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

SEQ_NO	1	Date of announcement	2024/02/29	Time of announcement	17:31:4(

Subject	Our company has applied to the Taiwan Food and Drug Administration (TFDA) for Phase I/II clinical trial of allogeneic natural killer cells (Magicell-NK)

Date of events	2024/02/29	To which item it meets	paragraph 10

Statement

1.Date of occurrence of the event:2024/02/29
2.New drug name or code:Allogeneic natural killer cells (Magicell-NK)
3.Indication:
The application of Phase I/II clinical trial of allogeneic natural kille (NK) cells submitted to the Taiwan Food and Drug Administration (TFDA) involves the use of our company's proprietary and independently develope allogeneic natural killer cell expansion technology, Magicell-NK. This technology utilizes blood from donors, which is cultured, activated, and expanded ex vivo to prepare natural killer cell products. These products are then administered back into the patients and will be used as adjuvan therapy post-surgery, in combination with chemotherapy, for pancreatic ductal adenocarcitnoma (PDA) or bile duct cancer patients, aiming to prevent recurrence and increase survival time.
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): Submitted an application for Phase I/II clinical trial to TFDA.
(2)Once disapproved by competent authority or each of clinical trials (include interim 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 approval from the TFDA and 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 related 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, indicating 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. Taiwan's Ministry of Health and Welfare announced that malignant tumors continued to be the leading cause of death in 2021 claiming the lives of 51,656 individuals, accounting for 28.0% of total deaths. Among these, lung cancer, liver and bile duct cancer, and colorectal cancer ranked as the top three cancers.
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.: