Medigen Biotechnology Corp. (3176 MEDIGEN)					
SEQ_NO	1	Date of announcement	2023/10/16	Time of announcement	07:09:24
Subject	Announcement on Topline Data Results from Phase II Clinical Trial evaluating OBP-301 for Esophageal Cancer in Japan				
Date of events	2023/10/16	To which item it meets	paragraph 53		
Statement	1. Date of occurrence of the event:2023/10/16 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, on October 16, 2023, that in the Phase II clinical trial of OBP-301 in combination with radiation therapy for esophageal cancer conducted in Japan, the primary efficacy endpoint, "Local Complete Response Rate" (L-CR), exceeded the pre-defined threshold set in the clinical trial protocol. This data shows efficacy of OBP-301 in treating advanced local esophageal cancer. This trial enrolled in total 37 patients with locally advanced esophageal cancer who were ineligible for curative resection or radiation therapy. Over the course of six weeks of radiation therapy, OBP-301 was administered to the affected area via endoscopy three times. The trial data, evaluated by a central endoscopy committee, showed that the primary efficacy endpoint, the "Local Complete Response Rate" (L-CR rate) was 41.7% (rounded to the nearest tenth, and same for all numbers hereafter mentioned), which exceeded the efficacy threshold of 30.2% set in the trial protocol. The secondary efficacy endpoint, the "Local Response Rate" (L-RR rate, indicating cases where the primary tumor did not completely disappear but showed significant reduction) was 16.7%. The overall local response rate (L-CR+L-RR) was 58.3%. As of the latest update, the one-year survival rate is 71.4%, surpassing the one-year survival rate of 57.4% for radiation therapy alone, as reported in the "Esophageal Association National Registry Data." The major side effects associated with OBP-301 were fever in 51.4% of cases and lymphocyte count reduction or lymphopenia in				

	48.6% of cases. However, these side effects were generally mild to moderate in severity and of short duration. We believe these results have clinical significance and will undergo further analysis. The submission for drug approval is anticipated for the second half of 2024. 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) New drug development involves lengthy timelines, high costs, and success is not guaranteed. Such factors introduce risks to investments, and investors should exercise caution and careful judgment when considering investments. (2) Medigen shares the research and development costs of OBP-301 with Oncolys BioPharma, and will also share future commercial benefits. (3) Link to the announcement by Oncolys BioPharma in Japan: https://ssl4.eir-parts.net/doc/4588/tdnet/2345760/00.pdf