巨生生醫 biomedical
MEGAPRO

Code: 6827

MegaPro Biomedical Co., Ltd.

- Nano Medicines to Conquer Clinical Unmet Needs

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Overview

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History	Founded on 2015. A start-up company spinoff from Industrial Technology Research Institute (ITRI), Taiwan.
Capital	Secured total fund size of US$ 28m after series D round raising
Positioning	Focus on Nano-medicine development
Technology platforms	- Nanoparticles - Nanomicelle
Employee	21

Nano Medicine, Mega Cure

Core Team

The experienced experts of nanomedicine

Rick Chiang

Chairman

- MBA, National Chung Hsing University
- CEO/Managing Director (MD) of H&Q Asia Pacific (Taiwan)
- Mr. Chiang has a successful track record of investing in various industries ranging from IT, semiconductor, optoelectronics, communications, passive components, electro mechanics, automobile components, pharmaceuticals and computer peripherals /accessories.

Jassy Wang

CEO

- Ph.D., Iowa State University
- Program Director of Nano Medicine Development of National Nano Initiative
- Lead many International Industrial Collaboration Program (USA, The Netherland, Hungary, Japan, China).

Yuan-Hong Hsu

AVP, RD Center

- Ph.D., National Chung Hsing University, Department of Chemical Engineering
- More than 15 years of experiences in developing nanomedicine including project/pipeline management, process development, contract manufacturing from API to final dosage form.
- Lead various development programs including novel polymeric micelle as carriers for insoluble drug and iron oxide nanoparticle for biomedical applications.

Nanoparticles

Nanoparticles Platform : IOP Injection

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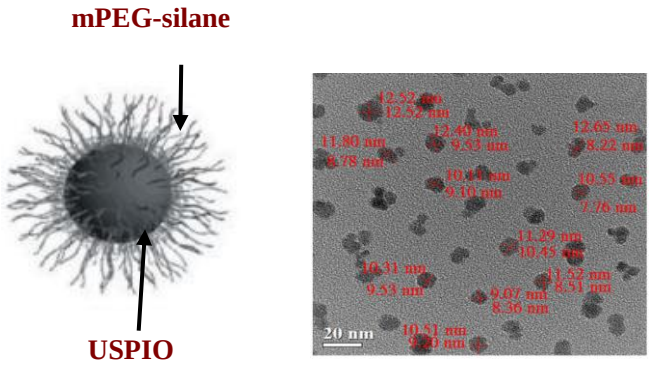
- **PEGylated iron oxide nanoparticle**
- **Key Features:**
  a. Non-dextran-based preparations with lower hypersensitivity issues.
  b. High r2 relaxivity as better T2 weighted MRI contrast agent
  c. High macrophage uptake efficiency with high conversion of Ferritin and transferrin saturation
  d. Low free/labile iron release and oxidative stress

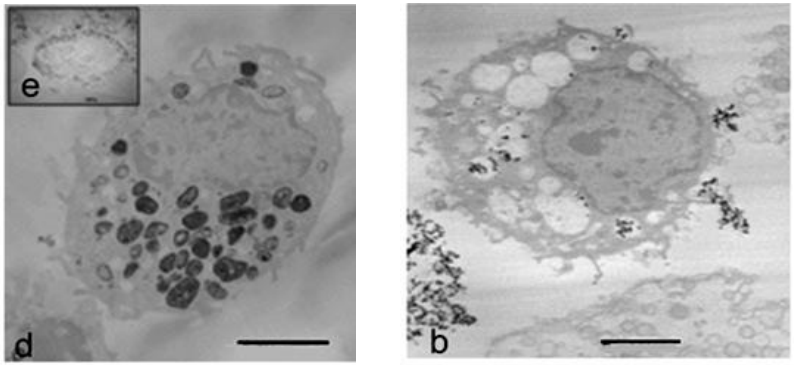
	IOP Injection	Feraheme
Size (TEM)	10-12 nm	4.2 nm
r2 $(mM \cdot s)^{-1}$*	130~170	70

