, Universidad Carlos III de Madrid and the Pasteur Institute, uniting global efforts to combat TB with greater speed and efficacy.

About Tuberculosis

Tuberculosis (TB) is a preventable and curable infectious disease caused by bacteria that primarily affect the lungs and are transmitted through the air. TB remains a major global health challenge, with an estimated 10.8 million people falling ill and 1.25 million dying from the disease worldwide in 2023. Between 2020 and 2023, the incidence of TB increased by 4.6%, reversing previous declines.

The burden of TB is disproportionately concentrated in low- and middle-income countries, particularly in South-East Asia (45% of cases), Africa (24%), and the Western Pacific (17%). Vulnerable populations, such as people living in poverty, individuals with HIV, and children, are especially at risk. In 2023, around 2.7 million people with TB were either undiagnosed or not officially reported, highlighting persistent gaps in detection and care.

TB continues to inflict severe health, social, and economic consequences, underscoring the urgent need for intensified efforts to detect, treat, and prevent this ancient yet still devastating disease.

2024 WHO Report on Tuberculosis: <https://www.who.int/teams/global-programme-on-tuberculosis-and-lung-health/tb-reports/global-tuberculosis-report-2024>

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® 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® 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® (BEPO® technology is licensed to Teva under the name SteadyTeq™). 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.

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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 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", "probably", "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.

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