巨生生醫 biomedical
MEGAPRO

Stock Code:6827

MegaPro Biomedical Co., Ltd.

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

President, Yuan-Hung Hsu, Ph.D.
yuanhsu@megaprobio.com
www.megaprobio.com

DISCLAIMER

- This material has been prepared by MegaPro Biomedical Co., Ltd. (“Megapro”).
- Any opinions expressed in this material are subject to change without notice as a result of using different assumptions. Megapro is under no obligation to update or keep current the information contained herein. The information contained in this presentation is Megapro’s confidential information.
- Any disclosure, copying, distribution or any action taken or omitted to be taken in reliance on it is prohibited and maybe unlawful.
- Statements made in this material include forward-looking statements, which include, without limitation, statements about the issues, plans and expectations of Megapro. Without limiting the foregoing, statements including the words “believes”, “anticipates”, “plans”, “expects” and similar expressions are also forward-looking statements. Forward looking statements reflect, among other things, management’s plans and objectives for future operations, current views with respect to future events and future economic performances and projections of various financial items. These forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause actual results to differ materially from those implied by such forward-looking statements.
- No representation or warranty, express or implied, is or will be made in or in relation to, and no responsibility or liability is or will be accepted by the Company as to, the accuracy or completeness of this material and any liability therefore is hereby expressly disclaimed.

Platform 505(b)(1) & (2) Dual Platform

Stock Code:6827

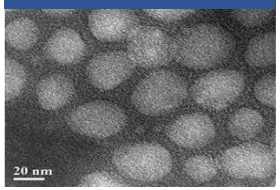
Platform	code	Indication	Research	Preclinical	Phase I	Phase II	Phase III	NDA
Nano Particle (505B1)	MPB-1514	Hematology (IDA)			Phase 2a completed (US)			
	MPB-1523	Diagnostic-HCC (MRI)				Phase 2 completed, prepare phase 3 (US/CN/TW)		
	MPB-2043	Diagnostic-lymph(MRI)				IIT enrolling (US/TW)		
	MPB-2354	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			

Nanomicelle

The Best Hydrophobic Drug Delivery System

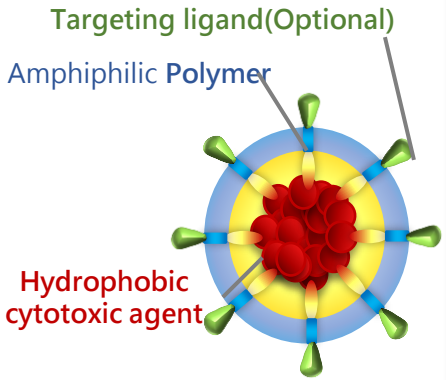
Stock Code:6827

Morphology (TEM)



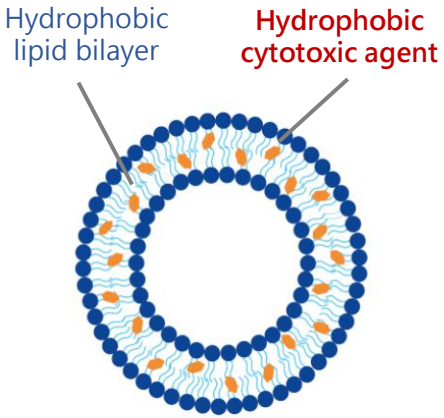
Nanomicelle

- Encapsulation with high drug loading capacity (>20%).
- Excellent tumor passive targeting (<70nm).
- Can be combined with targeting ligands.