MegaPro: IOP Injection



Macrophages uptake efficiency

IOP Injection **Feraheme**



MPB-1523 Under-estimated market

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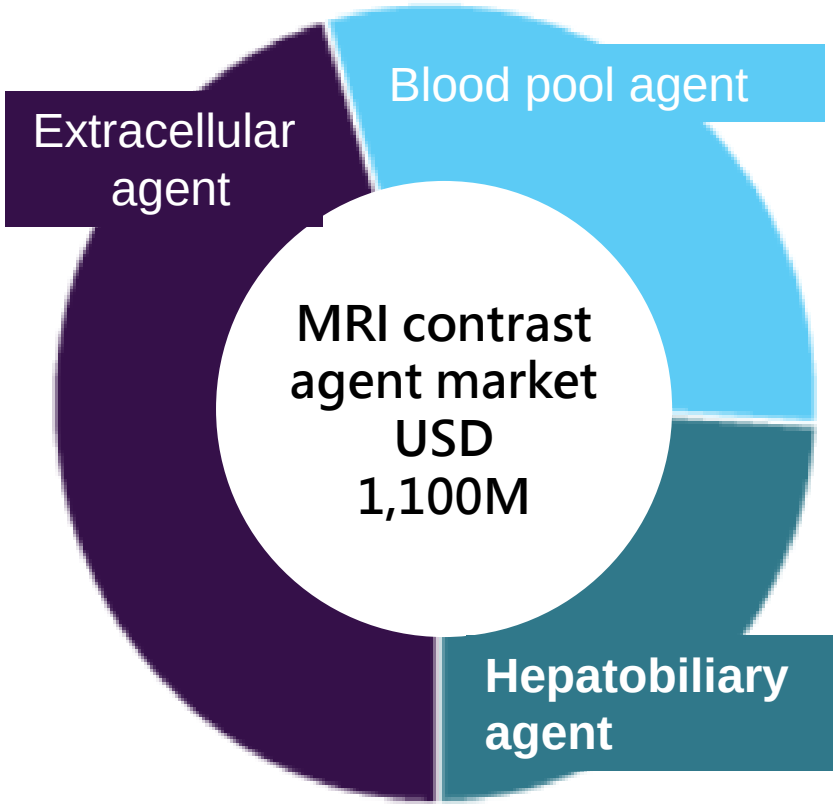

Source: www.grandviewresearch.com

- Gadolinium-based Contrast Agent Dominate MRI Contrast Agent Market
- Linear Gadolinium-based contrast agent not suitable for patients with eGFR<30 (potential Nephrogenic Systemic Fibrosis, NSF).
- **EMA's final opinion confirms restrictions on use of linear gadolinium agents in body scan** 21 July 2017

  ……. The intravenous linear agents gadoxetic acid and gadobenic acid can continue to be used for liver scans because they are taken up in the liver and meet an important diagnostic need. ……..

MPB-1523 has got orphan drug designation by the US FDA in June this year and approved for the tracking of hepatocellular carcinoma.

MPB-1523

HCC patient : CT confirmed vs MPB-1523

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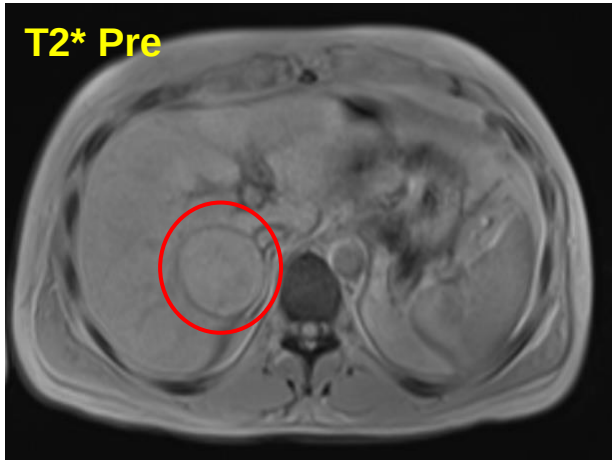
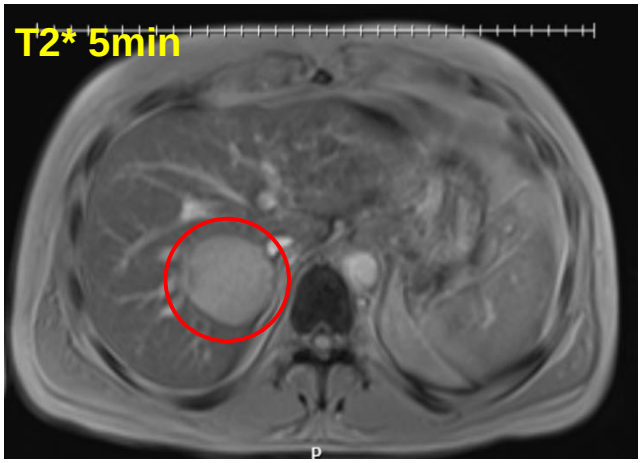
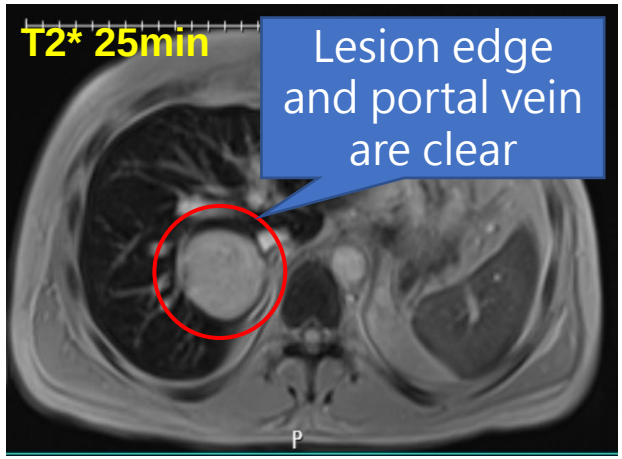
MPB1523 MR T2* image
(excellent contrast, lesion edge is clear, portal vein imaging is clear)

