PK MED

INNOVATIVE LOCAL DRUG THERAPIES

BIOTUESDAYS Meeting - July 1st 2025

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La Région Auvergne-Rhône-Alpes

bpifrance

LYONBIOPOLE

PK MED

Founded by Truffle Capital*

Truffle Capital
Business Builders

Local drug therapies in Rheumatology & Tissue Regeneration

"The right drug at the right place"

*A leading EU VC in transformative life sciences innovations (e.g Abivax, Carbios, Carmat, Vexim…)

- **Founded in 2019**
- **Based in Lyon Gerland (France)**
- **10 employees (6PhDs)**
- **Biology and formulation labs**

Lead project (PKM-01): a breakthrough in gout flares

- Ready to enter phase 2 clinical trial

A strong pipeline:

- **Gout flares** (PKM-01) and extension in **CPP arthritis**
- Osteoarthritis (PKM-011)
- Bone marrow transplantation (PKM-02):Pioneering cell-Homing technology for Tissue Regeneration

GOUT FLARES

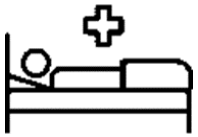
An excruciatingly painful and prevalent disease

Excruciatingly painful and disabling arthritis flares triggered by crystal deposits in joints (5-10days)

*"**hurting worse than a bone fracture**" or "**thousand needle poking**"*

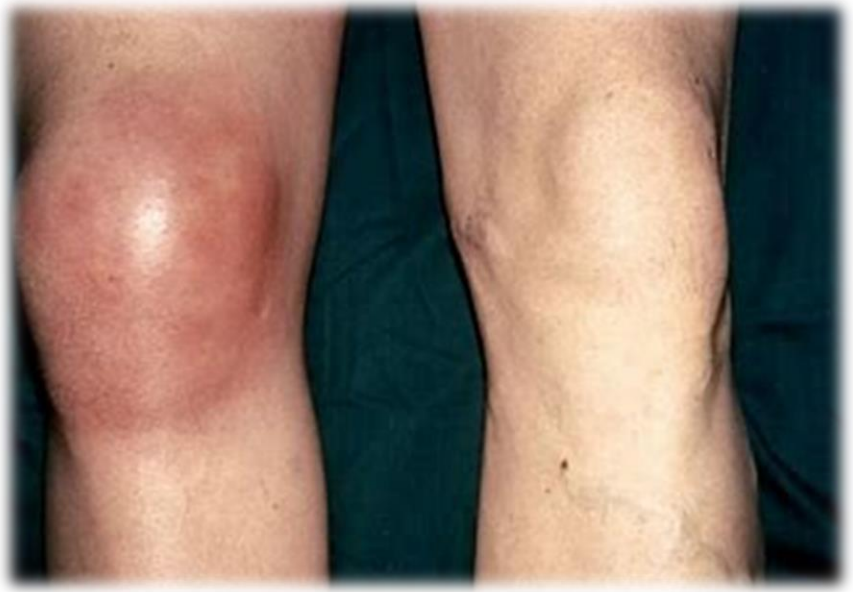
A common disease:

- Prevalence **~5% in the US**[1](~12M), **~1-2% in EU** (3-4M)
- **Increasing worldwide** (ageing, obesity…)



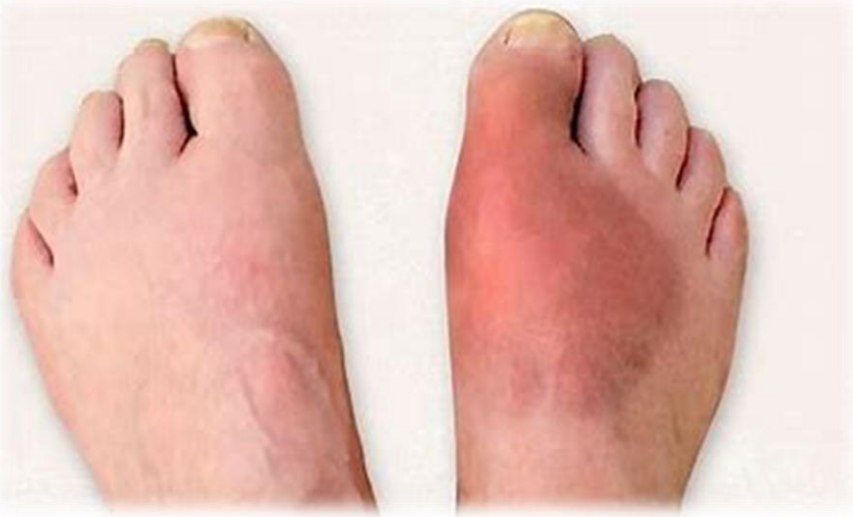
Patients with many comorbidities:

