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

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Oncolys BioPharma Inc.

Meeting of Safety Endpoint in the Initial Safety Cohort of the Phase I Clinical Trial for Telomelysin ™(OBP-301)-Chemoradiation Combination Therapy

Oncolys Biopharma ("Oncolys") today announces that the safety endpoint of the initial safety cohort of the NRG Oncology sponsored Investigator-Initiated Phase I Clinical Trial for Telomelysin™ (OBP-301) in combination with Chemoradiation therapy in advanced esophageal or gastro-esophageal cancer has been met. The study is funded by the National Cancer Institute and is being conducted via its National Clinical Trial Network (NCTN), led by NRG Oncology.

The primary objective of this clinical trial, NRG-GI007, is to evaluate the safety 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. Secondary objectives include toxicities, number of clinical complete responses, number of patients alive without progression and number of patients alive both at 1 and 2 years. The study is led by NRG Oncology, with Principal Investigator Dr. Geoffrey Y. Ku at Memorial Sloan Kettering Cancer Center, in New York, NY, and is open across the US in multiple NRG network centers.

To access the primary endpoint of this Phase 1 clinical trial with expansion cohort, the initial cohort of patients received three doses of 1-2 mL of OBP-301 at 1×10^{12}VP/mL given intratumorally in conjunction with chemoRT. If no more than 1 out of 6 evaluable patients developed dose-limiting toxicity (DLT), then the regimen would be declared safe and an expansion cohort of 9 more patients will be treated at this dose level to further evaluate toxicity and efficacy.

The study completed the enrollment of 6 DLT-evaluable patients in April 2023. DLT was evaluated for each patient from the start of treatment until 30 days after the completion of chemoRT. No DLT was observed during the DLT evaluation period. All 6 patients received all of their scheduled OBP-301 doses per protocol. The combination of three doses of 1-2 mL of OBP-301 at

1×10^{12} VP/mL plus chemoRT is therefore declared safe. With the safety endpoint met, enrollment to the study is now reopened to the expansion cohort to enroll 9 additional patients with this regimen.

Dr. Geoffrey Y. Ku, Principal Investigator of the study, added that "The standard of care for patients with locally advanced E/GEJ cancer who do not undergo surgery is definitive chemoRT. However, many patients develop persistent or recurrent local disease despite treatment, which can cause significant morbidity. There is therefore a high unmet medical need to improve upon the standard of care. Safety data from this study showed that the combination of OBP-301 with chemoRT is safe in this population. This important result supports the continued development of OBP-301 + chemoRT as definitive treatment for locally advanced E/GEJ cancer who are not candidates for surgery."

The design of this Phase I clinical trial with an expansion cohort is similar to the investigator-initiated study of Telomelysin™ (OBP-301) in combination with radiation therapy alone led by Dr. Toshiyoshi Fujiwara at Okayama University, Japan. While squamous cell cancer represents the majority of Japanese esophageal cancer, adenocarcinomas comprise the main histology of esophageal cancers in the US and Europe. By conducting both studies, we anticipate seeing the safety and efficacy of Telomelysin™ in both patient populations.

Telomelysin™ (OBP-301) was granted Orphan-Drug Designation by the U.S. Food and Drug Administration (FDA) for the treatment of Esophageal Cancer, in June 2020.

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.

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