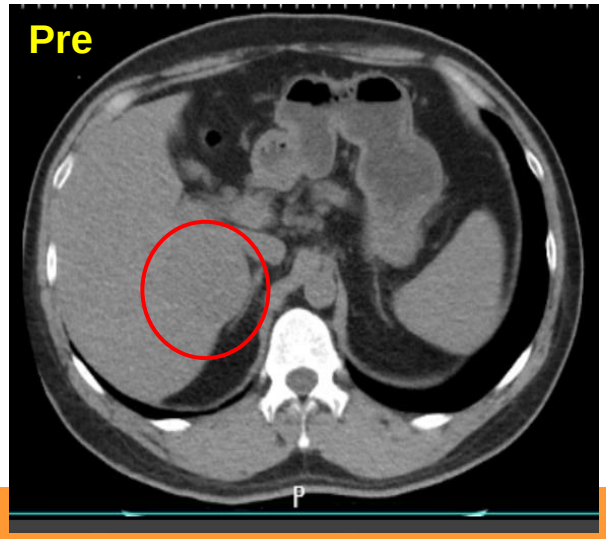
1-003-003

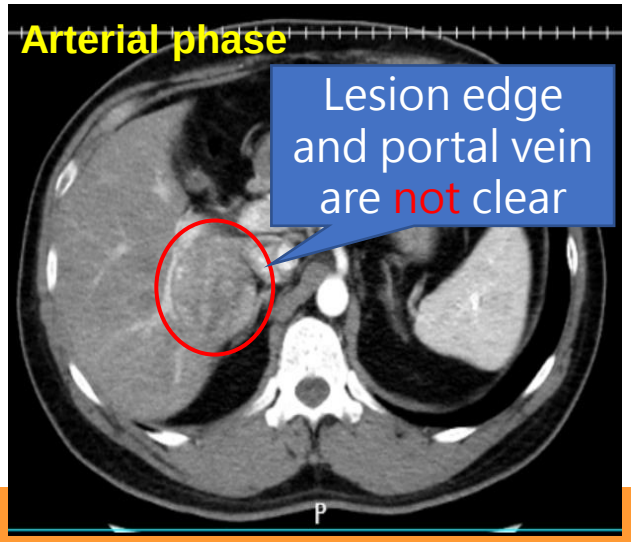


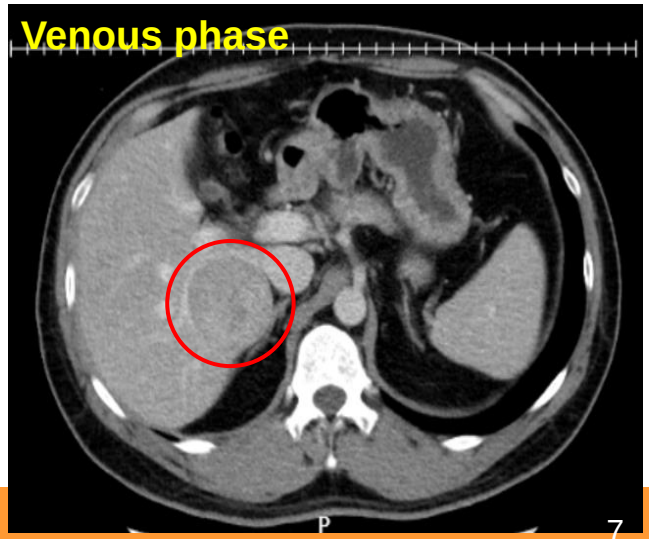




CT image (lower contrast , capillary is not clear)