- Diabetes, Hypertension, Chronic Kidney Disease, Cardiovascular diseases…



«Patients regularly rate their pain level at 9 or 10 on a pain scale »

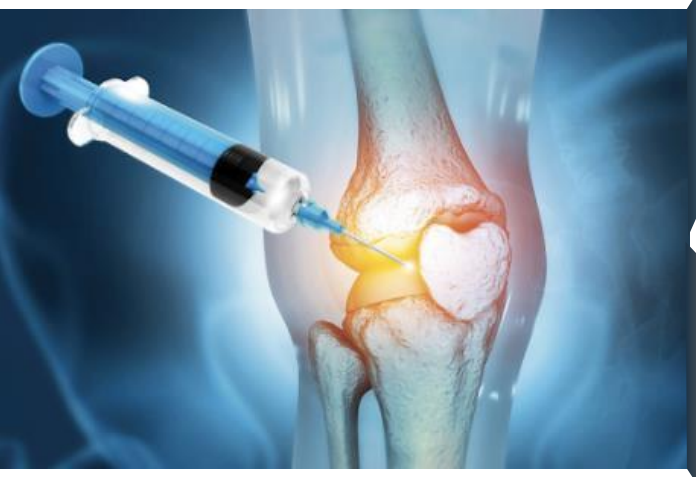
Gout Education Society



Note: Acute Calcium Pyrophospate (CPP) is a similar microcrystalline disease (previously known as Pseudo-gout)

PKM-01

An innovative combination of fast-acting and controlled-release drugs



First ever intra-articular colchicine product

Ropivacaine

Anesthetic

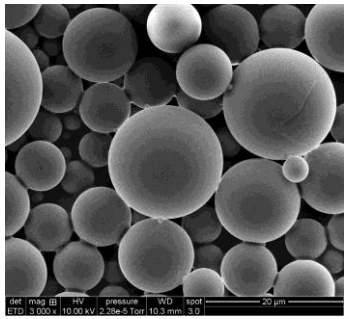
- **Fast pain relief** (within minutes)
- Routinely used

