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

28 July 2017

Oncolys BioPharma Inc.

Enrollment of First Patient in Melanoma Phase II Clinical Trial for Telomelysin® (OBP-301) in the US

Oncolys BioPharma ("Oncolys") is pleased to announce that it enrolled the first patient in its first sponsor-initiated Phase II clinical trial for Telomelysin® (OBP-301) for the treatment of melanoma in the US.

The aim of this clinical trial is to research the efficacy, safety and tumor immunity of Telomelysin® administered locally on unresectable or metastatic melanoma patients in clinical centers in the US. The trial expects to enroll up to fifty patients in five sites across the country. After obtaining the results of the trial, Oncolys will also consider an additional clinical trial of Telomelysin® in combination with immune check-point inhibitors in the US.

Currently Oncolys has a Phase I/II clinical trial for hepatocellular cancer in progress in Taiwan and Korea, and in July 2017 it successfully enrolled the first patient in its first sponsor-initiated Phase I clinical trial of Telomelysin®-radiation combination therapy for esophageal cancer in Japan. In addition, an investigator-initiated clinical study of the same therapy and tumor type by Dr. Toshiyoshi Fujiwara, Okayama University, has been in progress. Another investigator-initiated trial for a combination therapy of Telomelysin® and pembrolizumab, an anti-PD-1 therapy, for the treatment of patients with advanced or metastatic solid tumors, is in preparation for the enrollment of the first patient in the National Cancer Center Hospital East, Japan.

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. Currently OBP-601 is under an option agreement with LBR Regulatory & Clinical Consulting Services, Inc. in the USA.
For more information, please visit http://www.oncolys.com/en/

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