Medigen Biotechnology Corp.

(3176)

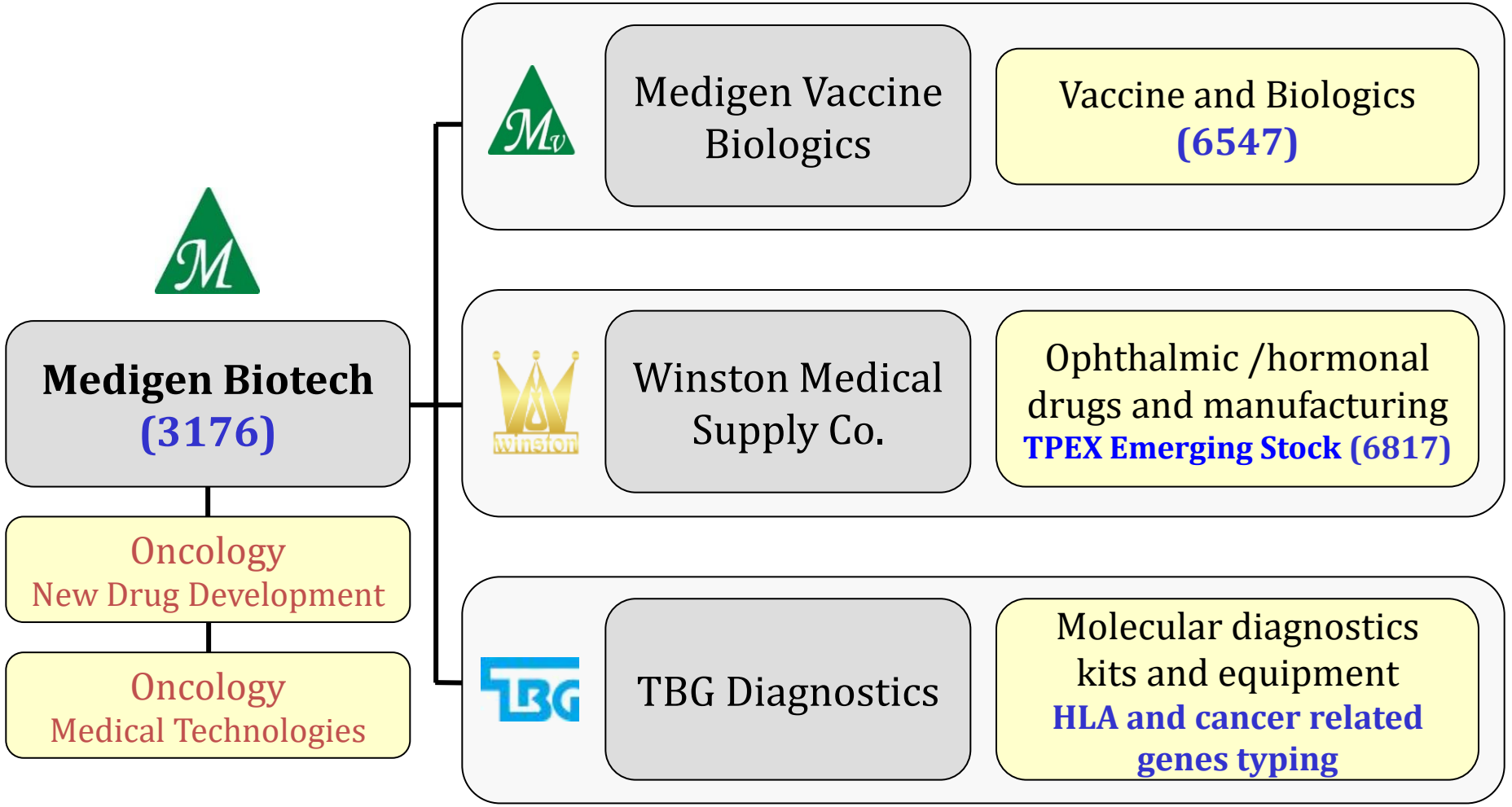
Investor Conference

2023.12.08

Arlene Chiang, Associate Vice President,
Operations Department

Our company, as part of the biotechnology industry, is facing business risks and financial risks associated with long research and development periods and the possibility of R&D failures. Investors should carefully evaluate these factors.

