

# MegaPro Biomedical Co., Ltd.

-A Dual-Platform New Drug Developer Entering the Value Harvest Phase

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## Key Highlight

### 1. Short-Term Goals

- ✓ **MPB-1523 (MRI contrast agent – HCC): Phase 3 clinical trial expected to commence in Q3.**
- ✓ **MPB-1734 (novel formulation): Bioequivalence (BE) study for prostate cancer planned next year.**

### 2. Mid-Term Goals

- ✓ **MPB-2043 (MRI contrast agent – lymph node imaging): IIT enrollment ongoing.**

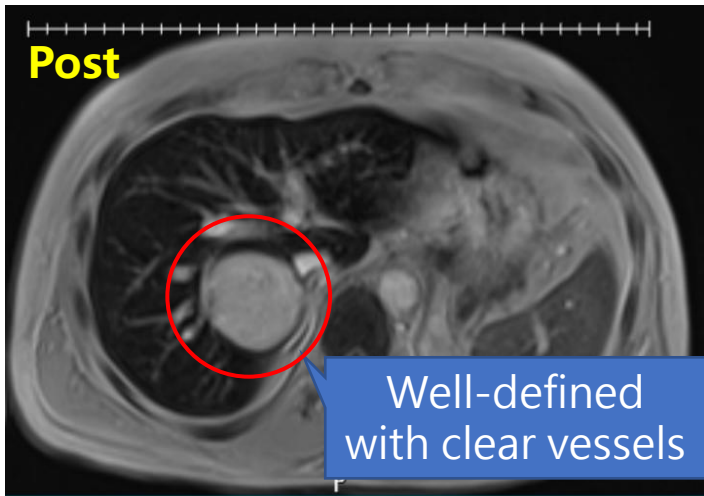
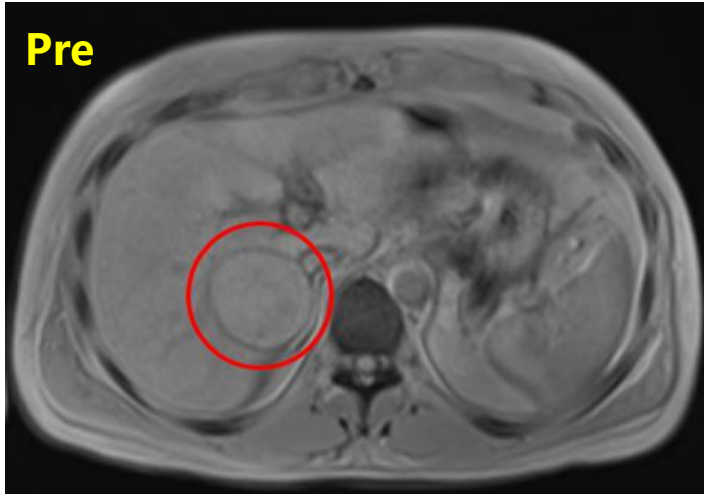
### 3. Long-Term Goals

- ✓ **Nanoparticle platform transforming cell therapy monitoring.**
- ✓ **Nanomicelle platform enabling rapid 505(b)(2) approval by replacing Tween-80.**

### 4. Two major pipelines entering value realization phase; current valuation remains significantly below industry peers.

MPB-1523

# MRI Contrast Agent for Hepatocellular Carcinoma (HCC)



- ✓ **Indications:** Diagnosis of primary and metastatic liver cancer
- ✓ **Unmet Needs Addressed:**
  - Non-heavy-metal, liver-specific MRI contrast agent
  - Clear visualization distinguishing benign vs malignant lesions
  - Safe for patients with impaired renal function
- ✓ **Mechanism of Action:**  
Differential uptake by Kupffer cells in the liver, delivering superior contrast compared to marketed products (Primovist®).
- ✓ **Regulatory Status:**  
U.S. Orphan Drug Designation granted  
Regulatory pathway: 505(b)(1) NDA

### 1. Market Pain Points & Competition

- Primovist® contains gadolinium (nephrotoxicity risk); global sales reached USD 130M in 2023.
- MPB-1523 is heavy-metal-free, offers clearer imaging, and expands coverage to ~20% renal-impaired patients.

### 2. Diagnostic Demand

- Primary HCC: ~1.75 million imaging procedures in Asia annually
- Metastatic liver cancer: ~6.21 million in Asia; >10 million in US/EU

### 3. Market Potential

- Asia / US-EU imaging demand: ~8M / 10M procedures
- Conservative estimate (20% renal-impaired population): **Total market value ~USD 500M**

**Indication:** Suspected primary or metastatic malignant focal liver lesions

**Sample Size** 140 patients (US, China, Taiwan) / Budget: ~NTD 200Million

**Comparator** Non-contrast MRI vs MRI with MPB-1523 (FDA-recommended)

**Endpoint**

Primary Endpoint:  
-Image quality scored on a 4-point scale  
-Phase 2 data: 2.05 (non-contrast) → 3.29 (with MPB-1523)

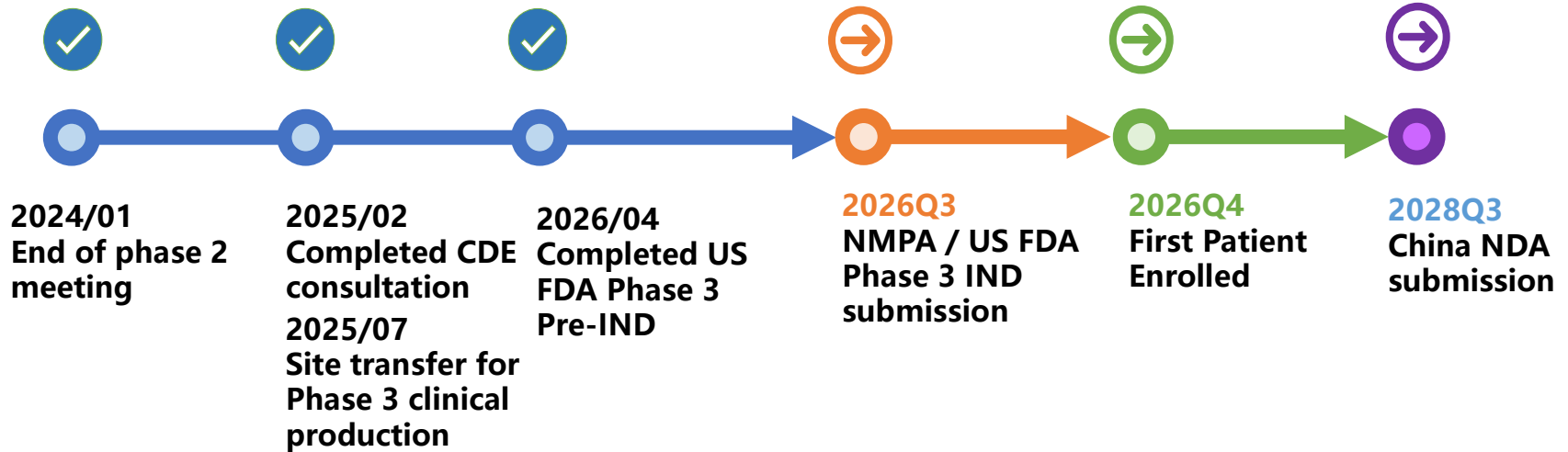
Secondary Endpoints:  
-Lesion size, number, quantitative signal intensity

**Evaluation** Three independent blinded radiologists

**Enrollment  
Duration** ~18 months

已完成

下一步



1. US FDA Phase 3 Pre-IND meeting completed (Apr 2026); CMC and trial design accepted
2. China Phase 3 consultation submitted (Mar 2026)
3. Dual strategy: Self-registration + licensing/distribution

- ✓ **Phase 3 entry: 2026 Q3**
- ✓ **Enrollment: 140 patients, NTD 2 billion budget**
- ✓ **Regions: US / China / Taiwan**
- ✓ **Completion: within 1.5 years**
- ✓ **NDA filing: 2028**
- ✓ **Estimated peak sales: >USD 500M.**

# Prostate Cancer: 3rd Most Common Cancer Worldwide Jevtana® Sales Limited by Black-Box Warnings

- Global annual incidence: 1.47 million patients
- Jevtana® is second-line therapy; limitations due to:
  - Severe neutropenia
  - Tween-80 hypersensitivity (requires steroid premedication)
- Market forecast (Verified Market Reports):
  - USD 350M (2024) → USD 750M (2033)
  - CAGR: 9.2%



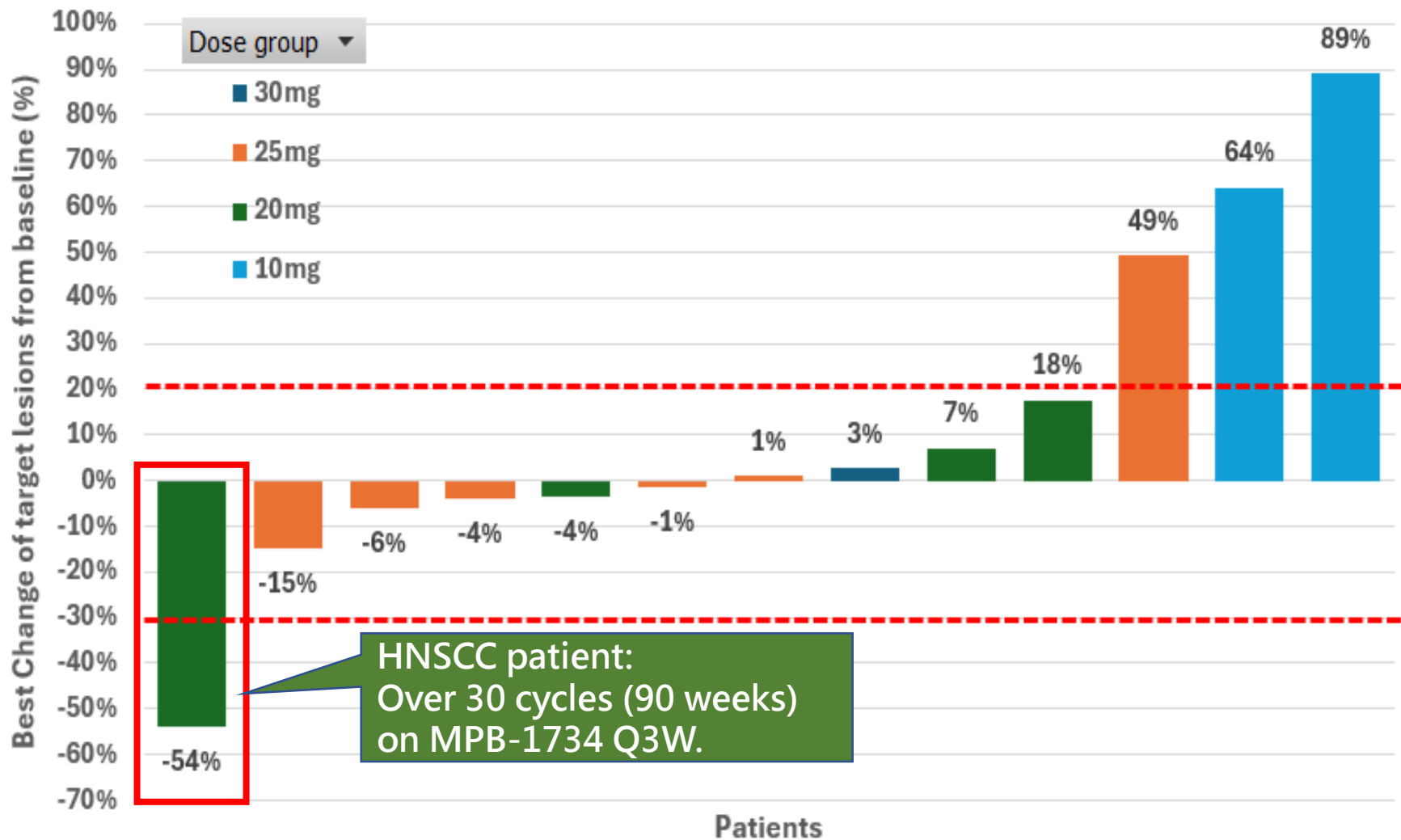
<p><b>Patent</b></p>	<p>✔ <b>composition patent in US/JP/CN/IN</b></p>	<p>API expired</p>
<p><b>Solubility</b></p>	<p>✔ <b>solubility increased &gt;1000 x</b></p>	<p>very low solubility, Tween80 must be used</p>
<p><b>Hypersensitivity</b></p>	<p>✔ <b>no steroid pre-treatment required.</b></p>	<p>hypersensitivity mainly caused by excipient Tween 80 (<b>Black box warning</b>)</p>
<p><b>Severe low neutropenia</b></p>	<p>✔ <b>neutropenia AE reduced</b></p>	<p>80% patients experienced life-threatening neutropenia (<b>Black box warning</b>)</p>
<p><b>Indication</b></p>	<p>✔ <b>Initial approval in prostate cancer, expansion to head &amp; neck cancer</b></p>	<p>Only Prostate cancer</p>

