June 6, 2023

**Oncolys BioPharma Inc.**

# ASCO 2023 ANNOUNCEMENT: Encouraging Preliminary Data of OBP-301 with Pembrolizumab in refractory gastroesophageal adenocarcinoma

- Oncolys BioPharma ("Oncolys") today announces 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 confirm promising safety and preliminary efficacy of OBP-301 in combination with pembrolizaumb as presented at ASCO 2023.

- The objectives of this clinical trial were to evaluate the safety and efficacy of Telomelysin (OBP-301), an oncolytic virus in combination with pembrolizumab, an anti-PD-1 antibody, for patients with PD-L1 positive advanced gastric and gastro-esophageal junction (GEJ) adenocarcinoma, and is led by Dr. Manish Shah at Weill Cornell Medicine, Meyer Cancer Center, in New York, NY.

- Patients received OBP-301 at $2x10^{12}$ viral particles via direct tumor injection every two weeks x 4 injections as well as pembrolizumab 200 mg IV every 3 weeks for up to 2 years. The primary endpoint was objective response rate (ORR). The null hypothesis that the ORR is < 15% was tested against the Ha ORR > 30%.

- The trial included 16 patients who had received at least 2 lines of prior therapy. The investigators observed clinical responses in 3 patients (ORR 19%). Two patients are without evidence of disease: one patient with brain metastases achieved a complete response and remains without evidence of disease for 3 years. Another patient with prolonged partial response proceeded to resection and remains without evidence of disease at 20 months. The third patient had a prolonged partial response of 15 months. All patients were PD-L1 positive, but mismatch repair proficient. One patient (with complete response) had progressed on pembrolizumab monotherapy, suggesting that OBP-301 could salvage immunotherapy refractory disease.

- OBP-301 viral particle injection into the tumor was well tolerated. Adverse events attributed to OBP-301 were limited to total grade 2-3 fatigue (37.5%), grade 2-3 fever (12.5%), grade 2-3 elevated LFT ( 12.5%), and a single incidence each of grade 2 nausea, grade 2 maculopapular rash, grade 2 mucositis, grade 3 anemia and grade 3 upper GI bleed.

- A formal phase II study of OBP-301 + checkpoint inhibitor in IO refractory GEA patients will be initiated later this year.

Manish Shah, MD, Lead PI of this study, added: "These data, while based on small numbers, are encouraging as we observed three patients who had durable responses with the combination of Telomelysin (OBP-301) and pembrolizumab in patients with advanced 3rd and 4th line disease. We also provide evidence of activity in a patient who progressed on pembrolizumab monotherapy. The combination therapy was well tolerated. Taken together, the data support the continued development of Telomelysin (OBP-301) and pembrolizumab in advanced gastroesophageal cancers. "

**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.

***About Oncolys BioPharma Inc.***

*Oncolys BioPharma is a TSE Growth-listed biopharmaceutical company which focuses on the development of novel biologics for the treatment of cancer and infectious diseases. The company's lead product for the treatment of cancer, Telomelysin (OBP-301), is based on replication-competent oncolytic virus, and is being tested in Phase I/II clinical trial in Asia and Phase II in the USA, for various solid tumors. A novel cancer diagnostic product, TelomeScan® (OBP-401/1101), is expected to be effective in detecting various types of cancer and inflammatory diseases and adopted in several private practices. The company also has a major program OBP-601 (Censavudine) for infectious diseases, for which it completed Phase II clinical trial in the U.S. for HIV/AIDS therapy, supported by BMS.*
*For more information, please visit http://www.oncolys.com/en/*

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