巨生生醫 biomedical
MEGAPRO

Stock Code:6827

MegaPro Biomedical Co., Ltd.

-505(b)(1) and (2) new drug development company

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Platform 505(b)(1) & (2) dual platform

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Platform	code	Indication	Research	Preclinical	Phase I	phase II	phase III
Nano Particle (Iron Oxide Particle)	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)			Prepare Phase 2 study (US/TW)		
	MPB-2354	Cell therapy			Prepare Phase 1 study		
	RD-001	Vaccine Adjuvant			RD		
	RD-002	Cell Imaging			RD		
	RD-003	Hyperthermia			RD		
Nano-micelles	MPB-1734	Oncology			Phase 1/2a on going (US/TW)		
	RD-004	CNS			RD		

Nanoparticles 505(b)(1) plantform

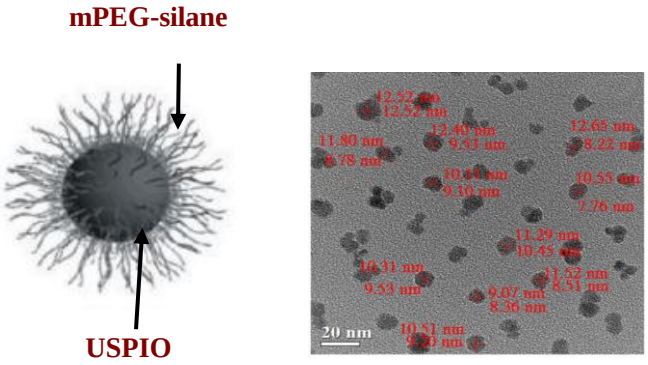
Stock Code:6827

◆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
e. Low FGF23 (fibroblast growth factor 23) elevation to avoid severe hypophosphatemia and long-term inflammation.

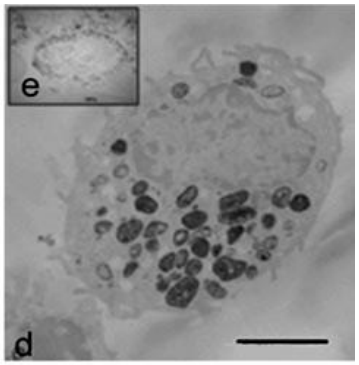
	IOP Injection	Feraheme
Size (TEM)	10-12 nm	4.2 nm
r2 $(mM \cdot s)^{-1}$*	130~170	70

MegaPro: IOP Injection

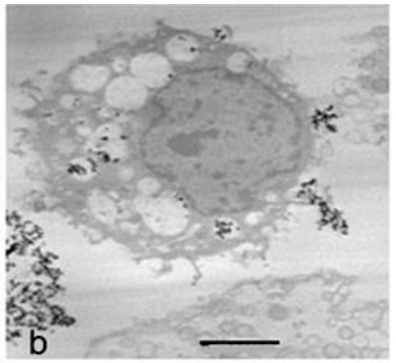


Macrophages uptake efficiency

IOP Injection



Feraheme

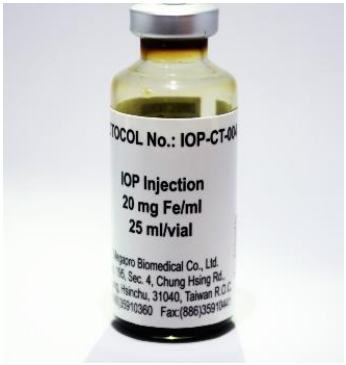


MPB-1514

The next-generation high-dose injectable iron preparation for the treatment of iron deficiency anemia

Stock Code:6827

Status	Phase 2a completed
Mechanism	High macrophage uptake efficiency with high conversion of ferritin and transferrin saturation; low labile iron generated
Position	High dose intravenous iron (IV iron) with higher potency and better safety profile
Indication	Iron deficiency anemia (IDA)
Patent	Comprehensive global patent portfolio

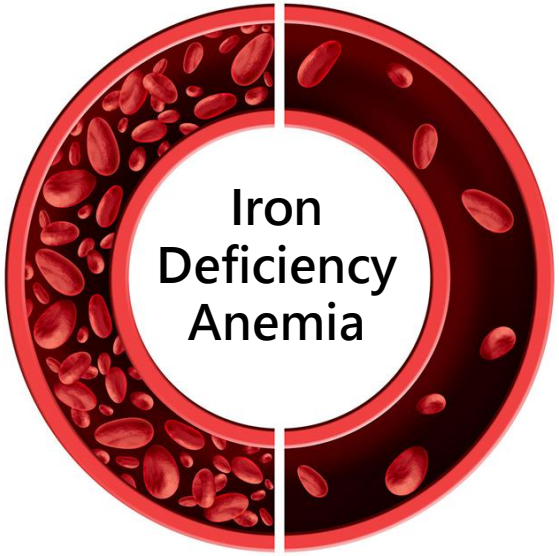


MPB-1514 Iron Deficiency Anemia Market Overview

Stock Code:6827

Indications (Patients number)

- CKD USD 684M
- Oncology USD 571M
- IBD USD 456M
- Heart Disease USD 214M
- Others USD 303M



2020 Total I.V iron Market $2,228M
CAGR rate ：9.3%

I.V iron product

- Ferinject USD 1,351M
- Venofer USD 371M
- Monofer USD 46M
- Feraheme USD 73M
- Others USD 387M

MPB-1514 Intravenous Iron Products Overview

Stock Code:6827

Best

	Venofer	Feraheme	Ferinject/ Injectafer	Monofer	MPB-1514
Approved(US)	2000	2009	2013	2020	Phase 2a
Type of Iron	Ferric hydroxide	Iron oxide	Ferric hydroxide	Ferric hydroxide	Iron oxide
Coating material	sucrose	dextran	Carboxy-maltose	Isomaltosid e-1000	PEG
Dose	100mg x 10	510 mg × 2	750 mg × 2	1000mg~ 2000mg	250 mg × 2
Hb (g/dL)	0.3-0.8	0.82 ± 1.24	1.13 ± 1.04	0.5-1.22	1.7 ± 1.27
Induced Hypo-phosphatemia	~4%	<2%	40-70%	4-8%	Not observed

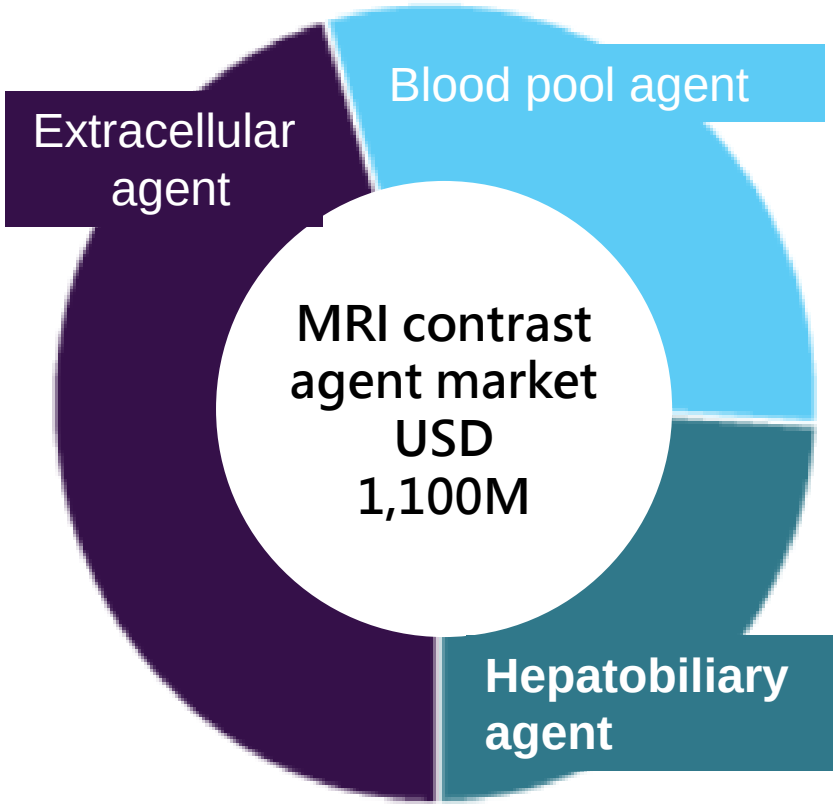
1. Results were adopted from FDA assessment report of Feraheme
2. Results were adopted from Injectafer's label

MPB-1523 Liver-specific MRI contrast agent (505b1)

Stock Code:6827

Status	Clinical Phase II completed (in the US and Taiwan). USFDA End of Phase 2 (EOP2) achieved. Clinical Phase III IND submission is expected in the second half of 2024 (in the US, China, and Taiwan).
Indications	Primary hepatocellular carcinoma and metastatic liver cancer diagnosis.
Mechanism	• Excellent phagocytic activity of liver parenchymal immune cells. • High relaxivity (R2).
Position	• Non-heavy metal liver-specific MRI contrast agent. • Excellent safety profile with superior imaging performance and diagnostic rates.
Regulatory Pathway	• 505(b)(1) New Drug Application. • Orphan Drug Designation (USFDA): Liver cancer monitoring.
Market (China)	Potential usage approximately 3.6 million times, RMB 700 per dose, with an estimated market share of 15%, totaling around RMB 380 million.
Liscense Progress	Completed due diligence (DD) and term sheet with a listed company in China, currently under negotiation.

MPB-1523 Under-estimated market



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 2023 and approved for the tracking of hepatocellular carcinoma.

MPB-1523

Primovist confirmed vs MPB-1523

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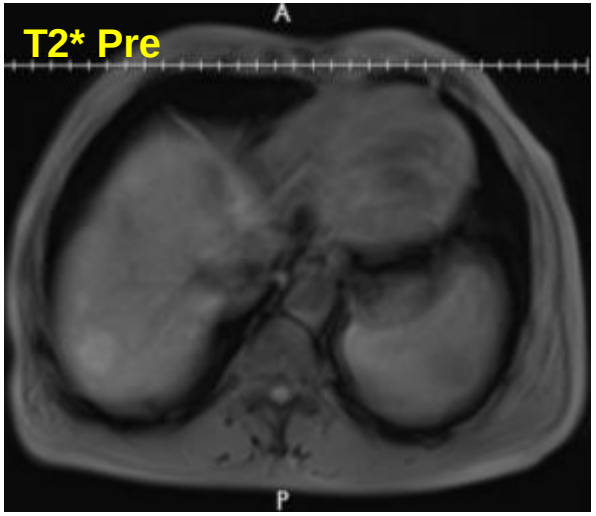
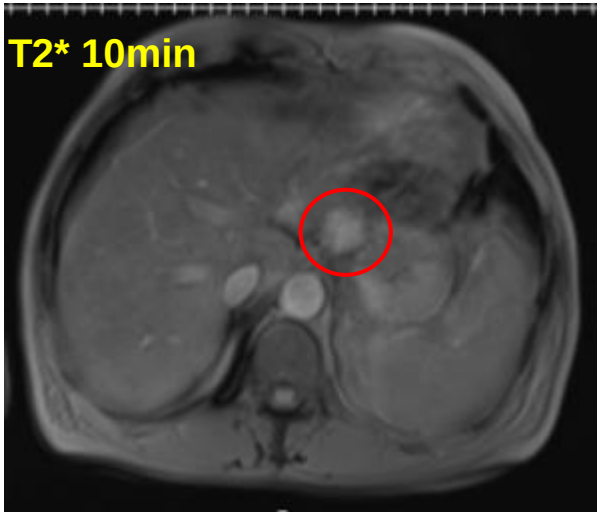
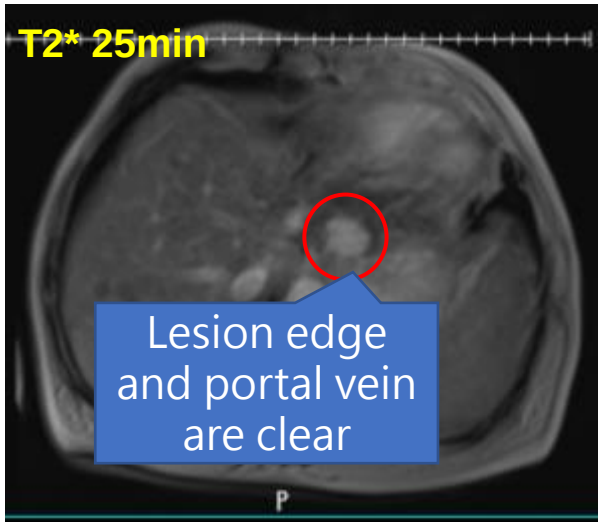
MPB1523 MR T2* image (excellent contrast, lesion edge is clear)

