

**Oncolys BioPharma Inc. submitted an IND for Festinavir (OBP-601), a novel anti-HIV drug, to the FDA to gain permission to initiate Ph-I clinical trial in human.**

Tokyo, Japan - March 18 - Oncolys BioPharma Inc. (Yasuo Urata, President & CEO) announced that Oncolys submitted an investigational new drug (IND) for Festinavir (OBP-601) to the FDA in the United States.

Festinavir is a new anti-HIV drug of which mechanism is inhibition of nucleotide reverse transcriptase (NRTI), which is essential for human immune-deficiency virus replication. Oncolys in-licensed worldwide rights of Festinavir from Yale University on June 2006. Festinavir key characteristics include:

- Potential to become the best-in-class thymidine analog
- Comparable or superior efficacy/safety profile versus existing NRTIs based on pre-clinical studies to date
- Activity in the presence of multiple resistant virus, and key NRTI/NNRTI mutation sequences
- Potential for once-a-day dosing based on its longer intracellular concentration
- Potential best "Partner" for co-formulation/combination for the HAART regimen

#### **About HIV infection and AIDS**

Acquired immune deficiency syndrome (AIDS) is a collection of symptoms and infections resulting from the specific damage to the immune system caused by the human immunodeficiency virus (HIV) in human. In 2007, an estimated 33.2 million people lived with the disease worldwide, and it claimed the lives of an estimated 2.1 million people, including 330,000 children, according to the statistics produced by UNAIDS (The Joint United Programme on HIV/AIDS). For the treatment of HIV infection, it is necessary to constantly maintain the effective concentration of drugs in the blood, in order to suppress the viral replication. Therefore it is very important to properly and sustainably take drugs. Otherwise, resistant virus would be appeared and this would cause further problem. For antiretroviral treatment to be effective for a long time, it has been found that patients need to take more than one antiretroviral drug at the same time, namely combination therapy is very important. The term highly active antiretroviral therapy (HAART) is used to

describe a combination of three or more anti-HIV drugs. Taking two or more antiretrovirals at the same time vastly reduces the rate at which resistance develops.

**About Oncolys BioPharma Inc.**

Oncolys BioPharma is a privately held biopharmaceutical company focused on the development of novel biologics for the treatment of cancer and infectious disease. The company's lead compound for the treatment of cancer, Telomelysin® (OBP-301), is based on replication-competent oncolytic virus, and is being tested in Phase-I clinical trial in the U.S. for various solid tumors. A novel cancer diagnostic candidate, Telomescan® (OBP-401), is at validation stage (feasibility studies) and is expected to be effective in detecting various types of cancer. The company also has a major program for infectious disease, Festinavir (OBP-601), at IND stage in the US for HIV/AIDS therapy. Festinavir is a novel NRTI with highly promising safety and resistance profiles. In addition, Oncolys secured the Asian rights for OBP-701 (TT-033), a novel therapeutic product containing three separate RNAi elements entrapped in an AAV protein coat, targeting HCV. For additional information, please visit [www.oncolys.com](http://www.oncolys.com).

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