MedinCell announces successful completion of patient enrollment in the Phase 3 study of F14 (mdc-CWM), a first-in-class therapy for localized pain relief after Total Knee Replacement

Euronext: MEDCL · Montpellier - France · August 30, 2023 · 6:30 pm (CEST)

- **Enrolment is complete following the randomization of 151 patients across seven centers in the US**
- **The study was initiated in November 2022 and is proceeding as planned with efficacy results anticipated in Q1 2024**
- **F14 (mdc-CWM) is a sustained-release formulation of the non-steroidal anti-inflammatory drug (NSAID), celecoxib, administered intraarticularly at the end of Total Knee Replacement surgery (TKR)**
- **F14 (mdc-CWM) aims to facilitate patient recovery from TKR surgery by providing post-operative pain relief by addressing inflammation, thereby accelerating improvement in knee function, and potentially decreasing the need for addictive opioids**
- **F14 (mdc-CWM) is the third product using MedinCell's proprietary technology BEPO® to reach, or to have completed, a Phase 3 clinical trial**

MedinCell today announces that its partner, Arthritis Innovation Corporation (AIC), who conducts and finances all development activities of F14 (MedinCell codename: mdc-CWM), has completed the patient enrollment in the first of two Phase 3 clinical studies of F14 in patients undergoing total knee replacement (TKR). F14 (mdc-CWM) is a sustained-release formulation of the non-steroidal anti-inflammatory drug (NSAID), celecoxib, administered into the intra-articular space at the end of TKR surgery.

Dr. Wayne Marshall, CEO at AIC said: *"TKR is a highly invasive surgery that results in prolonged knee pain and inflammation that last for many weeks, but current single-administration, post-TKR analgesics are limited to only hours or days in their durations of efficacy. F14 was designed and developed to reduce that surgical pain for much longer by addressing inflammation, accelerating functional improvement, and potentially reducing opioid consumption for TKR patients. Completing patient enrollment in our Phase 3 study brings us closer to demonstrating that F14 is a first-in-class therapy that will meet that major therapeutic gap around TKR recovery."*

151 patients have been enrolled in the multicenter, randomized, double-blind Phase 3 study designed to evaluate the efficacy and safety of a single administration of F14 (mdc-CWM) for post-operative analgesia in patients undergoing unilateral TKR. The primary analysis will be conducted following a 3-month follow-up period, and top-line data are anticipated in Q1 2024. More study information can be found at:
https://www.clinicaltrials.gov/study/NCT05603832?term=Total%20Knee%20Replacement&intr=F14%20%5C(celecoxib%5C)&rank=3

Dr. Richard Malamut, Chief Medical Officer at MedinCell said: *"F14 could have a major impact as it could offer physicians a simple, yet much-needed therapeutic solution, to manage patients' post-operative pain following TKR. Furthermore, today in the US, 15% of TKR patients become chronic opioid users and thus, a decrease in opioid consumption due to lower post-operative pain would be a positive factor in the long-lasting opioid crisis."*

About MedinCell

MedinCell is a commercial-stage technology pharmaceutical 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 already known and used active 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.

UZEDY™ and SteadyTeq™ are trademarks of Teva Pharmaceuticals

Contacts

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

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

Media Relations
Nicolas Mérigeau
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", "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.