Phase 3 study to be initiated for second long-acting injectable antipsychotic using MedinCell’s technology

Euronext : MEDCL • Montpellier - France • 29 August 2022 – 6pm CEST

Teva Pharmaceuticals has notified MedinCell that it made the decision to initiate the clinical Phase 3 trial for mdc-TJK.

MedinCell will receive immediately a $3 million payment from Teva Pharmaceuticals linked to the project development milestone.

The Phase 3 study will assess the efficacy and safety of potentially the first subcutaneous long-acting Injectable (LAI) formulation of olanzapine for the treatment of patients with schizophrenia.

mdc-TJK follows mdc-IRM (LAI risperidone), the first subcutaneous antipsychotic based on MedinCell’s technology currently under regulatory review by the U.S. FDA, with a launch target set for 2023.

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, the BEPO® technology is designed to provide the regular delivery of a drug at the desired dose for several days, weeks or months starting from the subcutaneous or local injection of a 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.

www.medincell.com

Contacts

MedinCell
David Heuzé
Communication leader
david.heuze@medincell.com
+33 (0)6 83 25 21 86

NewCap
Louis-Victor Delouvrier/Olivier Bricaud
Investor Relations
medincell@newcap.eu
+33 (0) 14 47 94 94

NewCap
Nicolas Merigeau
Media Relations
medincell@newcap.eu
+33 (0) 14 47 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 production 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”, “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 or revise 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.