Medigen Biotechnology Corp.

(3176)

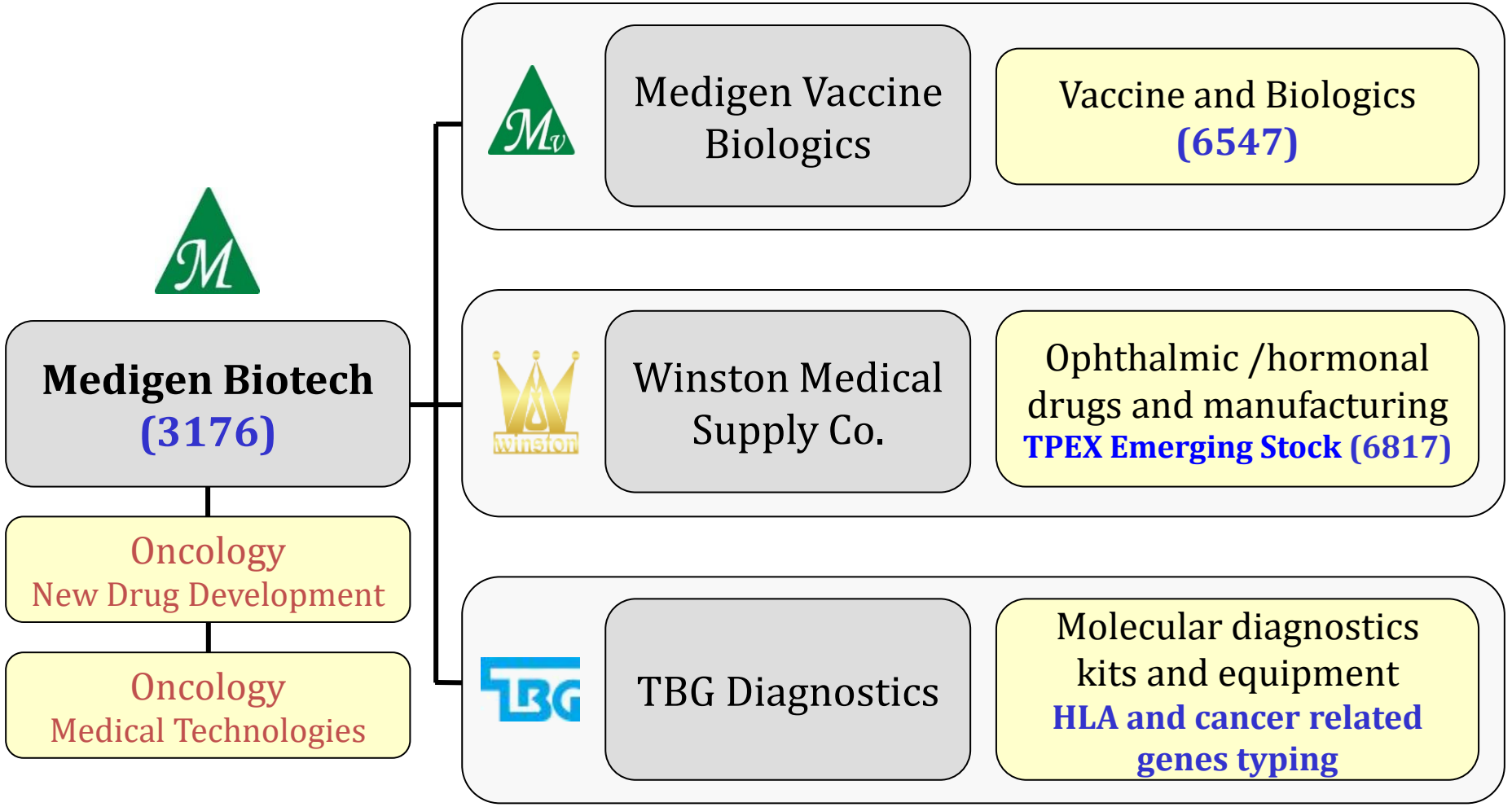
Investor Conference

2024. 12. 25

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



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 and medical team
  - Cell processing unit conforming with GTP guidelines
  - Experienced management team

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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。

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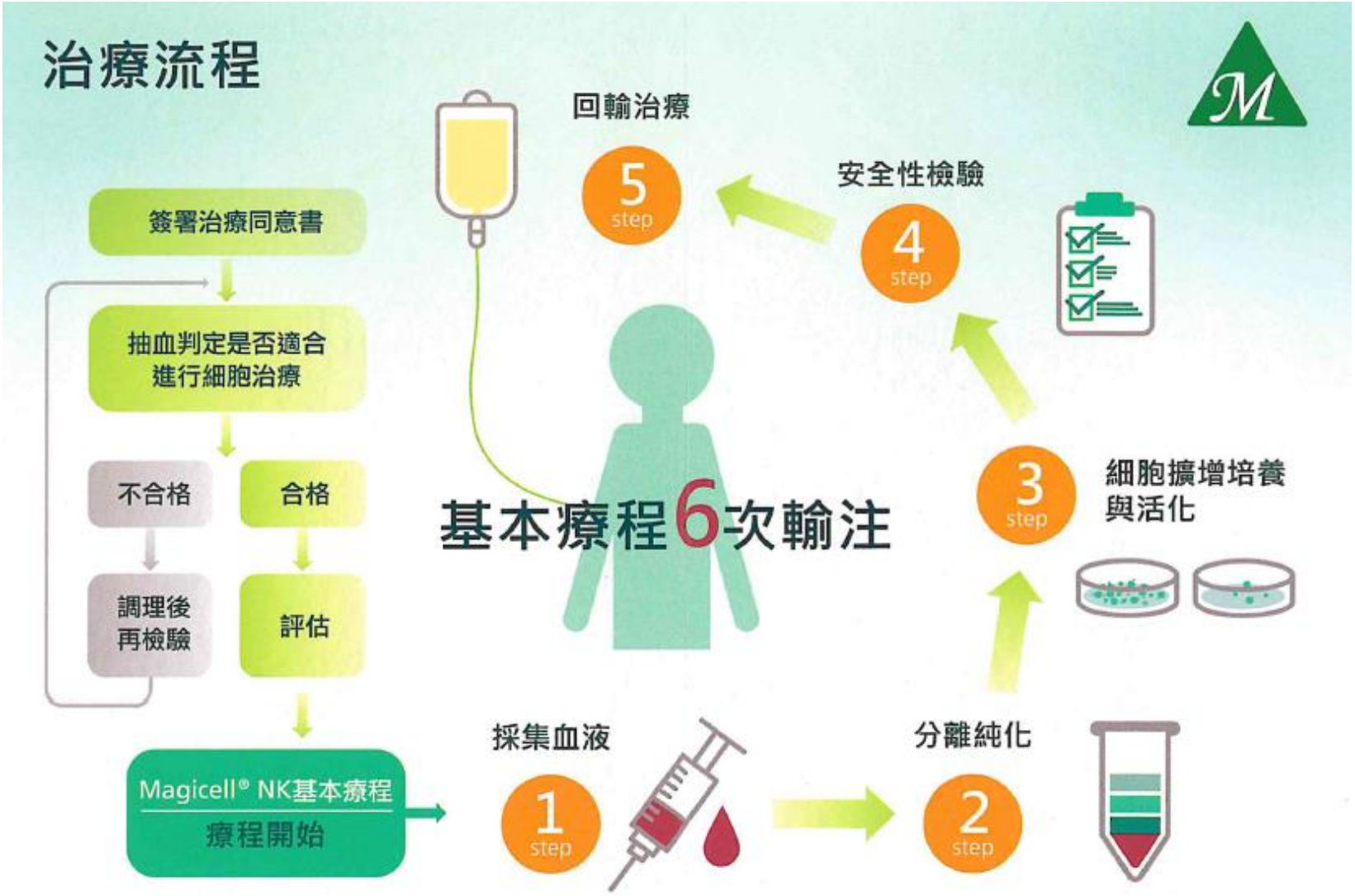
Medigen's Pipeline

類別	項目	R&D	Pre-clinical	IND	Phase I	Phase II	Phase III	NDA/特管法
New Drug Development	Autologous NK	**Colorectal Cancer**						
	Allogeneic NK	**Pancreatic cancer**						
	OBP-301	**Esophageal Cancer**						Sakigake Designation Scheme
Cell Therapy (Medical Technology)	Autologous NK	**Solid Tumor**						
	Autologous GDT	**Solid Tumor**						
Automation Equipment	Automated Cell Expansion			**NK, GDT, CAR-T, etc.**				

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: 10 approved; 1 under review
- GDT cell therapy: 8 approved; 1 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	●		●	●	●	●	●	●	●	●		●
Shin Kong Wu Ho-Su Memorial Hospital	●	●	●	●	●		●	●	●	●	●	●
Wan Fang Hospital	●		●	●	●	●	●	●	●	●		●
Taipei Mackay Memorial Hospital			●	●			●	●	●	●		●
TaiChung Veterans General Hospital	●		●	●	●	●	●	●	●	●		●
Show Chwan Memorial Hospital	●		●	●	●	●	●	●	●	●		●
Chang Bing Show Chwan Memorial Hospital	●		●	●	●	●	●	●	●	●		●

