



Medigen Biotechnology Corp.

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(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



2021 Financial Overview

Medigen Group's Income Statement of first three quarters compared to last year

Unit: thousand NTD

		Q1	Q2	Q3	Q1~Q3 Cumulative
2021	Operating income	185,654	174,871	1,385,005	1,745,530
	Net profit	(158,788)	(274,869)	596,605	162,948
	Net profit (loss) attributable to owners of the parent	(64,100)	(129,251)	63,607	(129,744)
2020	Operating income	131,054	140,307	154,125	425,486
	Net profit	(171,662)	(217,305)	(246,486)	(635,453)
	Net profit (loss) attributable to owners of the parent	(70,489)	(90,280)	(110,625)	(271,394)

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



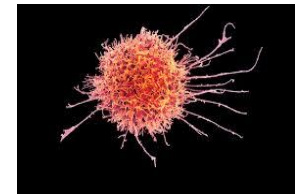
附表三

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 $\gamma\delta$ 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

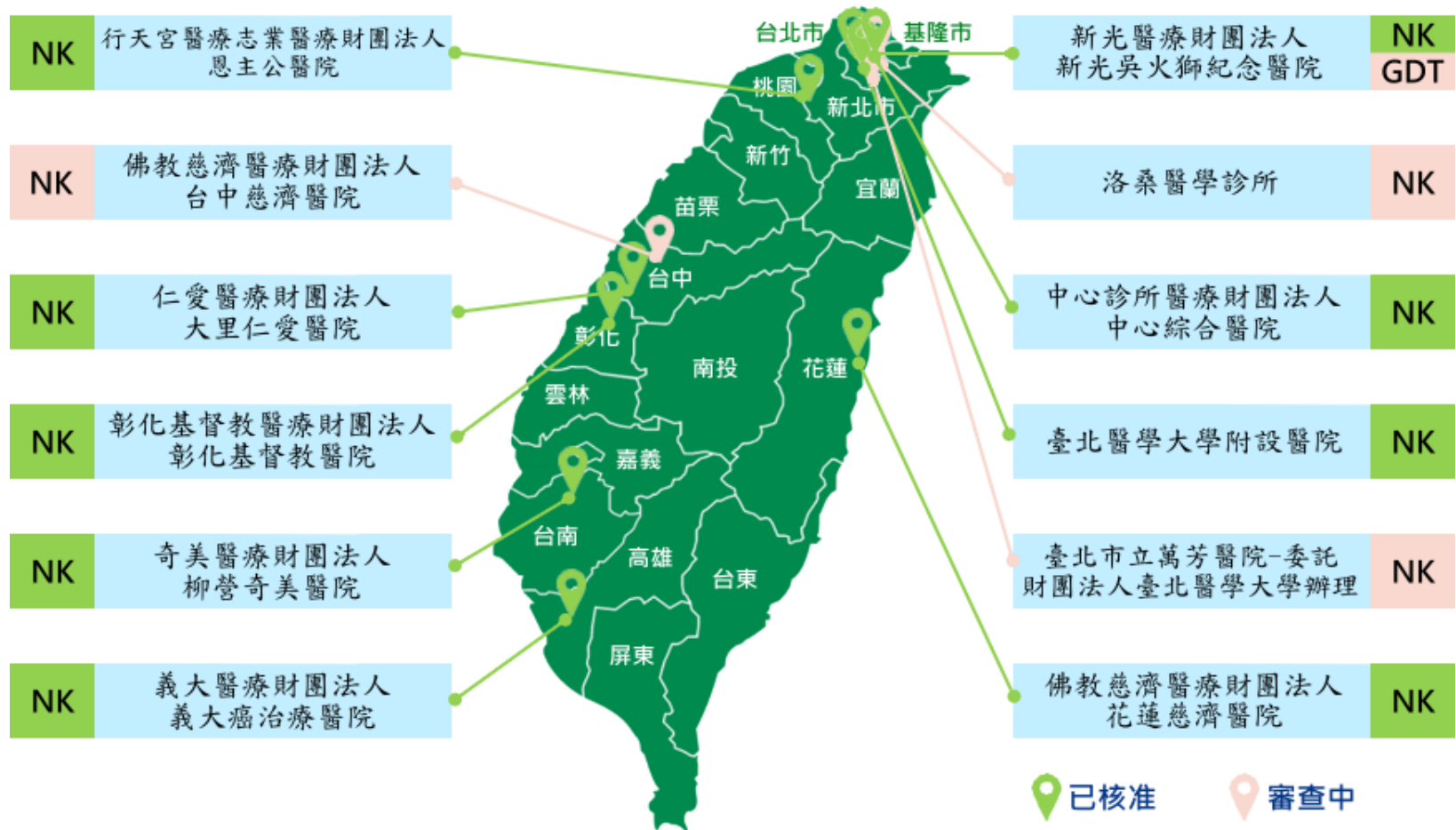
Cytotoxicity against Cancer cell : NK > $\gamma\delta$ T > $\alpha\beta$ T (CIK)

