



Medigen Biotechnology Corp.

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(3176)

Investor conference

(2020.12.22)



Business of Medigen Group



**Medigen Biotech
(3176)**

Oncology
Drug Development

Oncology
Medical Technologies



Medigen Vaccine
Biologics **(6547)**

Vaccine and biologics



Winston Medical
Supply Co.
(6817)

**Ophthalmic /hormonal
drugs** and manufacturing
Listed on TPEX Emerging
Stock (expected 2021 Q1)



TBG Diagnostics
(ASX: TDL)

Molecular diagnostics
and equipment
HLA typing and
COVID-19 diagnostics



Major achievements in 2020

■ Cell Therapy

- Natural Killer Cell (Magicell[®]-NK)

3 projects approved by MOHW: our cell therapy technology is approved to be used for cancer treatment in E-Da Cancer hospital, Hualien Tzu Chi Hospital and Chi Mei Hospital, Liouying.

- GDT Cell (Magicell[®]-GDT)

First GDT application submitted to MOHW on 2 November 2020.

■ COVID-19 Diagnostic Products

- Nucleic Acid Test Kit: Approved by Taiwan EUA, US EUA and CE-mark
- Antibody Rapid Test: Approved US EUA and CE-mark



Overview of OBP – 301 (oncolytic virus)

■ Licensing status

- (2019.04.08) Licensed to Chugai Pharmaceutical (Code: 4519); licensed territory includes Japan and Taiwan; optional for other territory excluding China.
- (2020.06.09) Jiangsu Hengrui Medicine Co. returned the rights of OBP-301 in China, Hong Kong and Macau.

■ Current status

- Upfront payment: 550 million yen received
- First milestone payment: 500 million yen received





Overview of OBP – 301 (oncolytic virus)

■ Current clinical trial status

Esophageal cancer (JP)
Combined with radiotherapy

Phase II (Initiated by Chugai)

Liver cancer (TW and KR)

Phase I

DSMB completed

Strategy to be discussed

Gastric and esophageal cancer
Combined with ICI (US)

Phase II (PI initiated)

Head and neck cancer
Combined with PD1 and
radiotherapy (US)

Phase II (PI initiated)

Gastric and esophageal cancer
Combined with radiotherapy
(US)

Phase I (PI initiated)

Cell therapy allowed under current Special Acts

- 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



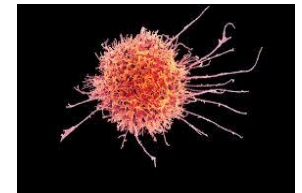
附表三

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、脊髓損傷。
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 GDT cell

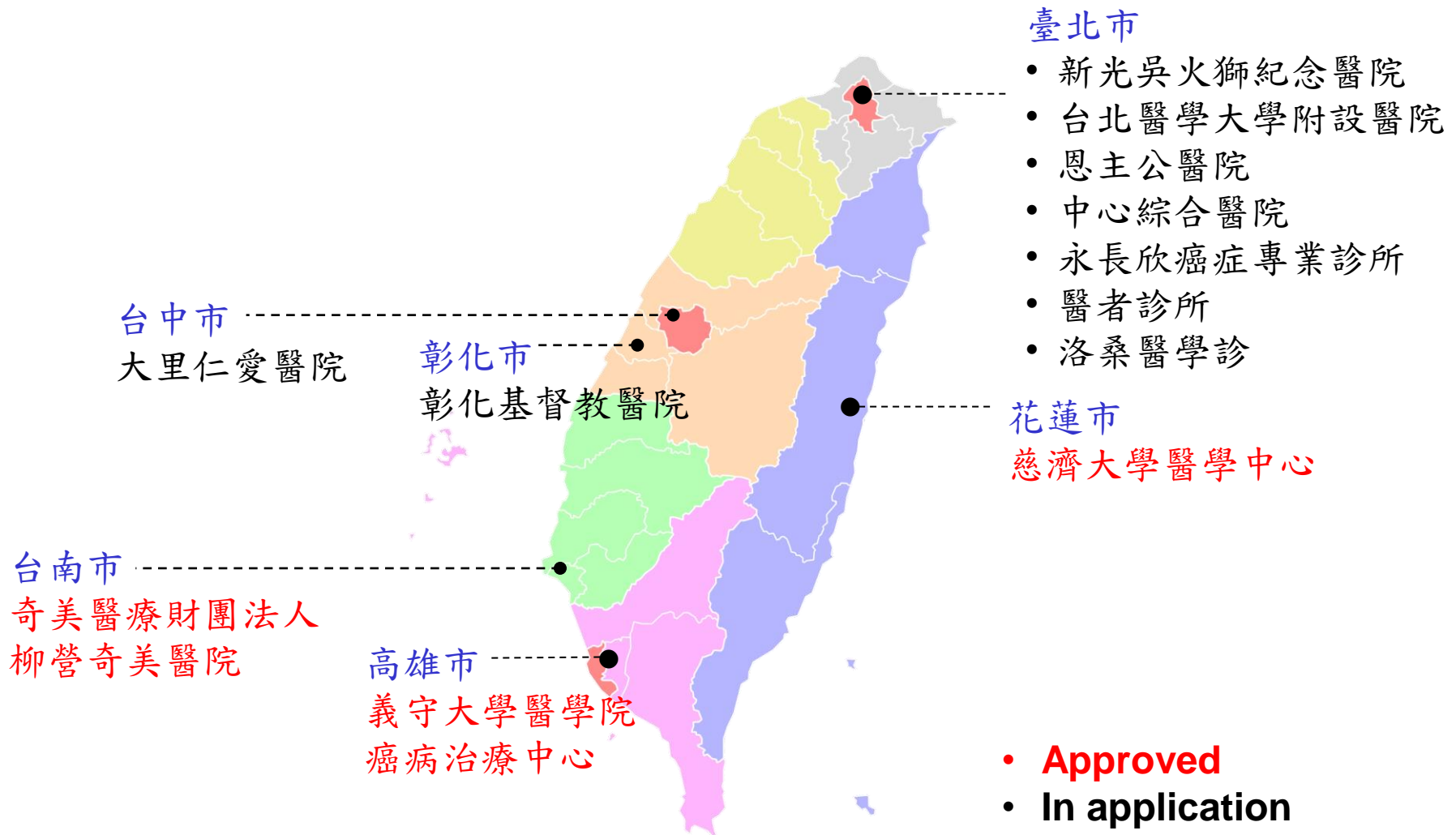
- With the highest cytotoxic activity against cancer cells
- Can be used off-the-shelf, without inducing GVHD
- Persist for longer period in vivo
- Recognize IPP expressed by some cancer types
- Possess better tumor infiltrating capability

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

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





Treatment course of Magicell[®]-NK



- 6 injections as a basic course
- 12 injections as a comprehensive course
- 1 injection every 1~4 weeks
- 100c.c. iv for 30 min for each injection
- Treatment data will be collected by physicians, including:
 - Image data
 - Life style data
 - Quality of life data
 - Survival data



Position of Medigen – High quality immune cells with special features

■ Advantages of facilities and services

- Cell processing unit conforming with GMP guidelines
- Integrated clinical trial team and medical advisory team
- Comprehensive patient support and adequate insurance
- Firm and long-term partnership with medical institutions and physicians

■ Advantages of our products

- The only company in Taiwan approved for NK cell therapy
- The only company in Taiwan submitting application for GDT (gamma-delta T) cell therapy
- Of high purity and cytotoxicity





Future Business Targets

■ GDT cells

To acquire the approval from MOHW for Medigen's GDT cell therapy

■ NK cells

Expand collaboration with more medical institutions to increase the market size

■ Clinical Trials

- Expect to initiate 1~2 clinical trials of NK cells
- Continue OBP-301 clinical development and out-licensing



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.