PK MED announces FDA clearance to initiate its clinical program for PKM-01, for local treatment of gout flares, directly by a Phase 2 trial.

Paris, France, February 26th, 2024 – PK MED, a biotechnology company developing *injectable smart implants* for drug release in rheumatology and cell homing for bone marrow transplantation, today announced a significant potential breakthrough in the fight against gout, a form of arthritis that is widespread throughout the world. During a *Type B pre-IND meeting*[1], the Food and Drug Administration gave its clearance to directly initiate the clinical program for PKM-01 with a phase 2 trial for gout patients, without undertaking phase 1 studies. PKM-01 is a local intra-articular injection treatment for gout flares, developed by PK MED, aiming to provide a fast an effective pain relief and powerful and safe anti-inflammatory effect. Thanks to its low-risk toxicity profile, PKM-01's clinical program will start directly in phase 2, which should considerably speed up time-to-market.

Gout is characterized by repeated intense inflammatory acute episodes and excruciating pain, called *gout flares*, due to deposits of uric acid microcrystals in the joints (e.g. knee, ankle, foot…). This most common form of acute arthritis affects more than 10 million patients in the United States and is increasingly prevalent worldwide due to an aging population, changing lifestyles, diet and obesity. Oral colchicine is a reference anti-inflammatory treatment, however, only a low daily dose can be used due to its significant systemic exposure and severe potential toxicity. Furthermore, its delayed effect on inflammation relieves only partially, and typically not before one day, the excruciating pain resulting from an inflamed joint.

PKM-01, an innovative intra-articular injectable treatment candidate for gout flares, is a combination of a controlled release colchicine, with an anesthetic molecule, *ropivacaine*. In contrast to the existing treatments, the anesthetic effect of *ropivacaine* is expected to act on pain within minutes after injection in the affected joint. In addition, the high and sustained local colchicine concentration is anticipated to provide a powerful and long-lasting effect on inflammation and pain without systemic exposure and toxicity. This dual-action approach is expected to provide immediate and prolonged pain relief induced by gout flares, an effective treatment of inflammation, while providing a favorable safety profile.

The phase 2 trial, a dose range study assessing three doses of PKM-01 in a prospective, randomized trial, will evaluate safety, pain relief and effect on inflammation, to select the PKM-01 optimal dose for the pivotal phase 3 trial.

The market targeted by PKM-01 is considerable, with annual sales estimated, depending on indication and pricing, at over $1 billion in the US alone, driven by a strong unmet medical need, and a high and rising prevalence of gout worldwide.

Prof. Angelo Gaffo, head of the rheumatology section specializing in microcrystalline arthritis at the VA Hospital in Birmingham, Alabama, USA, says: *"This product will fill a very important gap in the treatment of gout attacks: an effective and safe alternative for all patients and for those with contraindications to other therapies. As the gout population ages and diversifies, there are more and more patients with contraindications, and there are no good alternatives for them."*

[1] Type B Meetings (fda.gov)

Gauthier Pouliquen, Ph.D., CEO of PK MED, comments: *"This FDA feedback is excellent news for clinicians and patients suffering from gout flares. It should significantly accelerate the time-to-market for PKM-01. PK MED is now entering the fund-raising phase to finance PKM-01 phase 2 clinical trials. With a robust patent protection and a clear path to deliver phase 2 results, PKM-01 represents an attractive and low-risk opportunity for investors and partners."*

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About PK MED

PK MED is a French biotechnology company, founded in 2019 by Truffle Capital, developing *injectable smart implants* for drug release in rheumatology and cell homing for bone marrow transplantation. PK MED's unique expertise and technological know-how enable evolving existing systemic treatments into new, safer and more effective patented local therapies.

PK MED has developed a portfolio of projects in indications where medical needs are high, starting with gout (PKM-01) and Hematopoietic Stem Cells transplants (PKM-02).

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