MedinCell: mdc-CWM clinical phase 3 will start in 2021

Euronext: MEDCL • Montpellier - France • March 25, 2021 - 5:45pm CET

MedinCell confirms that late-stage clinical trials in patients receiving intra-articular mdc-CWM at the time of Total Knee Replacement (TKR) are planned as follows:

> The first of two phase 3 studies will start in H2 2021

> An open label[1] safety study to supplement the mdc-CWM long-term safety database will start in Q2 2021

Injected into the intra-articular space during Total Knee Replacement surgery and potentially active for as long as three months post-surgery, mdc-CWM is a sustained-release formulation of celecoxib for the reduction of post-operative pain & inflammation

Total Knee Replacement is the first investigational indication

The mdc-CWM program development is led and financed by MedinCell's partner, Arthritis Innovation Corporation (AIC), who closed a $23 million CAD private equity financing in February 2021 to support clinical and manufacturing activities

---

"Total Knee Replacement is one of the most invasive and painful surgeries" declares Christophe Douat, CEO of MedinCell. *"mdc-CWM has the potential to reduce post-surgical pain and swelling, accelerate functional improvement, and reduce opioid consumption for TKR patients. Today in the US, 15% of TKR patients become chronic opioid users for many months after surgery, and thus, a decrease in opioid consumption due to lower post-operative pain could be a very positive factor in the current opioid crisis."*

A 12-month phase 2 clinical trial of mdc-CMW ended in March 2020 with favorable results:

- No safety concerns identified compared to controls administered standard of care analgesia
- Improved pain outcomes for both 2-week and 3-month endpoints following mdc-CWM treatment combined with standard of care analgesia, compared to controls treated with standard of care analgesia alone
- Improvement over standard of care analgesia for multiple other endpoints including knee function and range of motion

The next stage in development is planned to start in Q2 2021 with the initiation of an open label safety study to supplement the mdc-CWM long-term safety database.

The regulatory development in pain commonly includes two phase 3 efficacy trials to provide convincing evidence of benefit for regulatory agencies. The first phase 3 study of mdc-CWM is planned to start in the second half of 2021. AIC has the potential to initiate the second phase 3 trial prior to the completion of the first.

The mdc-CWM project is a collaboration with Arthritis Innovation Corporation (AIC), based in Toronto, Canada. The drug is based on the API, celecoxib, which benefits from an established position as part of the rapid recovery protocols used increasingly over the past two decades in the management of pain associated with arthroplasty procedures. Regulatory development is led and funded by AIC which is backed by strong private investors.

For more information about MedinCell and our portfolio, visit our website at www.medincell.com

Note: As programs based on MedinCell's technology move into more advanced phases, data, analyses and conclusions are communicated on an ad hoc basis to preserve clinical study integrity and competitive positioning.

---

[1] Open-label study: a clinical study in which both investigators and patients are aware of the treatment administered; in this case mdc-CWM.

About MedinCell

MedinCell is a clinical stage pharmaceutical company 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. Based in Montpellier, MedinCell currently employs more than 140 people representing over 25 different nationalities.

Contacts

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

NewCap
Mathilde Bohin / Louis-Victor Delouvrier
Investor relations
medincell@newcap.eu
+33 (0)1 44 71 98 53

NewCap
Nicolas Merigeau
Media relations
medincell@newcap.eu
+33 (0)1 44 71 94 98