



**Medigen Biotechnology Corp.**

# Medigen Biotechnology Corp.

(3176)

## Investor conference

(2021.11.24)

Medigen is a biotechnology company. It takes considerable time to develop of which success cannot be guaranteed. Investors shall bear such investment risk that warrants careful assessment before making investment decisions.



# Business of Medigen Group



**Medigen Biotech**  
**(3176)**

Oncology  
Drug Development

Oncology  
Medical Technologies



Medigen Vaccine  
Biologics

Vaccine and biologics  
**(6547)**



Winston Medical  
Supply Co.

Ophthalmic /hormonal  
drugs and manufacturing  
**TPEX Emerging Stock (6817)**



TBG Diagnostics

Molecular diagnostics and  
equipment  
HLA typing and  
**COVID-19 diagnostics**

# Cell therapy allowed under current Special Act

- 2018年6月8日公告特管辦法草案
- 2018年7月17日公開說明會
- 2018年9/4公告，9/6實施



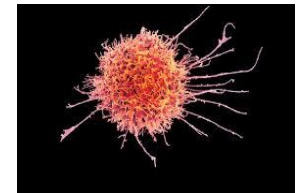
附表三

項目名稱	適應症
一、自體 CD34+ selection 周邊血幹細胞移植	一、血液惡性腫瘤 (hematological malignancies) : (一) 白血病 (不包括慢性骨髓白血病之慢性期)。 (二) 淋巴瘤。 (三) 多發性骨髓瘤。 二、慢性缺血性腦中風。 三、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、自體脂肪幹細胞移植	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 (含) 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。 五、其他表面性微創技術之合併或輔助療法。
四、自體纖維母細胞移植	一、皮膚缺陷：皺紋、凹洞及疤痕之填補及修復。 二、皮下及軟組織缺損。 三、其他表面性微創技術之合併或輔助療法。
五、自體骨髓間質幹細胞 (bone marrow mesenchymal stem cell) 移植	一、退化性關節炎及膝關節軟骨缺損。 二、慢性缺血性腦中風。 三、骨髓損傷。
六、自體軟骨細胞移植	膝關節軟骨缺損。



# 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



## Cell Therapy – Advantages of NK and GD T cell

- With the highest cytotoxic activity against cancer cells
- Can be used off-the-shelf, without inducing GVHD
- Persist for longer period *in vivo*
- Recognize IPP expressed by some cancer types
- Possess better tumor infiltrating capability

**Cytotoxicity against Cancer cell : NK >  $\gamma\delta$ T >  $\alpha\beta$ T (CIK)**

Ex vivo-expanded natural killer cells kill cancer cells more effectively than ex vivo-expanded  $\gamma\delta$  T cells or  $\alpha\beta$  T cells. *International Immunopharmacology*. 2014





## Cancer Indications with Medigen NK cells Under Special Act

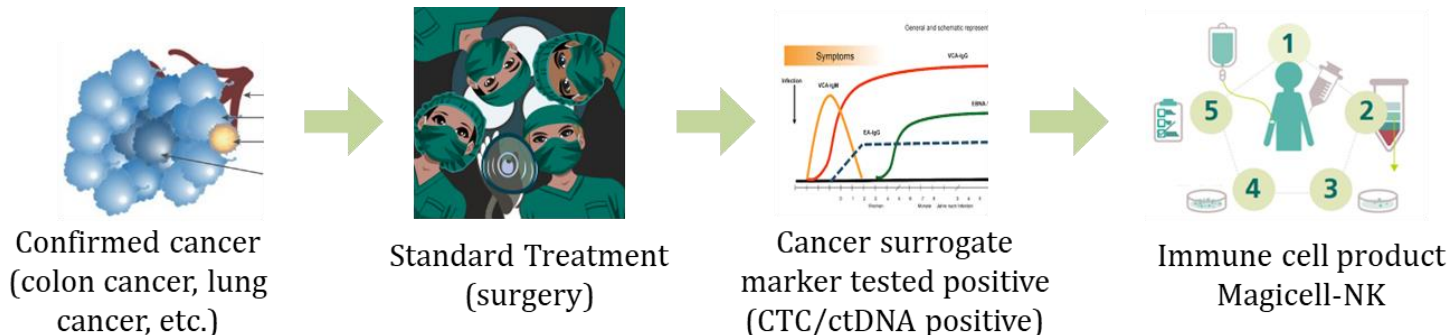
NK 適應症-第四期實體癌：已核准

醫療機構	腦癌	頭頸癌	肺癌	乳癌	食道癌	胃癌	肝癌	膽管癌	胰臟癌	攝護腺癌	卵巢癌	結腸直腸癌
義大癌治療醫院		●	●	●			●	●	●	●		●
彰化基督教醫院	●	●	●	●			●	●	●		●	●
花蓮慈濟醫院	●	●	●	●			●	●	●	●		●
台中慈濟醫院			●	●			●	●	●	●		●
柳營奇美醫院	●		●	●	●	●			●	●	●	●
恩主公醫院			●	●					●	●		●
新光醫院	●	●	●	●	●		●	●	●	●	●	●
大里仁愛醫院		●	●		●	●	●	●	●	●		●
中心綜合醫院	●		●	●					●	●		●
萬芳醫院	●		●	●		●			●	●	●	●
北醫附設醫院	●		●	●		●			●	●		●

