

SEQ_NO	2	Date of announcement	2024/12/19	Time of announcement	19:43:12
Subject	The progress update of the new drug under development, OBP-301				
Date of events	2024/12/19	To which item it meets	paragraph 53		
Statement	<p>1.Date of occurrence of the event:2024/12/19</p> <p>2.Company name:Medigen Biotechnology Corp.</p> <p>3.Relationship to the Company (please enter "head office" or "subsidiaries"):head office</p> <p>4.Reciprocal shareholding ratios:N/A</p> <p>5.Cause of occurrence:</p> <p>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 (December 19, 2024) that it has reached a consensus with the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan to initiate a pre-application consultation before the submission for drug approval of OBP-301. The consultation is expected to take place in the first half of 2025. Oncolys aims to submit for drug approval by the end of 2025.</p> <p>6.Countermeasures:none</p> <p>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.):</p> <p>(1)The pre-application consultation is a pre-review mechanism under the Sakigake Designation Scheme. It evaluates quality, non-clinical, clinical, reliability, and GCTP data based on the information available before the submission for drug approval. By identifying and resolving potential issues in advance, this mechanism aims to shorten the review process.</p> <p>(2)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.</p> <p>(3)Our company shares the development costs of OBP-301 with Japan's Oncolys and will share in the future commercial benefits.</p> <p>(4)Link to the announcement from Japan's Oncolys: https://ssl4.eir-parts.net/doc/4588/tdnet/2541737/00.pdf</p>				