Business of Medigen Group



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Positioning and Competitive Advantages of Medigen

- Our Position
  - Focusing on new drug development in the field of cancer treatment.
  - Focusing on cell therapy and development of comprehensive treatment solution.
  - Integrating resources of Medigen group and continuously building the group's capabilities in diagnosis, prevention, treatment, manufacturing, and sales.

- Competitive Advantages
  - Integrated clinical trial team
  - Cell processing unit conforming with GTP guidelines
  - Experienced management team

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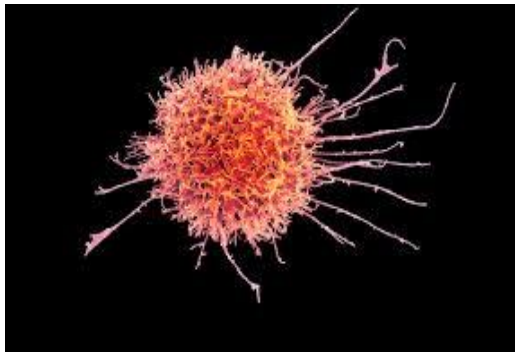
Introduction of Cell therapy

- **Definition:** Cells isolated from a subject, purified and expanded in vitro to increase cell number and activity, then injected to the subject for the purpose of disease treatment or health enhancement.
- **Mechanism:** Modulate physiological and biochemical function of human body through cell activity.
- **Sources:**
  - Autologous cells：cells for treatment come from the same subject
  - Allogeneic cells：cells for treatment come from other subject
- **Cell characteristics：**
  - Genetically modified cells (such as CAR-T or CAR-NK)
  - Non-genetically modified cells (MSC, IKC, NK, CIK, gamma-delta T, LAK or DC cells)



MSC: Mesenchymal Stem Cell; IKC: Immune Killer Cells; NK: Natural Killer Cells;
LAK: Lymphokine Activated Killer Cells; CIK: Cytokine Induced Killer Cells; DC: Dendritic Cells

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Cell therapy allowed under current Special Act

- 2018/6/8 Draft Notice of the Act
- 2018/9/6 Act Promulgated and enforced
- 2021/2/9 Act Amended and enforced

項目名稱	適應症
一、自體CD34+ selection周邊血幹細胞治療	一、慢性缺血性腦中風。 二、嚴重下肢缺血症。
二、自體免疫細胞治療 (包括CIK、NK、DC、DC-CIK、TIL、gamma-delta T之 adoptive T細胞輸入療法)	一、血液惡性腫瘤 (hematological malignancies) 經標準治療無效。 二、第一期至第三期實體癌(solid tumor)，經標準治療無效。 三、實體癌第四期。
三、自體脂肪幹細胞治療	一、慢性或滿六週未癒合之困難傷口。 二、占總體表面積百分之二十以上之大面積燒傷或皮膚創傷受損。 三、皮下及軟組織缺損。 四、退化性關節炎及膝關節軟骨缺損。
四、自體纖維母細胞治療	皮膚缺陷：皺紋、凹洞及疤痕之填補及修復。
五、自體骨髓間質幹細胞 (bone marrow mesenchymal stem cell) 治療	一、退化性關節炎及膝關節軟骨缺損。 二、脊髓損傷。
六、自體軟骨細胞治療	膝關節軟骨缺損。

Positioning and Competitive Advantages of Medigen in Cell Therapy

- Competitive Advantages
  - We developed immune cells with special features, high purity and high cytotoxicity: Natural Killer Cells and Gamma-delta T cells
  - Cell processing unit conforming with GTP guidelines
- Position and Strategies
  - Providing total solution through development of off-the-shelf product, genetic modified immune cells and automation equipment
  - Parallel development of medical technologies (under Special Act) and new drug (under clinical trials)

