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

SEQ_NO	1	Date of announcement	2025/08/05	Time of announcement	17:58:09
Subject	The Progress Update of the New Drug under Development, OBP-301				
Date of events	2025/08/05	To which item it meets	paragraph 53		

Statement

1.Date of occurrence of the event:2025/08/05
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 (August 5, 2025) that the pre-application consultation has progressed to the ”Reliability” Category.
With the commencement of this “Reliability” consultation, the pre-application consultation will now be underway in all five categories.
Starting from the third quarter of this year, we expected to receive the “application confirmation documents” from the PMDA, which means that “OBP-301 is eligible for submit NDA application in each of the following categories: Clinical, Non-clinical, Quality, GCTP, and Reliability. The company aims to submit NDA application for OBP-301, as a regenerative medical product with esophageal cancer as its first indication, by the end of 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 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, 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.
(4)Our company shares the development costs of OBP-301 with Japan's Oncolys and will share in the future commercial benefits.
(5)Link to the announcement from Japan's Oncolys:
https://ssl4.eir-parts.net/doc/4588/tdnet/2665858/00.pdf