SEQ_NO	1	Date of announcement	2026/06/08	Time of announcement	15:07:39

Subject	Telomelysin (OBP-301) Officially Obtains Manufacturing and Marketing Approval in Japan

Date of events	2026/06/08	To which item it meets	paragraph 53

Statement

1.Date of occurrence of the event:2026/06/08
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 (June 08, 2026) that the oncolytic virus drug, Telomelysin Injection (International Nonproprietary Name: suratadenoturev; development code: OBP-301), has officially received manufacturing and marketing approval from the Ministry of Health, Labour and Welfare (MHLW) of Japan. The approved indication is for esophageal cancer that is unsuitable for curative resection and chemoradiotherapy.
Telomelysin Injection is the world's first oncolytic adenovirus formulation indicated for esophageal cancer. Based on the results of a pivotal clinical trial conducted across 17 medical institutions in Japan, the new drug application was submitted to the regulatory authority on December 15, 2025. Today, the manufacturing and marketing approval for Telomelysin Injection has been officially granted. Furthermore, this approval is regular approval, meaning that the conditional and time-limited approval will not apply.
Following the completion of the National Health Insurance (NHI) price listing, Telomelysin will be marketed and distributed by FUJIFILM Toyama Chemical Co., Ltd. (hereinafter ”FUJIFILM Toyama Chemical”). This arrangement is in accordance with the commercialization agreement signed in February 2024, with the official commercial launch in Japan planned for fiscal year 2026.
Upon obtaining this manufacturing and marketing authorization for Telomelysin Injection, a milestone payment will be received from FUJIFILM Toyama Chemical; however, the specific financial details will not be disclosed.
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 “regular approval” of Japanese pharmaceuticals means that without any emergency situations, after completing full clinical trials and review procedures and confirming its efficacy and safety, the drug is officially approved for marketing by the Japanese government (Ministry of Health, Labour and Welf).
(2) Our company and Oncolys in Japan jointly share the development costs of OBP-301 and will share the future commercial benefits.
(3) Link to the announcement by Oncolys,Japan:
https://ssl4.eir-parts.net/doc/4588/tdnet/2832908/00.pdf