

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

31 Aug 2016

Oncolys BioPharma Inc.

## Protocol Submission of OBP-301 (Telomelysin®) for Phase II Clinical Trial in the United States

Oncolys BioPharma (“Oncolys”) is pleased to announce that today it submitted a protocol of OBP-301 (Telomelysin®) to the Food and Drug Administration (FDA), for a Phase II clinical trial in the United States.

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. Once the submission is accepted by the FDA, Institutional Review Board (IRB) and other relevant bodies will review the protocol before Oncolys initiates the trial. 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.

The safety of Telomelysin was observed in a 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 non-Telomelysin-administered tumor was observed. Currently, Oncolys has a Phase I/II clinical trial for hepatocellular cancer in progress in Taiwan and Korea, while in Japan, an investigator-initiated clinical trial of a combination therapy with Telomelysin and radiation for esophageal cancer by Dr. Toshiyoshi Fujiwara, Okayama University is on-going. Recently Oncolys also signed a new investigator-initiated trial agreement with a group led by Dr. Toshihiko Doi, National Cancer Center Hospital East, 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 2016.

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### About OBP-301 (Telomelysin®)

*Telomelysin® is a therapeutic modality derived from adenovirus. Telomelysin® is generated by replacing the normal transcriptional regulatory element of the E1A gene in the human adenovirus type 5 with the human telomerase reverse transcriptase (hTERT) promoter. Telomerase is an enzyme expressed in approximately 90% of all types of cancer cells. The hTERT promoter is the key for the expression of telomerase, as well as for the complete replication of chromosomal ends. Telomelysin® is able to achieve a high replication rate, due to the internal ribosome entry site*

(IRES) gene inserted between the E1A and E1B genes. **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)

**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, OBP-301 (Telomelysin®), is based on replication-competent oncolytic virus, and is being tested in Phase I/II clinical trial in Asia, for various solid tumors. A novel cancer diagnostic product, OBP-401 (TelomeScan), 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 (Festinavir) for infectious diseases, which has completed Phase II clinical trial in the U.S. for HIV/AIDS therapy, supported by BMS. OBP-601 is a novel NRTI with highly promising safety and resistance profiles. For more additional information, please visit [www.oncolys.com](http://www.oncolys.com)

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