

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

SEQ_NO	2	Date of announcement	2025/05/23	Time of announcement	17:04:26
Subject	The Progress Update of the New Drug under Development, OBP-301				
Date of events	2025/05/23	To which item it meets	paragraph 53		

1.Date of occurrence of the event:2025/05/23
 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 (May 23, 2025) that the pre-application consultation has advanced to the consultation stage of the "quality" item. The remaining items for "Reliability" and "GCTP (Manufacturing and Quality Control of Regenerative Medicine Products)" will commence in the third quarter. The company aims to submit its drug approval application 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 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/2624275/00.pdf>