

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 7, 2023

**Oncolys BioPharma Inc.**

## SITC 2023 ANNOUNCEMENT: Phase II study of Telomelysin (OBP-301) in combination with pembrolizumab in gastroesophageal (GEA) adenocarcinoma

Oncolys BioPharma (“Oncolys”) today announces that the results from an investigator-initiated phase II clinical trial for Telomelysin™ (OBP-301) in combination with pembrolizumab in advanced gastric and gastroesophageal junction (GEA) adenocarcinoma was presented at Society for Immunotherapy of Cancer (SITC) 2023, held in San Diego, California, from November 1st to 6th.

- The objectives of this clinical trial were to evaluate the safety and efficacy of Telomelysin in combination with pembrolizumab for patients with PD-L1 positive advanced gastric and GEJ adenocarcinoma, and is led by Dr. Manish Shah at Weill Cornell Medicine, Meyer Cancer Center, in New York, NY.
- Study results showed 2 patients with a partial response and 1 patient with a complete response out of 16 evaluable patients, thereby meeting the Simon two-stage threshold. The responses were durable; two patients are currently without evidence of disease and the 3rd patient received 17 months of therapy before progression.
- One patient with brain metastasis demonstrated regression of metastatic disease following progression on immunotherapy alone. Complete response was associated with delayed increase in CD8 cytotoxic T cells, based on single cell RNA Seq expression.

Manish Shah, MD, Lead PI of this study, added: - "We showed that OBP-301 can be safely administered to patients with gastroesophageal cancer. Importantly, we also showed preliminary activity of OBP-301 when combined with checkpoint inhibition. I'm looking forward to continuing this investigation in partnership with Oncolys Biopharma!"

### **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.

<b>Oncolys BioPharma Inc.</b>	
Tel: +81 (0) 5472 1578	
Email: <a href="mailto:oncolys_information@oncolys.com">oncolys_information@oncolys.com</a>	

**Ends**

TRANSLATION