## **Dencolys** BioPharma Press Release

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

ONCOLYS BIOPHARMA INC. (TSE Mothers: 4588) 30 May 2019

# Phase II Clinical Trial Protocol for Telomelysin (OBP-301)-Pembrolizmab Combination Therapy to be Presented at the 2019 ASCO Annual Meeting

A Phase II clinical trial combining Oncolys Biopharma's Telomelysin (OBP-301), oncolytic viral immunotherapy, with pembrolizumab, an anti-PD-1 antibody, for patients with PD-L1 positive advanced gastric and gastro-esophageal junction adenocarcinoma is in progress at Weill Cornell Medicine, and will be presented at the American Society of Clinical Oncology ("ASCO") conference. The conference is held in Chicago, Illinois from May 31 – June 4, 2019.

Details of the presentation are as below:

## [Poster Presentation: The 2019 ASCO Annual Meeting]

Time & Date: Mon 03 Jun 2019, 8:00 – 11:00 (CDT)

Venue: McCormick Place Hall A, Poster No.248a (Abstract TPS4145)

**Title:** Phase II study of a telomerase-specific oncolytic adenovirus (OBP-301, Telomelysin) in combination with pembrolizumab in gastric and gastro-esophageal junction adenocarcinoma.

Speakers: Uqba Khan, MD et al. (Weill Cornell Medical College)

### Procedures:

- OBP-301: 1x10<sup>12</sup>VP/tumor injection every 2 weeks x four injections, injected directly into tumor via upper endoscopy (EGD)
- Pembrolizmab: every 3 weeks for 2 years or until disease progression

### Design:

- Patients will be enrolled in a two-stage design, with 18 patients in the first stage and 19 patients in the second stage, a maximum of 37 patients. If 3 or more patients respond to the combination therapy, the study will move forward to second stage

## Primary Endpoint:

- To examine objective response rate and safety of OBP-301 with pembrolizumab

(The 2019 ASCO Annual Meeting HP : https://meetings.asco.org/am/attend-meeting)

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 granted an exclusive license, with sublicensing rights, to Chugai Pharmaceutical Co., Ltd. concerning the development, manufacturing and marketing in Japan and Taiwan for Telomelysin. In addition, Oncolys and Medigen Biotechnology Corp. in Taiwan have a 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, For more information, please visit <u>http://www.oncolys.com/en/</u>

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