

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

November 2, 2023

Oncolys BioPharma Inc.

Announcement of Enrollment of First Expansion Cohort Patient in Phase I Clinical Trial for Telomelysin™(OBP-301)-Chemoradiation Combination Therapy

Oncolys Biopharma (“Oncolys”) today announces that the first patient has been enrolled to the expansion cohort and started protocol treatment, including their first OBP-301 injection for the NRG Oncology sponsored Phase I Clinical Trial for Telomelysin™ (OBP-301) in combination with chemoradiation in advanced esophageal or gastro-esophageal cancer. This NRG Oncology led study is being conducted via the National Cancer Institute (NCI) National Clinical Trials Network (NCTN).

As previously disclosed in the press release on August 10, 2023, the objective of this clinical trial, NRG-GI007, is to evaluate the safety and efficacy of Telomelysin™ (OBP-301), oncolytic adenoviral immunotherapy, when added to weekly carboplatin, paclitaxel and radiation therapy (ChemoRT), for patients with locally advanced esophageal or gastro-esophageal (GEJ) cancer who are not candidates for surgery. In the expansion cohort, additional patient enrollment will be conducted to further evaluate the safety of Telomelysin with chemoradiation and obtain preliminary efficacy information.

Currently, in Japan, Telomelysin has been confirmed to be effective in combination with radiation therapy for locally advanced esophageal cancer, and Oncolys is planning to submit NDA to Japanese regulatory Authority by the end of 2024.

About Telomelysin (OBP-301)

Telomelysin (OBP-301) is a novel, condition-restricted, replication-competent adenovirus derived from human adenovirus type 5 (Ad-5). The normal transcriptional regulatory element of the Ad5 E1A gene is replaced by the human Telomerase Reverse Transcriptase gene (hTERT) promoter. The hTERT promoter encodes for the catalytic protein subunit of telomerase, a polymerase that acts to stabilize telomere lengths and is highly expressed in tumors but not in normal, differentiated adult cells. Additional modifications to enhance specificity of the OBP-301 construct include the replacement of the normal transcriptional element of viral E1B gene by an internal ribosomal entry

site (IRES) sequence to minimize “leakiness”). Furthermore, OBP-301 is the first replication-competent adenovirus that retains a fully functional viral E3 region, which codes for proteins that regulate the immune response to the virally infected cell.

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

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