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Oncolys BioPharma Inc.

First Patient Enrolled in Investigator Initiated Phase 2 Study of Suratadenoturev (OBP-301) in Combination with Pembrolizumab in Immunotherapy Refractory Esophagogastric Adenocarcinoma

Oncolys BioPharma Inc. (hereafter "Oncolys") today announced the enrollment of the first patient in the investigator-initiated Phase 2 study of OBP-301 in combination with pembrolizumab in patients with esophagogastric adenocarcinoma (GEA) who are refractory to immunotherapy.

This study is led by Dr. Manish Shah, the Bartlett Family Professor in Gastrointestinal Oncology in the Division of Hematology and Medical Oncology, Department of Medicine, Member of the Sandra and Edward Meyer Cancer Center, Weill Cornell Medicine, and Chief of the Solid Tumor Oncology Service and Co-Director of the Center for Advanced Digestive Care, NewYork-Presbyterian/Weill Cornell Medical Center. Support of the study comes from a collaborative development framework for OBP-301 and pembrolizumab between Oncolys, Weill Cornell Medicine and Merck (known as MSD outside the US and Canada).

OBP-301 is a novel oncolytic adenovirus that is injected directly into the tumor and is combined with pembrolizumab to improve the chances of an immune response in this Phase 2 study. The study is built on the promising results of a prior investigator-initiated study led by Dr. Manish Shah in the third-line treatment setting. This study will investigate the efficacy and safety of using the same combination of OBP-301 and pembrolizumab in advanced gastric, gastroesophageal junction, and esophageal adenocarcinoma in second-line setting, following progression of first-line immunotherapy-containing regimen. Due to the lack of satisfactory therapy for patients who are refractory to immunotherapy, this study hopes to help potentially address the unmet medical need for this difficult-to-treat patient population. The study will enroll up to 27 evaluable patients and is currently recruiting at Weill Cornell Medicine, with further investigational sites to join.

Oncolys is committed to finding "Cure without Surgery" by developing effective cancer therapies, such as OBP-301, combined with other anti- tumor treatments.

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About OBP-301

OBP-301 is a genetically modified type 5 adenovirus which can specifically replicate in and destroy cancer cells. Type 5 adenovirus causes common cold symptoms and exists in nature. We are anticipating that OBP-301 may induce strong anti-tumor activity after causing oncolysis by specific replication in cancer cells and may be safe because of its low replication ability in normal cells. In addition, serious adverse reactions such as vomiting, hair loss and hematopoietic disorders have not been reported in clinical studies we conducted so far, and thus it is expected to improve patients' Quality of Life (QOL). Furthermore, recent publication in clinic showed that cancer cells destroyed by virotherapy may enhance cancer immunity by directly transmitting the signal of their specific antigen to immune cells such as dendritic cells. Therefore, we are expecting that OBP-301 in combination with an immune checkpoint inhibitor such as anti-PD-1 antibody may have a systemic anti-cancer efficacy together with good local control.

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 OBP-301 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/

Oncolys BioPharma Inc.	
Email: oncolys_information@oncolys.com	

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