MPB-1523 Detect Small HCC (<1.0 cm) with Well/Moderate Differentiated Type

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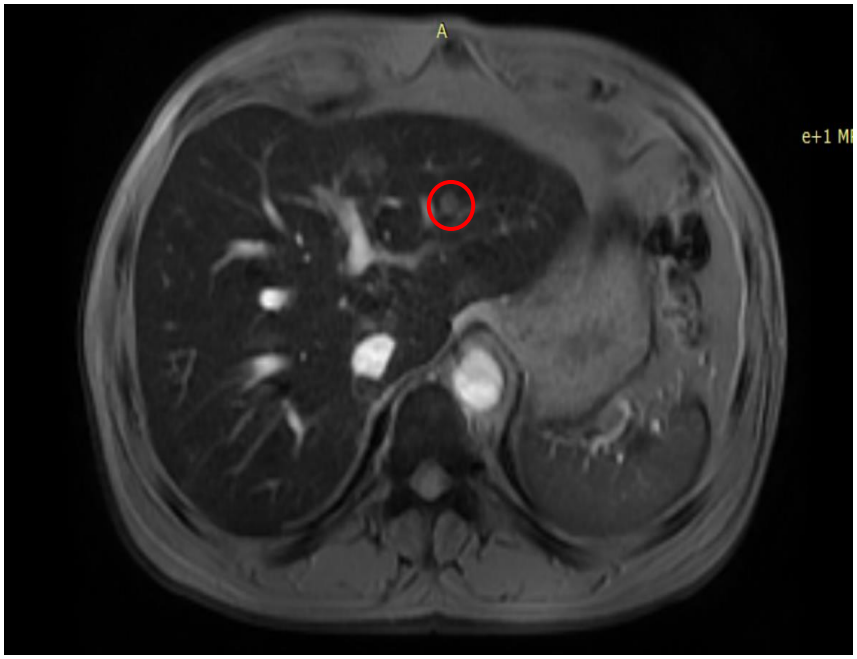
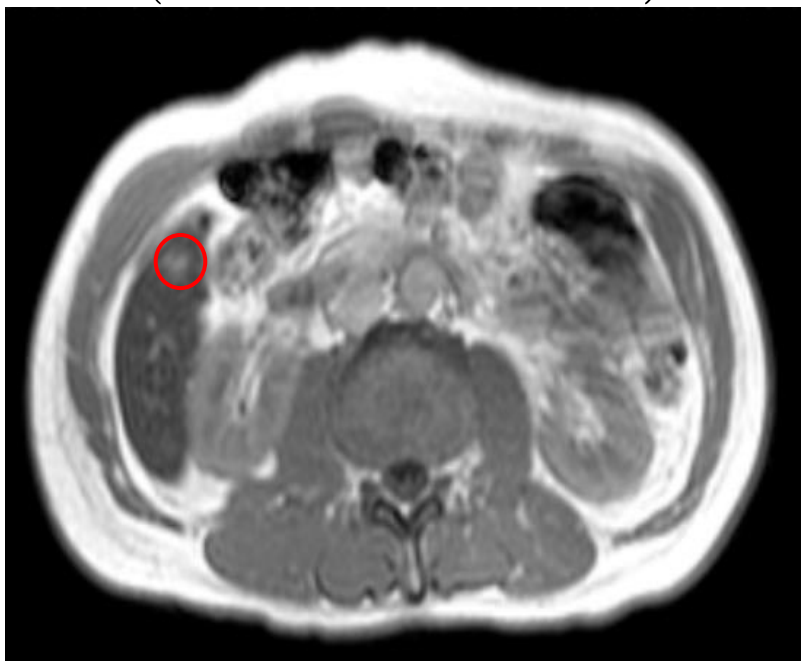
In well-differentiated HCC, Kupffer cell density would be maintained but Kupffer cell function could be reduced compared to surrounding liver. However, MPB-1523 still can detect small HCC (<1.0 cm) with well/moderate differentiated type.

Size: 1.5 cm * 1.0 cm
(well differentiated)



Size 0.9 cm *0.7 cm
(moderate differentiated)



MPB-1523 The safety is better

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- There are only two drug relative AEs in MPB-1523 phase 2 trial, rash (grade 1) and pruritus (grade 2).

  The DRAE percentage of MPB-1523 phase 2 trial is only 3.84%, which is better than Resovist 14.8%, an old iron oxide nanoparticle product.

Table 14.3.1.4 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Severity (Safety Population)

System Organ Class Preferred Term	Severity	Statistic	All Subjects (N =52)
Pruritus	Mild	n (%) E	0
	Moderate	n (%) E	1 (1.92) 1
	Severe or worse	n (%) E	0
Rash	Mild	n (%) E	1 (1.92) 1
	Moderate	n (%) E	0
	Severe or worse	n (%) E	0

E: Number of events; N: Number of subjects in the safety population; n: Number of subjects with adverse event with particular severity;

%: Calculated using the number of subjects in the safety population as the denominator (n/N*100).