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Challenges in Cell Therapy

Process of the cell the therapy

Consultation → Sample Collection → Logistics → **Cell Processing** → Logistics → Cell Infusion → Monitoring

Difficulties in prior immune cell therapy

Low Cell Number

<5 x 10^8/infusion

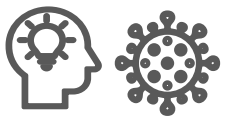
Low Purity

Mixture
NK only 5~30%

Low Cytotoxicity

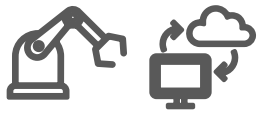
<10% at E/T = 1 or no data available

Solutions and Strategies



Strong R&D capabilities

Off-the-shelf product



Automation equipment

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Cell Therapy Pipeline

Type	Pipeline	R&D	Pre-clinical	IND	Phase I	Phase II	Phase III	NDA/ Spe. Act
Immune Cells	Autologous NK (New Drug)				Colorectal Cancer			
	Allogeneic NK (New Drug)				Pancreatic/ bile duct cancer			
	Autologous NK (Medical Technology)				Solid Tumor			
	Autologous GDT (Medical Technology)				Solid Tumor			
	Genetic modified mRNA-CAR-NK				Solid Tumor			
Automation Equipment	Automated Cell Expansion				NK, GDT, CAR-T, etc.			
	Automated Cell Purification and Harvest				NK, GDT, CAR-T, etc.			

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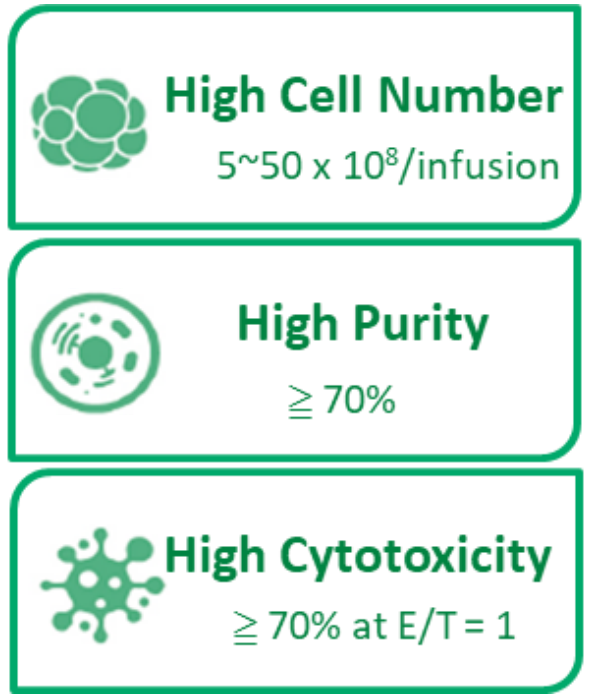
Magicell®-NK Technology

- Independently developed cell processing method and cell culture medium, which makes our technology innovative and self-reliant.
- Using whole blood or PBMCs as starting material, which is a safer and simpler procedure for patients and physicians.
- High quality and efficiency: We achieved 3H standards, which are High cell number, High purity and High cytotoxicity
- Certified in-house GTP laboratory, following regulatory standards for production preparation, with quality under strict control