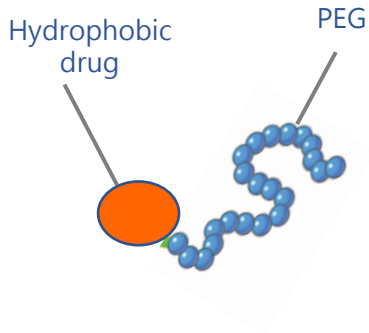
Liposome

- Hydrophobic drug loading capacity approximately 3~5%.
- Typical particle size range is 100–200 nm



PEGylation

- Chemical bonding, must be dissociate when delivery.
- A single polymer can only bond 1~4 molecules



MPB-1734

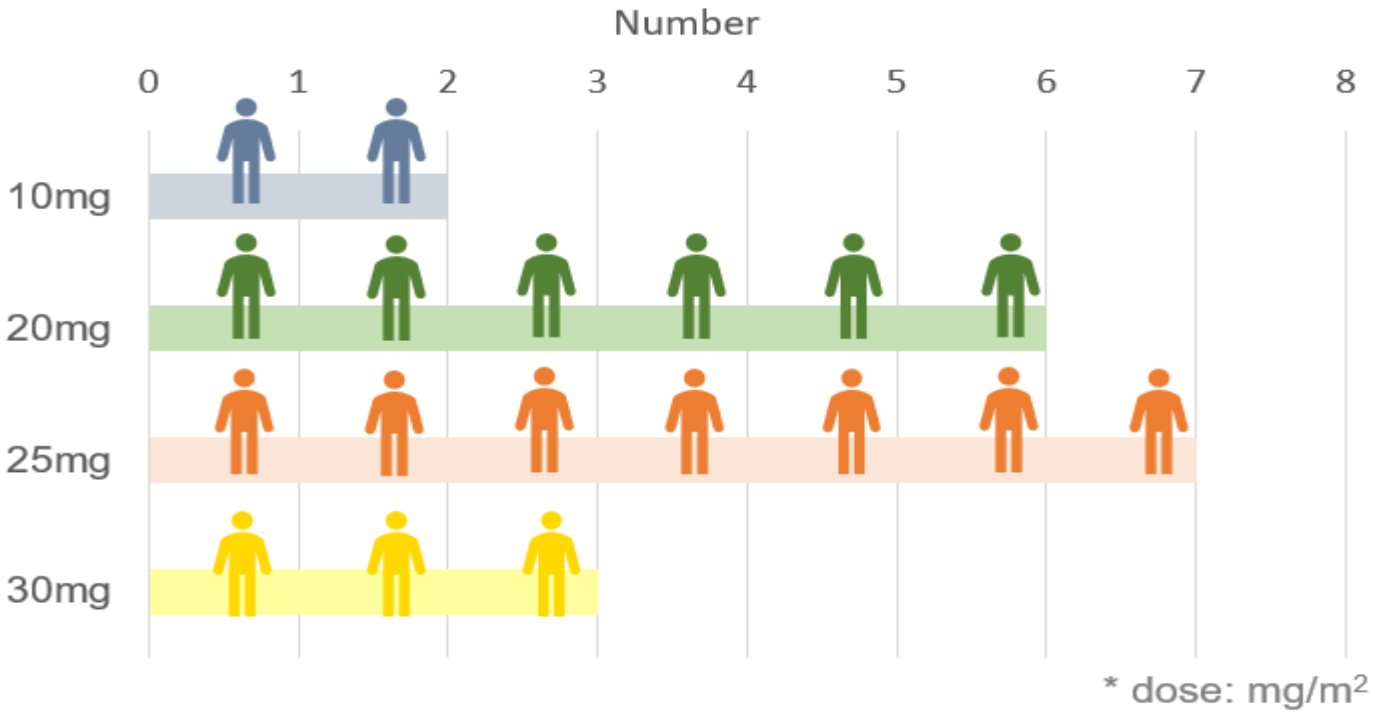
Jevtana (Cabazitaxel) New Generation to Overcome Taxane Resistance

Stock Code:6827

	MegaPro MPB-1734	Sanofi Jevtana
		
Patent	composition patent in US/JP/CN/IN	API expired
Solubility	solubility increased >1000 x	very low solubility, Tween80 must be used
Hypersensitivity	no steroid pre-treatment required.	hypersensitivity mainly caused by excipient Tween 80 (Black box warning)
Severe low neutropenia	neutropenia AE reduced	80% patients experienced life-threatening neutropenia (Black box warning)
Indication	focus on Head & neck and Prostate cancer	Only Prostate cancer

