

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

13 May 2019

Oncolys BioPharma Inc.

First Patient Enrollment in Phase II Clinical Trial for Telomelysin (OBP-301)-Pembrolizumab Combination Therapy

Oncolys BioPharma (“Oncolys”) today announces that the first patient has been enrolled and treated in the Weill Cornell Medicine/ New York-Presbyterian Investigator-Initiated Phase II Clinical Trial for Telomelysin (OBP-301) in combination with Pembrolizumab in advanced gastric and gastroesophageal junction adenocarcinoma.

The objectives of this clinical trial are to evaluate the efficacy and safety of Telomelysin (OBP-301), oncolytic viral immunotherapy, in combination with pembrolizumab, an anti-PD-1 antibody for patients with PD-L1 positive advanced gastric and gastro-esophageal junction (GEJ) adenocarcinoma, and is led by Dr. Manish Shah at Weill Cornell Medicine, Meyer Cancer Center, in New York, NY. The study will be open across the US in multiple centers.

The design of this two- stage Phase II clinical trial is similar to the investigator-initiated study of Telomelysin (OBP-301) in combination with pembrolizumab led by Dr. Takashi Kojima at the National Cancer Center Hospital East, Japan. While squamous cell cancer represents the majority of Japanese esophageal cancer, adenocarcinomas represent majority of esophageal cancer in the US and Europe. By conducting both studies, we anticipate to see the efficacy of Telomelysin in both patient populations.

One of the research concepts of Telomelysin is a “Cure without Surgery”, and Oncolys is determined to continue to make a contribution to the development of effective cancer therapy by discovering the potential of Telomelysin combined with another anti- tumor treatment

As we announced on February 8, 2019 by the summary of financial results for fiscal year of 2018, we do not disclose financial forecast this year, since it is unrealistic to attempt to calculate appropriate and realistic numerical values for financial results at this current situation of the Company.

Ends

###

About Telomelysin (OBP-301)

Telomelysin or OBP-301 is genetically modified type 5 adenovirus which can specifically replicate in and destroy cancer cells. Type 5 adenovirus causes common cold symptoms and exists in nature. We are anticipating that Telomelysin may induce strong anti-tumor activity after causing oncolysis by specific replication in cancer cells and may be safe because of its low replication ability in normal cells. In addition, serious adverse reactions such as vomiting, hair loss and hematopoietic disorders have not been reported in clinical studies we conducted so far, and thus it is expected to improve patients' Quality of Life (QOL). Furthermore, recent publication in clinic showed that cancer cells destroyed by virotherapy may enhance cancer immunity by directly transmitting the signal of their specific antigen to immune cells such as dendritic cells. Therefore, we are expecting that Telomelysin in combination with an immune checkpoint inhibitor such as anti-PD-1 antibody may have a systemic anti-cancer efficacy together with good local control. Oncolys and Medigen Biotechnology Corp. in Taiwan had long-term collaborative relationship for the development of Telomelysin.

About Oncolys BioPharma Inc.

Oncolys BioPharma develops novel cancer therapeutics and diagnostic products using gene modified viral technologies and aims to contribute to fulfill unmet medical needs for cancer and severe infectious diseases.

Especially in oncology area, we utilize technology platform for oncolytic virus and develop Telomelysin and its next-generations for cancer treatment and TelomeScan for early detection of cancer and recurrence monitoring after surgery. We have established broad range of product pipeline to cover early detection of cancer, early treatment of local cancer, post-operative examination, and treatment of metastatic cancer. For more information, please visit <http://www.oncolys.com/en/>

Oncolys BioPharma Inc.	
Tel: +81 (0) 5472 1578	
Email: oncolys_information@oncolys.com	