All adverse events are coded using MedDRA version 20.0.

MPB-2043 MRI Contrast Agent for Lymph Node Image

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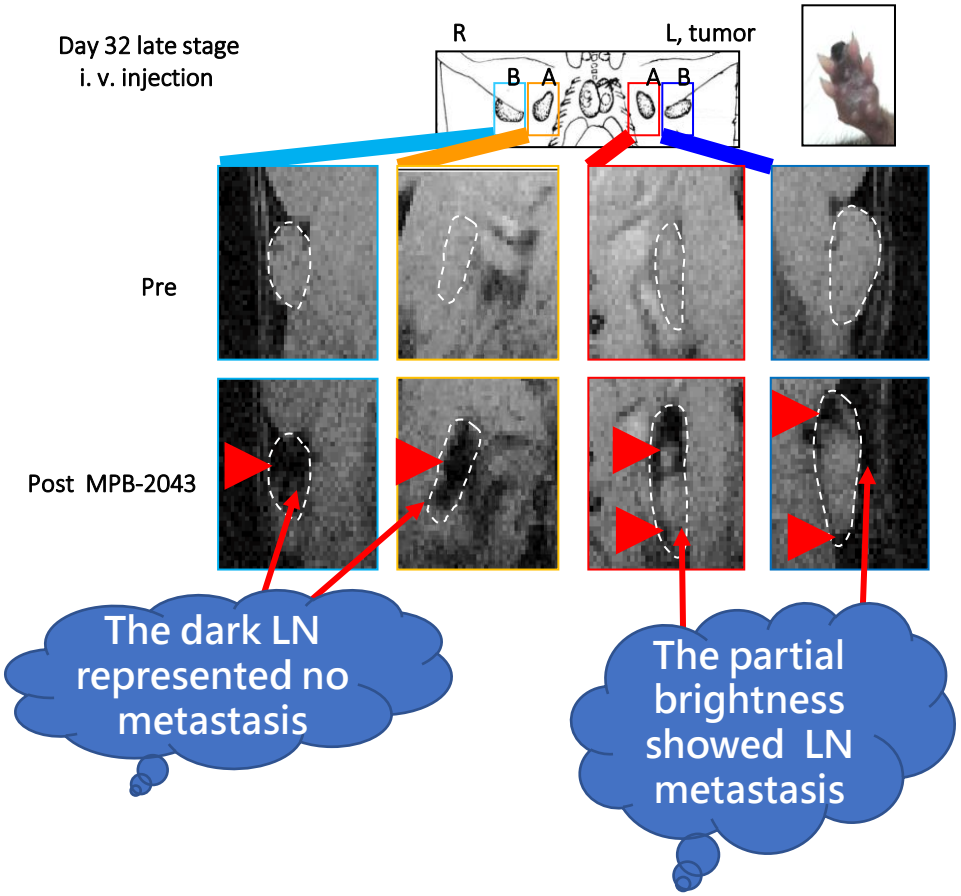

- ✓ Staging of cancer is dependent upon identification of LN meta.
- ✓ Precision lymphadenectomy is important to avoid the burden from the over-surgery.
- ✓ Not all LN can be reached by biopsy. The swollen LN can have many causes.
- ✓ Thus LN meta diagnosis remained to be the clinical unmet needs.

MPB-1734

An Immuno-Oncology Combination Therapy Candidate

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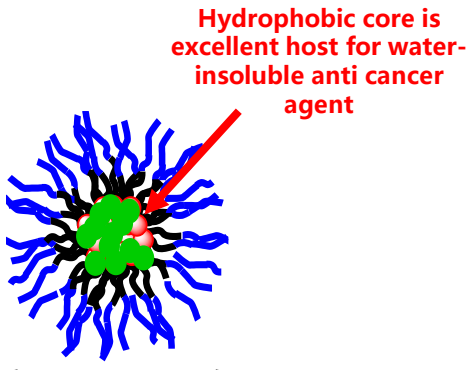
The Phase 1/2a of MPB-1734 approved by USFDA/TFDA and enrolling the patients now.

