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Medincell Provides Update on Phase 3 mdc-CWM Clinical Trial

Medincell will Host Videoconference on May 15, 2024, at 10:30 AM CEST to Discuss Company's Latest News, Outlook, and R&D Activities

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Medincell today announced that the Phase 3 trial for F14 (mdc-CWM) being conducted by Arthritis Innovation Corporation (AIC) did not meet its primary endpoint of time-weighted AUC[1] of pain intensity over 14 days when comparing treatment with multimodal analgesia (MMA) alone to MMA concurrent with a single dose of F14 administered in the knee at the time of Total Knee Replacement (TKR). The MMA control analgesia that every patient received was defined by the protocol as standard of care periarticular infiltration with bupivacaine, oral acetaminophen and opioid rescue medication.

A numerical improvement favoring F14 was observed for the primary endpoint. Secondary endpoints of time-weighted AUC of pain over 3 and 7 days also demonstrated numerical improvement favoring F14. The safety profile for F14 was consistent with the prior Phase 2 study, and no new safety signals were identified, and no SAEs[2] were reported as related to F14 treatment.

Based on Medincell's BEPO® technology, F14 represents a novel sustained-release, non-steroidal anti-inflammatory drug (NSAID) for intra-articular, targeted delivery. Thus, this study also investigated multiple outcomes related to inflammation (and not simply pain) following TKR. Substantial improvement was observed for F14-treated patients for the key secondary endpoint of knee range of motion (ROM) at 6 weeks, as well as at 3 months ($p<0.005$ and $p<0.0005$ respectively; unadjusted for multiplicity). Treated-knee effusion (i.e., swelling) showed highly improved outcomes for the F14-treated patients compared to MMA at 6 weeks and 3 months ($p<0.005$ and $p<0.05$ respectively, unadjusted for multiplicity). The widely used clinical-performance based measure of lower extremity function, the Timed-Up-and-Go (TUG) test was also improved for the F14 group at 6 weeks.

Notably, far greater improvements were observed for the endpoints of time-weighted AUC of pain, ROM, effusion, and TUG in a sub-group of patients representing over 70% of the trial population (108/151) who had not previously undergone TKR in their contralateral (non-study) knee. This subset analysis was pre-specified in the protocol, but not alpha-controlled for formal statistical testing. AIC intends to discuss the results from this trial with regulators and explore alternative approval pathways for F14 in this sub-group of patients.

Dr. Wayne Marshall, CEO of Arthritis Innovation Corporation and a practicing orthopedic surgeon commented: *"Local inflammation is a serious adverse result of TKR, in addition to pain. So, although we did not meet our primary pain endpoint, the totality of our data which includes positive outcomes for multiple inflammatory and functional measures, gives us continued confidence that F14 is a critical adjunctive component to current standard of care MMA. The identification of a large sub-group of TKR patients where the impact of F14 is more clearly measured will likely be the focus of our future clinical development."*

Dr. Richard Malamut, CMO of Medincell, added: *"AIC has collected encouraging data through this study, confirming that F14 can significantly enhance recovery and reduce pain for a substantial portion of patients undergoing TKR. This paves the way for regulatory authority interactions to formulate a pathway for approval. It should not have significant impact on our timeline assumptions."*

[1] Time-weighted Area Under the Curve (AUC) of pain is a statistical measure used in clinical trials and pain management studies to quantify the overall experience of pain over a specified period. It integrates both the intensity of pain and the duration for which that pain is experienced.

[2] Severe Adverse Events

About Medincell

Medincell is a clinical- and commercial-stage biopharmaceutical licensing 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 active pharmaceutical

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.

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