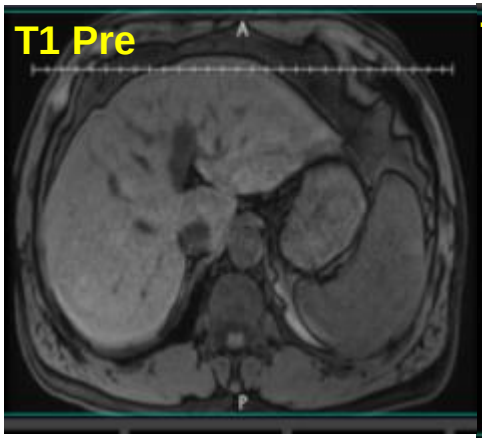
1-001-001

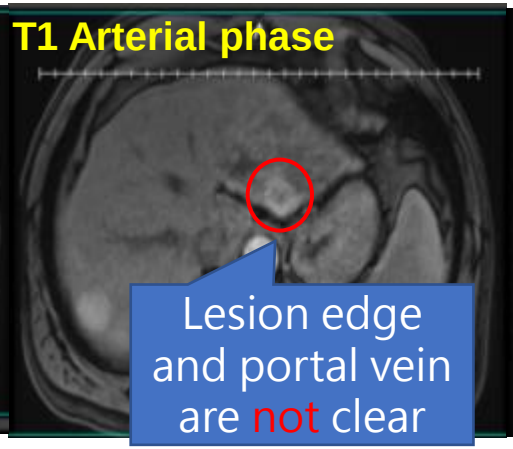


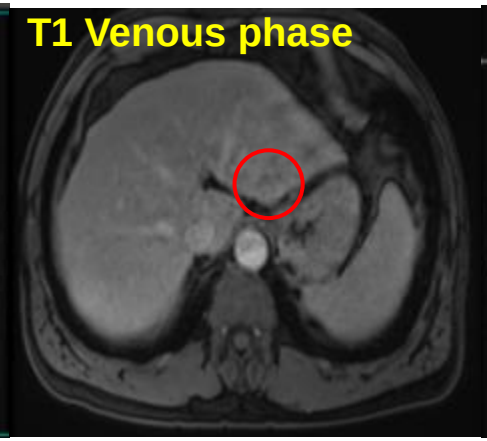


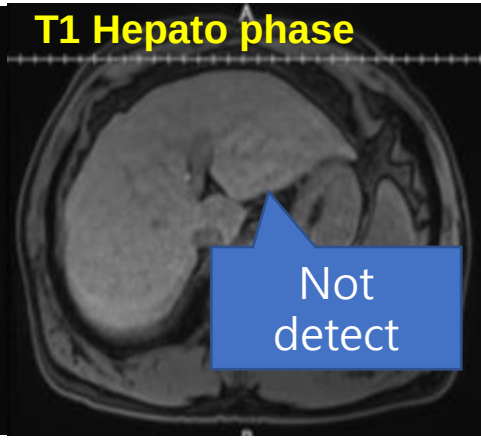


Primovist image(The lesion doesn't be detected in hepato pahse)









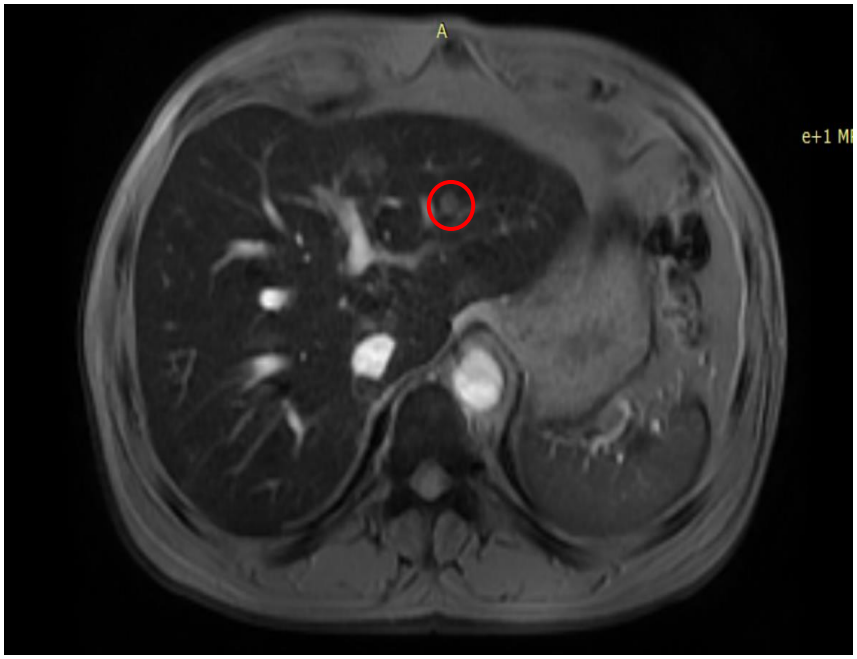
MPB-1523

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

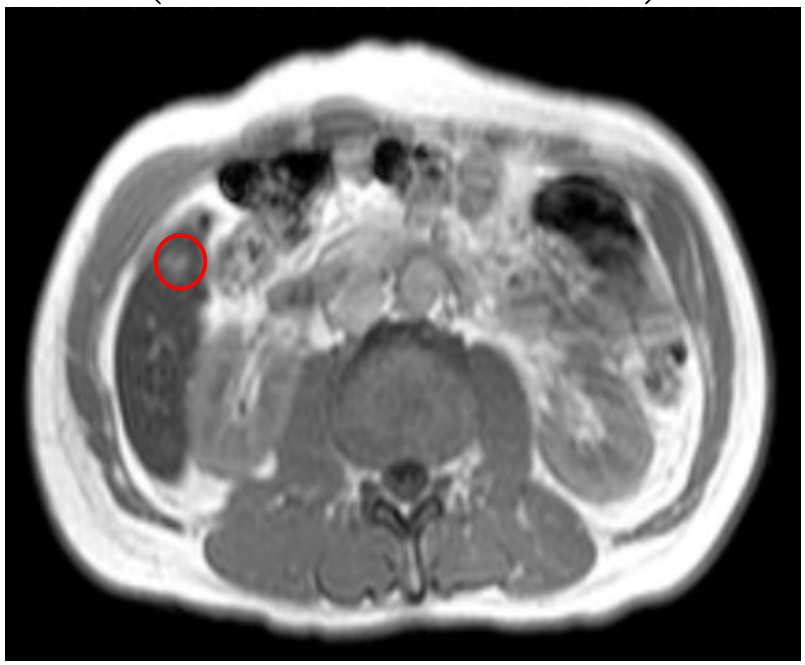
Stock Code:6827

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-2043

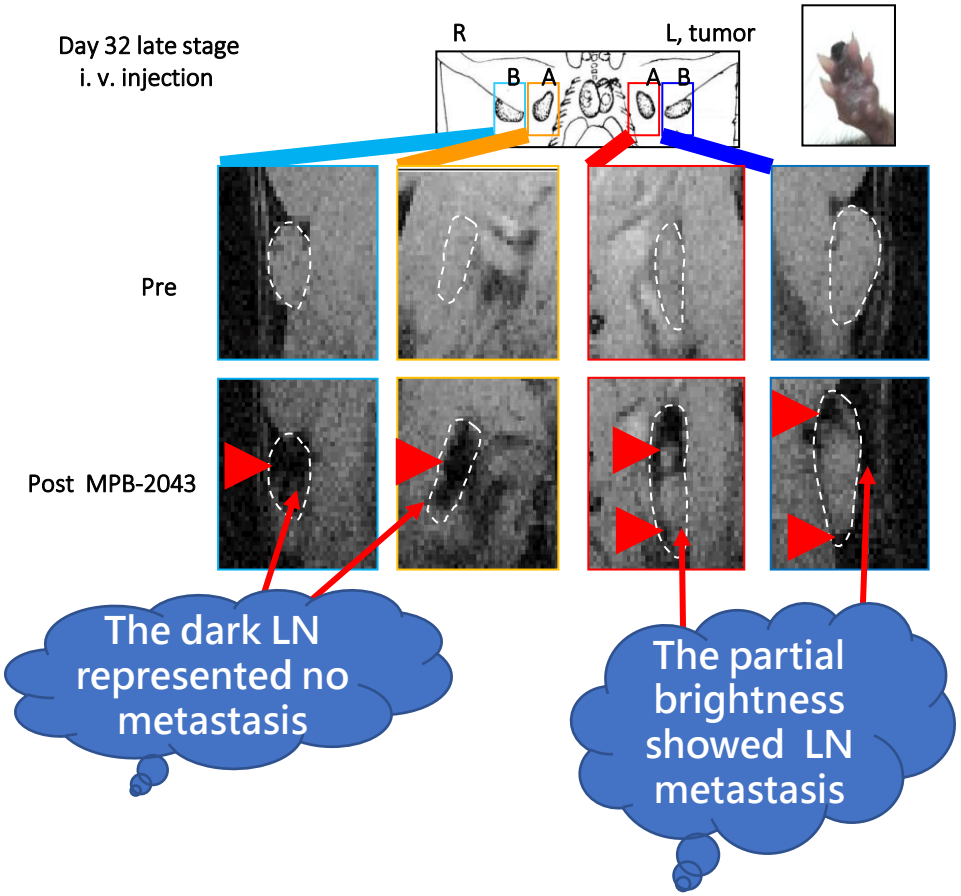
Focuses on diagnosing tumor cell lymph node metastasis

