Prestige Biopharma's First-in-Class Pancreatic Cancer Treatment, PBP1510, Receives Approval for Phase 1/2a Study in Spain

Singapore, [17 February 2022] / Prestige BioPharma Limited (950210: KRX), a Singapore-based biopharmaceutical with operations in USA and South Korea, announced that the Spanish Agency of Medicines and Medical Devices (Agencia Española de Medicamentos y Productos Sanitarios, AEMPS) 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 La Paz University Hospital based in Madrid, Spain, in pancreatic cancer patients. PBP's affiliate, Prestige Biologics (334970: KOSDAQ) will be providing drugs for the clinical trial.

Pancreatic Adenocarcinoma Up-regulated Factor (PAUF) found in majority of pancreatic cancers can partly explain limited efficacy of treatment modalities and rapid progression of pancreatic cancer. PAUF plays an important role in disease progression, but no targeted molecular therapy against PAUF currently exists. Prestige's anti-PAUF antibody PBP1510 is envisioned to provide significant benefit in all patients affected by PAUF-positive pancreatic cancer.

The company will identify an optimal dose of PBP1510 in combination with gemcitabine through Phase 1 study and investigate the efficacy of the recommended dose from Phase 1 in combination with gemcitabine through Phase 2 study.

The European Medicines Agency (EMA), the U.S. Food and Drug Administration (FDA) and Korean MFDS granted Orphan Drug Designation (ODD) to PBP1510 in 2020. 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 and the U.S. for certain years.

Prestige is also preparing an IND submission to the FDA for Phase 1/2a study of PBP1510.

Lisa S. Park, CEO of Prestige BioPharma, commented: "We are very pleased to initiate the Phase 1/2a clinical trial of PBP1510 in Spain" 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".