Tween 80 free formulation

- Improved safety (hypersensitivity), >1000 x solubility increased
- No steroid pre-treatment required.
- 1 vial package with simple preparation process

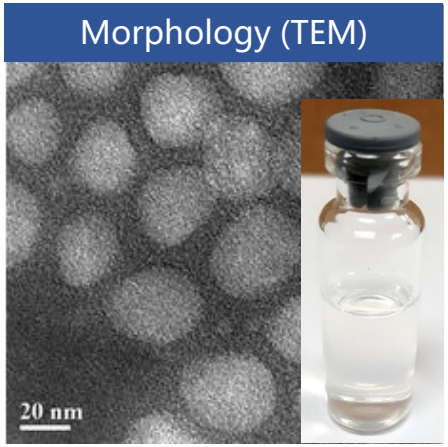


Reduced side effect:

- Reduction of major dose-limiting side effect (neutropenia and hypersensitivity)

Improved efficacy:

- Better drug targeting to tumor by nanosized particle (30~90 nm)
- Higher maximum tolerated dose
- Overcome taxane resistance



Benefit in combination

- Synergistic benefit in combination with immuno-oncology agents
- No steroid pre-treatment particularly well suited to combine with IO

MPB-1734

Combination Therapy with anti-PD-1-Ab in Murine H&N Cancer Model

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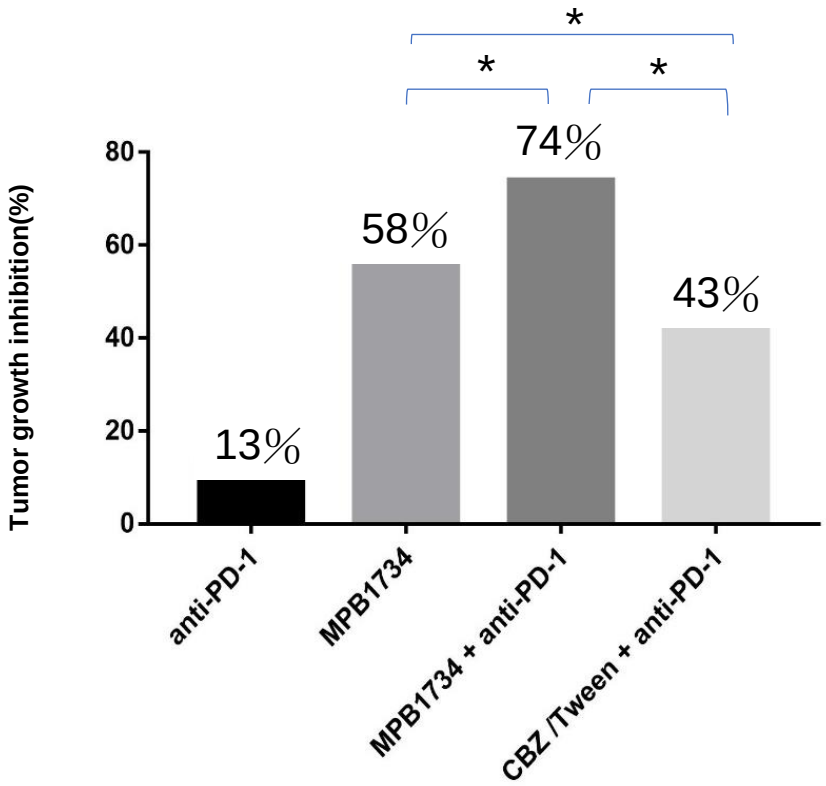
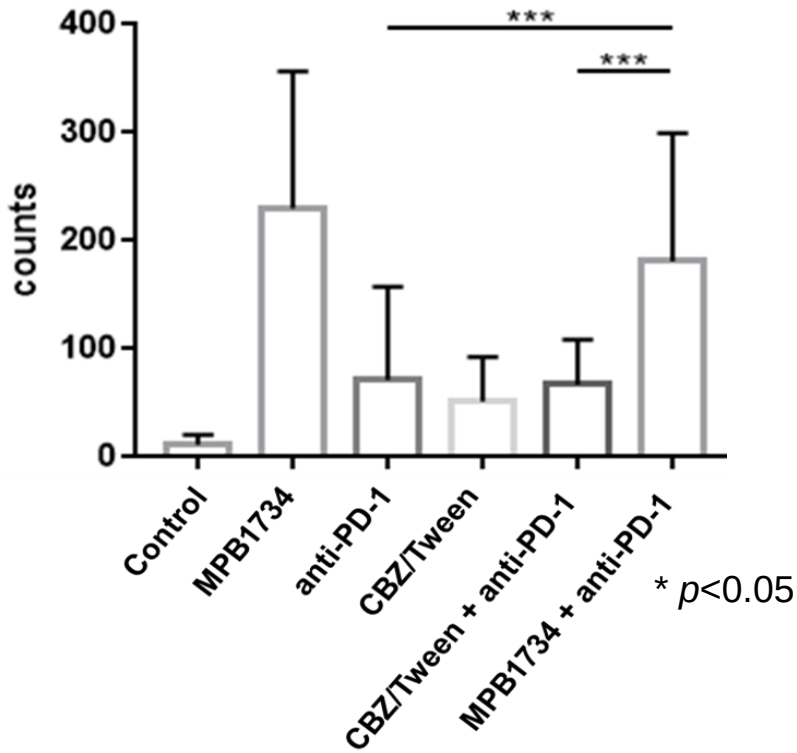
Cell line: MOCL2-1 (H&N cancer)

