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

SEQ_NO	1	Date of announcement	2025/06/06	Time of announcement	16:07:23

Subject	Company has withdrawn its US FDA IND application for PhaseI/II human clinical trials of allogeneic natural killer cells (Magicell-NK)

Date of events	2025/06/06	To which item it meets	paragraph 10

Statement

1.Date of occurrence of the event:2025/06/06
2.New drug name or code:Allogeneic NK cell (Magicell-NK)
3.Indication:
The Phase I/II human clinical trial of allogeneic natural killer (NK) cells applied to U.S. Food and Drug Administration (US FDA). The proposed trial involves administering allogeneic NK cells in combination with chemotherapy following surgical resection in patients with pancreatic ductal adenocarcinoma (PDA) or bile duct cancer, with the aim of preventing disease recurrence and extending survival.”
4.Planned development stages:Obtain US FDA approval to conduct a Phase I/II clinical trial.
5.Current development stage:
(1)Application submission/approval/disapproval/each of clinical trials (include interim analysis): The Company has withdrawn its US FDA IND application for the Phase I/II human clinical trial following an internal evaluation.
(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:A decision of plan will be made after Company’s evaluation.
7.Market situation:Not applicable.
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.):
(1) During a quick call meeting, the U.S. FDA informed that the test kits used for screening donors, as well as the laboratories conducting the tests, must meet the qualifications specified in 21 CFR 1271.80(b) and (c), including the requirement that laboratories be certified under the CLIA (U.S. Clinical Laboratory Improvement Amendments). After internal evaluation, the Company determined that it would not be able to meet these requirements in the short term and therefore voluntarily withdrew the application.
(2) This withdrawal will not affect the Company’s ongoing clinical trials, development programs, financial position, or business operations.
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.: