26 Mar 2018

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

Oncolys BioPharma Inc.

Oncolys Receives DSMB Approval to Start Higher Dose Patient Cohort 2 in Phase I Clinical Trial for Telomelysin® in Japan

Oncolys BioPharma ("Oncolys") is pleased to announce that the Data Safety Monitoring Board ("DSMB") has authorized Oncolys to move forward with enrollment for Cohort 2, officially confirming the safety of Telomelysin[®] in Cohort 1 of the Phase I dose escalation clinical trial for esophageal cancer in Japan.

This is the first clinical trial Oncolys sponsors and conducted in Japan. It aims to research the safety, exploratory efficacy and immune responses of Telomelysin[®] administered locally in combination with radiation on esophageal cancer patients refractory to existing cancer treatments such as surgery and definitive chemotherapy. Since its start with Cohort 1 with lower dose administration in July 2017, three patients in total have been enrolled to date. In DSMB's view, the results from Cohort 1 showed the safety of Telomelysin[®] administered intra-tumor and there was no adverse effects which can be regarded as an issue to proceed to the next stage. Oncolys plans to complete the Phase I, with continuous careful attention to safety, advancing the program to Cohort 2, the final patient group of this clinical trial.

The announcement above will not affect Oncolys' earnings for the fiscal year ending 31 December 2018.

Ends

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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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