Stock Code:6827

Status	Investigator-initiated trial (TFDA), expected to commence patient enrollment in the second half of 2024
Indications	Focuses on diagnosing tumor cell lymph node metastasis.
Mechanism	• Excellent phagocytic activity of liver parenchymal immune cells. • High relaxivity (R2).
Position	• Currently, there are no clinically available diagnostic reagents for this purpose. • This diagnostic reagent meets an unmet need and offers high safety and diagnostic rates.
Regulatory Pathway	505(b)(1) New Drug Application.
Market (China)	Accurate lymph node metastasis diagnosis is crucial for breast cancer, prostate cancer, head and neck cancer, lung cancer, and others, with a potential market exceeding $1 billion USD.
Liscense Progress	• Completed due diligence (DD) and term sheet with a listed company in China, currently under negotiation. • Discussions are also ongoing with a major Japanese contrast agent manufacturer.

MPB-2043 MRI Contrast Agent for Lymph Node Image

Stock Code:6827



- ✓ 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-2043 Will begin to enroll in 2024H2

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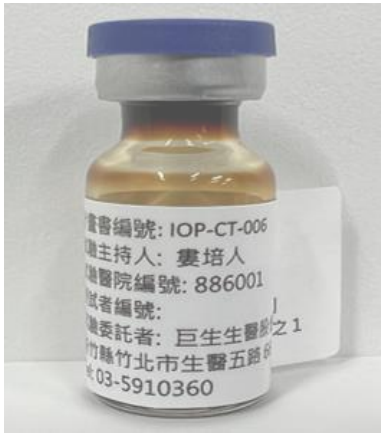
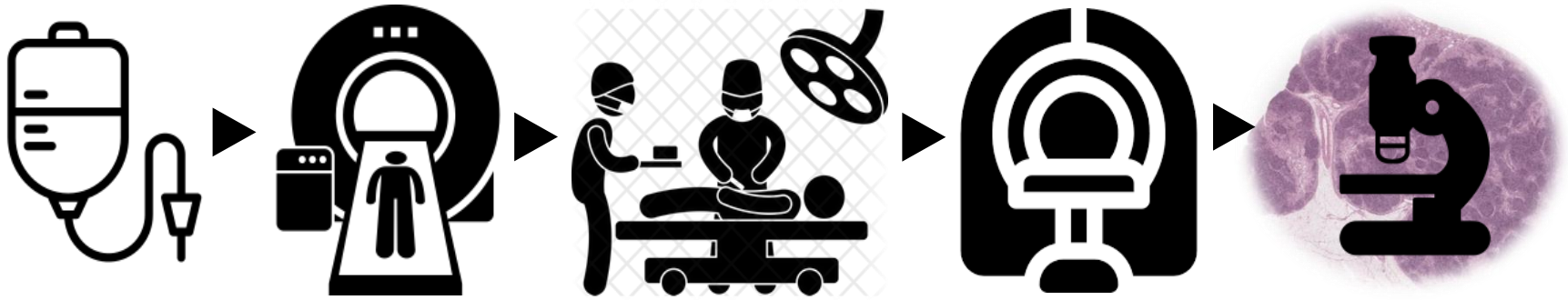


- TFDA has approved the IIT trial.
- Collaboration with National Taiwan University Hospital
- There exists an unmet clinical need for lymph node imaging.



IOP Injection infused 60 mins

3T MR Scan T1/T2/T2*

Lymphadenectomy

Ex vivo MRI For Specimen

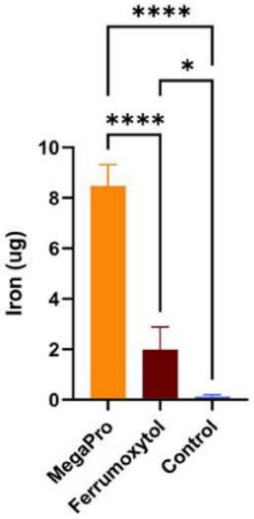
Lymph nodes histopathology

Cell tracking platform

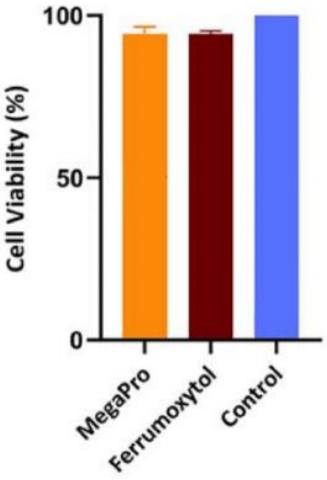
Stock Code:6827

- MRI is considered the best imaging tool for in vivo cell tracking (no penetration depth issues, repeatable examinations...).
- Currently, there are limitations in the sensitivity and detection time for cellular MRI imaging.

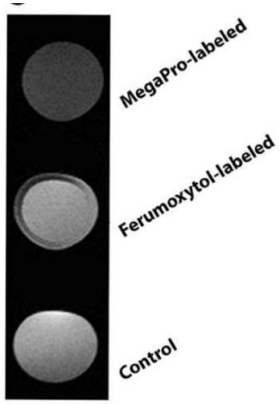
High uptake efficiency



No toxicity



High MRI (T2) contrast



Ferumoxytol: The only commercially available product now.

Key features of the Macrocellular Imaging Platform:

- High cellular uptake of IOP without cytotoxicity, preserving cell phenotype.
- High sensitivity in cellular MRI detection, with extended detection time upon implantation.
- IOP possesses comprehensive safety data in both animals and humans, supporting rapid clinical translation of relevant cellular applications.