+

Colchicine

Anti-inflammatory

Controlled-release microspheres

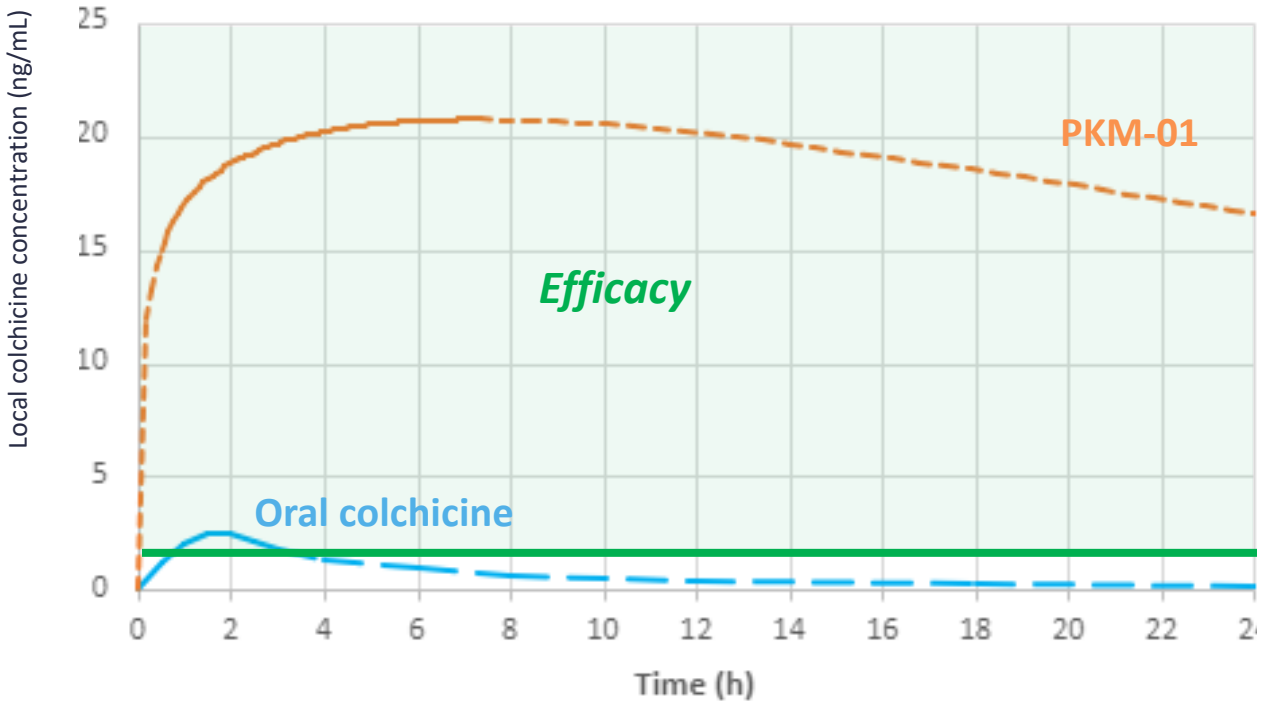


- *Oral colchicine: Suboptimal efficacy limited by toxicity*
- **PKM-01 increases and maintains local colchicine concentration**
- **PKM-01 induces a negligeable systemic exposure**

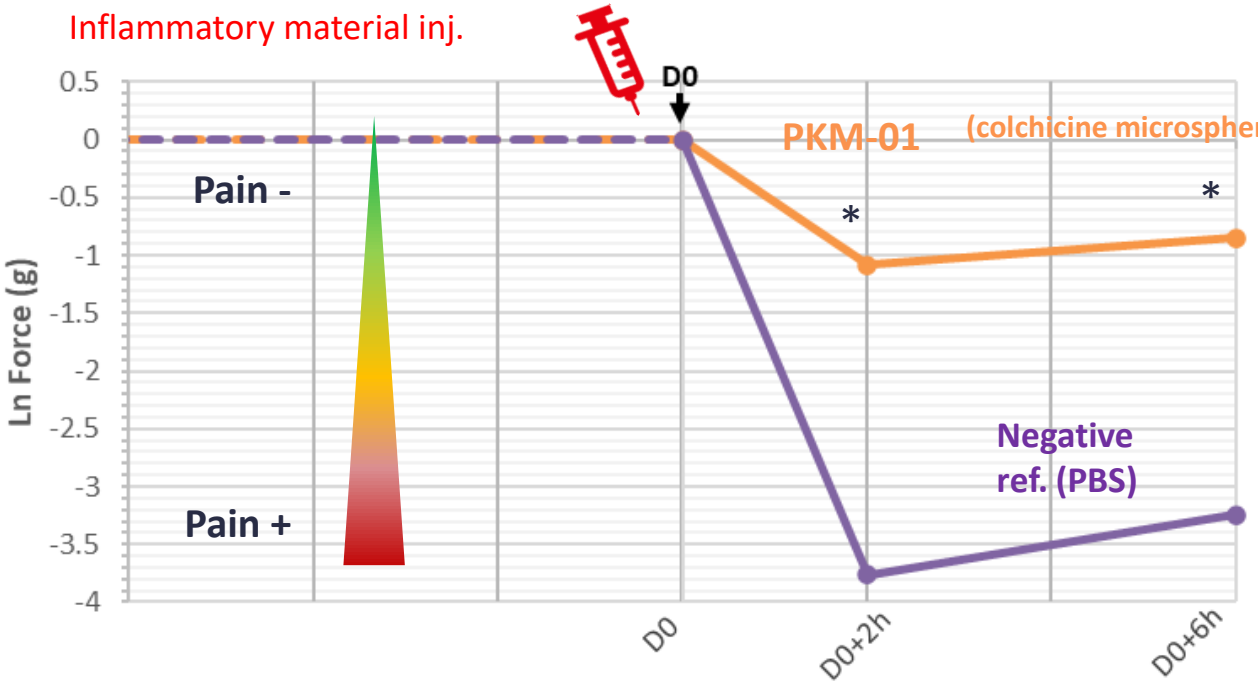
[Poster at the ACR conference (Nov 2024)]
[Poster at the EULAR conference (June 2025)]