NK Magicell®

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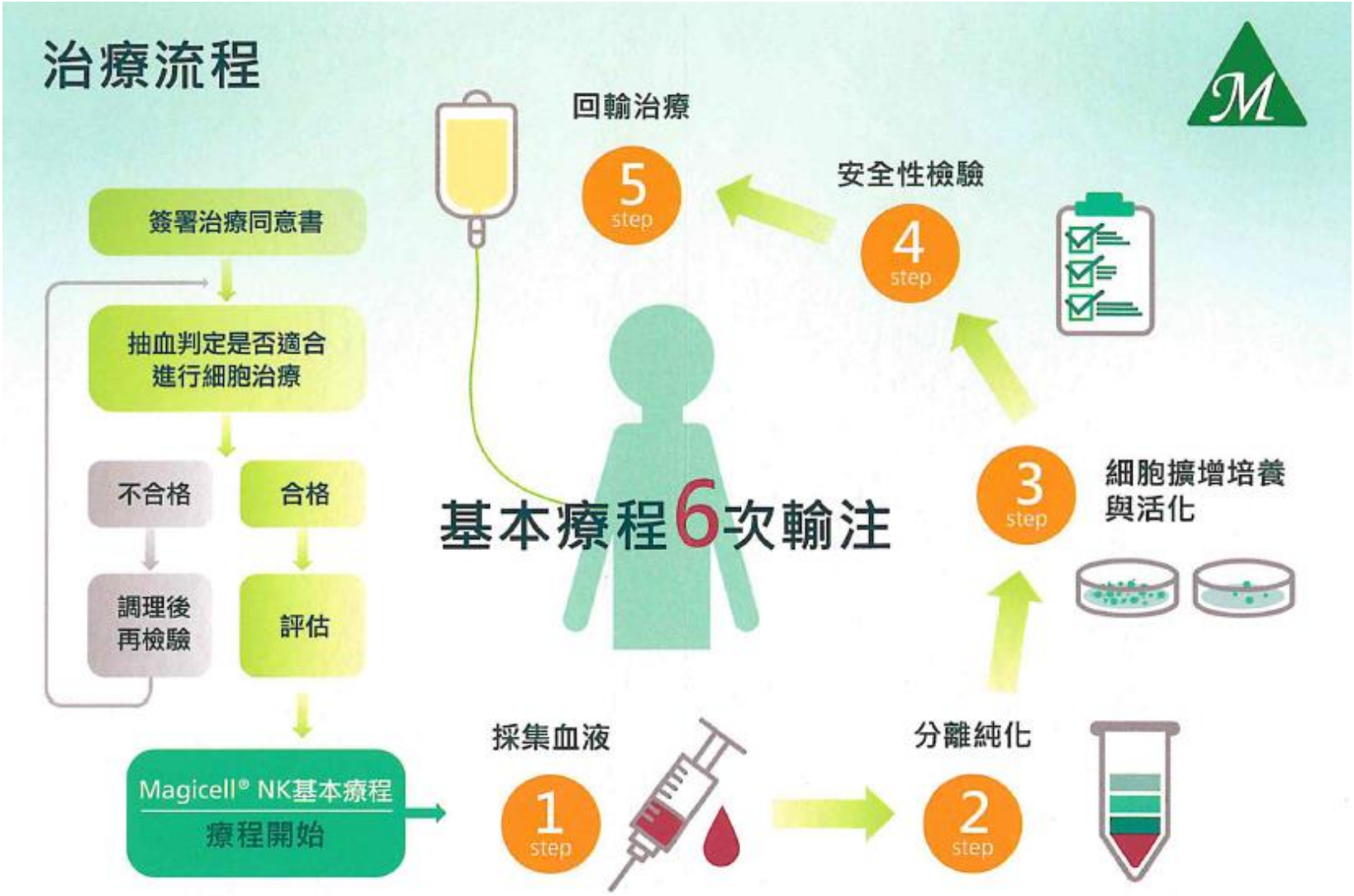
Magicell®–GDT Technology

- **GDT cells**
  - GDT stands for gamma-delta T (γδ T)
  - Could be used in allogeneic context and possess high cytotoxicity
  - Licensed from **MEDINET Co., Ltd**, a listed Japanese company
  - 2023/02/20 First allowed under the Special Act to be used in Shin Kong Wu Ho-Su Memorial Hospital for the treatment of stage IV solid tumor

- **MEDINET Co., Ltd.**
  - Listed Japanese company and Japan's first biotechnology company to provide immune cells for medical institutions
  - GDT developed by MEDINET have clear clinical research evidence in patients with lung cancer, gastric cancer, and bone metastasis

Treatment procedure for Magicell® NK and GDT (Special Act)