- Significant reduction in Grade  $\geq 3$  adverse events vs Jevtana®
- Durable tumor response observed in head & neck cancer patients

	Jevtana Phase 1		MPB-1734 Phase 1			
	Lable	n=21	Phase 1		N=18	
	TEAE		TEAE		TRAE	
	Grade 1-4	Grade 3-4	Grade 1-4	Grade 3-4	Grade 1-4	Grade 3-4
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
<b>Blood and Lymphatic System Disorders</b>						
Anemia 貧血	95%	10%	44%	28%	6%	6%
Neutropenia 中性白血球減少症 (DLT)	76%	48%	56%	28%	56%	28%
<b>Gastrointestinal Disorders</b>						
Diarrhea 腹瀉 (DLT)	48%	14%	22%	0%	17%	0%

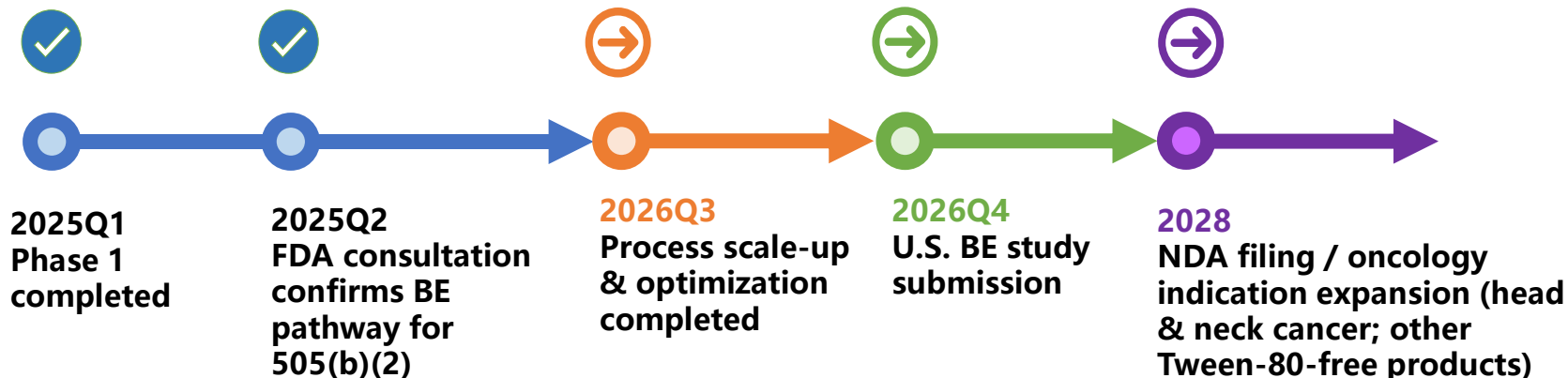
\* Diéras, V. et al.  
European Journal of Cancer, 2013, Volume 49, Issue 1, 25 - 34

