

Material Information (3176 MEDIGEN)

SEQ_NO	2	Date of announcement	2025/11/21	Time of announcement	06:40:54
Subject	OBP-301, the New Drug under Development, Receives Preliminary Orphan Drug Designation Approval from Japan MHLW				
Date of events	2025/11/21	To which item it meets	paragraph 53		

Statement	1.Date of occurrence of the event:2025/11/21 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 (TSE stock code 4588) are jointly developing the oncolytic virus new drug OBP-301 (Telomelysin). Oncolys announced today (November 21, 2025) that OBP-301 has been preliminary approved for Orphan Drug Designation by Japan's Ministry of Health, Labour and Welfare (MHLW). At the meeting of the"Pharmaceuticals and Medical Devices Council - Subcommittee on Regenerative Medical Products and Biological Technologies," held yesterday (November 20, 2025), the MHLW agreed to designate OBP-301 as a Regenerative Medical Product for Rare Diseases (Orphan Drug), with the formal designation expected to be issued in the coming days. 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. 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)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. (2)Our company shares the development costs of OBP-301 with Japan's Oncolys and will share in the future commercial benefits. (3)Link to the announcement from Japan's Oncolys: https://ssl4.eir-parts.net/doc/4588/tdnet/2723120/00.pdf
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