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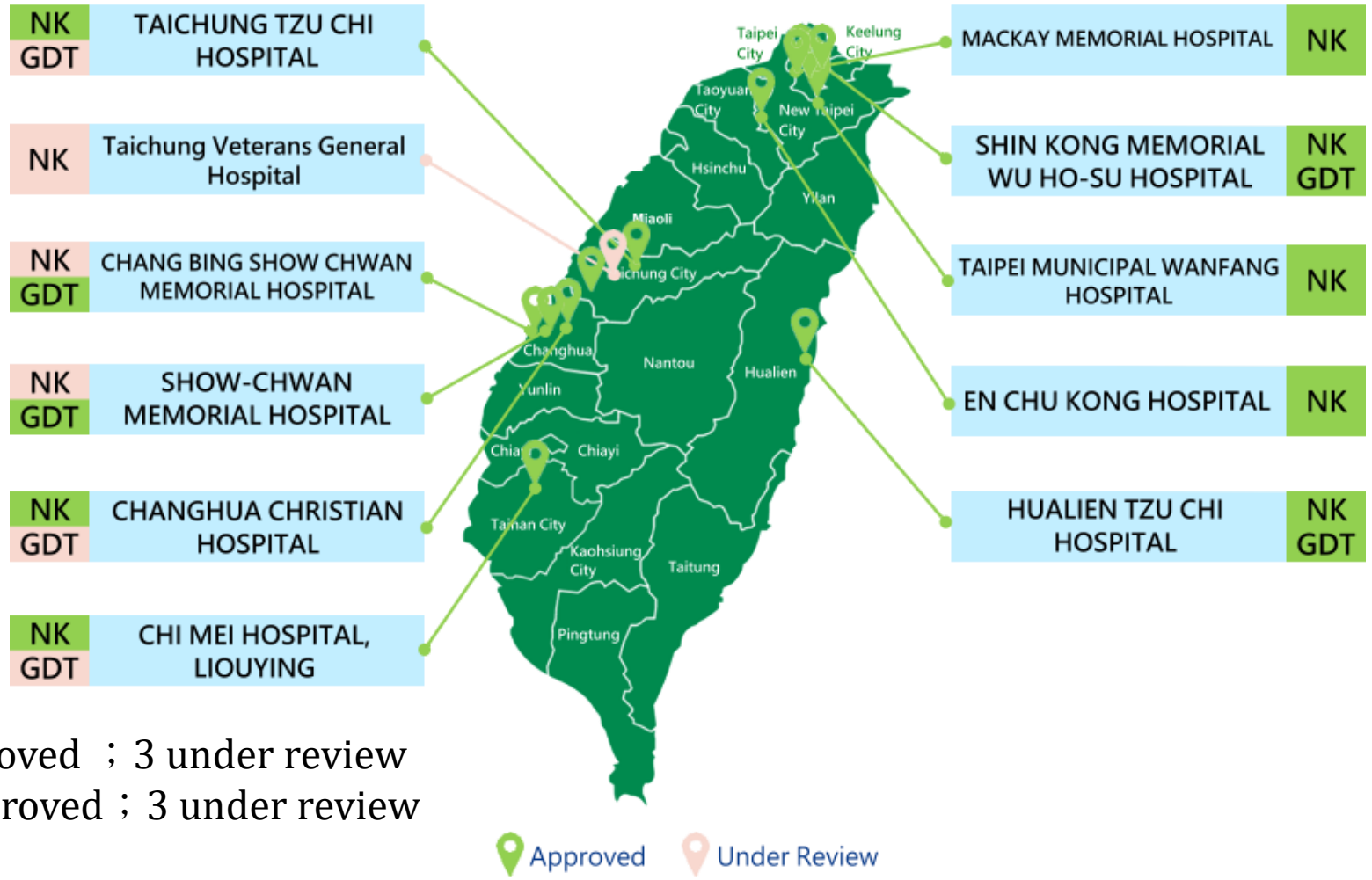
Collaborations with Medical Institutions approved under the Special Act



