SEQ_NO	1	Date of announcement	2025/12/15	Time of announcement	13:43:35

Subject	OBP-301, a New Drug Under Development, has been Submitted to Japan’s PMDA for New Drug Application
Date of events	2025/12/15 To which item it meets paragraph 53

Statement

1.Date of occurrence of the event:2025/12/15
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 (December15, 2025) that OBP-301, developed as a regenerative medicine–related product with esophageal cancer as its indication, has been submitted today to Japan’s Pharmaceuticals and Medical Devices Agency (PMDA) for New Drug Application (NDA). Under the SAKIGAKE Designation System, approval is in principle expected to be granted approximately six months after submission. Medigen and Oncolys plans to obtain the approval from the Health, Labour and Welfare with the eligibility of “the world’s first oncolytic adenovirus drug approved for the treatment of esophageal cancer.” Following official drug price listing in Japan, sales of OBP-301 are planned to commence in fiscal year 2026.
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 SAKIGAKE Designation System is a series of priority and incentive policies proposed by Japan to accelerate the research and development and market launch of novel and regenerative medicine products.
(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.
(3) Our company and Oncolys in Japan jointly share the development costs of OBP-301 and will share the future commercial benefits.
(4) Link to the announcement by Oncolys, Japan:
https://ssl4.eir-parts.net/doc/4588/tdnet/2731115/00.pdf