MedinCell announces the initiation of Phase 3 study of F14 (mdc-CWM), a therapeutic first-in-class that aims to provide weeks of localized pain relief after Total Knee Replacement

Euronext: MEDCL Montpellier - France November 7, 2022 - 7pm (CET)

- **The study is being conducted in the U.S. and financed by MedinCell's partner, Arthritis Innovation Corporation (AIC)**
- **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)**
- **The investigational product aims to facilitate patient recovery by providing post-operative pain relief for weeks and accelerating improvement in knee function, and potentially decreasing the need for addictive opioids**
- **The 150-patient, multicenter, randomized, double blind Phase 3 safety and efficacy trial was designed in consultation with the U.S. FDA**
- **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 announced that its partner, Arthritis Innovation Corporation (AIC), who conducts and finances all development activities of F14 (MedinCell codename: mdc-CWM), has registered its multicenter, randomized, double blind Phase 3 safety and efficacy study on the public trials registry, clinicaltrials.gov. Enrollment of first patients is expected this month.

Additional details about the study can be found on clinicaltrials.gov:
https://beta.clinicaltrials.gov/study/NCT05603832?distance=50&term=F14&rank=3

F14 (mdc-CWM) is a sustained-release formulation of the non-steroidal anti-inflammatory drug (NSAID), celecoxib, designed to reduce pain and inflammation and enhance recovery after TKR. F14 (mdc-CWM) is administered into the intra-articular space at the end of TKR surgery and may provide pain relief over several weeks post-surgery.

Dr. Wayne Marshall, CEO at AIC said: "*TKR is one of the most invasive and painful surgeries. F14 was designed and developed to reduce surgical pain and swelling, accelerate functional improvement and potentially reduce opioid consumption for TKR patients. Current single administration post-TKR analgesics have limited durations of efficacy on the order of days, and do not address the prolonged pain and inflammation that typically lasts for many weeks after TKR. F14 is a first-in-class therapy which can address this therapeutic gap and improve the quality of patient outcomes after TKR.*"

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. This trial will be complemented by an additional trial since two confirmatory efficacy studies are required by regulatory authorities in pain."*

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 150 people representing over 30 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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