- NK cell therapy: 8 approved ；3 under review
- GDT cell therapy: 4 approved；3 under review

Magicell® NK: Approved collaborations and indications (Special Act)

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NK Indications: Type of stage IV solid tumor approved

Medical Institutions	Brain	Head & Neck	Lung	Breast	Esophageal	Gastric	Liver	Bile Duct	Pancreatic	Prostate	Ovarian	Colorectal
Changhua Christian Hospital	●	●	●	●			●	●	●		●	●
Hualien Tzu Chi Hospital	●	●	●	●			●	●	●	●		●
Taichung Tzu Chi Hospital			●	●			●	●	●	●		●
Liouying Chi-Mei Medical Center	●		●	●	●	●			●	●	●	●
En Chu Kong Hospital			●	●					●	●		●
Shin Kong Wu Ho-Su Memorial Hospital	●	●	●	●	●		●	●	●	●	●	●
Wan Fang Hospital	●		●	●		●			●	●	●	●
Taipei Mackay Memorial Hospital			●	●			●	●	●	●		●

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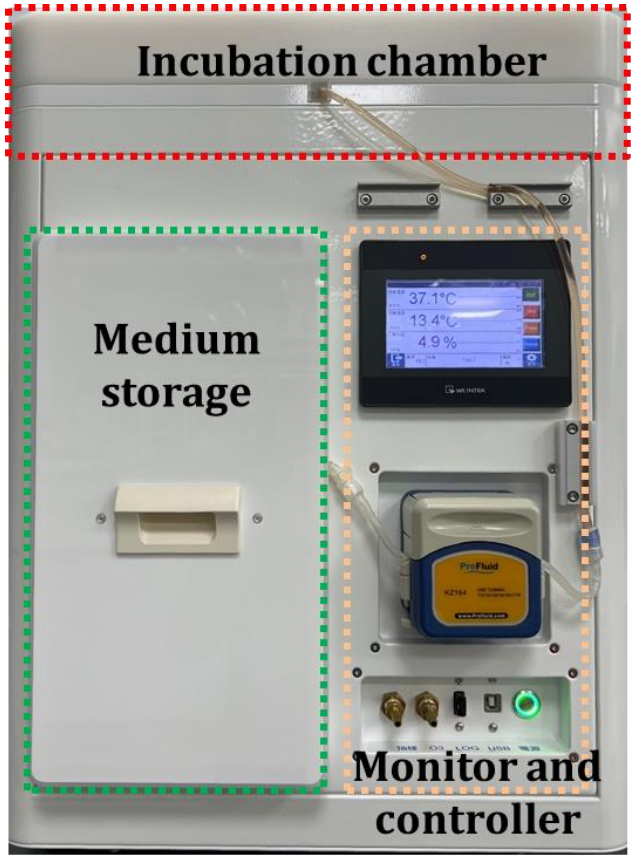
Magicell® GDT Approved collaborations and indications (Special Act)

GDT Indications: Type of stage IV solid tumor approved

Medical Institutions	Lung	Breast	Pancreatic	Kidney	Prostate	Colorectal
Shin Kong Wu Ho-Su Memorial Hospital	●	●	●	●	●	●
Show Chwan Memorial Hospital	●	●	●	●	●	●
Chang Bing Show Chwan Memorial Hospital	●	●	●	●	●	●
Hualien Tzu Chi Hospital	●	●	●	●	●	●

Automated Cell Expansion Equipment

- **β version prototype** of Medigen's ACE™
- ACE™ : **A**utomated **C**ell **E**xpansion
- Used to expand various immune cells, including NK, GDT, CIK, CAR-T cells
- Sealed cell culture bag to avoid contamination during manual operations.
- Multiple parameter settings to fine tune optimal cell culture conditions
- Certified with ISO 13485:2016




Certificate

This is to certify that the Medical Device Quality Management System of

applicable to

2. Automated Cell Expansion System, ACEs (Non-Sterile) ODM, OEM, and selling services

has been assessed and registered by Best ISO against the provisions of

ISO 13485 : 2016

This registration is subject to the company maintaining a medical device quality management system, to the above standard, which will be monitored by Best ISO

Unique Identification Code (UIC)

MSCB-166-123014

Certificate No: M230037
Initial issued: 2023/01/04
Last issued: 2023/01/04
Valid Until: 2026/01/03

IAS ACCREDITED MSCB-166

IAF International Accreditation Forum

Shu-Ling Yang, Manager director
Best ISO Certification Co., Ltd.