LOCAL PHARMACOKINETIC (PK) & EFFICACY

High and sustained local colchicine concentration levels



Local Colchicine PK in human (modeled from preclinical data)



Allodynia in rats (n = 8-10)

- **High local colchicine concentrations**

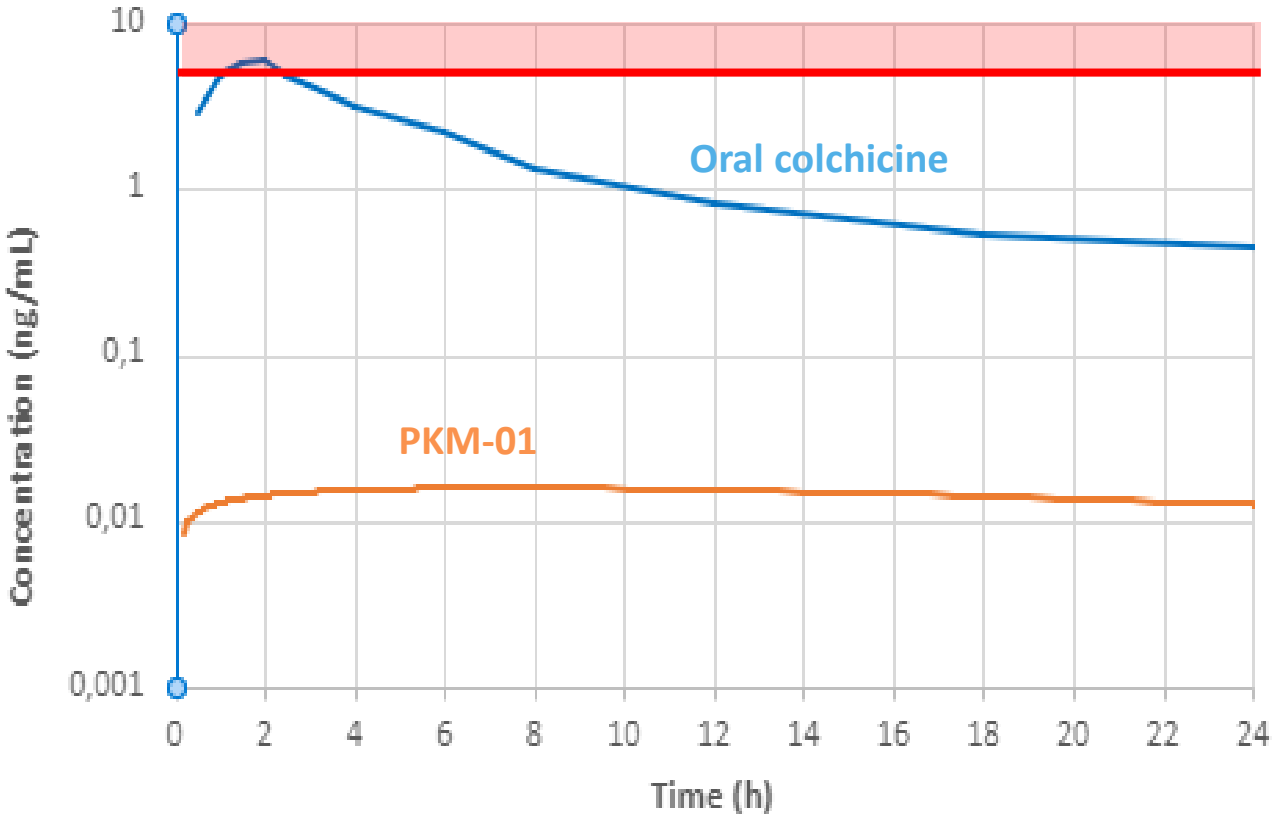
- **Swift and highly effective pain relief**
- **Strong cartilage protection**
  (not shown here)

