NEWS RELEASE

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Oncolys BioPharma Inc.
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Initiation of Phase I/II Clinical Study of Telomelysin (OBP-301)
- Gene Therapy/Oncolytic Virus for Hepatocellular Carcinoma -

Oncolys BioPharma Inc. (Oncolys) and Medigen Biotechnology (HQ: Taiwan, Chairman: Stanley Chang, MD., Ph.D.) jointly announced today that the first patient has been enrolled on November 18 in a Phase I/II clinical study of oncolytic virus, Telomelysin (Development Code: OBP-301) for hepatocellular carcinoma (HCC) in Taiwan and Korea.

The purpose of this Phase I/II clinical study initiated in Taiwan and Korea is to evaluate safety, exploratory efficacy in patients with hepatocellular carcinoma, who failed standard of care, by loco-regional injection of Telomelysin into tumors.
Oncolys completed Phase I clinical study in the U.S. in patients having various solid tumors during 2006 to 2012. Another clinical research on Telomelysin for the treatment of head and neck and thoracic malignant tumor has been initiated from December 2013 in the department of gastroenterological surgery at Okayama University Graduate School of Medicine, Dentistry and Pharmaceutical Sciences led by Professor Toshiyoshi Fujiwara.

The patients with hepatocellular carcinoma (HCC) are prevalent in Asia. Those patients tend to be infected with hepatitis B or C and will become HCC after becoming chronic hepatitis and hepatic cirrhosis. According to the World Health Organization (WHO), it is reported that there are about new 600,000 patients with liver cancer per year in Asia, and about 40,000 in Japan. The patient with HCC is treated mainly by surgery, Transcatheter Arterial Chemo-Embolization (TACE), Radiofrequency Ablation (RFA) or Percutaneous Ethanol Injection Therapy (PEIT). Currently, although Nexavar (sorafenib, Bayer) is used as treatment for the first line drug for HCC, some patients with HCC treated with Nexavar are not sufficiently effective. Thus, novel medical treatment for HCC is still needed.

Telomelysin is genetically modified type 5 adenovirus and selectively replicates in cancer cells which telomerase activity is increased and kills them by its oncolytic effect, while Telomelysin does not replicate in normal cells and does not show cytotoxicity. Thus, we expect that Telomelysin may provide safer cancer therapy. Oncolys and Medigen is developing Telomelysin to establish “3rd generation of loco-regional therapy for cancer” following surgery and radiation.

There is no financial impact associated with this announcement.