**Significantly safer**



## Completed

## Next

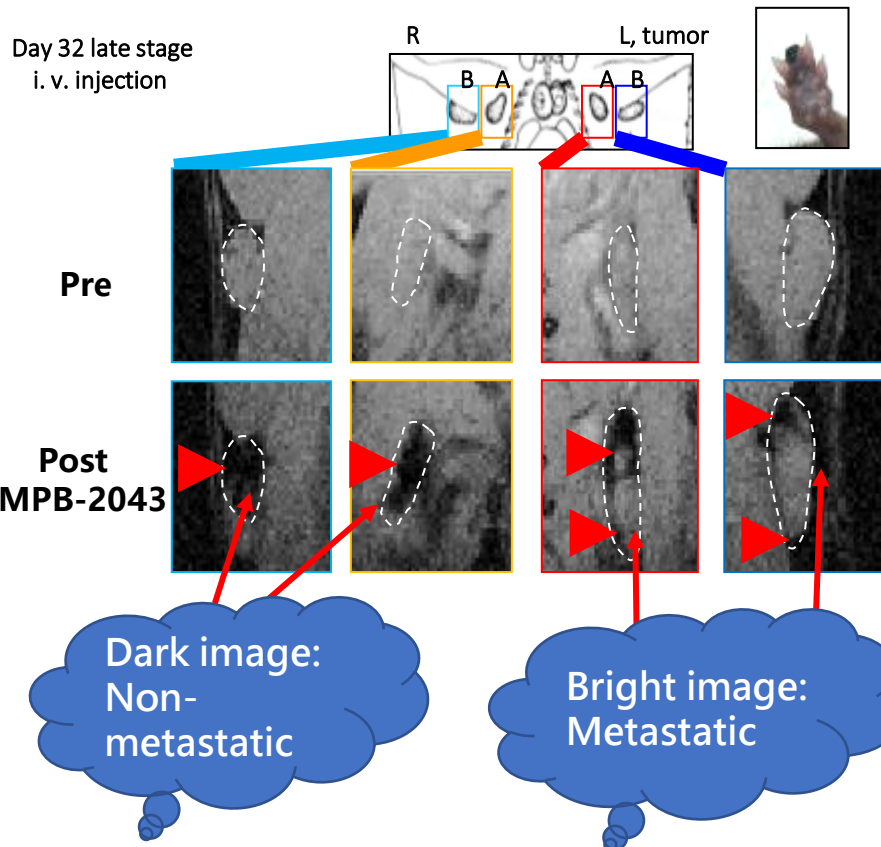


## MPB-1734 for Prostate Cancer

1. The U.S. FDA has agreed to waive Phase 2/3 clinical trials and allow filing for a 505(b)(2) NDA via a Bioequivalence (BE) study.
2. Process optimization for CMC is expected to be completed in 2026 Q3.
3. A BE study IND will be submitted in 2026 Q4, enrolling prostate cancer patients in the U.S. and Taiwan.
  - Estimated cost: within NTD 60 million
  - Blinded crossover design within the same patient
  - Enrollment expected to complete within one year
4. NDA submissions are planned for the U.S., Canada, and Europe in 2028, with parallel preparation for commercial partners.

- ✓ **BE study IND submission: 2026 Q4**
- ✓ **Clinical design:**
  - **Total cost: ~NTD 60 million**
  - **Enrollment regions: United States and Taiwan**
  - **BE study completion: within 12 months**
  - **NDA filing target: 2028**
- ✓ **Market potential:**

**With significantly improved safety, global peak sales are projected to exceed USD 700 million.**



- **Indication:** Differentiation of metastatic vs non-metastatic lymph nodes
- **Clinical Value:**
  - Enables pre-operative assessment of lymph node involvement
  - Improves cancer staging and treatment strategy
  - Avoids unnecessary lymph node dissection and severe post-operative edema
- **Mechanism:** Uptake by immune cells followed by lymphatic transport, creating contrast differences in lymph nodes
- **Regulatory Pathway:** 505(b)(1) NDA
- **Competition:** None; limited use of self-paid PET imaging
- **Market Opportunity:** Across breast, lung, prostate, colorectal, and gastric cancers, annual incidence and 5-year survival exceed **20 million patients**
  - Pricing assumption: USD 150 per dose
  - **Estimated market size: >USD 2 billion annually**

- Based on clear **clinical unmet needs**, MPB-2043 is being evaluated in collaboration with **National Taiwan University Hospital** for lymph node staging in head and neck squamous cell carcinoma.
- One patient has completed enrollment; seven additional patients have been pre-screened and recruitment is ongoing.