* Stastically signatificative difference between PKM-01 and reference

Sources: (1) Internal PK Med simulation report - (2) Estimation based on Leung Y.Y. et al. Osteoarthritis Cartilage 26(5), 631-640 (2018) - (3) Terkeltaub R.A. et al. iArthritis Rheum. 62(4), 1060-1068 (2010) –(4) Leung et al. Seminars in Arthrtis and Rheumatisms, 2015- (5) Paschke et al. Journal of Leukocyte biology, 2013

SYSTEMIC PHARMACOKINETIC (PK)

Negligeable systemic colchicine concentrations in human



Simulated systemic colchicine concentration in human
(From preclinical data)

PKM induces very low systemic concentration levels:

- 2-3 log lower than oral colchicine/toxicity threshold

➢ **Very safe as demonstrated by preclinical studies**

Oral colchicine: a marked toxicity*

- ***Induces gastric side effects at therapeutic levels***
- ***Associated with many drug-drug interaction risks***
- ***May cause fatal outcomes in cases of overdose***

* The French drug agency (ANSM) published recommendations in Oct 2023 to lower the dosage of Colchicine in Gout flare treatments to reduce the excessive number of intoxications

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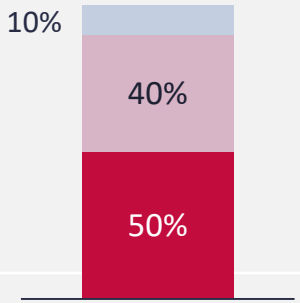
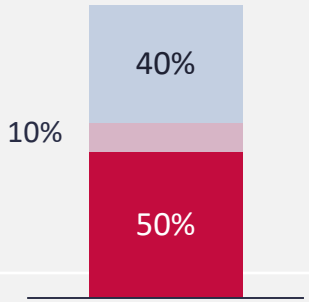
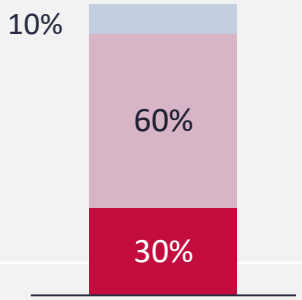
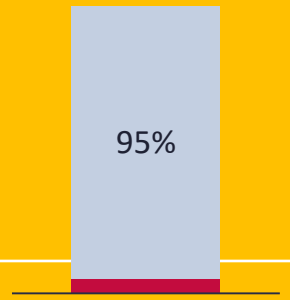
OUTSTANDING EXPECTED PERFORMANCES COMPARED TO EXISTING TREATMENTS

Treatments	Oral NSAIDS	Oral colchicine	Glucocorticoids	PKM-01 (expected)
Efficacy (Time to decrease pain by 50%)	1-3 days for 33% to 50% of patients			• 5 minutes • 1 day for 80% decrease (all patients)
Contraindication(s) (3)				
Adverse reactions (i.e., >1% occurrence) (4)	Risk of serious cardiovascular or GI AEs	Frequent risks of GI AEs	Increased risk of infections	No expected AEs

Strong Moderate No contraindication

Strong efficacy and safety differentiation

Khanna P.P. et al. Semin. Arthritis Rheum. 44(1), 31-38 (2014) - Keenan R.T. et al. Am. J. Med. 124(2), 155-163 (2011)

