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

January 27, 2025

Oncolys BioPharma Inc.

Announcement of Final Safety and Clinical Complete Response Data Presentation of Phase I Clinical Trial for Telomelysin™ (OBP-301)-Chemoradiation Combination Therapy at American Society of Clinical Oncology Gastrointestinal Cancers Symposium (ASCO GI) 2025 in San Francisco, California

Oncolys Biopharma ("Oncolys") announces that final safety data and clinical complete response (cCR) rate of 15 patients from the NRG Oncology sponsored Phase I Clinical Trial for Telomelysin™ (OBP-301) in combination with chemoradiation (CRT) in advanced esophageal or gastro-esophageal cancer were being presented at ASGO GI 2025. This NRG Oncology led study is being conducted via the National Cancer Institute (NCI) National Clinical Trials Network (NCTN).

This clinical trial, NRG-GI007, aims to evaluate the safety and efficacy of Telomelysin™ (OBP-301), oncolytic adenoviral immunotherapy, when added to weekly carboplatin, paclitaxel and radiation therapy, for patients with locally advanced esophageal or gastro-esophageal (GEJ) cancer who are not candidates for surgery. The study comprises of a dose finding cohort and a dose expansion cohort. After demonstrating the safety of the combination in 6 patients in the dose finding cohort, an additional 9 patients were enrolled in the expansion cohort to further evaluate the safety and preliminary efficacy of Telomelysin with CRT. The 15 enrolled patients had a median age of 74 years. Eleven patients (73%) had adenocarcinoma and 4 had squamous cell carcinoma. Eleven patients had node positive disease.

Fourteen out of 15 patients (93%) received all planned OBP-301 injections and radiation therapy. No dose limiting toxicity was reported. The most commonly seen treatment-related grade 3 or 4 adverse events were decreased neutrophil (40%), and decreased lymphocyte counts (33%).

Two patients died prior to restaging: one patient developed grade 5 respiratory failure (unlikely related to OBP-301) 6 weeks after CRT; one patient had an unrecognized tracheoesophageal fistula at time of enrollment, which worsened during week 3 of CRT (possibly related to OBP-301). Of the 13 remaining patients who underwent restaging, all of them (100%) achieved cCR.

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Dr. Geoffrey Ku from Memorial Kettering Cancer Center, Lead PI of the study, added: "We showed that OBP-301 can be safely administered in combination with CRT to patients with GEJ and esophageal cancer. Importantly, we also showed encouraging efficacy results. The 100% cCR rate of OBP-301 when combined with CRT in the 13 patients who underwent restaging compares favorably to the historical control of 58% from the control arm of the phase III NRG/RTOG 0436 study. I'm looking forward to continuing this investigation in the next randomized study in partnership with Oncolys Biopharma!"

"Oncolys is encouraged by the clinical trial results showing that OBP-301 can be safely administered when given in combination with CRT. The treatment also demonstrated a high clinical complete response rate in patients with locally advanced tumors who may not be candidates for surgery. We are hopeful that OBP-301 will become a viable treatment option for these patients who currently have limited alternatives.", added Talia Biran, the President of Oncolys USA.

Results from this study further support the efficacy of OBP-301 in combination with radiotherapy in the completed Japanese clinical trial in locally advanced esophageal cancer. These findings strengthen Oncolys BioPharma's global strategy alignment in developing OBP-301 in patients who are ineligible for surgery. Oncolys BioPharma is planning to submit a NDA to Japanese regulatory Authority by the end of 2025.

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 viralE3 region, which codes for proteins that regulate the immune response to the virally infected cell.

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