Platform	code	Indication	Research	Preclinical	Phase I	Phase II	Phase III	NDA
Nano Particle (505B1)	MPB-1514	Hematology (IDA)	Phase 2a completed (US)					
	MPB-1523	Diagnostic-HCC (MRI)	Phase 2 completed, prepare phase 3 (US/CN/TW)					
	MPB-2043	Diagnostic-lymph(MRI)	IIT enrolling (US/TW)					
	MPB-2354	Cell therapy	Prepare Phase 1 study					
	RD-001	Vaccine Adjuvant	RD					
	RD-003	Hyperthermia	RD					
Nano-micelles (505B2)	MPB-1734	Oncology	Phase 1/2a, Phase 1 completed (US/TW)					
	RD-004	CNS	RD					

# Nanoparticles Can Transform Cell Therapy Workflows

## Core Challenges in Cell Therapy

- Where do the cells ultimately localize?
- How long do they survive in vivo?
- What happens to the cells after administration?

## Advantages of MegaPro's Nanoparticle Labeling

- Enables accurate medical decision-making by transforming uncertainty into predictability and timely intervention
- Supported by comprehensive animal and human safety data, enabling rapid clinical translation
- High uptake by MSCs, T cells, dendritic cells, and other cell therapy products without altering intrinsic cell characteristics



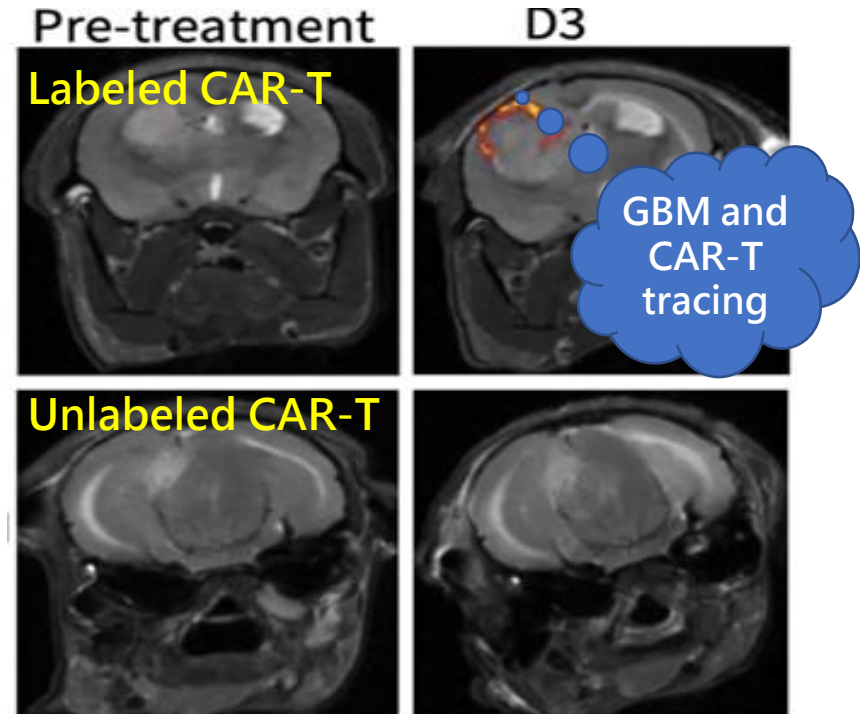
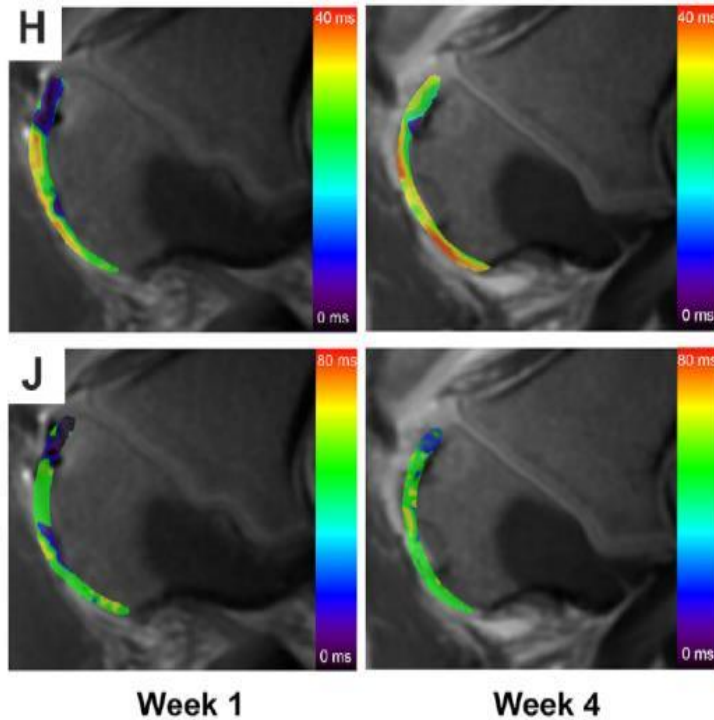
# Successful Labeling of MSCs and CAR-T Cells

## Minipig Cartilage Stem Cell Tracking

- ✓ MPB-1523 detectable at week 4
- ✓ Published in Theranostics, 2023

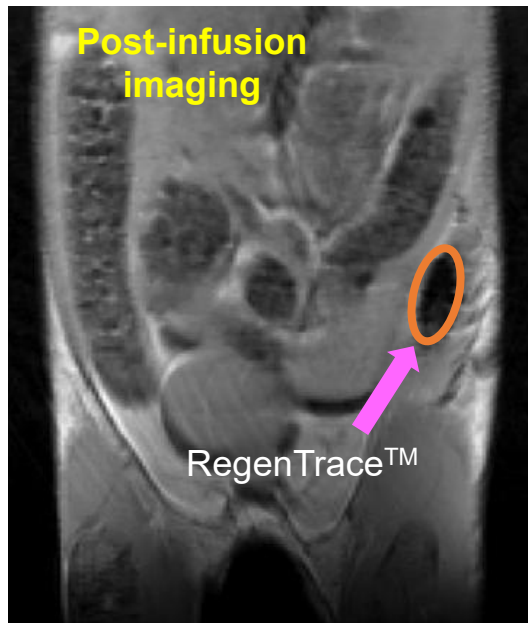
## Real-time CAR-T tracking in brain tumor models

- ✓ Real-time tracking of CAR-T cells in brain tumor animal models
- ✓ Published in Investigative Radiology, 2022



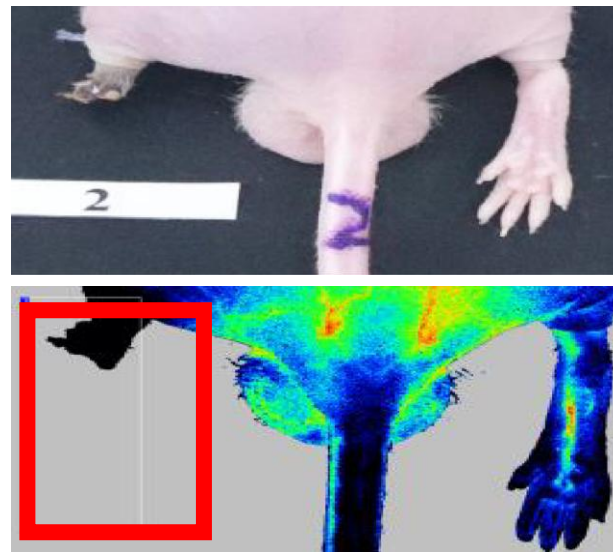
- Direct visualization of cell localization and retention addresses inter-patient variability and inconsistent clinical outcomes
- Mouse hind-limb ischemia model demonstrates comparable recovery to control by Day 14

