

Material Information (3176 MEDIGEN)

SEQ_NO	1	Date of announcement	2025/12/14	Time of announcement	13:17:17
Subject	OBP-301, the New Drug under Development, Obtained Orphan Drug Designation Approval from Japan MHLW				
Date of events	2025/12/12	To which item it meets	paragraph 53		
Statement	<p>1.Date of occurrence of the event:2025/12/12</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: 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 December 12, 2025 that OBP-301 has received notification from Japan's Ministry of Health, Labour and Welfare (MHLW) designating OBP-301 as a Regenerative Medical Product for Rare Diseases (Orphan Drug) for the treatment of esophageal cancer patients who are not eligible for curative surgery or chemotherapy. Products designated as Rare Disease Regenerative Medical Products are granted up to 10 years of data exclusivity, during which regulatory authorities will not accept applications for generic products, thereby providing market exclusivity. An application for marketing approval of OBP-301 as a regenerative medical product, with esophageal cancer as the first indication, is planned to be submitted to Japan's PMDA by the end of December 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)This announcement provides an update following the progress of OBP-301 announced on November 21, 2025.</p> <p>(2)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.</p> <p>(3)Our company and Oncolys in Japan jointly share the development costs of OBP-301 and will share the future commercial benefits..</p> <p>(4)Link to the announcement from Japan's Oncolys: https://ssl4.eir-parts.net/doc/4588/tdnet/2730700/00.pdf</p>				