Tumor growth inhibition (%TGI)



CD8+ T cell counts (tumor)



* $p<0.05$

- Synergistic benefit in combination with immuno-oncology agents anti-PD-1
- CD8+ T cells in tumor region significantly increased for MPB-1734 groups. Original cold tumor might be potentially turned toward hot tumor after MPB-1734 treatment

MPB-1734 US FDA IND for Phase 1/2a Approved

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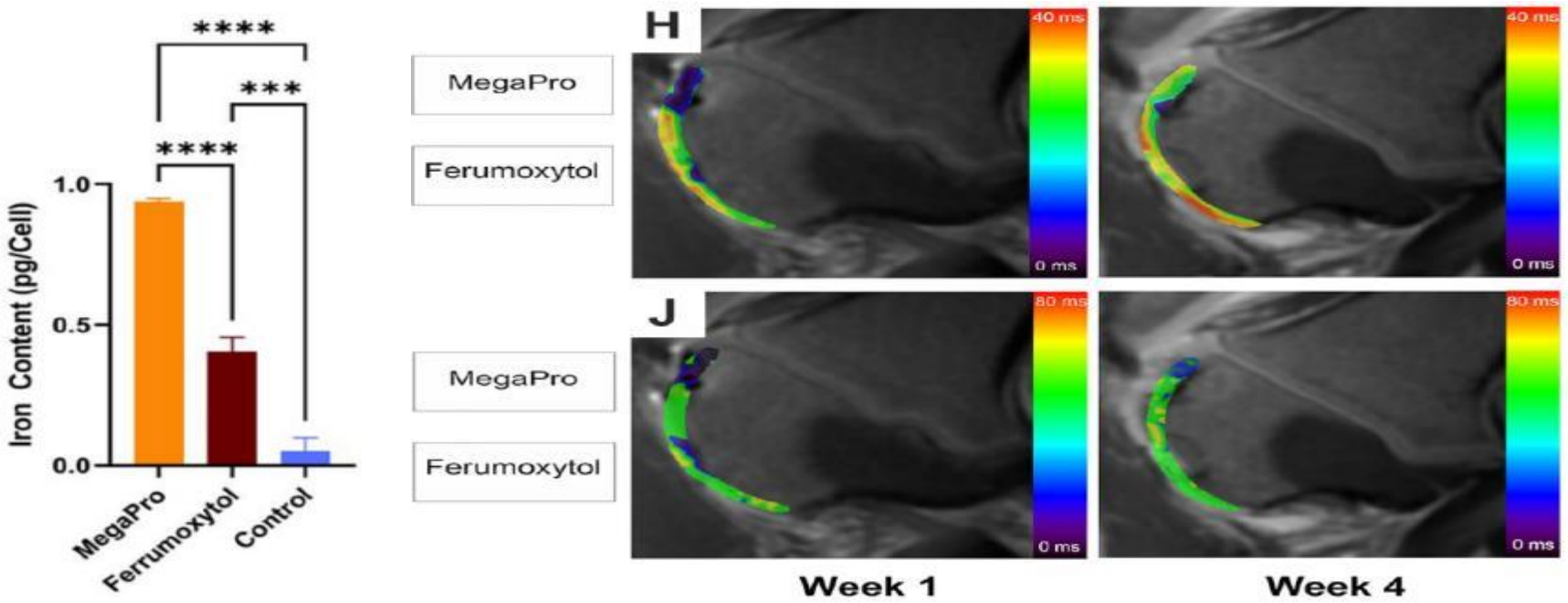
- ✓ USFDA/TFDA approved MPB-1734 phase I/IIa clinical study.
- ✓ Will enroll advanced solid tumor patients (including ovarian, SCHNN, prostate cancer)
- ✓ Up to 2023, two patients were enrolled in first cohort (10 mg/m^2) and no drug related AE were reported.
- ✓ MPB1734 + Immunoncology combination therapy will be the next target

Cell therapy

Tracking Chondrogenic Stem Cells for Cartilage Repair in Minipigs (Stanford U.)

