

NB: this is a summary translation of the press release original drafted in Japanese for the disclosure required in compliance with the TSE regulations.

31 May 2016

Oncolys BioPharma Inc.

Announcement of Option Agreement for Anti-HIV Drug OBP-601 (Censavudine®)

Oncolys BioPharma (“Oncolys”) is pleased to announce that the boards of Oncolys approved today that it enters into an option agreement for OBP-601 (Censavudine®), a novel investigational anti-HIV drug, with LBR Regulatory & Clinical Consulting Services, Inc. (“LBR”).

LBR is a professional firm based in Kentucky, USA, specializing in clinical development, regulatory consulting and marketing services in broad therapeutic areas including oncology, anti-inflammatory, gastroenterology, and women’s health. The company, led by Dr. Lois Rosenberger who is a prominent expert with more than 35 years of experience in the pharmaceutical industry, has a proven track record of success in its integrated professional service covering the entire process of new drug development from clinical protocol designs and clinical trial management to regulatory application, commercialisation and launch.

The outcomes of an OBP-601 Phase IIb clinical trial led by Bristol-Myers Squibb Co.(BMS), which had started in February 2012 involving 300 patients in 17 countries worldwide to explore optimal dosage and administration of OBP-601, confirmed that the endpoint of the trial was achieved although BMS decided to terminate the license contract with Oncolys nonetheless. Since then, Oncolys has been making its best efforts looking for a partner to move on to a Phase III.

With this option agreement, Oncolys grants LBR an option to consider and to negotiate an exclusive worldwide license for OBP-601 excluding Japan, Korea, and China including mainland China, Hong Kong, Macau and Taiwan for a certain period of time, on the premise that LBR will do necessary research and arrangements to meet the guidelines and to respond to questions given by FDA in relation to the foresaid Phase IIb, and will start a discussion with FDA aiming to advance to Phase III. If both parties agree on the outcome of the discussion and on whether to proceed to enter into a license agreement and/or a strategic partnership, relevant details shall be disclosed as soon as practicable.

This option agreement will not affect Oncolys’ earnings for the fiscal year ending 31 December 2016.

Ends

About OBP-601 (Censavudine®)

OBP-601 (Censavudine) is a novel nucleotide reverse transcriptase inhibitor for HIV infection and is effective on a wide range of resistant virus. Furthermore, OBP-601 (Censavudine) has a potential to show better profile on safety having less side effects such as nerve damage and abnormal lipid metabolism which has been a problem in existing anti-HIV drugs. In June 2006, Oncolys BioPharma concluded an exclusive license agreement with Yale University (U.S.A.) having patents and patent applications of OBP-601 (Censavudine). From the results of clinical trials that have been conducted so far, including Phase IIb clinical trial led by BMS started in February 2012 with 300 patients in 17 countries worldwide, clinically significant side effects were not observed and all the endpoints were achieved. Oncolys now looks forward to advance the program to Phase III in cooperation with a strong partner.

About Oncolys BioPharma Inc.

Oncolys BioPharma is a TSE Mothers-listed biopharmaceutical company with focuses on the development of novel biologics for the treatment of cancer and infectious diseases. The company's lead product for the treatment of cancer, OBP-301 (Telomelysin®), is based on replication-competent oncolytic virus, and is being tested in Phase I/II clinical trial in Asia, for various solid tumors. A novel cancer diagnostic product, OBP-401 (TelomeScan), is expected to be effective in detecting various types of cancer and inflammatory diseases and adopted in several private practices. The company also has a major program OBP-601 (Censavudine) for infectious diseases, which has completed Phase II clinical trial in the U.S. for HIV/AIDS therapy, supported by BMS. OBP-601 is a novel NRTI with highly promising safety and resistance profiles. For more additional information, please visit www.oncolys.com

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