Prestige Biopharma's First-in-Class Pancreatic Cancer Treatment, PBP1510, Receives Approval for Clinical Trial in France

SINGAPORE, [21 June 2021] / Prestige BioPharma Limited (PBP) specializing in the development of antibody therapeutics, announced that French National Agency for the Safety of Medicines and Health Products (L'Agence nationale de sécurité du medicament, ANSM) has approved a Phase 1/2a clinical trial of its first-in-class anti-PAUF monoclonal antibody, PBP1510, for the treatment of pancreatic cancer.

The clinical trial will be conducted in the Research Institute against Digestive Cancer (IRCAD) based in Strasbourg, France, in pancreatic cancer patients who have an overexpression of a gene called Pancreatic Adenocarcinoma Up-regulated Factor (PAUF) found in majority of pancreatic cancers. PBP's affiliate, Prestige Biologics will be providing drugs for the clinical trial.

PBP is also in the process of preparing for the conduct of this trial in other countries such as the U.S., Australia and Belgium. Korea's Ministry of Food and Drug Safety (MFDS) is currently reviewing PBP's application for conduct of this clinical trial in Korea as well.

Pancreatic cancer is a highly aggressive malignancy originating in the exocrine or endocrine pancreatic cells suspected to be caused by poor diet, smoking, and genetic factors. It contributes to high morbidity and mortality with a survival rate of 9% at five years in the U.S. Currently, the only curative options are limited to surgical resection in combination with adjuvant chemotherapy. However, only 10 to 15% of patients are candidates as the diagnosis occurs in advanced or metastatic stages that are surgically inoperable. Limited efficacy of treatment modalities and rapid progression of pancreatic cancer can be partly explained by PAUF and it plays an important role in disease progression, but no targeted molecular therapy against PAUF currently exists. Prestige BioPharma's anti-PAUF antibody PBP1510 is envisioned to provide significant benefit in all patients affected by PAUF-positive pancreatic cancer.

The European Medicines Agency (EMA), the U.S. Food and Drug Administration (FDA) and Korean MFDS granted Orphan Drug Designation (ODD) to PBP1510 last year. ODD is granted to investigational drugs intended for the safe and effective treatment of rare diseases with an unmet medical need that affect very few individuals but cause great suffering. This designation provides companies with certain benefits and incentives including clinical protocol assistance, differentiated evaluation procedures for health technology assessments in certain countries, and if approved, marketing exclusivity in the EU for 10 years, in the U.S. for 7 years.

Lisa S. Park, CEO of Prestige BioPharma, commented: “We are very pleased to initiate the Phase 1/2a clinical trial of PBP1510 in France” and “PBP will accelerate the development of PBP1510 to provide better treatment for pancreatic cancer, an extremely difficult to treat indication with a poor response to the currently available treatments”.