Oncolys BioPharma
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Oncolys Biopharma Inc.

NEWS

Oncolys BioPharma Inc. Presented A Result of Phase Ia Clinical Study for Festinavir™ (OBP-601), A Novel Anti-HIV Drug, at 16th CROI Held in Montreal, Canada.

Tokyo, Japan – February 10 – Oncolys BioPharma Inc. (Yasuo Urata, President & CEO) today announced that Oncolys presented a result of phase Ia clinical study for Festinavir™ (OBP-601) in male healthy volunteers at 16th CROI (Conference on Retroviruses and Opportunistic Infections) held in Montreal, Canada, on Feb 9th, 2009.

Festinavir™ is a new anti-HIV drug, a nucleotide reverse transcriptase inhibitor (NRTI). Oncolys conducted a single dose phase Ia clinical study in 64 healthy male volunteers in New Jersey, USA. And the result was presented at 16th CROI held in Montreal, Canada. The purpose of the study was to evaluate the safety and pharmacokinetics of Festinavir™ after single dose administration at various doses.
It was indicated that Festinavir™ is safe, and no drug-related adverse event was observed at all doses used. Good pharmacokinetic profile was also observed, and the blood concentration of Festinavir™ 24 hours after administration was over IC_{90} value of anti-HIV activity, which indicated that Festinavir™ could be once-daily dosing regimen.

After completing the phase Ia clinical study, Oncolys submitted an application to start phase Ib clinical study to AFFSAPS (Agence française de sécurité sanitaire des produits de santé) in France, in order to evaluate safety, pharmacokinetics, and the efficacy in a 10-day repeated dose of Festinavir™. After obtaining approval from the French regulatory agency, Oncolys initiated this study at 6 French institutions including the Lyon University Hospital.

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 Nations 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 viral replications. Therefore it is very important to properly and sustainably take drugs. Otherwise, resistant virus would emerge and this would cause further problems. For an antiretroviral treatment to be

effective and maintained for a long time, patients are required to take more than one antiretroviral drug at the same time. Combination therapy with multiple active agents is the cornerstone of today's HIV treatment. 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 circulating tumor cells in the blood. The company also has a major program for infectious disease, Festinavir™ (OBP-601), at phase I stage 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

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