

PRESS RELEASE

OCTOBER 31, 2006 ONCOLYS BIOPHARMA INC.

# Oncolys BioPharma announces that the first patient is in the Phase I Clinical Study of Telomelysin® for Solid Tumors in U.S.

Tokyo, Japan, October 31, 2006 --- Oncolys BioPharma, Inc. (Tokyo, Japan, President & CEO, Yasuo Urata) announces that its oncolytic adenovirus, Telomelysin®, was given to a patient with breast cancer as the first case of the Phase I Clinical Study. Telomelysin® is administered locally into the tumors. FDA approved the IND file of Telomelysin in August. The Phase I Study is conducted at Mary Crowley Medical Research Center, Texas, USA, with focus on the evaluation of the safety profile of Telomelysin®, including evaluations of the injection sites and aims to complete dosing to the total of 24 patients with progressive various solid cancers by the end of 2007.

## About Telomelysin®:

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

Through genetic engineering, a transcriptional element of the E1A adenovirus gene, which plays a significant role in replication, has been replaced by an inserted human telomerase reverse transcriptase (hTERT) gene promoter sequence (Fig1).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 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 severely restricted in normal cells lacking Telomerase activity, resulting in little damage (Fig 2).

The early animal studies demonstrated that human colon cancer cells transplanted and grown in mice were destroyed 15 days after Telomelysin® was injected. Oncolys has already completed preclinical studies which has shown high anti-tumor efficacy on human tumor without any abnormal findings.

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

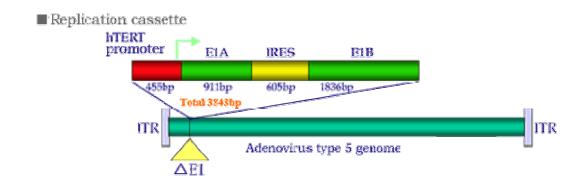
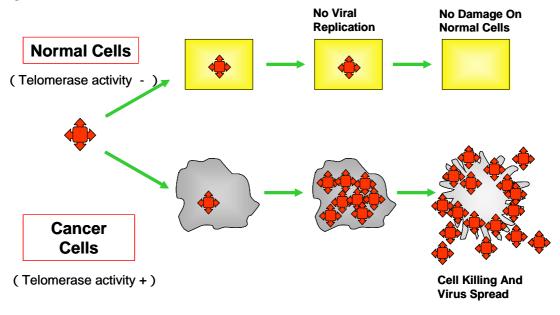


Fig. 2



### 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" invented by Professor Noriaki Tanaka, Associate Professor



Toshiyoshi Fujiwara of Okayama University and their colleague.

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 Professor Yung-Chi Cheng of Yale University School of Medicine, for a novel anti-HIV candidate therapeutic agent. The agreement will grant Oncolys BioPharma global exclusive rights of clinical development and commercialization.

President and CEO: Yasuo Urata

Headquarters: 3-16-33 Roppongi, Minato-ku, Tokyo 106-0032, Japan

Capital: ¥1,058.2 million

#### **About Mary Crowley Medical Research Center**

The Mary Crowley Medical Research Center, located within the Baylor University Medical Center in Dallas, offers a full-service oncology clinic devoted to patient comfort and overall well-being.

Exploring investigational vaccine, gene, and cellular therapies with the goal of expanding treatment options for all cancer patients is the primary mission of the Mary Crowley Medical Research Center. The highly trained personnel conduct early-phase studies utilizing novel therapeutic strategies in one of the most well equipped facilities in the country.

The center conducts early-phase trials aimed at identifying new cancer-specific therapies administered in an outpatient setting.

http://www.marycrowleymedicalresearch.com/default.asp

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