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

October 16, 2023

**Oncolys BioPharma Inc.**

# Achievement of Primary Endpoint for Efficacy in the Phase II Clinical Trial for Telomelysin ™(OBP-301)-Radiation Combination Therapy

Oncolys BioPharma (“Oncolys”) today announces that the primary endpoint of the Phase II study, has shown exceeding the predefined threshold of L-CR (Local Complete Response) rate, which confer the clinical benefit of Telomelysin in locally advanced esophageal cancer. The study has been conducted at 17 clinical sites in Japan, and patient enrollment has been completed in December 2022.

Thirty-seven patients with locally advanced esophageal cancer who were not eligible for curative resection or chemoradiation therapy were enrolled to this study. OBP-301 was endoscopically administered to the local tumor area via endoscope three times during 6 weeks of radiation period. As a result, the primary endpoint L-CR rate assessed by the Central Review Board for Endoscopic Findings (CRBEF), was 41.7%, which confers to exceed the predefined threshold of 30.2% derived from a historical data in the study protocol.

Local remarkable response (“L-RR”) rate as a secondary endpoint, which defined the ratio of remarkable shrinkage or reduction of target tumor legion in non-CR / non-PD patients estimated by CRBEF, was 16.7%. "Total Local Response Rate (TLRR)" consisting of both L-CR and L-RR was 58.3%.

One-year survival rate was 71.4%, surpassing the control data of 57.4% reported in the "Comprehensive Registry of Esophageal Cancer in Japan" by the Japan Esophageal Society.

The most common adverse events related to Telomelysin were fever in 51.4% and lymphocyte count reduction or lymphopenia in 48.6%, both of which were mild to moderate and transient.

Based on these findings, Oncolys is planning to submit NDA to Japanese regulatory Authority until the end of 2024 as a drug for treatment of locally advanced esophageal cancer.

**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 construction 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.


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