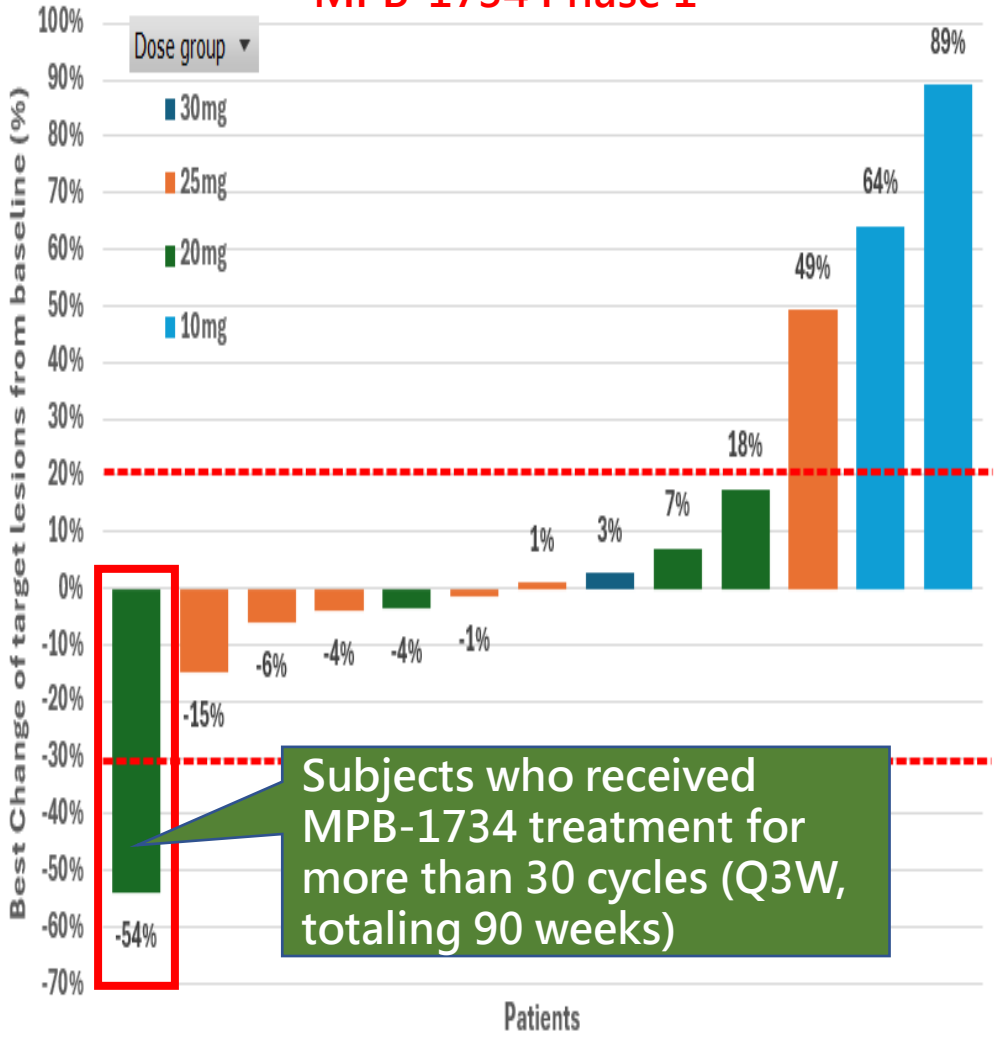
MPB-1734 Phase 1 Overview

- **Phase 1 study completed 2024:**
  - 18 patients enrollment
  - A data review committee (DRC) determined RP2D (requested phase 2 dose) will be 25 mg/m^2



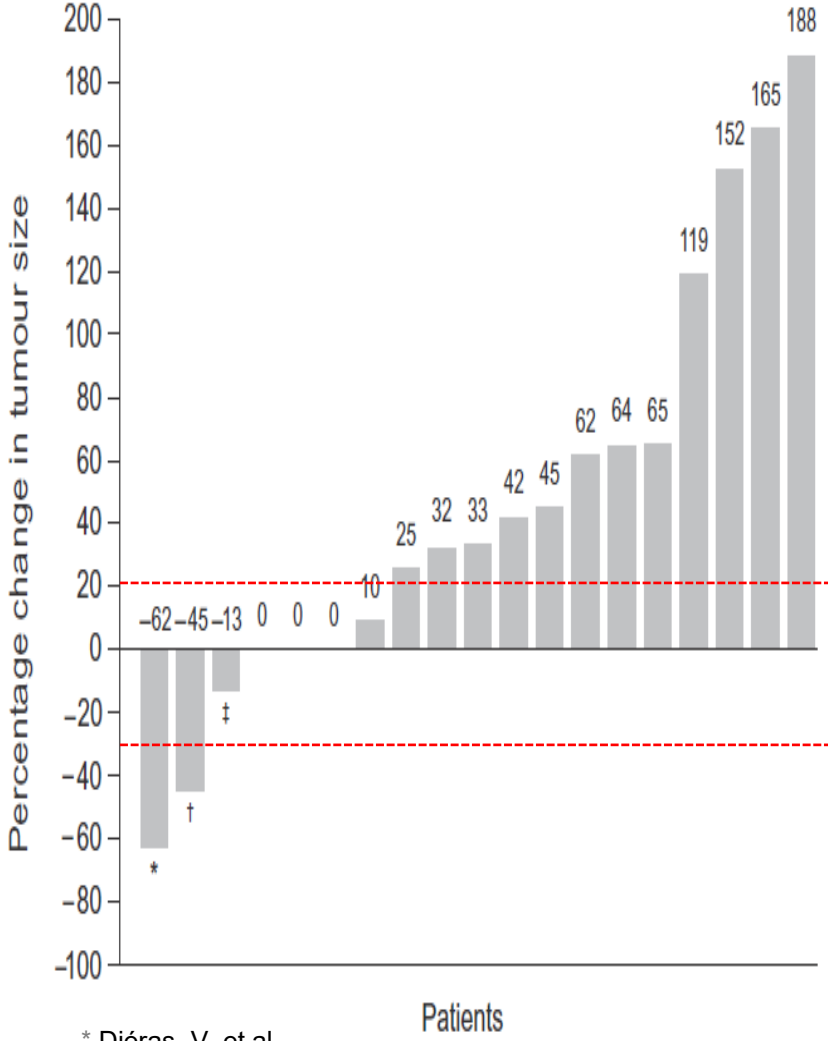
MPB-1734 Disease Control Rate (DCR) =77% (n=13)

MPB-1734 Phase 1



Subjects who received MPB-1734 treatment for more than 30 cycles (Q3W, totaling 90 weeks)

Jevtana Phase 1



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

Hematologic and Gastrointestinal Adverse Events Reduced

- TEAE (treatment-emergent adverse events) observation showed hematologic and lymphatic system disorders (neutropenia, anemia, diarrhea) reduced among all grades.
- The severity of neutropenia and diarrhea (grade ≥3) significantly reduced with MPB-1734.

	Jevtana Phase 1		MPB-1734 Phase 1			
	Lable	n=21	Phase 1			N=18
	TEAE		TEAE		TRAE	
	Grade 1-4 n (%)	Grade 3-4 n (%)	Grade 1-4 n (%)	Grade 3-4 n (%)	Grade 1-4 n (%)	Grade 3-4 n (%)
Blood and Lymphatic System Disorders						
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%
Gastrointestinal Disorders						
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

MPB-1734 Clinical Advantages

Jevtana 去癌達	MPB-1734
Dual-vial packaging; requires multiple steps with the risk of stability and preparation errors	**Single-vial lyophilized powder**; easy to use to reduce the burden of treatment providers
Contains Tween-80, The AE and SAE include hypersensitivity, fatal anaphylactic shock.	**Tween-80 free.** Clinical benefits has been demonstrated in many cases.
High ethanol content poses a risk to patients with ethanol intolerance, especially when combined with taxanes.	**Ethanol-free formulation.**
Requires premedication with corticosteroids and antihistamines.	No need for steroid or antihistamine premedication before injection.

MPB-1734

The 505(b)(2) New Drug Application (NDA) Expected in 2028.

MPB-1734 for Prostate Cancer (mCRPC)

1. U.S. FDA responded MegaPro through a Type C meeting
   - MPB 1734 qualify for a 505(b)(2) regulatory pathway, with the company's new material and preclinical data sufficient to support the submission.
   - FDA requested one extra hypersensitivity animal studies and a bioequivalence (BE) study to submit for the 505(b)(2) NDA application.
2. MegaPro planed a fundraising to support
   - CMC optimizations, including process scale-up and new excipient registration
   - One BE study before NDA submissions
   - NDA expected to the U.S., Canada, and Europe, arround 2029.

MPB-1734 for Head and Neck Cancer (HNSCC)

1. The efficacy and safety profiles has been demonstrated in phase 1 among 5 HNSCC patients.
2. MegaPro plans to proceed HNSCC phase II clinical combination with anti-PD-1 therapy with collaborators.

Clinical Benefits from Tween80 Free Formulations – Cinvanti case

Cinvanti vs Emend

- **Emend®** (by Merck): Originally the only injectable aprepitant, for the prevention of chemotherapy-induced nausea and vomiting (CINV).
- **Cinvanti®** (by Heron Therapeutics): The first Tween80 free injectable aprepitant formulation, pproved by the U.S. FDA 2017,
- After the patent of Emend expired, Cinvanti captured up to 43% market share of the U.S. in 2019. This share later still maintained at 25–28% even with generics challenge.
- Cinvanti reached annual sales of USD 100 million in 2024.

Clinical Benefits from Tween80 Free Formulations – Beizray case

1. Beizray vs Docetaxel

- **Docetaxel:** Widely used in the treatment of breast cancer, non-small cell lung cancer, prostate cancer, gastric cancer, and head and neck squamous cell carcinoma.
- **BEIZRAY®** (by Zhuhai Beihai Biotech): no Tween80 formulation, significantly improving clinical safety, successfully approved by the U.S. FDA in 2024.
- The annual sales of Docetaxel in the U.S. market is approximately 531,000 vials 2024.
- Beihai Biotech has licensed BEIZRAY to Zydus Pharmaceuticals 2024 with upfront payment of USD 15 million, an additional USD 10 million milestone payment and high double-digit profit-sharing arrangement.

Nanoparticles 505(b)(1) Platform

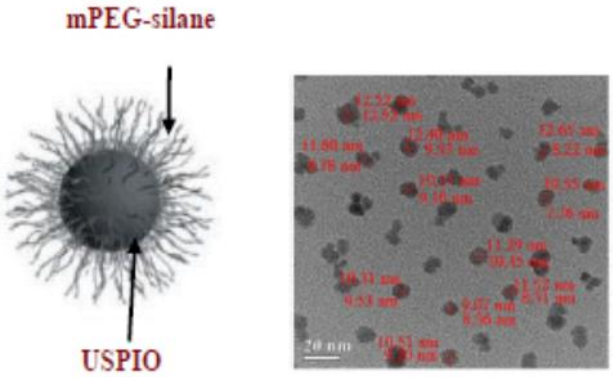
Stock Code:6827

- **PEGylated iron oxide nanoparticle**
- **Key Features of the IOP Injection**
  - Higher r2 relaxivity
  - High macrophage uptake efficiency
  - Low free iron release
  - Low oxidative stress generated
  - Non-sugar base formulation, Low risk for hypersensitivity,

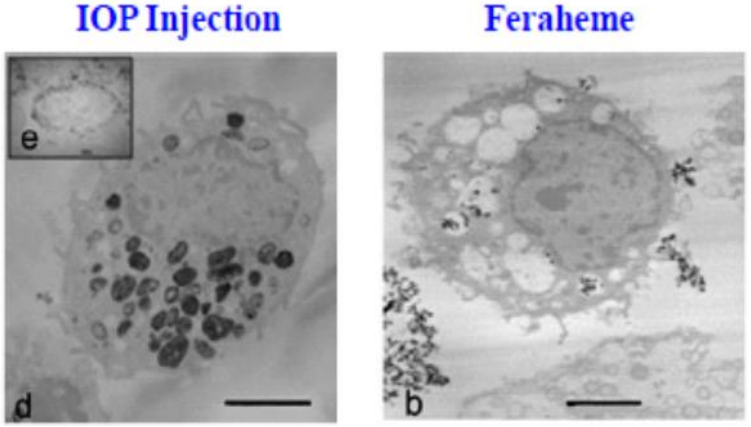
	IOP Injection	Feraheme
Size (TEM)	10-12 nm	4.2 nm
r2 $(mM \cdot s)^{-1}$*	170	70

* Measured with 0.47T minispec

MegaPro: IOP Injection



Macrophages uptake efficiency



MPB-1523 vs Primovist

	MPB1523	Primovist
Phase 1 Benchmark	SNR 80%	SNR 50%
Phase 2 Benchmark	C/N 50%	C/N 5%
Product analysis	• With Kupffer cell specific function, MPB1523 image can differentiate benign and malignant liver lesions at hepatophase. • Applicable to patients with eGFR <30 or bilirubin malfunction. • The portal vein imaging is clear, thus, to judge the portal vein invasion easier. • Iron is an endogenous element so that there will be no NSF and brain deposition issues.	• Due to the modification, 50% of Primovist is metabolized by liver so that it can provide both arterial and hepatophase imaging. • Around 20% HCC patients usually have liver and kidney dysfunction, and Primovist cannot be used for those patients. • Around 15% patients who use Primovist have transient severe motion. It will affect the image quality of arterial phase.
Proposal of Phase 3 trial	Phase 3 of MPB1523 will target to patients with known or suspected focal liver lesion.	

MPB-1523 Updated Progress

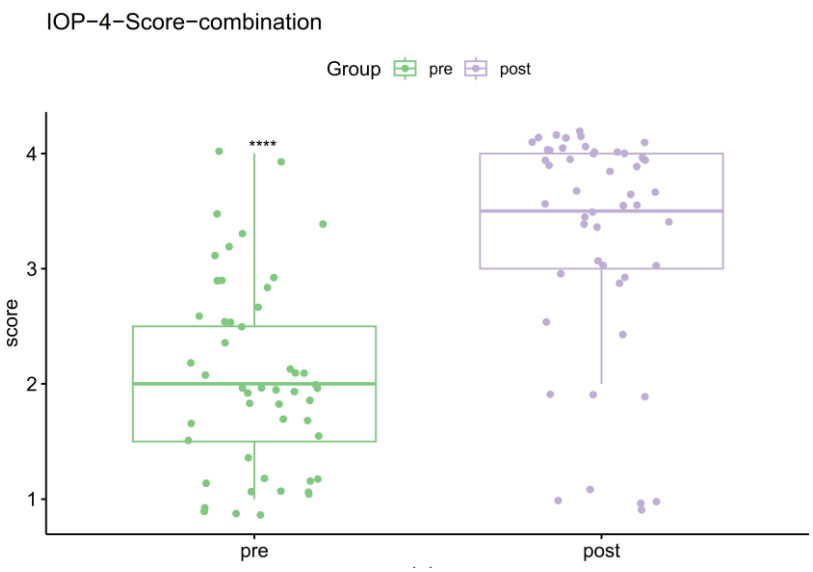
1. The conclusion from End-of-Phase 2 (EOP2) meeting with the U.S. FDA :
   - ✓ Clinical protocol: suggest MegaPro to conduct a retrospective analyses and phase 3 design to compare pre and post-IOP
   - ✓ CMC: The method validate should completed before IND phase 3. MegaPro plans to complete the manufacturing specifications for MPB-1523 by 2025.
   - ✓ A pre-IND submission for the Phase III clinical trial is targeted 2025.
2. The GMP-compliant CDMO who certified U.S., EU, and China regulatory is identified.
3. MegaPro also conducted a consultation meeting with the Center for Drug Evaluation (CDE) in China, and get their response that only animal bridging study would be required to support the tech transfer.
4. Licensing negotiation with several Chinese pharmaceutical companies are underway.

