NB: this is a summary translation of the press release original drafted in Japanese for the disclosure required in compliance with the TSE regulations.

13 December 2017

Oncolys BioPharma Inc.

Enrollment of First Patient in Investigator-Initiated Clinical Trial for Telomelysin® (OBP-301) - pembrolizumab combination therapy

Following our press release "Announcement of Investigator-Initiated Trial Agreement with National Cancer Center Hospital East ("NCCHE") Using OBP-301" dated 10 August, 2016, Oncolys BioPharma ("Oncolys") is pleased to announce that the first patient has been successfully enrolled in the world's first investigator-initiated Phase I clinical trial of Telomelysin® (OBP-301), oncolytic viral immunotherapy, in combination with pembrolizumab, an anti-PD-1 therapy marketed by Merck & Co., Inc., Kenilworth, NJ, USA (known as MSD outside the United States and Canada), for the treatment of patients with advanced or metastatic solid tumors.

The purpose of this clinical trial is to evaluate safety and tolerability of Telomelysin® with anti-PD-1 therapy and it expects to enroll up to twenty eight patients in NCCHE in Japan.

Currently Oncolys has a Phase II clinical trial for melanoma in the US, and a Phase I/II clinical trial for hepatocellular cancer in Taiwan and Korea. In Japan, Oncolys' first sponsor-initiated Phase I clinical trial of Telomelysin®-radiation combination therapy for esophageal cancer is in progress. In addition, an investigator-initiated clinical study of the same therapy and tumor type by Dr. Toshiyoshi Fujiwara, Okayama University, has been ongoing.

The announcement above will not affect Oncolys' earnings for the fiscal year ending 31 December 2017.

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About Telomelysin® (OBP-301)

Telomelysin® is an oncolytic adenovirus in which gene is modified to be able to selectively replicate in cancer cells by introducing human telomerase reverse transcriptase (hTERT) promotor. Oncolytic adenovirus has much potential for cancer immunotherapy because its viral replication is highly immunogenic, and oncolysis induced by such virus releases tumor epitopes and provides costimulatory danger signals. From the result of phase I clinical trial in the US, Oncolys obtained promising data showing abscopal effect in melanoma patients after single injection into one single tumor and found that not only increasing infiltration of CD8 and antigen presenting cells but diminishing Treg cells

in injected tumor site. ***Clinical Research****: Co-development with Medigen Biotechnology Corporation: esophageal cancer (Phase I, in combination with radiotherapy, Japan); hepatocellular cancer (Phase I/II, Taiwan/South Korea); melanoma (Phase II, USA); and solid tumors (clinical investigation, in combination with pembrolizumab, NCCHE, Japan)*

About Oncolys BioPharma Inc.

Oncolys BioPharma is a TSE Mothers-listed biopharmaceutical company with focuses on the development of novel biologics for the treatment of cancer and infectious diseases. The company's lead product for the treatment of cancer, Telomelysin® (OBP-301), is based on replication-competent oncolytic virus, and is being tested in Phase I/II clinical trial in Asia and Phase II in the USA, for various solid tumors. A novel cancer diagnostic product, TelomeScan® (OBP-401/1101), is expected to be effective in detecting various types of cancer and inflammatory diseases and adopted in several private practices. The company also has a major program OBP-601 (Censavudine) for infectious diseases, for which it completed Phase II clinical trial in the U.S. for HIV/AIDS therapy, supported by BMS.
For more information, please visit http://www.oncolys.com/en/

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