

Material Information (3176 MEDIGEN)

SEQ_NO	1	Date of announcement	2025/11/25	Time of announcement	18:23:40
Subject	The Progress Update of the New Drug under Development, OBP-301				
Date of events	2025/11/25	To which item it meets	paragraph 53		
Statement	1.Date of occurrence of the event:2025/11/25 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 (November 25, 2025) that OBP-301 is currently undergoing the "Sakigake Comprehensive Evaluation Consultation" with the PMDA (Pharmaceuticals and Medical Devices Agency). The company recently received the application confirmation document for the "Reliability" category and expects to receive confirmation documents for the remaining categories in due course. OBP-301 is planned to be submitted as a regenerative medical product with esophageal cancer as its first indication, with the marketing application scheduled to be filed 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)This announcement provides an update and additional explanations following the progress of OBP-301 announced on August 5, June 24, May 23, May 13 and March 18, 2025. (2)The pre-application consultation is a pre-review mechanism under the Sakigake Designation Scheme. Before applying for the approval of new drugs, its aim is to accept the evaluation of data regarding five items, namely "clinical", "non-clinical", "quality", "reliability", and "GCTP (Good Gene, Cellular, and Tissue-based Products Manufacturing Practice)". By identifying and resolving potential issues in advance, this mechanism aims to shorten the review process. (3)The development timeline for new drugs is long, requires substantial investment, and does not guarantee success. These factors may pose risks to investors, who are advised to exercise prudent judgment before making investment decisions. (4)Our company and Oncolys in Japan jointly share the development costs of OBP-301 and will share the future commercial benefits. (5)Link to the announcement by Oncolys, Japan: https://ssl4.eir-parts.net/doc/4588/tdnet/2723866/00.pdf				