

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

May 6, 2021

**Oncolys BioPharma Inc.**

## **Announcement of First Patient Enrolled in Oncology Investigator-Initiated Phase 2 Clinical Trial for Telomelysin™ (OBP-301)-Pembrolizumab and Stereotactic Radiation Combination Therapy for Head and Neck Cancer Patients**

Oncolys Biopharma (“Oncolys”) today announces that the first patient has been enrolled in the investigator-initiated phase II clinical trial for Telomelysin™ (OBP-301) in combination with Pembrolizumab and Stereotactic Radiation in patients with recurrent, inoperable head and neck cancer who are not candidates for surgery. This clinical trial is led by Doru Paul, MD, PhD, Associate Professor in the Division of Hematology and Medical Oncology, Department of Medicine, and member of the Sandra and Edward Meyer Cancer Center at Weill Cornell Medicine and an oncologist at New York-Presbyterian/Weill Cornell Medical Center.

1. This clinical trial consists of a combination of 3 therapies: Telomelysin™ (OBP-301), pembrolizumab and stereotactic radiation.
2. At present, radiation therapy is the only effective local treatment except for surgical operation that can be offered with a curative intent to patients with inoperable head and neck cancers.
3. The study will enroll 36 patients with recurrent, inoperable head and neck cancer and the goal is to improve both the quality of life and the response rate to radiation therapy.
4. Oncolys will evaluate whether the addition of an anti-PD-1 antibody can increase the clinical benefits even further, and add a systemic effect to the synergistic interaction of the combination of local Telomelysin™ (OBP-301) injections and stereotactic radiation therapy.

Oncolys’s vision is to help cancer patients by developing novel cancer therapies and continue to conduct research and development on Telomelysin and other treatments based on the concept of “cure cancer without surgery”.

**Ends**

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### **About Telomelysin (OBP-301)**

*Telomelysin or OBP-301 is a genetically modified type 5 adenovirus which can specifically replicate inside cancer cells and subsequently destroy them. Type 5 adenovirus is known to cause symptoms similar to the common cold. 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”. Our hypothesis is that Telomelysin induces a strong immune anti-tumor response after a targeted destruction of the cancer cells where it replicates and is also safe because of its low replication potential in normal cells. Furthermore, a recent publication showed that cancer cells destroyed by virotherapy may enhance cancer immunity by directly and specifically transmitting the signal to immune cells such as dendritic cells. Therefore, we are hopeful that Telomelysin in combination with an immune checkpoint inhibitor such as anti-PD-1 antibody may improve the efficacy of the anti-PD-1 antibody.*

**About Oncolys BioPharma Inc.**

*Oncolys BioPharma develops novel cancer therapeutics and diagnostic products using gene modified viral technologies and aims to contribute to fulfill unmet medical needs for cancer and severe infectious diseases. Especially in oncology area, we utilize technology platform for oncolytic virus and develop Telomelysin and its next-generations for cancer treatment and TelomeScan for early detection of cancer and recurrence monitoring after surgery. We have established broad range of product pipeline to cover early detection of cancer, early treatment of local cancer, post-operative examination, and treatment of metastatic cancer. For more information, please visit <http://www.oncolys.com/en/>*

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