MedinCell provides additional information regarding the new drug application for mdc-IRM
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As announced, Teva recently received a Complete Response Letter (“CRL”) from the U.S. Food and Drug Administration (“FDA”) regarding the New Drug Application (NDA) for TV-46000/mdc-IRM.

Christophe Douat, CEO of MedinCell, said “We fully trust that our partner, Teva, will remedy this quickly given the positive results of the Phase 3 studies. Teva remains confident in MedinCell’s technology for the development of extended-release injectable products.”

A Complete Response Letter is issued when the FDA determines that it cannot approve the application in its current form. Where possible, the FDA will recommend corrective actions that the applicant might take to place the application in condition for approval.

Dr. Richard Malamut, President of MedinCell’s Medical Advisory Board, said “CRLs are a common part of the FDA regulatory process and resubmission after addressing identified deficiencies frequently leads to approval”.

Teva remains committed to the development of extended-release injectable risperidone and other products based on MedinCell’s technology.

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 140 people representing over 25 different nationalities.

www.medincell.com

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) its 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, including statements regarding Company’s expectations for (i) the timing, progress and outcome of its clinical trials; (ii) its 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.

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