## Real-time in vivo tracking



## Clinical efficacy matrix

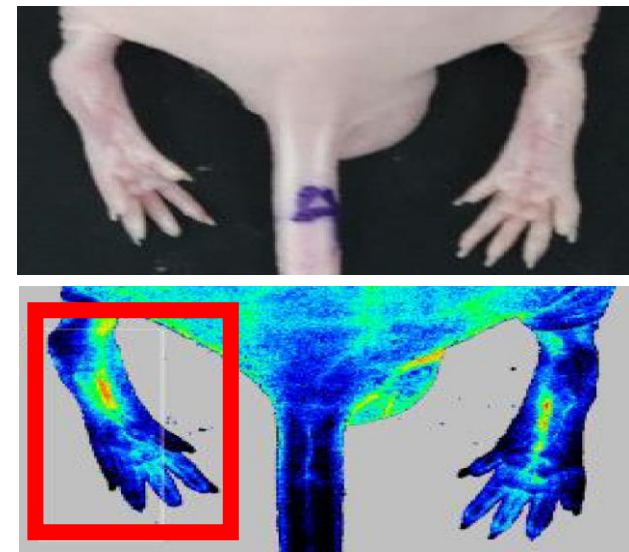
Control (untreated)



**Outcome:**

- severe necrosis and amputation;
- necrosis score = 4

RegenTrace™



**Outcome:**

- limb preserved with restored perfusion;
- necrosis score = 1

- ✓ **Applicable across MSCs, T cells, dendritic cells, and other cell therapy products**
- ✓ **Clear MoA via iron-oxide nanoparticle tracking**
- ✓ **Enables predictive efficacy assessment and timely clinical intervention**

# Nanomicelles Mitigate Tween-80 Adverse Effects

- ✓ Tween-80 is commonly used as a solubilizer for hydrophobic injectables
- ✓ Associated adverse effects: nausea, vomiting, and systemic hypersensitivity, requiring premedication
- ✓ Nanomicelle technology eliminates these risks and allows premedication-free administration
- ✓ Successful Precedent  
Emend IV® (contains Tween-80) replaced by Cinvanti®, the first Tween-80-free injectable formulation
- ✓ Regulatory Path  
Bioequivalence (BE) study → 505(b)(2) approval

# Nanomicelle Platform – Rapid Approval Opportunity

- Micelles replace Tween 80 to enhance hydrophobic drugs; 505(b)(2) via BE for rapid approval.

Drug	Indications	Market Forecast
<b>Docetaxel</b>	Breast, lung, prostate, gastric, head & neck cancers	USD 1.37B (2024) CAGR 5.7% → USD 2.37B (2034)
<b>Etoposide IV</b>	Testicular, lung cancer, lymphoma, leukemia	USD 0.72B (2023) CAGR 5.8% → USD 1.06B (2030)
<b>Amiodarone IV</b>	Arrhythmia	USD 1.4B (2023) CAGR 6.5% → USD 2.5B (2032)

# Two NDAs by 2029 – Value Investment Opportunity

- MPB-1523 & MPB-1734: combined market size >USD 1 billion
- MPB-2043: first-in-class, no competitors
- MPB-2354: early licensing potential + platform expansion
- Multiple programs entering late-stage development; current valuation represents a clear value inflection point.

Technology Platform	Code	Indication	RD	P1	P2	P3/BE	NDA	Market Size
Nano-particles 505B1	MPB-1523	MRI-Liver cancer	Completed EOP2, preparing P3				2028 Submit	Global market > USD 3 billion
	MPB-2043	MRI-Lymph node	IIT enrolling					No competitors, Global market > USD 2 billion
	MPB-2354	No-option CLI	Preparing P1					United States >USD 2 billion
Nano micelles 505B2	MPB-1734	Prostate cancer	Prepare CMC and BE trials				2028 Submit	United States >USD 750 million
	MPB-1734	Other Tween 80 drugs	Screening					Global > USD 1 billion

✓ **Short-term (1–2 years):**

Two NDA applications; new drug approvals targeted by 2029

✓ **Mid-term (3–5 years):**

First-in-class lymph node metastasis imaging with clinical validation

✓ **Long-term (5+ years):**

Cell therapy monitoring platform redefining treatment standards  
Tween-80-free formulations accelerated via 505(b)(2) pathway

Thank You