



January 22, 2014
Oncolys BioPharma Inc.

Oncolys BioPharma Initiates Phase I/II Clinical Study of OBP-301 (Telomelysin) in Liver Cancer

Oncolys BioPharma Inc. (Oncolys) announced the initiation of Phase I/II clinical study of OBP-301 (Telomelysin), oncolytic adenovirus, since an Investigational New Drug (IND) approval was obtained from the Ministry of Food and Drug Safety in Korea as of January 21, 2014.

This Phase I/II clinical study will be conducted to evaluate safety, pharmacokinetics and antitumor effect in patients with liver cancer, who failed standard of care, by loco-regional injection of Telomelysin into tumors. One hundred and two patients at most in Korea and Taiwan will be enrolled.

Oncolys completed Phase I clinical study in the U.S. after obtaining an IND approval from the U.S. Food and Drug Administration in 2006, and 22 patients having a variety of solid tumors were enrolled. In this Phase I clinical study, tumor shrinkage in a part of patients was observed, and clinically significant side effects were not observed.

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 has no effect on normal cells. Thus, we expect that Telomelysin may provide safer cancer therapy. Oncolys is developing Telomelysin to establish “3rd loco-regional therapy for cancer” following surgery and radiation.

The number of patients with liver cancer in Asia is comparably larger than that in the other area. There is the number of patients in Asia with hepatitis B or C infected by mother-to-child transmission, blood transfusion, needle sharing, or transmission through sexual contact, and it will become liver cancer after becoming chronic hepatitis and hepatic cirrhosis. According to the World Health Organization (WHO), it is reported that there are about 600,000 patients with liver cancer in Asia, and about 40,000 in Japan. Liver cancer is treated mainly by surgery, Transcatheter Arterial Embolization (TAE), or Percutaneous Ethanol Injection Therapy (PEIT). Currently, medical treatment for liver cancer is not sufficient and novel medical treatment is still needed.

This announcement will have no effect on the business performance for the fiscal year of 2014.