Real Time Material Information

This information is provided by 3176 Medigen Biotech Corp. (TPEx Listed Company)

Item	1	Announcement Date	2021/06/11	Announcement Time	16:17:34
Spokesperson	Arlene Chiang	Spokesperson Position	Assistant Vice President, Operations Department	Contact Information	[02]2653-5200#890
Subject	The Company has submitted the autologous natural killer cell therapy (Magicell-NK) phase 1 clinical trial application to the Taiwan Food and Drug Administration (TFDA) of the Ministry of Health and Welfare (MOHW)				
Pursuant To Article	4	Subparagraph	53	Date of occurrence of event	2021/06/11
Details	1. Date of occurrence of the event: 2021/06/11 2. Company name: Medigen Biotechnology Corporation 3. Relationship with the Company (please enter "the company itself" or "subsidiaries"): The Company itself. 4. Reciprocal shareholding percentage: NA 5. Cause of occurrence: The phase 1 clinical trial of autologous natural killer cell therapy that the Company had submitted to the TFDA for approval this time applies the Magicell-NK natural killer cell in vitro expansion technology independently developed by the company. This technology utilizes the subjects' own blood, which is processed into natural killer cells through the steps of culturing, activation and expansion, and then delivered back into the subjects' body. The Company's Magicell-NK technology is developed in accordance with the relevant regulations such as the Regulations on Human Trials and the Regulations for Good Clinical Practice, and does not utilize any animal-derived serum and feeder cells, generating through in vitro culture high yield, high purity and high cytotoxicity autologous natural killer cells. In addition, the Company's GTP laboratory cell processing unit (CPU) has been accredited by the MOHW on February 3, 2020 to comply with the Good Tissue Practice (GTP), and will be used for cell processing in this phase 1 clinical trial and to provide autologous natural killer cell products that abide by the relevant clinical regulations. The Company has now compiled the data and submitted the application for phase 1 clinical trial to the TFDA. 6. Countermeasures: None 7. Any other matters that need to be specified: I. Name or code of the investigational new drug: Autologous natural killer cell (Magicell-NK). II. Indication: Used as an adjuvant therapy for patients with resected colon cancer to prevent recurrence and increase survival time. III. All stages of development that are expected to be carried out: Phase I clinical trial. IV. The current stage of development: 1) Application submitted/ application approved/ application rejected/ results release of various phases of clinical trials (including interim analysis)/ occurrence of other major events affecting the development of investigational new drugs: Submission of phase 1 clinical trial application to the TFDA. 2) Risks faced by the Company and corresponding measures for those				

	who have not obtained the approval by the competent authority, or when the results of any clinical trial phase (including interim analysis) are not statistically significant, or other major events affecting the development of investigational new drugs: NA 3) Future business direction for those who have obtained the approval by the competent authority, or when the results of any clinical trial phase (including interim analysis) have attained statistical significance, or other major events affecting the development of new drugs: NA 4) Cumulative research and development investment expenditure incurred: Based on business strategy considerations, this information will not be disclosed for the time being. V. The next stage of development that will be carried out: The Company will be carrying out phase 1 clinical trial once the approval by the TFDA and the Institutional Review Board (IRB) is obtained. 1) Estimated completion date: The clinical trial is estimated to be completed by 2024, and the actual schedule will be adjusted according to progress. 2) Estimated obligation: Expenses related to clinical trial and registration will be paid. VI. Current Market Status: According to the Global Cancer Statistics 2020 by the World Health Organization (WHO), an estimated 19.3 million new cancer cases and almost 10 million deaths occurred in 2020 worldwide, and the global cancer burden will continue to rise. Taiwan's Ministry of Health and Welfare has announced that in 2019, malignant tumors had remained as the leading cause of death for 38 consecutive years, claiming a total of 50,232 lives and accounting for 28.6% of the country's total deaths, a record high. Among them, lung cancer, liver cancer, and colorectal cancer were ranked among the top 3, posing an escalating threat to the lives and health of the Taiwanese people. VII. It takes considerable time and expenses to develop a new drug of which success cannot be guaranteed. Investors shall bear such investment risk that warrants careful assessment before making investment decisions.