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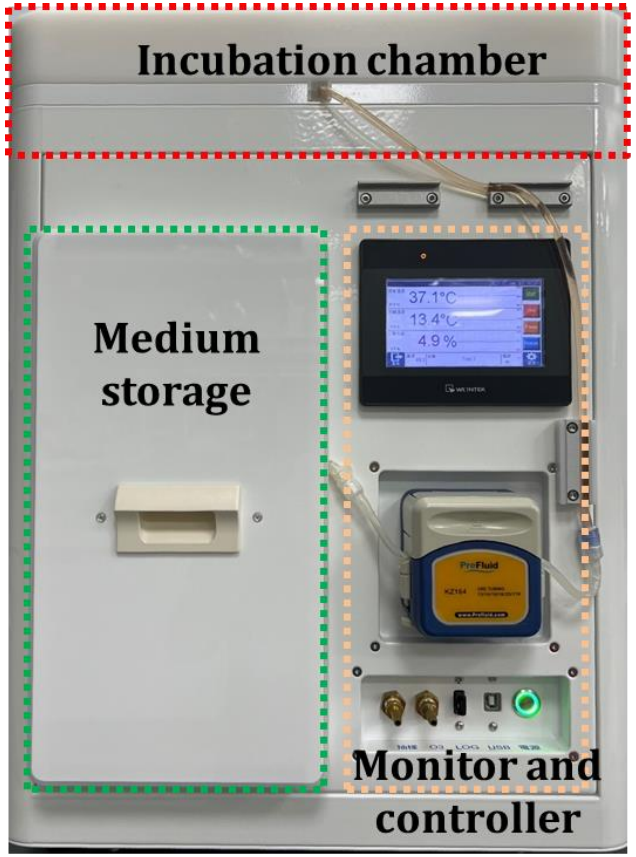
Magicell® GDT Approved collaborations and indications (Special Act)

GDT Indications: Type of stage IV solid tumor approved

Medical Institutions	Lung	Breast	Esophageal	Gastric	Liver	Pancreatic	Kidney	Prostate	Ovarian	Colorectal
Shin Kong Wu Ho-Su Memorial Hospital	●	●				●	●	●		●
Wan Fang Hospital	●	●				●	●	●		●
Taichung Tzu Chi Hospital	●	●				●	●	●		●
Changhua Christian Hospital	●	●		●		●	●	●		●
Show Chwan Memorial Hospital	●	●				●	●	●		●
Chang Bing Show Chwan Memorial Hospital	●	●				●	●	●		●
Liouying Chi-Mei Medical Center	●	●	●	●	●	●	●	●	●	●
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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Manual operation v.s. Magicell® -ACE system

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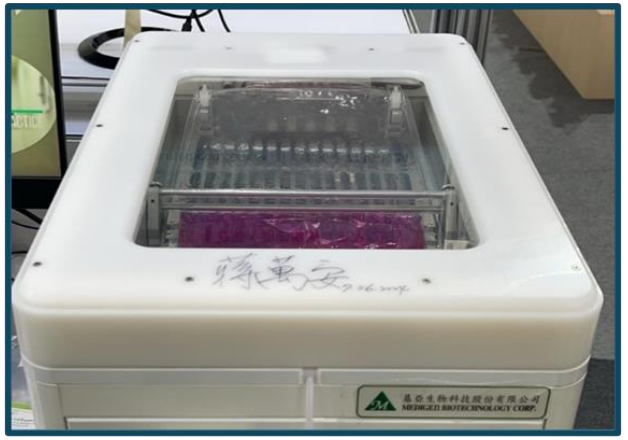
Promotion for Magicell® -ACE system

Taipei Mayor Chiang Wan-an visited the 2024 Bio Asia-Taiwan Exhibition and signed on Medigen's ACE equipment at the booth. (Photo credit: 中央社記者翁睿坤, July 26, 2024)

Medigen participated in the 2024 Bio Asia-Taiwan, showcasing its independently developed automated cell expansion system, Magicell®-ACE System.



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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**		**6 subjects Required** • 1 subjects completed • 3 subjects withdrew • 2 subjects in treatment • Recruitment ongoing

* 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 6-12 participants; Phase II clinical trial 30 participants. Anticipated enrollment period: September 2024 to December 2029. 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."
Note	Approved by the Taiwan Food and Drug Administration, Ministry of Health and Welfare (announced on 2024/9/16) (ClinicalTrials.gov: NCT06730009)

Status and plans of OBP-301 clinical trial

- 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.
- The "Pre-Application Consultation" under Sakigake designation in Japan is expected to take place in the first half of 2025. Oncolys aims to submit for drug approval by the end of 2025.
- Medigen and Oncolys has signed an amendment in Dec. 2024 to establish a collaborative sales arrangement of OBP-301, including:
  - Japan market: Oncolys responsible for sales
  - Taiwan market: Medigen responsible for sales

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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

基亞生物科技股份有限公司
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