腦癌  
Brain cancer  
頭頸癌  
Head and neck cancer  
肺癌  
Lung cancer  
乳癌  
Breast cancer  
食道癌  
Esophageal cancer  
胃癌  
Stomach cancer  
肝癌  
Liver cancer  
膽管癌  
Bile duct cancer  
胰臟癌  
Pancreatic cancer  
攝護腺癌  
Prostate cancer  
卵巢癌  
Ovary cancer  
結腸直腸癌  
Clonal rectal cancer

# Initiation of NK Cell Therapy Phase I Clinical Trial

- Approved to initiate Magicell-NK Phase I clinical trial
  - TFDA approval for trial initiation received (2021/8/13 announcement)  
(ClinicalTrials.gov : NCT05394714)
  - Used as an adjuvant therapy for patients with resected colon cancer to prevent recurrence and increase survival time.
- To expand the scope of use and to increase patient number
  - NK cell therapy is expected to prevent recurrence and increase survival time of cancer patients after surgery
  - Used with ctDNA testing to achieve precision medicine
  - Scope of use will expand outside of the Special Act and will be no restriction on the location of use, so that more patients can access to NK cell therapy.







# Cell Therapy Policies and Regulations

Cell therapy regulations  
under discussion

Regenerative Medicine  
Development Act

Aug. 2021

Draft

Regenerative  
Medicine  
Implementation Act

Dept. Medical Affairs, MOHW  
Amendment of "Special Act"

Regenerative  
Medicinal  
Products Act

TFDA, MOHW  
Not yet in force

## ■ Current regulation

- Dual Track: Medical Technology and Medicinal Product
- Use of Medical Technology restricted to the approved scope under "Special Act"

## ■ Regulations under discussion

- Bridging of Medical Technology and Medicinal Product
- Expected to **accelerate development of medicinal products** and to **reduce cost of clinical development**



# Position of Medigen and Business Outlook

## ■ Competitive Advantages

- Cell processing unit conforming with GMP guidelines
- Integrated clinical trial team with product development experiences

## ■ Advantages of our products

- We develop unique immune cells with high purity and cytotoxicity: NK cell and GD T (gamma-delta T) cell
- With ongoing clinical trial and using precision medicine, we can have more patients accessible to cell therapy products



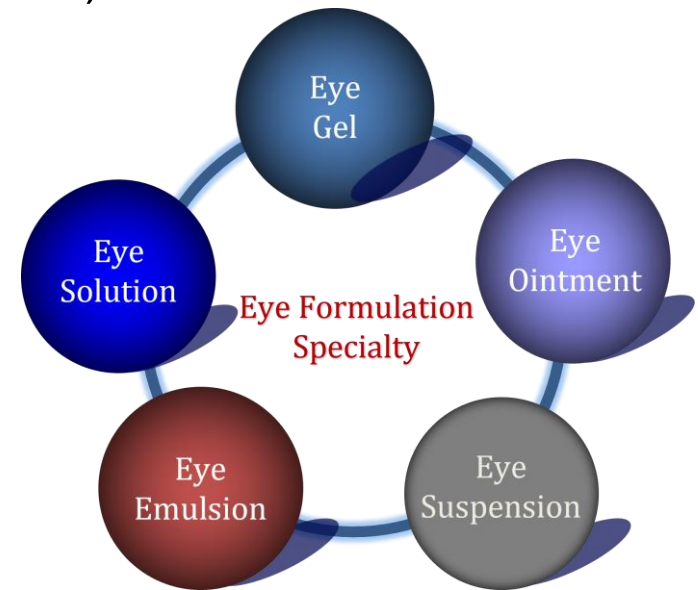


# Winston: Subsidiary listed on TPEX Emerging Stock



- Holding 10,906 (thousand shares)  
(as of 30 Nov. 2022)

- **Position: leading ophthalmic drug company in Taiwan**
- **Competitive Advantages**
  - Expertise in eye drug formulation
  - 5 different formulations developed
  - 37 drug licenses
  - PICs/GMP manufacturing facility





# Winston: Major Achievements and Plan

- Business and financial achievements in 2021
  - Stable increase of revenue
  - Increase in gross profit
- Important plan for 2023
  - In 2023, complete the development of eye drugs ( M901 & T103) for Glaucoma
  - Stable and positive business outlook





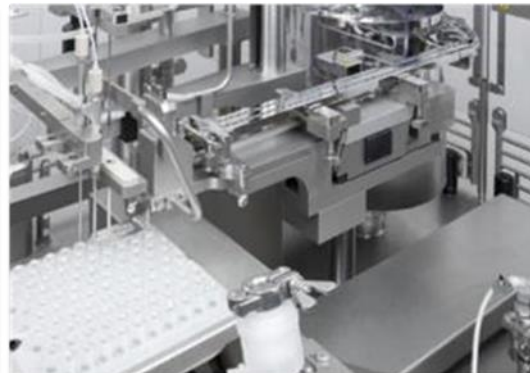
# Medigen Vaccine: Subsidiary listed on TPEX



Medigen Vaccine

- Holding 64,949 (thousand shares)  
(as of 11 Nov. 2022)

- Please refer to the announcements of Medigen Vaccine (6547)





MEDIGEN BIOTECHNOLOGY CORP.

*Thank  
you*

A close-up of a fountain pen nib, showing the gold-colored metal and the black resin body. The nib is positioned at the end of the word 'you' in the cursive text, as if it has just finished writing it.