Current findings

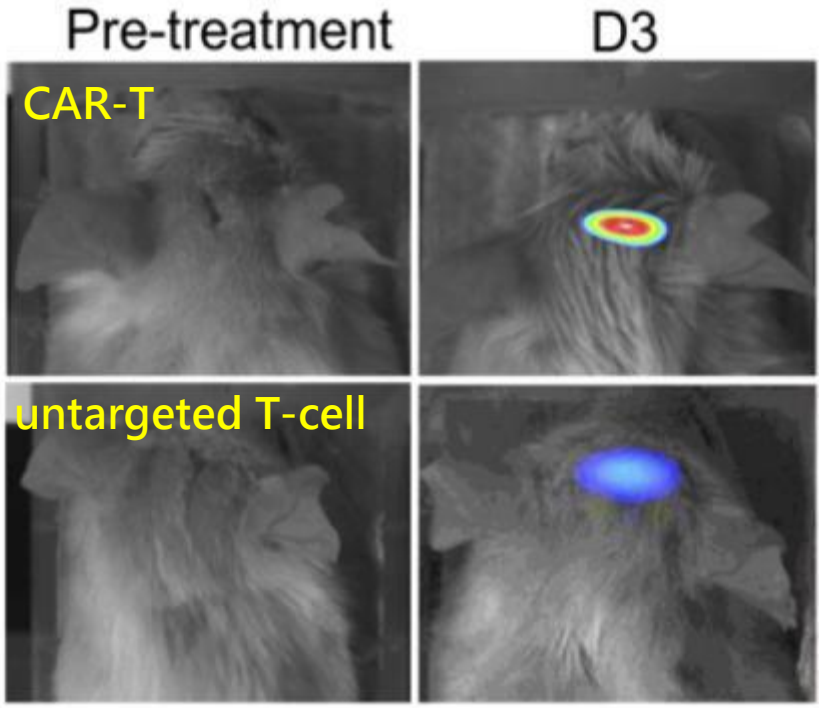
- Both IOP and Ferumoxytol showed hypointense (dark) signal at week 1.
- Ferumoxytol signal rapid loss at week 2 while IOP maintain signals for week 4.



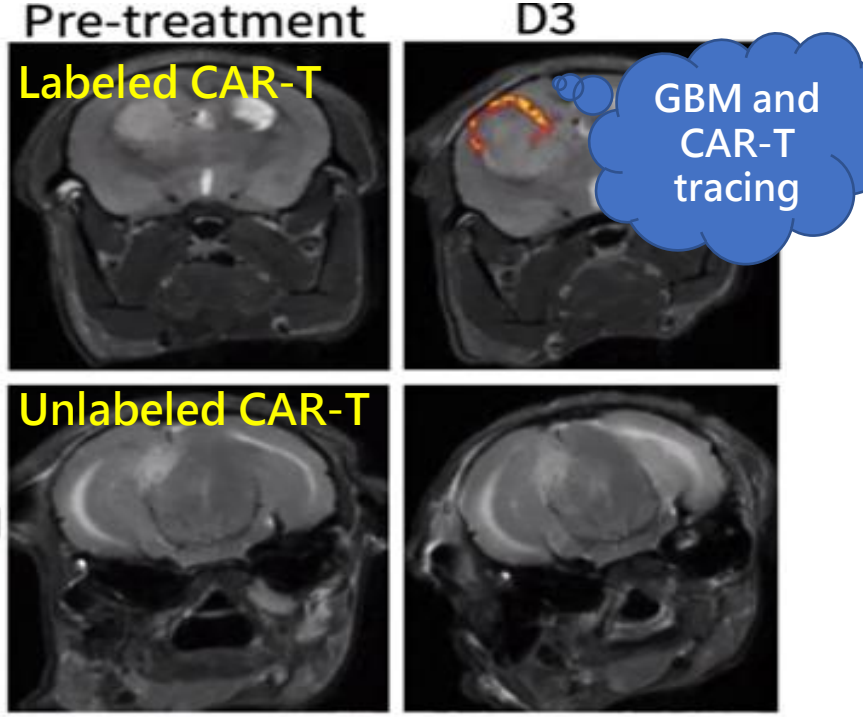
Real Time Cell Tracking - Collaboration with Stanford U.

- ✓ The absence of a clinically viable tracking technique for CAR T-cells has been recognized as a main hurdle to optimize CAR T cell therapy for solid tumors.
- ✓ **Multimodal in vivo tracking of CAR T-cells in preclinical glioblastoma models by MPB-1523 (*Investigative Radiology, 2022*)**

CAR-T vs untargeted T-cell



Labeled CAR-T vs unlabeled CAR-T



Goals

Development Strategy

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Short Term

- To out-license and collaborate with MNC on MPB1523/1514 NDA development

Mid Term

- Enter into Immuno and Cell Therapy Domain
- To apply NDA by MegaPro

Long Term

- Become a Specialty Pharmaceutical Company
- Double Engine to develop product pipeline and NDA application

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