MedinCell: mdc-TJK’s (Teva’s codename: TEV-44749) Phase 1 study pharmacokinetics to be presented for the first time by Teva at SIRS 2023 (May 11-15, 2023, Toronto, Canada)

Euronext: MEDCL • Montpellier - France • May 4, 2023 – 6:00pm CEST

An original presentation describing pharmacokinetic characteristics of an investigational long-acting subcutaneous formulation of olanzapine (mdc-TJK or TEV-44749) will be communicated by MedinCell’s partner Teva Pharmaceuticals at the 2023 Schizophrenia Investigational Research Society (SIRS) later this month.

Data to be presented comes from a 127-participant phase 1 clinical study evaluating, among other things, the pharmacokinetics of single ascending doses of mdc-TJK (TEV-44749) in healthy volunteers and single and multiple once-monthly doses in patients with schizophrenia or schizoaffective disorder. After injection, mdc-TJK (TEV-44749) reached a therapeutic concentration within a day and maintained it throughout the 28-day dosing interval.

mdc-TJK (TEV-44749) is the second antipsychotic based on MedinCell’s BEPO® technology. The pharmacokinetic analysis to be presented at SIRS informed the doses of the pivotal Phase 3 clinical study initiated in January 2023 by Teva. MedinCell is eligible for development milestones, royalties on net sales, and future commercial milestones.

“These findings confirm the power of our technology to reach targeted therapeutic profile, said Christophe Douat, CEO of MedinCell. Now we are awaiting the safety and efficacy results of the ongoing Phase 3 study. If favorable, they may allow patients with schizophrenia to finally benefit from an easy-to-use olanzapine long-acting injectable treatment. It remains a huge unmet medical need for patients with more severe symptoms of schizophrenia.”

MedinCell and Teva announced on April 28th, 2023 that UZEDY™, the first product based on MedinCell’s proprietary BEPO technology (licensed to Teva under the name SteadyTeq™) obtained U.S. FDA approval and will be available for schizophrenia patients in the coming weeks. Several presentations related to studies that supported the regulatory development and the approval of UZEDY will also be communicated at SIRS 2023 by Teva.

UZEDY and mdc-TJK (TEV-44749) are part of MedinCell’s growing portfolio that includes other breakthrough treatments, all of which aim at offering innovative therapeutic options that may ensure patient adherence and provide other benefits that address unmet medical need.

About MedinCell

MedinCell is an innovative pharmaceutical company, from development to market, with a portfolio of long-acting injectable products in various therapeutic areas by combining its proprietary BEPO® technology (licensed to Teva under the name SteadyTeq™) 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 collaborates 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

Contacts

MedinCell
David Heuzé
Head of Communications
david.heuze@medincell.com
+33 (0)6 83 25 21 86

NewCap
Alban Dufumier / Louis-Victor Delouvrier
Investor Relations
medincell@newcap.eu
+33 (0)1 44 71 94 94

NewCap
Nicolas Mergieu
Media Relations
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

1/2
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.

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.