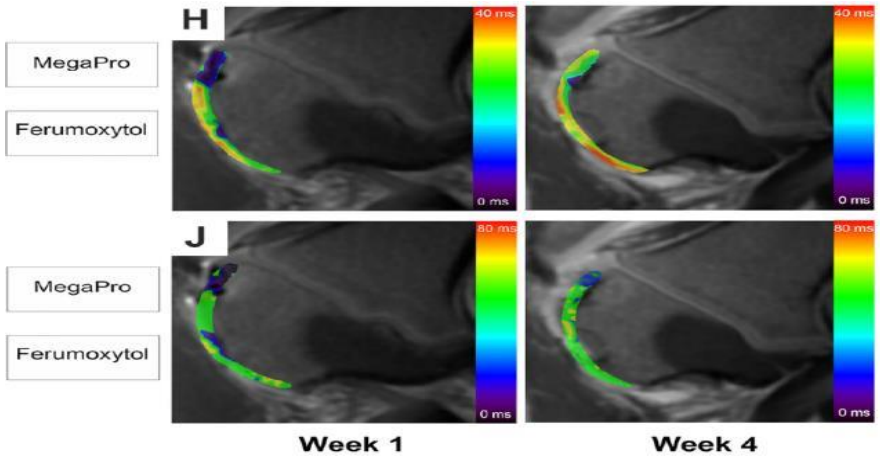
Cell therapy

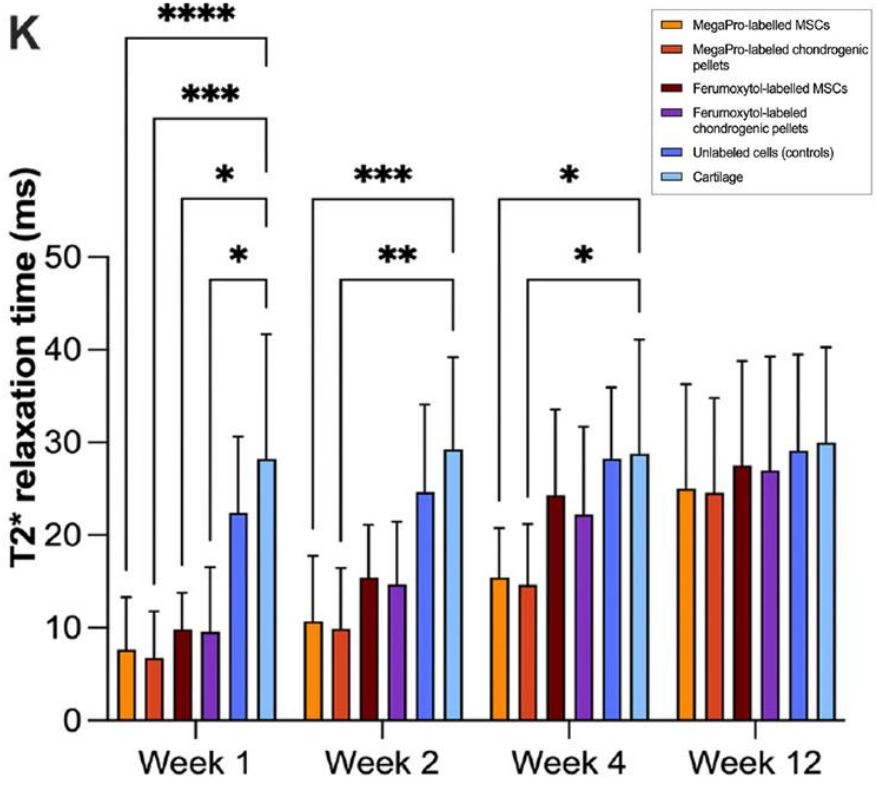
Tracking Chondrogenic Stem Cells for Cartilage Repair in Minipigs (Stanford U.)

Stock Code:6827

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.





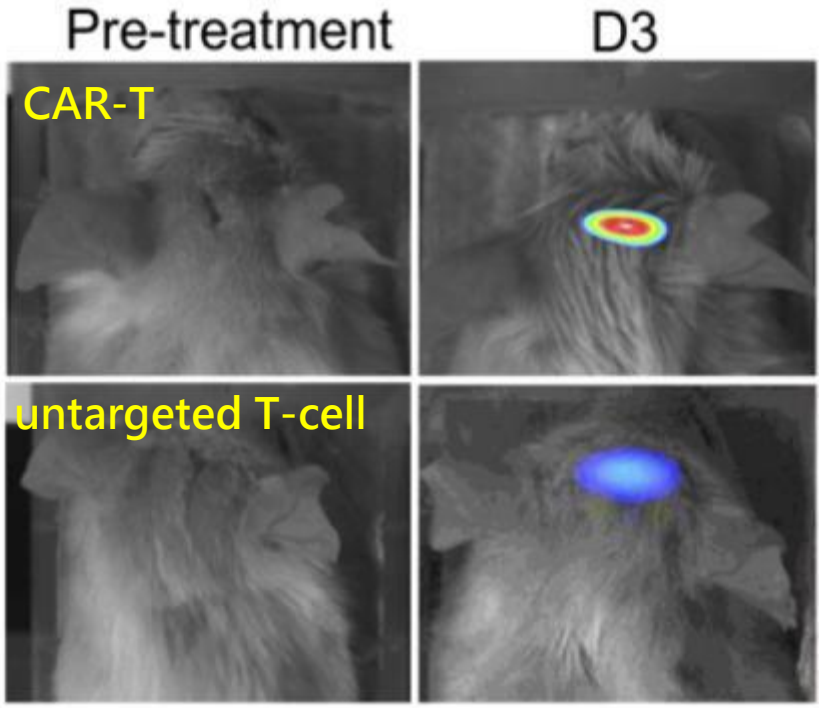
CAR-T

Real Time Cell Tracking - Collaboration with Stanford U.

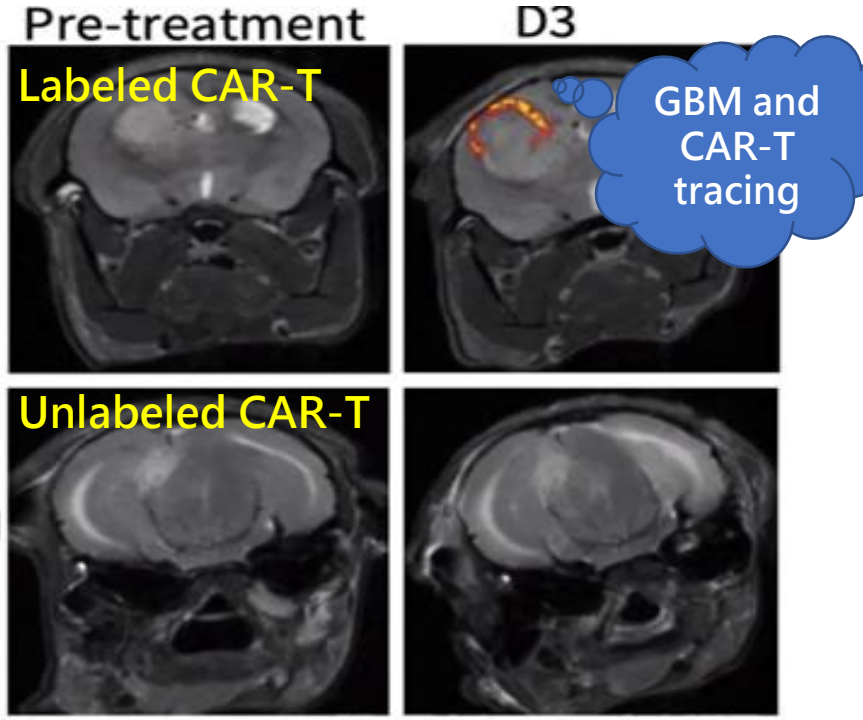
Stock Code:6827

- ✓ 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



MPB-2354

Allogeneic stem cell with dual functions of enhanced anti-inflammatory effect and in vivo cell tracking

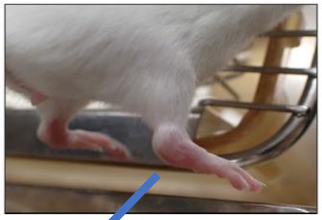
Stock Code:6827

Status	Pre-clinical studies (begin Phase 1 clinical trials in 2025)
Indications	Inflammatory and autoimmune disorders.
Mechanism	• By using IOP to enhance the expression of IDO in stem cells, the anti-inflammatory effects can be improved. • The in vivo tracking function helps reduce treatment disparities and individual differences, thereby enhancing treatment efficacy.
Position	• Current allogeneic stem cell therapies have not met expectations, with no method for predicting efficacy. • MPB-2354 offers both therapeutic enhancement and in vivo tracking capabilities, potentially improving treatment outcomes and addressing the current inability to predict treatment efficacy.
Regulatory Pathway	505(b)(1) New Drug Application.
Patent	A PCT patent application has been completed.

