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Oncolys BioPharma Inc.

First Patient Dosed in NRG Oncology Phase I Clinical Trial for Telomelysin ™(OBP-301)-Chemoradiation Combination Therapy for Esophageal Cancer Patients, NRG-GI007

Oncolys Biopharma ("Oncolys") today announces that the first patient has been enrolled in the NRG Oncology sponsored phase I clinical trial for Telomelysin™ (OBP-301) in combination with chemoradiation in patients with locally advanced esophageal or gastroesophageal junction (GEJ) adenocarcinoma who are not candidates for surgery. The study is funded by The National Cancer Institute and is being conducted as part of its National Clinical Trial Network (NCTN).

The objective of this clinical trial, NRG-GI007, is to evaluate the safety of Telomelysin™ (OBP-301), an oncolytic adenoviral immunotherapy, when added to carboplatin/paclitaxel and radiation therapy, for patients with locally advanced esophageal or GEJ adenocarcinoma, who are not candidates for surgery. The trial is led by NRG Oncology investigator Dr. Geoffrey Y. Ku from Memorial Sloan Kettering Cancer Center, in New York, NY. The trial will be open across the US in multiple NRG Oncology centers.

The design of this two- stage Phase I clinical trial with an expansion cohort is similar to the investigator-initiated trial of Telomelysin™ (OBP-301) in combination with radiation therapy led by Dr. Toshiyoshi Fujiwara at Okayama University, Japan. While squamous cell cancer represents the majority of Japanese esophageal cancer, adenocarcinomas represent the majority of esophageal cancers in the US and Europe. By conducting both trials, the safety and preliminary activity of Telomelysin™ using clinical complete response as the primary endpoint will be assessed 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.
NRG Oncology is one of the five National Clinical Trial Network (NCTN) research groups funded by the National Cancer Institute (NCI), part of the National Institutes of Health, to conduct practice-changing, multi-institutional clinical trials.

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 Mothers-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/

Contact:	
Oncolys BioPharma Inc. Email: oncolys_information@oncolys.com	

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