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Research on mRNA-CAR-NK

Journal of Clinical Oncology > List of Issues > Volume 41, Issue 16_suppl >

Meeting Abstract | 2023 ASCO Annual Meeting I

DEVELOPMENTAL THERAPEUTICS—IMMUNOTHERAPY

Development of allogenic nonviral RNA-based CAR-NK therapy targeting CDH17 in relapsed/refractory gastrointestinal cancer.

Jaydeep Roy, Vivian Lin, Mehran Rahmani, Kronos Chow, James Chieh-Liang Lin, Alarng Chang, John Moon Luk, Anthony Chun Fung Chan

Arbele, Sha Tin, Hong Kong; Arbele, Shatin, Hong Kong; Medigen Biotechnology Corp., Taipei, Taiwan; Medigen Biotech Corp., Taipei, Taiwan; Arbele, Shatin, China

Show Less

Abstract Disclosures

- mRNA-CAR-NK: Magicell-NK developed by Medigen are genetically modified using mRNA
- In vitro results were published at 2023 ASCO annual meeting
- Evidence shows that Magicell-NK could be genetically modified without using viral transfection and could has the effect of killing gastrointestinal cancer cells
- Potential candidate for allogeneic and off-the shelf CAR-NK product.

co-culture with AGS-CDH17+ cells at 1:1 and 2:1 E:T ratio.

Conclusions: Our findings suggest that a non-viral based CDH17 CAR-NK cell therapy could be a potential allogeneic, off-the-shelf CAR-NK therapy candidate in GI cancer and support the rationale of further investigating it *in vivo* and clinical trials.

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Medigen Autologous NK cell therapy phase I clinical trial

Title	A Dose-Escalating Phase I Study to Determine the Safety, and Maximum Tolerated Dose/ Maximum Feasible Dose of Autologous ex Vivo Expanded and Activated NK Cell, Magicell-NK, Infusion for Colon Cancer Post Resection
Aim of the study	After surgery for Stage I or IIa colorectal cancer, the safety, dose-limiting toxicity, and maximum tolerated dose/highest achievable dose of intravenous infusion of autologous NK cells (Magicell-NK) in postoperative patients.
Recruitment information	Expected recruitment of 12-18 participants. Anticipated enrollment period: November 2021 to December 2024. Principal Investigator: Liao Chun-Kai. Trial Institution: Colorectal, Anal, and Intestinal Surgery, Linkou Chang Gung Memorial Hospital.
Notes	Approved by the Taiwan Food and Drug Administration, Ministry of Health and Welfare (announced on 2021/8/13) (ClinicalTrials.gov: NCT05394714)

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Medigen Autologous NK cell therapy phase I clinical trial: Current status

Cohort	Dose	Recruitment status
Cohort 1	**2 x 10^8**	**3 subjects completed***
Cohort 2	**6 x 10^8**	**3 subjects completed***
Cohort 3	**18 x 10^8**	**recruiting**

* After review and assessment by the Safety Monitoring Committee, the doses for Cohort 1 and Cohort 2 are deemed safe and well-tolerated.

