

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

24 Mar 2017

Oncolys BioPharma Inc.

Oncolys signs a revised strategic alliance agreement for Telomelysin® (OBP-301) with Medigen Biotechnology Corp.

Oncolys BioPharma (“Oncolys”) is pleased to announce that today the board of the company resolved to enter into a revised strategic alliance agreement with Medigen Biotechnology Corp. (Taiwan, Chairman/CEO: Dr. Stanley Chang, hereinafter “Medigen”), a strong collaborator of a Phase I/II clinical trial for hepatocellular cancer currently in progress in Taiwan and Korea, which was initiated under the strategic alliance agreement between the parties signed in March 2008.

The new revised agreement specifies that Oncolys grants Medigen a co-development right for esophageal cancer and melanoma, in addition to hepatocellular carcinoma of which the current Phase I/II shall continue as planned. In return, Medigen shall share the research and development costs of Telomelysin® incurred in connection with the foregoing cancers at a rate set according to the terms of the agreement. The said right’s coverage shall be worldwide but excluding the regions where Telomelysin® is and will be licensed to the third parties.

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 an investigator-initiated clinical study of Telomelysin®-radiation combination therapy at Okayama University, Oncolys submitted Clinical Trial Notification (CTN) to the Pharmaceuticals and Medical Devices Agency (PMDA) in March 2017, for the first sponsor-initiated Phase I clinical trial of Telomelysin® for esophageal cancer. Oncolys also entered into a new investigator-initiated trial agreement with National Cancer Center Hospital East in August 2016, to study the safety, efficacy and tumor immunity of a combination therapy with Telomelysin® and other cancer treatment. All these clinical trials shall be subject to the terms of the revised strategic alliance agreement therefore Oncolys and Medigen split the relevant costs accordingly.

In China, including the regions of Hong Kong and Macau, preparations for clinical trials of Telomelysin® led by Jiangsu Hengrui Medicine Co., Ltd. (“Hengrui”), have been in progress, under a license agreement between Oncolys and Hengrui signed in November 2016.

The announcement above will not significantly affect Oncolys’ earnings for the fiscal year ending 31 December 2017, however, the said revised agreement is expected to lead to a long-term benefit of continuing reduction of research and development costs for Oncolys, compared to the case where the relevant costs of clinical trials for Telomelysin® are assumed independently by Oncolys.

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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 (1. Clinical investigation, in combination with radiotherapy, Okayama University, Japan 2. Radiation-combination Phase I, 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.

For more information, please visit <http://www.oncolys.com/en/>

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