PROJECT STATUS

FDA clearance to initiate clinical development in phase 2

Product development
-CMC-

- ✓ *Prototyping*
- ✓ *Transfer to CDMO*
- ✓ *Manufacturing process scale-up (Ongoing)*

Preclinical

- ✓ *Successful efficacy studies*
- ✓ *Successful PK studies*
- ✓ *Successful prelim. local tolerance studies*
- ✓ *GLP tox program initiated*

Regulatory/clinical

FDA (Pre-IND Jan. 2024)

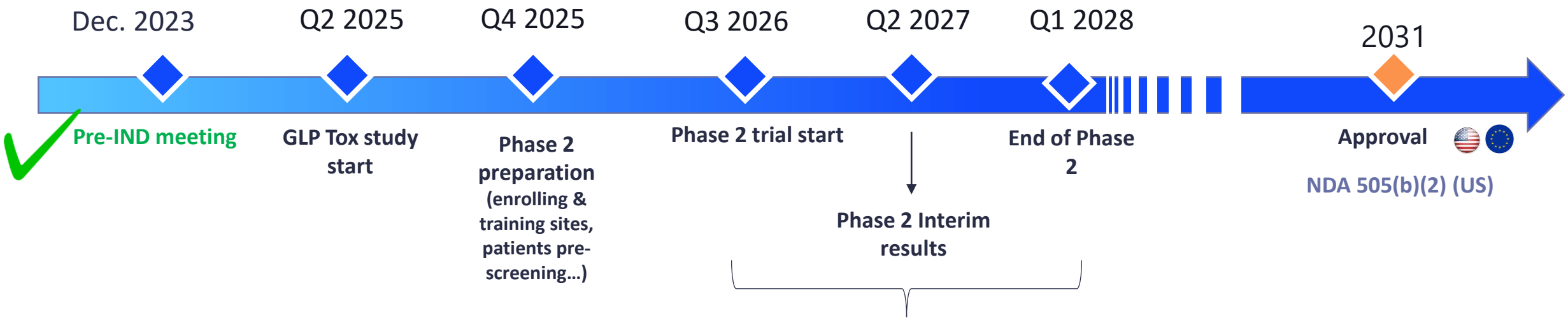
- ✓ *Direct access to Phase 2*
- ✓ *Agreement on Phase 2 clinical design*
- ✓ *Limited « safety population »*

- ✓ *EMA Scientific Advice submission (June 2025)*

- ✓ *Final draft of clinical protocol*

PKM-01 CLINICAL DEVELOPMENT PLAN

An approval planned in 2030-31



Study design

- ✓ **Randomized**
- ✓ Double-blind
- ✓ Multicenter

Endpoints

- ✓ Primary endpoint: **Safety**
- ✓ Primary endpoint: **Pain reduction** during the 1st day

Patients

- ✓ **120-160** patients
- ✓ **All gout patients, including** patients **contraindicated** to existing treatments

Treatment arms

- Control: Ropivacaine
  30-40 patients
- **PKM-01 low colchicine dose + Ropivacaine**
  30-40 patients
- **PKM-01 medium colchicine dose + Ropivacaine**
  30-40 patients
- **PKM-01 high colchicine dose + Ropivacaine**
  30-40 patients

PKM-01: AN EXCELLENT CANDIDATE FOR INVESTMENT

$20M series B funding

DERISKED PROJECT

- Known compounds
- **Successful preclinical studies**
- Patent protection until 2042

SHORTENED DEVELOPMENT

- **FDA approval to go directly in Phase 2**
- **Phase 2 (US + EU) planned on Q3 2026**

STRONG POTENTIAL

- **High anticipated peak sales + Acute CPP**
- Limited competition
- **Extension in Osteoarthritis**

SHORT-TERM RETURN

- End of Phase 2 clinical trial: 2028
- **Exit at 3 years through a Pharma deal**
- In-market objective: 2031

➢ **Seeking $20M Series B funding to support Phase 2 trial in gout: a short-term exit**

Thank you

To contact us:

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