

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

26 May 2016

Oncolys BioPharma Inc.

Completion of Highest Single-Dose Level Clinical Trial of OBP-301 (Telomelysin®), Phase I/II in Taiwan and Korea

Oncolys BioPharma (“Oncolys”) is pleased to announce that following the Data Safety Monitoring Board’s (DSMB) meeting on 12 May 2016, it received a report that the safety and tolerability of OBP-301 (Telomelysin®) on three patients in Cohort 3 of the Phase I/II dose escalation clinical trial for hepatocellular carcinoma (HCC), were officially confirmed.

The aim of this clinical trial is to research the safety and exploratory efficacy of OBP-301 administered locally on HCC patients refractory to existing cancer treatments. Since its start with Cohort 1 with a minimum single-dose administration in November 2014, nine patients in total have been enrolled to date in Taiwan and Korea, with careful attention to safety under a DSMB’s step-by-step monitoring. In DSMB’s view, the results from Cohort 3 showed the safety of OBP-301 administered intrahepatically and there was no adverse effects which can be regarded as an issue to proceed to the next stage of the clinical trial, while the exploratory efficacy of OBP-301 continues to be under review.

Oncolys and Medigen Biotechnology Corp. (Taiwan, Chairman/CEO: Dr. Stanley Chang), a strong collaborator of this Phase I/II clinical trial, will discuss the next step, with a careful attention to the safety, to advance the program to a further higher single-dose and multi-dose administration of OBP-301.

According to the WHO’s report, many HCC cases are Hepatitis B/Hepatitis C-related and approximately 600,000 new cases are diagnosed in Asia and 40,000 new cases in Japan every year. At present, standard topical treatments such as surgery, radiofrequency ablation (RFA) and transcatheter arterial chemoembolization (TACE) are common and available to HCC patients. Nexavar (sorafenib) is also available to HCC patients refractory to existing treatments as first-line therapy, however, not every patient can benefit from its efficacy and there is still a demand for more therapeutically-effective new treatment for HCC patients.

The announcement above will not affect Oncolys’ earnings for the fiscal year ending 31 December 2016.

Ends

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

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