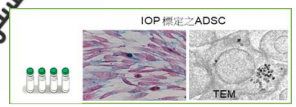
MPB-2354 In vivo imaging by MRI

Stock Code:6827

Intra-articular injection

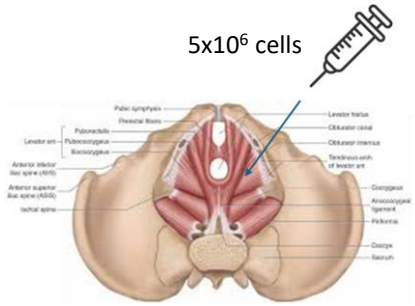


5x10^6 cells



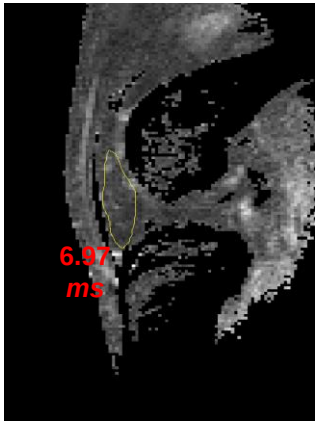
Intra-perineum injection

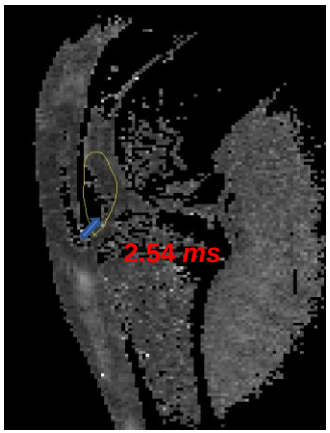
5x10^6 cells

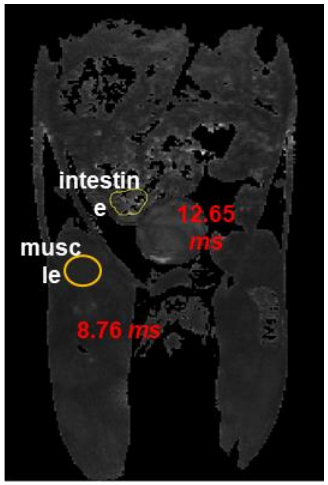


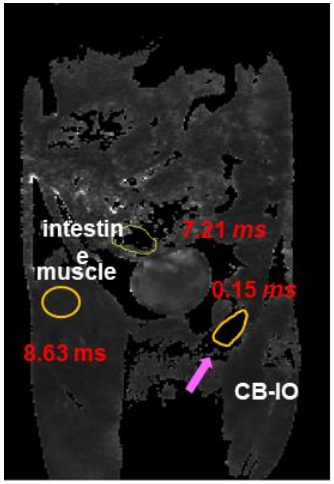
Pre-injection

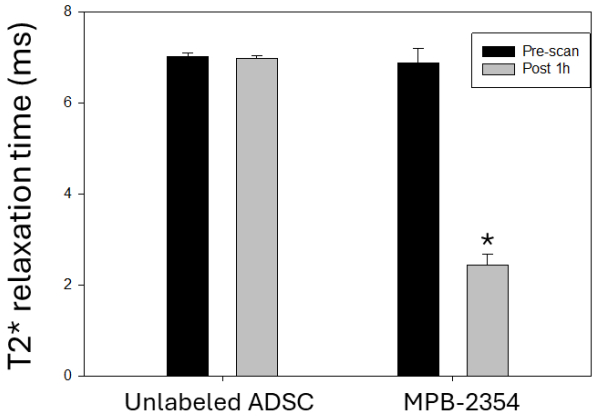
Post-injection

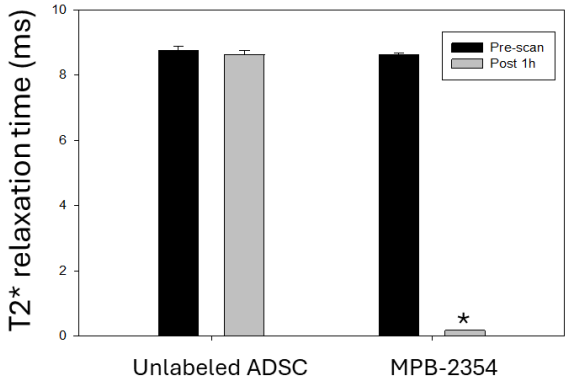












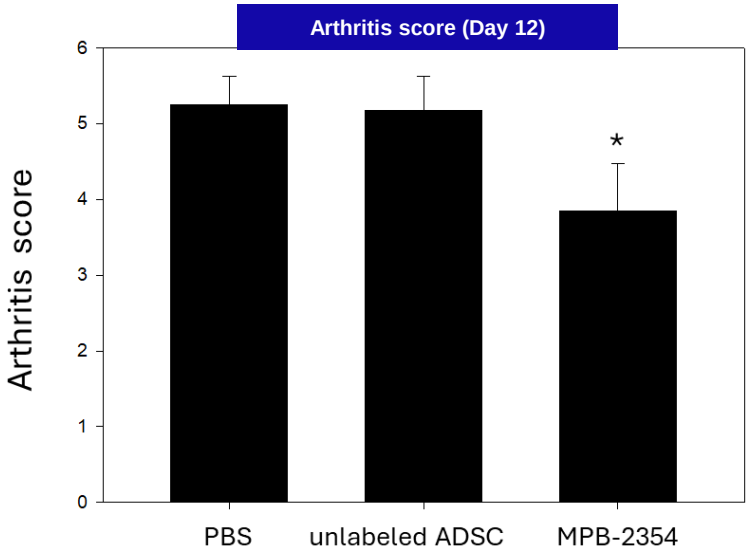
* p<0.05 pre vs post

7T MRI scanning showed a significant decline of the T2*-signal in injection site

MPB-2354 In vivo efficacy

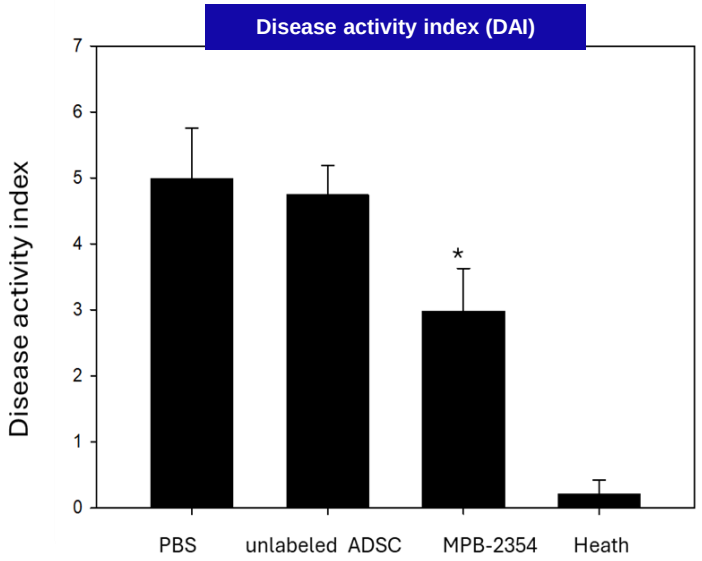
Stock Code:6827

Rheumatoid arthritis (RA)
Collagen-induced Arthritis (CIA) rat model



* $p<0.05$ MPB-2354 vs unlabeled ADSC

Inflammatory Bowel Disease (IBD)
Dextran sulphate sodium (DSS) induced colitis mice model



