

PRESS RELEASE

AUGUST 25, 2006  
ONCOLYS BIOPHARMA INC.

**Japan's First Anti-cancer Adenovirus is now GO for clinical studies in US**

Tokyo, Japan, August 25, 2006 --- Oncolys BioPharma (Tokyo, Japan, President & CEO, Yasuo Urata) announces that the company has obtained an FDA's approval by which the company can commence the Phase I clinical trial in which the patients with solid cancers will be receiving the viral treatment with Telomelysin or OBP301. The company submitted the IND to FDA in March this year and the authority has held its approval until the company responded to the issues raised by the authority. As the company's responses are all accepted by the company, Telomelysin is now the first Japanese adenovirus which enters a clinical evaluation in USA.

The Phase I study will enroll the patients with solid tumors who have been resistant to the existing or conventional therapy and who have no other good alternatives.

The first patient is expected to receive the trial medication before October in the Mary Crowley Medical Research Center, Dallas of Texas in the United States. The company also expects that the study will be completed by the end of 2007.

**About Telomelysin:**

Telomelysin is a novel, conditional-restricted, replication-competent adenovirus.

Through a novel vector approach, a transcriptional element of the E1A adenovirus gene, which plays a significant role in replication, has been replaced by an inserted human telomerase reverse transcriptase (hTERT) gene promoter sequence (Fig1).

The hTERT is one of the components of Telomerase, of which expression is up-regulated exclusively in tumor cells. The enzyme is expressed in approximately 90% of all types of cancer cells.

Telomelysin is able to achieve a high replication rate due to Internal Ribosome Binding Site (IRES) gene inserted between E1A and E1B genes.

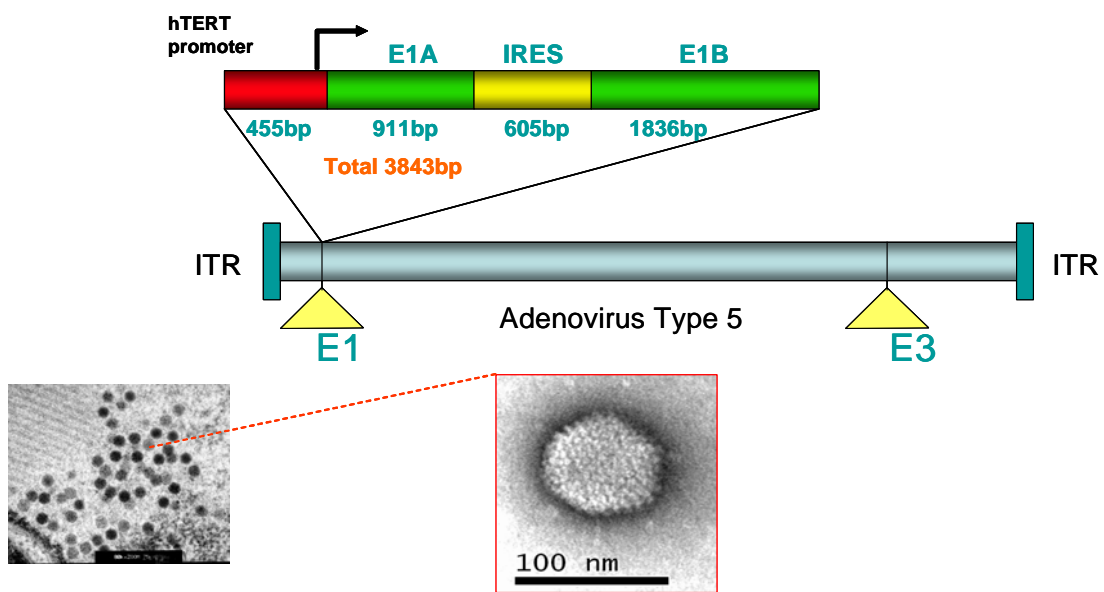
With the said unique features, Telomelysin replicates in cancer cells and such replication leads to cell death, but replication is restricted in normal cells lacking Telomerase activity, resulting in little damage (Fig 2).

Oncolys has already completed preclinical studies which has shown high anti-tumor efficacy on human tumor without any abnormal findings. The early animal studies

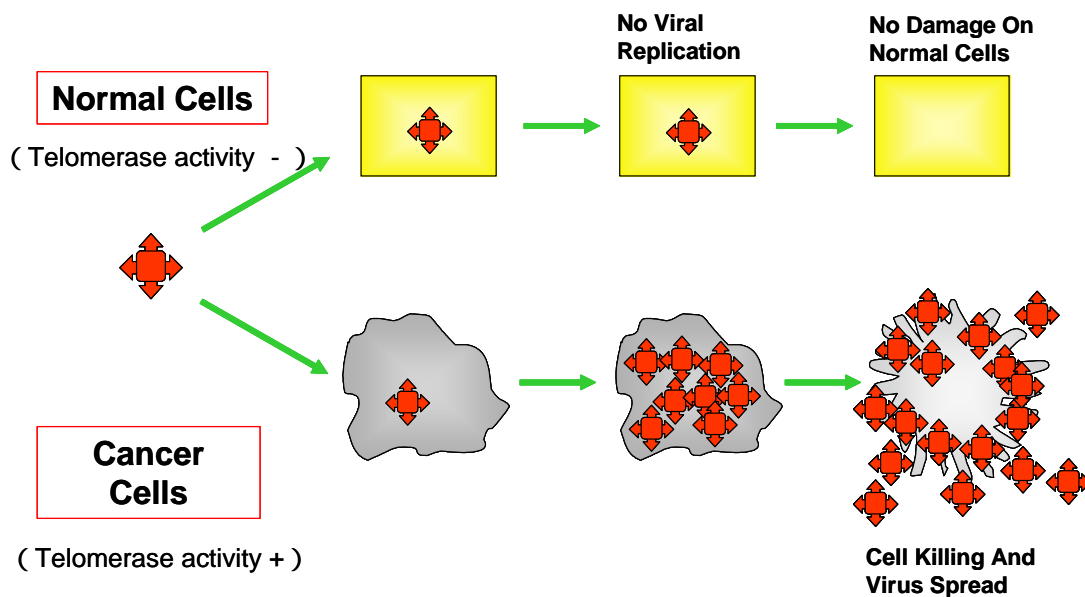
demonstrated that human colon cancer cells transplanted and grown in mice were destroyed 15 days after Telomelysin was injected.

The anti-cancer treatment using Telomelysin is expected to have high efficacy with low adverse effects as it works specifically on the cancer cells. Therefore, patients treated with Telomelysin could get relief from severe adverse effects normally seen with the existing and conventional therapies, and could eventually enjoy better quality of life (QOL).

**Fig. 1**



**Fig. 2**



**About Oncolys BioPharma Inc.**

<http://www.oncolys.com>

The company was founded in March 18, 2004.

The early business objective is to develop and commercialize a newly discovered oncolytic virus “Telomelysin” which is a joint invention by Professor Noriaki Tanaka and Associate Professor Toshiyoshi Fujiwara of Okayama University.

The company has added ‘infectious disease’ as its strategic franchise and concluded an exclusive license agreement with Yale University on behalf of Professor Masanori Baba of Kagoshima University and Professor Hiromichi Tanaka of Showa University in Japan, and Yung-Chi Cheng of Yale University School of Medicine, for a novel anti-HIV candidate therapeutic agent. The agreement will grant Oncolys BioPharma a global exclusive right of clinical and business development.

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Capital: ¥1,058.2 million

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