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



Medical Institutions Collaborating with Medigen under Special Act

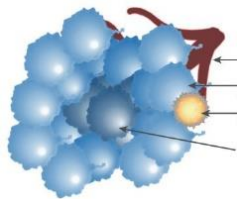
9 medical institutions approved to use Medigen's NK cell therapy





Initiation of NK Cell Therapy Phase I Clinical Trial

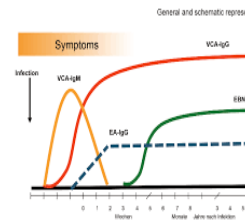
- Approved to initiate Magicell-NK Phase I clinical trial
 - TFDA approval for trial initiation received (2021/8/13 announcement)
 - Used as an adjuvant therapy for patients with resected colon cancer to prevent recurrence and increase survival time.
- To expand the scope of use and to increase patient 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.



Confirmed cancer
(colon cancer, lung
cancer, etc.)



Standard Treatment
(surgery)



Cancer surrogate
marker tested positive
(CTC/ctDNA positive)



Immune cell product
Magicell-NK



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



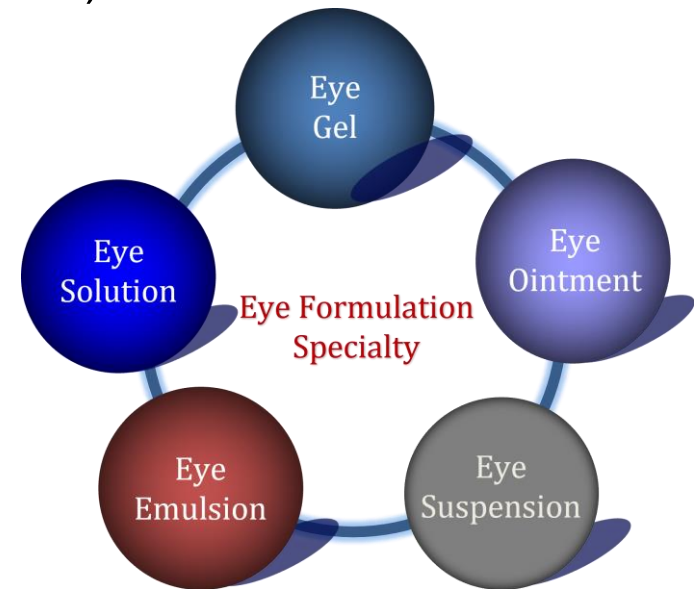


Winston: Subsidiary listed on TPEX Emerging Stock



- Holding 10,906 (thousand shares)
(as of 30 Sep. 2021)

- **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 2022
 - Prepare for TPEX listing application
 - Stable and positive business outlook





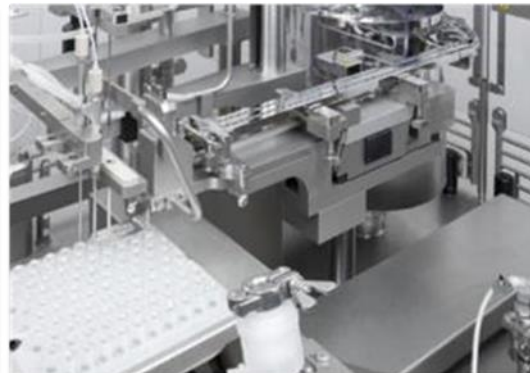
Medigen Vaccine: Subsidiary listed on TPEX



Medigen Vaccine

- Holding 45,238 (thousand shares)
(as of 30 Sep. 2021)

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





MEDIGEN BIOTECHNOLOGY CORP.

*Thank
you*

A close-up, detailed view of a fountain pen nib. The nib is made of polished metal, likely gold or brass, and is shown from a side-on perspective. It is positioned at the end of the word 'you' in the cursive text, as if it has just finished writing it. The nib has a classic split-globe design with a small hole at the tip.