Material Information (3176 MEDIGEN??????)

SEQ_NO	1	Date of announcement	2024/09/16	Time of announcement	17:46:34

Subject	The Company Has Obtained an Approval from TFDA to Conduct a Phase I/II Clinical Trial using Allogeneic NK Cells

Date of events	2024/09/16	To which item it meets	paragraph 10

Statement

1.Date of occurrence of the event:2024/09/16
2.New drug name or code:Allogeneic natural killer cells (Magicell-NK)
3.Indication:
The company submitted to the Taiwan Food and Drug Administration (TFDA) for an approval to conduct a Phase I/II clinical trial which using allogeneic natural killer cell (Magicell-NK) as an adjuvant therapy for post-surgery combined with chemotherapy for patients with pancreatic ductal adenocarcitnoma (PDA) or bile duct cancer. Magicell-NK is the company's proprietary and independently developed natural killer cell ex vivo expansion technology. Today, the company received the notification from the TFDA that the Phase I/II clinical trial has been approved to process.
4.Planned development stages:Phase I/II clinical trial.
5.Current development stage:
(1)Application submission/approval/disapproval/each of clinical trials (include interim analysis): Approval for conducting a Phase I/II clinical trial from TFDA.
(2)Once disapproved by competent authority or each of clinical trials (includeinterim analysis) results less than statistically significant sense, the risks& the associated measures the Company may occur: Not applicable.
(3)After obtaining official approval or the results of statistically significant sense, the future strategy: Not applicable.
(4)Accumulated investment expenditure incurred: Due to considerations of commercial strategy, disclosure is temporarily withheld.
6.Upcoming development plan:
Our Phase I/II clinical trial will commence upon obtaining an approval from the Institutional Review Board (IRB).
(1) Estimated Completion Time: Expected to be completed in 2029, the actual schedule will be adjusted according to the progress of execution.
(2) Expected Obligations: Our company will bear the expenses related to clinical trials and registration fees.
7.Market situation:
According to the latest global cancer statistics from the World Health Organization (WHO) in 2022, there were approximately 20 million new cancer cases and around 9.7 million cancer-related deaths worldwide in 2022, highlighting a worsening global cancer burden. By 2050, the number of new cancer cases is projected to increase by 77% compared to 2022, a staggering rise.
In Taiwan, the Ministry of Health and Welfare reported that malignant tumors remained the leading cause of death in 2023, with cancer claiming 53,126 lives, which accounts for 25.8% of all deaths. The most common cancers were ranked as follows: (1) trachea, bronchus and lung cancer, (2) liver and intrahepatic cholangiocarcinoma, (3) colon, rectum and anus cancer, (4) female breast cancer, (5) prostate cancer, (6) oral cancer, (7) pancreatic cancer, (8) gastric cancer, (9) esophageal cancer and (10) ovarian cancer.
8.Any other matters that need to be specified(the information disclosure also meets the requirements of Article 7, subparagraph 8 of the Securities and Exchange Act Enforcement Rules, which brings forth a significant impact on shareholders rights or the price of the securities on public companies.):none
9.New drug development requires long process, vast investments and with no guarantee in success which may pose investment risks.The investors are advised to exercise caution and conduct thorough evaluation.: