SEQ_NO	2	Date of announcement	2025/10/14	Time of announcement	14:22:54
Subject	The Final Result of Phase II Clinical Trial of OBP-301 Presented in ESMO Congress 2025				
Date of events	2025/10/14	To which item it meets	paragraph 53		

Statement

1.Date of occurrence of the event:2025/10/14
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 (TSE stock code 4588) are jointly developing the oncolytic virus new drug OBP-301 (Telomelysin). Oncolys announced today (October 14, 2025) that the final results of the Phase 2 clinical trial of OBP-301 (suratadenoturev) in combination with radiation therapy (hereinafter referred to as the “OBP101JP trial”) will be presented at the European Society for Medical Oncology (ESMO) Congress 2025, to be held from October 17 to 21, 2025.

The key highlights of the presentation are as follows:
(1) The OBP101JP trial enrolled 37 patients for safety evaluation, of whom 36 patients were included in the efficacy analysis.
(2) The local complete response (L-CR) rate over the 18-month study period was 18 out of 36 patients (50.0%), exceeding the pre-specified threshold of 30.2%.
(3) The overall survival rate at 18 months was 56.6%, and the cancer-specific survival rate was 70.1%.
(4) These efficacy outcomes suggest that the combination therapy achieved better results compared with radiation therapy alone.
(5) The most frequently observed adverse events were lymphocyte count decrease (26 of 37 cases, 70.3%) and fever (23 of 37 cases, 62.2%), both of which were transient and manageable.
(6) Treatment of esophageal cancer with OBP-301 is considered to be clinically beneficial.
An application for marketing approval of OBP-301 as a regenerative medical product, with esophageal cancer as the first indication, is planned to be submitted to Japan’s PMDA by the end of December 2025.
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/2696689/00.pdf