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

SEQ_NO	1	Date of announcement	2024/06/03	Time of announcement	20:03:42

Subject	The first participant has been enrolled in the investigator-initiated Phase II clinical trial of the new drug OBP-301 in the United States.
Date of events	2024/06/03
To which item it meets	paragraph 53

Statement

1.Date of occurrence of the event:2024/06/03
2.Company name: Medigen Biotechnology Corp.
3.Relationship to the Company (please enter ”head office” or ”subsidiaries”):head office
4.Reciprocal shareholding ratios:N/A
5.Cause of occurrence:
Regarding the oncolytic virus new drug OBP-301 (Telomelysin), jointly developed by Medigen Biotechnology Corp. and the Japanese listed company Oncolys BioPharma (TSE: 4588), Oncolys announced today (June 3, 2024) that the first participant in the investigator-initiated Phase II clinical trial has been enrolled. Oncolys announced that this trial, conducted at Cornell University in the United States, is studying the combination of OBP-301 with immune checkpoint inhibitors in patients with gastric cancer and gastroesophageal junction cancer (hereinafter referred to as G/GEJ) who have anti-PD-1/PD-L1 antibodies.
This trial is supported by a joint development agreement between Oncolys, Cornell University, and Merck (hereinafter referred to as ”Merck”). Previous results from an investigator-initiated Phase II clinical trial indicated that combining OBP-301 with pembrolizumab (an immune checkpoint inhibitor) could enhance tumor immunity and reactivate the therapeutic effects of pembrolizumab. The purpose of this trial is to verify the efficacy and safety of using OBP-301 in combination with pembrolizumab in patients with gastric cancer and gastroesophageal junction cancer who exhibit resistance to immune checkpoint inhibitor treatments. The trial aims to enroll up to 27 patients.
Currently, the standard first-line treatment for gastric cancer is a combination of immune checkpoint inhibitors and chemotherapy. However, approximately 80% of patients fail this treatment and must move on to second-line therapies. There is no effective treatment for patients who develop resistance to immune checkpoint inhibitors, making it an unresolved medical issue. It is hoped that this trial, through in-depth collaboration with partners, will enable OBP-301 to contribute to the second-line treatment of gastric cancer.
6.Countermeasures: none
7.Any other matters that need to be specified(the information disclosure also meets the requirements of Article 7, subparagraph 9 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) Previous announcements about this Phase II clinical trial: announcements made on September 25, 2023, November 7, 2023, and December 20, 2023.
(2)Currently, OBP-301 is undergoing several clinical trials in the United States, including:
An investigator-initiated Phase II clinical trial combining OBP-301 with immune checkpoint inhibitors for gastric and esophageal cancers.
A Phase II trial combining OBP-301 with pembrolizumab (an anti-PD-1 antibody) and radiation therapy for head and neck cancer.
A Phase I trial combining OBP-301 with chemoradiotherapy for esophageal cancer.
(3) Our company and Oncolys share the development costs of OBP-301 and will also share the future commercial benefits.
(4) The development timeline for new drugs is long, the investment costs are high, and there is no guarantee of success. These factors can pose risks to investments, so investors should carefully evaluate and invest cautiously.
(5)Link to the announcement by Oncolys BioPharma in Japan:
https://ssl4.eir-parts.net/doc/4588/tdnet/2454650/00.pdf