MPB-1523

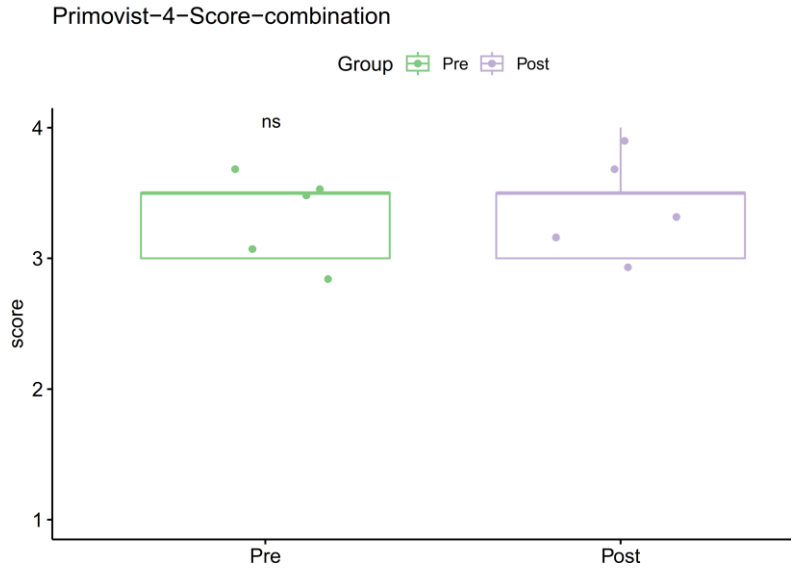
Phase 2 Retro specific Image Analysis

Combination of border delineation and contrast enhancement by 4-point scoring method: : MPB1523 vs Primovist, pre-contrast and post contrast 2.05 ± 0.85 vs. 3.29 ± 0.96, p<0.001)

