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

SEQ_NO 1 Date of announcement 2025/01/24 Time of announcement 14:42:20

Subject: Reporting the Result of PI-initiated Phase I Clinical Trial for OBP-301-Chemoradiation Combination Therapy in ASCO

Date of events 2025/01/24 To which item it meets paragraph 53

Statement:

1.Date of occurrence of the event:2025/01/24
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:
Medigen Biotechnology Corp. and the Japanese publicly traded company Oncolys BioPharma (“Oncolys”, TSE stock code 4588), are jointly developing the oncolytic virus new drug OBP-301 (Telomelysin). Oncolys announced today (January 24, 2025) the investigator-initiated phase I clinical trial for OBP-301 in combination with chemoradiation in esophageal or gastro-esophageal cancer conducted in the United States (“the Study”), reported its results at the American Society of Clinical Oncology (ASCO) Gastrointestinal Cancers Symposium on January 23, 2025 (U.S. time). A summary of the report is as follows:
(1) The patients administered OBP-301
The Study recruited 15 patients who were ineligible for surgery, including 12 patients with esophageal cancer and 3 patients with gastro-esophageal junction (GEJ) cancer. The Study evaluated the safety and preliminary efficacy of OBP-301 with chemoradiation. Ultimately, 14 participants completed the Study complying with the protocol treatment.
(2) Results of the Study
A.Safety Assessment
Among the 14 participants who completed the trial complying with the protocol treatment, the most common treatment-related serious or life-threatening adverse events included 6 cases of moderate to severe neutropenia and 5 cases of lymphopenia. However, no adverse events leading to the termination of the OBP-301 trial (dose-limiting toxicity, DLT) were reported.
B. Preliminary Efficacy Assessment
Of the 15 enrolled patients, 2 died before efficacy could be confirmed, leaving 13 patients for the efficacy evaluation. Among the two patients who died before efficacy confirmation, one experienced worsening severe respiratory failure and died in the sixth week of treatment; this death was determined to be unrelated to OBP-301 administration. The other patient was diagnosed with a previously unrecognized condition involving a tracheo-esophageal fistula, which led to treatment discontinuation and was considered might relate to OBP-301 administration.
C. Efficacy Determination
Based on EGD/biopsy evaluations, tumor disappearance at the OBP-301 administration site was confirmed in all 13 patients (clinical Complete Response: cCR).
To date, the safety of OBP-301 in combination with chemoradiotherapy has not yet been fully confirmed. However, the results of the Study indicate that OBP-301 can not only be safely with chemoradiation but also demonstrates groundbreaking therapeutic effects, with a response rate of 100%. Given the currently low five-year survival rate for esophageal cancer, the team will consider the next phase of clinical trials to maximize the potential of OBP-301 and expand its reach in the global market.
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)The development timeline for new drugs is long, the investment costs are high, and success is not guaranteed. These factors may pose risks to investors, who should make careful judgments and invest cautiously.
(2)Our company shares the development costs of OBP-301 with Japan's Oncolys and will share in the future commercial benefits.
(3)Link to the announcement from Japan's Oncolys:
https://ssl4.eir-parts.net/doc/4588/tdnet/2551094/00.pdf