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

14 Mar 2017

Oncolys BioPharma Inc.

Oncolys Submitted CTN of the First Sponsor-Initiated Clinical Trial for Telomelysin® (OBP-301) in Japan

Oncolys BioPharma ("Oncolys") is pleased to announce that today it submitted a clinical trial notification (CTN) of Telomelysin® (OBP-301) to the Pharmaceuticals and Medical Devices Agency (PMDA), for the first sponsor-initiated Phase I clinical trial to be conducted in Japan.

The aim of this clinical trial is to research the safety, efficacy and tumor immunity of Telomelysin® administered in combination with radiation to esophageal cancer patients who are not eligible for surgical excision or definitive chemoradiotherapy, which Oncolys acknowledges is the first sponsor-initiated Phase I clinical trial of Telomelysin® in Japan, while an investigator-initiated clinical study of Telomelysin®-radiation combination therapy for esophageal cancer by Dr. Toshiyoshi Fujiwara, Okayama University, has been in progress.

The safety of Telomelysin® had been observed in the US Phase I clinical trial for various solid tumors, where some of the cases showed tumor shrinkage and relevant immune response following a local administration of Telomelysin®. Several cases also indicated an abscopal effect (*) where a cytoreduction in Telomelysin®-unadministered tumor was observed.

Currently, Oncolys has a Phase I/II clinical trial for hepatocellular cancer in progress in Taiwan and Korea, and a Phase II clinical trial for melanoma in the US. In Japan, in addition to the foregoing investigator-initiated clinical study at Okayama University, Oncolys entered into a new investigator-initiated trial agreement with National Cancer Center Hospital East in 2016, to study the efficacy of a combination therapy with Telomelysin® and other cancer treatment.

The announcement above will not affect Oncolys' earnings for the fiscal year ending 31 December 2017, and within the same fiscal year Oncolys does not plan any equity funding which involves dilution, aimed at forging ahead with the above clinical trial.

(*) The abscopal effect is a phenomenon where localized treatment of a tumor causes not only a shrinking of the treated tumor, but also a shrinking of tumors outside the scope of the localized treatment

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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****: esophageal cancer (clinical investigation, in combination with radiotherapy, Okayama University, Japan); hepatocellular cancer (Phase I/II, with Medigen Biotechnology Corp., Taiwan/South Korea); and melanoma (Phase II, USA).*

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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