(a) IOP Injection



(b) Primovist

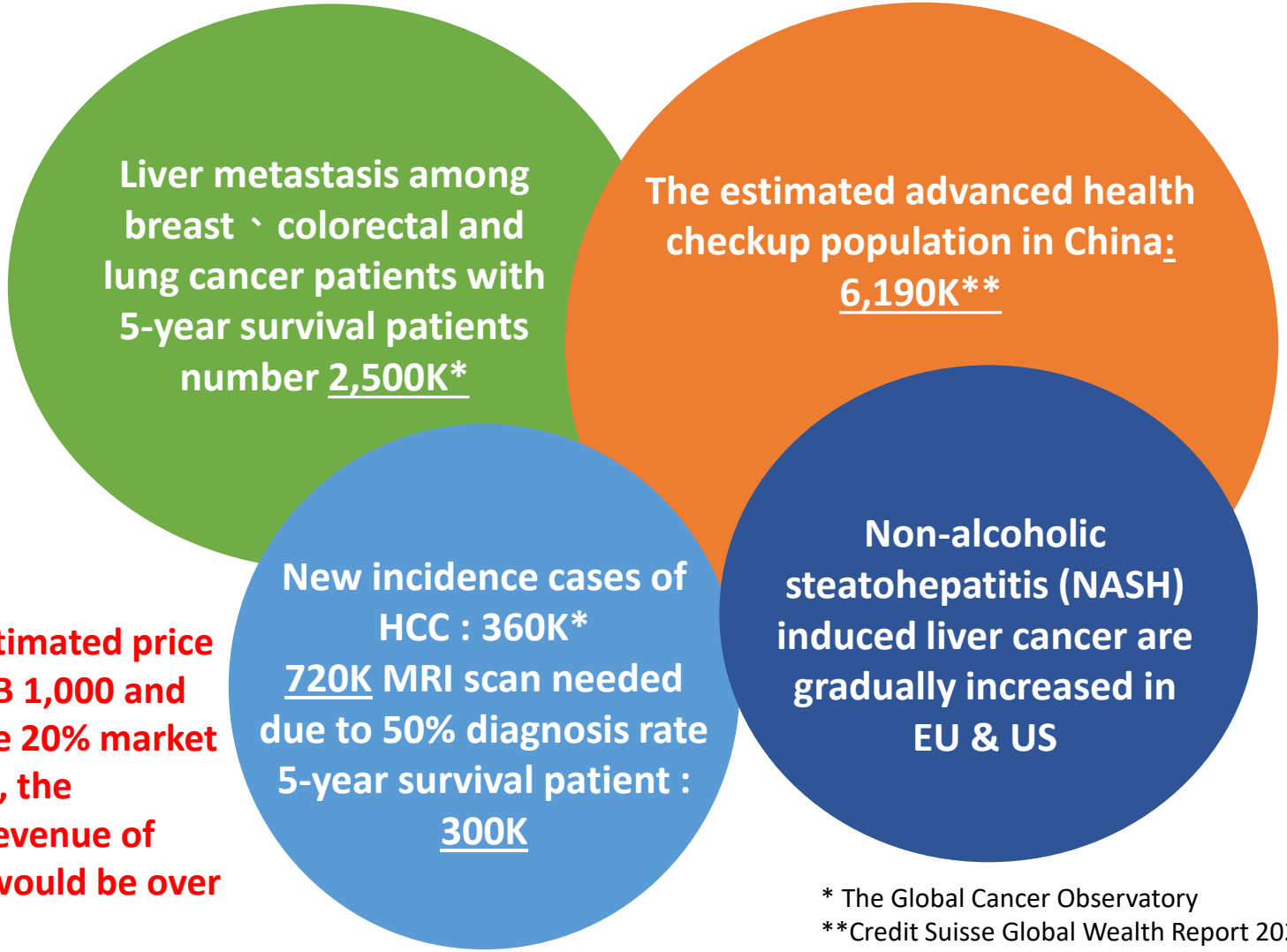


MPB-1523 Phase 3 Clinical Protocol Design

PHASE 3 STUDY:
Focal Liver Lesions with suspected primary or secondary malignant liver tumors

Patients	**MRCT (China, US, Taiwan)** Multicenter, Double-blinded, Randomized, Active control study
Comparator	Pre-CA MRI vs. post-MPB1523 MRI **(FDA recommends switching to Pre)**
Endpoint	Primary Objective: The superiority of paired pre-contrast and IOP-enhanced multiphase MRI to pre-contrast MRI will be assessed through a 4-point scoring. Secondary Endpoints: Number of specific lesion sizes (<1 cm, 1-3 cm, >3 cm), Sensitivity and Specificity.
Follow-up	3 months
Evaluation	Centralized image center, 3 independent readers

Market Estimation: China as an Example



- **With the estimated price per vial RMB 1,000 and conservative 20% market penetration, the estimated revenue of MPB-1523 would be over RMB 700M.**

* The Global Cancer Observatory
**Credit Suisse Global Wealth Report 2022

Future

Two Pivotal Pipeline of MegaPro

- **505(b)(1) New Drug MPB-1523**
  - submit a pre-IND for Phase III by the end of 2025
  - product licensing agreements hopefully 2026
  - NDA submission expect 2028
- **505(b)(2) New Formulation Drug MPB-1734**
  - mCRPC:
    - a Tween80 free formulation targeting the original indication
    - After the fundraising 2025, MegaPro plans to conduct CMC optimizations & scale up, and one BE clinical study.
    - NDA submission expected at 2028
    - The licensing collaborator will be searched during the process
  - HNSCC, the anti-PD-1 combination phase II clinical trials is expected to collaborate with partners.

Pipelines Update

- **MPB-1514: Intravenous iron for the treatment of iron deficiency anemia.**
  - Phase 2b clinical trial design has been discussed with FDA.
  - The trial will be initiated once sufficient funding is secured.
- **MPB-2043: A novel MRI contrast agent for lymph node metastasis.**
  - An IIT is ongoing. The first dose cohort enrollment completed, the second dose cohort is in preparation.
  - MegaPro plans to accelerate the clinical development of MPB-2043.
- **MPB-2354: A cell therapy drug capable of tracking implanted cells.**
  - Preparation for the Phase 1 clinical trial
  - Pre-IND submission is underway.


Thank You