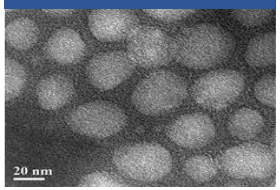
- MPB-2354 demonstrated superior efficacy to unlabeled ADSCs
- Treg cells infiltration ↑, TGF-β↑ and IL-10↑， proinflammatory cytokines IL-6 ↓ in RA bone tissue. (vs unlabeled ADSC)

Nanomicelle

The best hydrophobic drug injectabl nanocarrier technology on the market

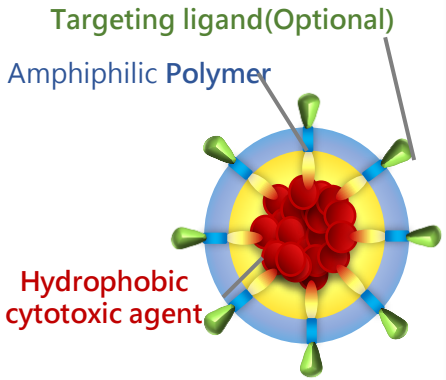
Stock Code:6827

Morphology (TEM)



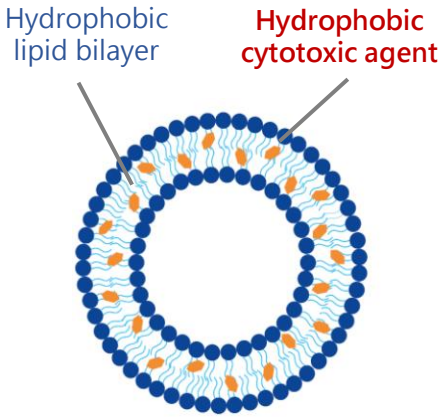
Nanomicelle

- Physical encapsulation, high loading capacity for hydrophobic drugs (>20%).
- Excellent tumor penetration ability (<70nm).
- Can be combined with targeting ligands.



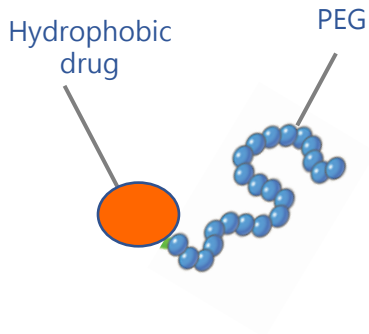
Liposome

- Physical encapsulation, hydrophobic drug loading capacity of approximately 3~5%.
- Typical particle size range is 100–200 nm



PEGylation

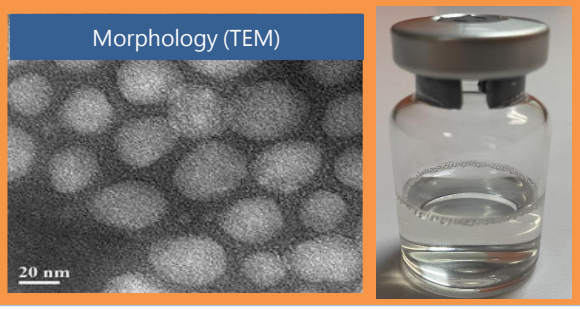
- Chemical bonding, more complex process.
- A single polymer can only bond 1~4 molecules