Medigen Allogeneic NK cell therapy phase I/II clinical trial

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Title	A dose-exploration phase I study, followed by a phase II study, to evaluate the safety and efficacy of allogeneic natural killer cells, Magicell-NK, of the same species as adjuvant therapy in combination with chemotherapy for postoperative pancreatic or bile duct cancer patients.
Aim of the study	Phase I clinical trial: Evaluating the safety, dose-limiting toxicity, and maximum tolerated dose/highest achievable dose of intravenous infusion of allogeneic NK cells (Magicell-NK) in combination with chemotherapy for postoperative Stage II or III pancreatic or bile duct cancer patients. Phase II clinical trial: Assessing the effectiveness of intravenous infusion of allogeneic NK cells (Magicell-NK) in combination with chemotherapy for postoperative Stage II or III pancreatic or bile duct cancer patients."
Info on Recruitment	Expected recruitment: Phase I clinical trial 9-12 participants; Phase II clinical trial 30 participants. Anticipated enrollment period: June 2024 to December 2027. Principal Investigator: Shen Yansheng (Dean of the College of Medicine, National Cheng Kung University). Trial Institutions: Phase I Clinical Trial - National Cheng Kung University Hospital; Phase II Clinical Trial - 2-3 hospitals."

Status and plans of OBP-301 clinical trial

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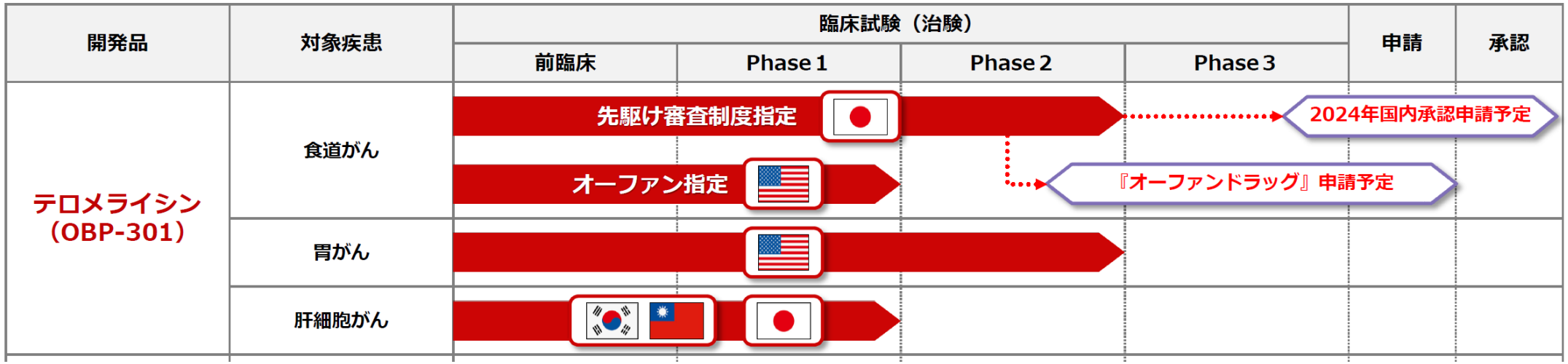
- OBP-301 combined with Radiotherapy for Esophageal Cancer: A Phase II Clinical Trial conducted in Japan. The primary efficacy endpoint, Local Complete Response Rate(L-CR), exceeded the threshold pre-set in the clinical trial protocol, demonstrating the effectiveness of OBP-301 for locally advanced esophageal cancer. It is anticipated that in the second half of 2024, a regulatory application for product approval will be submitted based on Sakigake designation in Japan.
- Combination of OBP-301 with Immune Checkpoint Inhibitors for the Treatment of Gastric Cancer and Gastroesophageal Junction Cancer: The principal investigator initiates a Phase II clinical trial conducted in the United States. The trial involves 16 participants, with one achieving complete response (CR) and two showing partial response (PR).



Source: Oncolys BioPharma, “Mid-Year Financial Results Briefing for December 2023” (2023/8/3)

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Operations and Financials of Medigen Affiliates

高端疫苗生物製劑股份有限公司
MEDIGEN VACCINE BIOLOGICS CORP

(6547)

溫士頓醫藥股份有限公司
WINSTON MEDICAL SUPPLY CO.,LTD.

TPEX emerging stock (6817)

Please refer to the material information announced by Medigen Vaccine Biologics Corp. and Winston Medical Supply Co.

Thank you

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