Press Release

ONCOLYS BIOPHARMA INC. (TSE Mothers: 4588)

24 May 2017

Oncolys' First Telomelysin® Phase I Clinical Trial in Japan Received IRB Approval

Tokyo, JAPAN: Oncolys BioPharma ("Oncolys") is pleased to announce that the Institutional Review Board (IRB) of Okayama University Hospital, has approved the Phase I clinical trial protocol of Telomelysin® (OBP-301) for esophageal cancer and patient enrollment for the study at Okayama University Hospital.

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. It 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 IRB review took place, after the Pharmaceuticals and Medical Devices Agency ("PMDA")'s 30 days review period following the submission of a clinical trial notification ("CTN") of Telomelysin® (OBP-301) to PMDA on 14th March 2017. With the green light on, Oncolys is now stepping up, with its utmost attention to the safety of the patients, preparations for the enrollment of the first patient in the clinical trial in Japan.

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About OBP-301 (Telomelysin®):

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 Status: esophageal cancer (clinical investigation and sponsor-initiated Phase I, 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 as companion diagnostic tool 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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