MPB-1734

Jevtana (Cabazitaxel) Second generation taxane to overcome taxane resistance

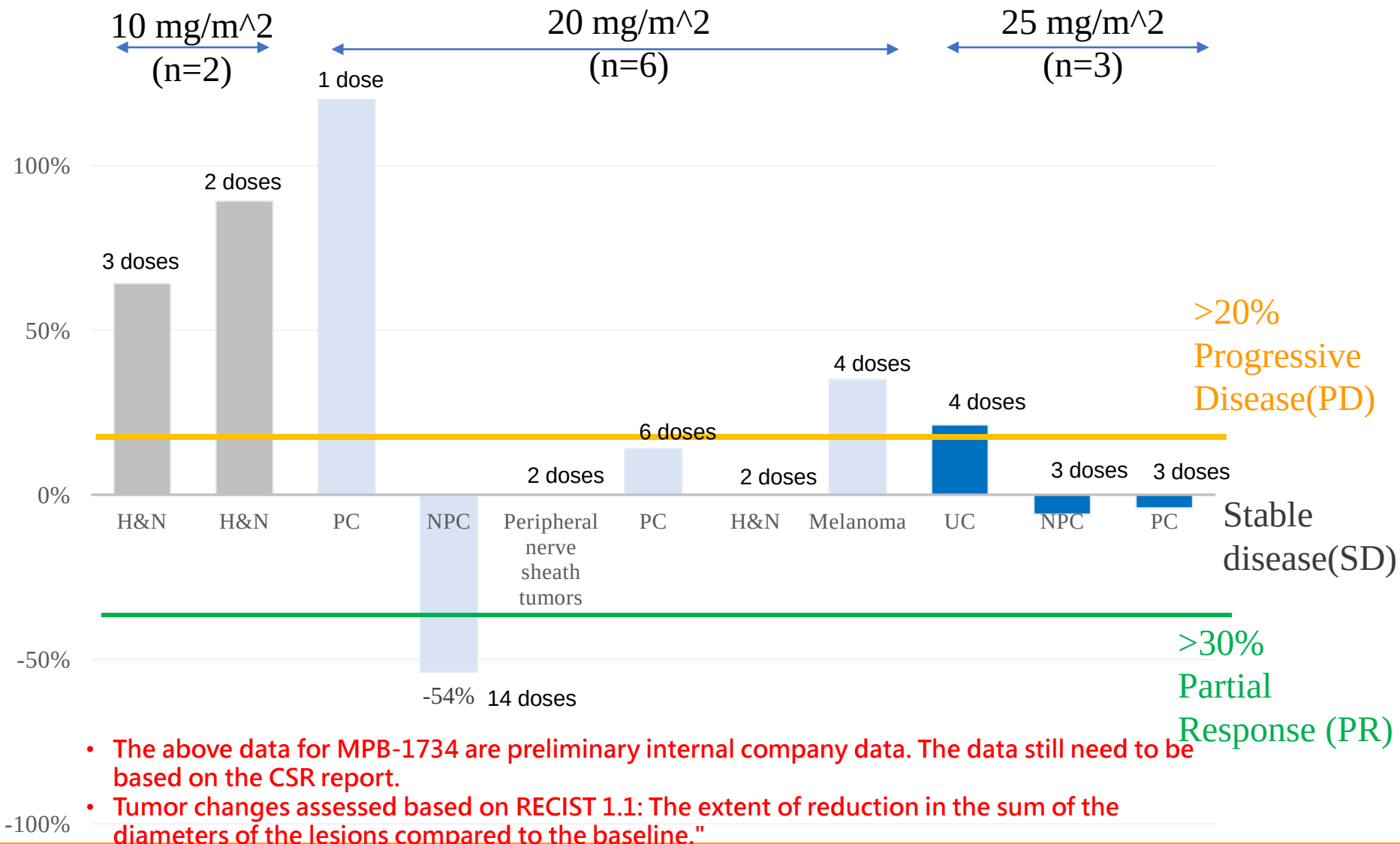
Stock Code:6827

	巨生 MPB-1734	Sanofi Jevtana
		
Patent	**Obtained a composition patent in 2022 in US**	**Expired**
Solubility	**>1000 x solubility increased**	**Very low water solubility**
Hypersensitivity	**No steroid pre-treatment required.**	**Hypersensitivity is mainly caused by excipient Tween 80(Black box warning)**
Severe low neutropenia	**Reduction of neutropenia**	**80% patients experienced life-threatening neutropenia (Black box warning)**
Indication	**Focus on Head & neck and Prostate cancer**	**Only Prostate cancer, the sales peak is USD 633M in 2020**

MPB-1734

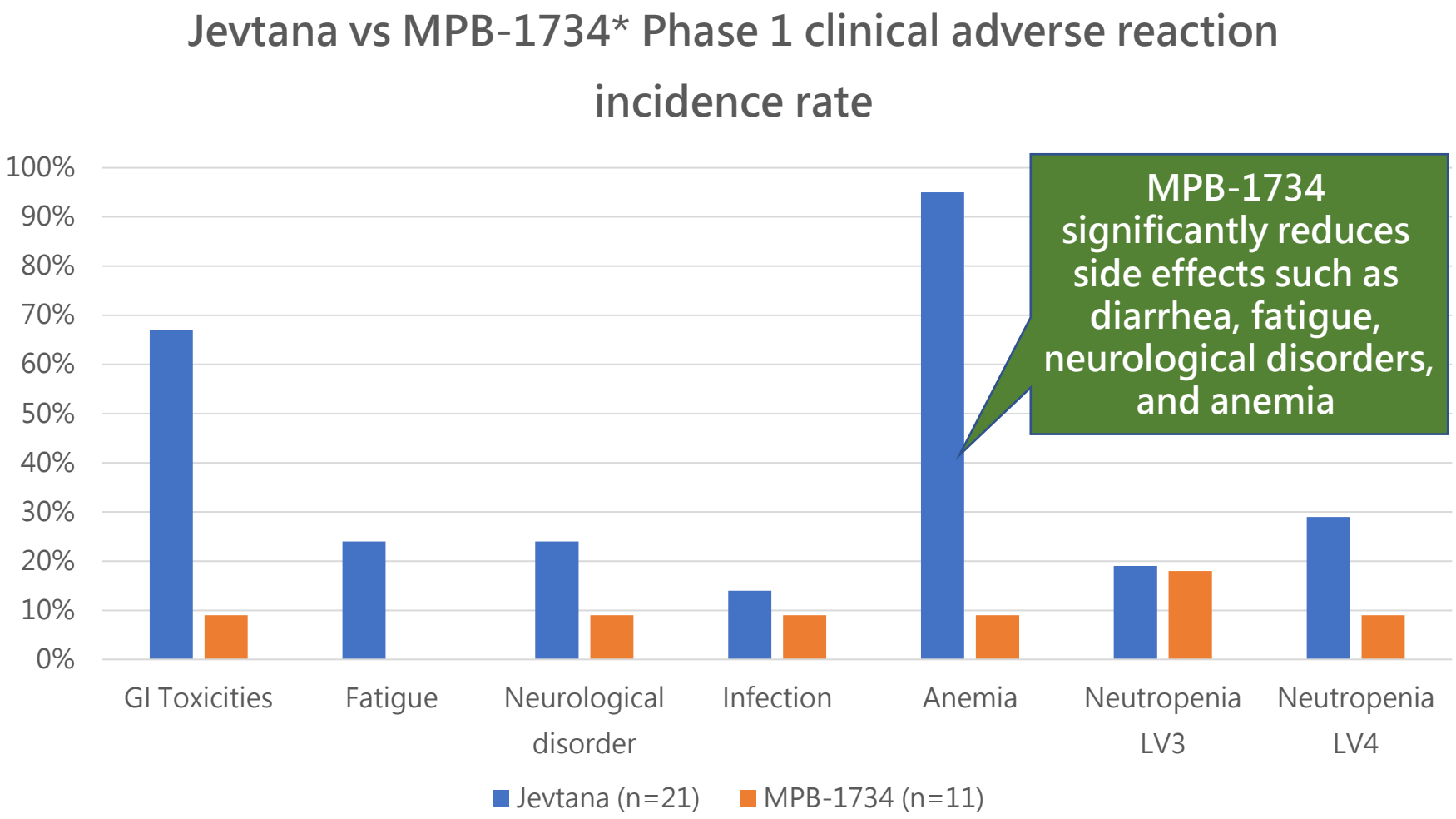
Preliminary tumor change analysis in clinical trials

Stock Code:6827



- The above data for MPB-1734 are preliminary internal company data. The data still need to be based on the CSR report.
- Tumor changes assessed based on RECIST 1.1: The extent of reduction in the sum of the diameters of the lesions compared to the baseline."

Significantly improve the safety of the Jevtana



*The above data for MPB-1734 are preliminary internal company data. The data still need to be based on the CSR report.

MPB-1734 Summary

1. USFDA/TFDA approved MPB-1734 phase I/IIa clinical study.
2. Will enroll advanced solid tumor patients (including ovarian, SCHNN, prostate cancer). Up to 2023, the 4th cohort (30 mg/m^2) is enrolling (Jevetana only approved 20 mg/m^2), and no drug related AE were reported. The 2nd/3rd cohort (20 & 25 mg/m^2) has four subjects with their conditions under control and are currently receiving medication.
3. The phase 2a clinical trial will assess prostate cancer and head and neck cancer. It will explore the possibility of combination therapy with anti-PD-1 and hormonal drugs.
4. MPB-1734 obtains the government grant and will receive NTD 14,370K.
5. MPB-1734 has begun to prepare the global licensing.

Development Strategy

Short Term

- To out-license and collaborate with MNC on MPB1523/1514 NDA development
- By using a multi-country and multi-center approach, obtain drug approval for MPB-1523 and MPB-1514 through licensing or co-development models.
- Complete MPB-2043 IIT data.

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


Thank You