

Dec 20, 2023

Oncolys BioPharma Inc.

Announcement of Investigator-Initiated Phase 2 Clinical Trial Agreement For Immunotherapy refractory Esophagogastric adenocarcinoma

Oncolys BioPharma Inc. (hereafter “Oncolys”) is pleased to announce that the investigator-initiated Phase 2 clinical trial (hereinafter “this clinical trial”) agreement with Weill Cornell Medicine, for Immunotherapy refractory Esophagogastric adenocarcinoma has been executed. This clinical trial 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, New York-Presbyterian/Weill Cornell Medical Center. This agreement establishes a collaborative development framework for Suratadenoturev (OBP-301) and Pembrolizumab among three parties: Oncolys, Weill Cornell Medicine and Merck & Co., Inc.'s (“Merck”). Costs of this study will be shared between Oncolys and Merck.

1. A prior Phase 2 study in 3rd line esophagogastric adenocarcinoma (GEA) patients combining suratadenoturev (OBP-301) and an anti-PD-1 therapy previously led by Dr. Manish Shah and demonstrated that the combination is well tolerated and has encouraging activity in GEA, with durable responses and demonstration of activity in immunotherapy refractory disease.
2. This new phase II multi-center clinical study of suratadenoturev (OBP-301) with an anti-PD-1 therapy in an immunotherapy (IO) refractory advanced gastric, gastroesophageal junction, or esophageal adenocarcinoma patients, targets an important unmet need in drug development.
3. The impact of Immune check point inhibitors (ICI) therapy on survival for upper gastrointestinal cancers has been transformative, with a majority of patients receiving ICI therapy with chemotherapy in the first line treatment setting.
4. However, there are no therapies involving ICI therapy in patients who are refractory to immunotherapy, which is an important unmet medical need to develop new targeted therapies for gastroesophageal cancer in an immunotherapy refractory population.
5. Oncolys expects that the combination of suratadenoturev (OBP-301) with pembrolizumab will lead to clinical efficacy and ultimately improved patient survival.

Oncolys aims to contribute to the development of cancer therapies that helps the medical field by continue to conduct research and development on the combination of Telomelysin based on the concept of “cure cancer without

surgery,” and other treatment.

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About Telomelysin (OBP-301)

Telomelysin or OBP-301 is 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 Telomelysin 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 Telomelysin 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 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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