Prestige Biopharma Announces its Adalimumab Biosimilar, PBP1502's Phase 1 Study Plan

SINGAPORE, [07 December 2021] / Prestige BioPharma Limited (PBP, 950210: KRX), a Singapore-based biopharmaceutical with operations in USA and South Korea, announced that the company's Adalimumab biosimilar, PBP1502's phase 1 study has been registered at US National Institutes of Health (NIH)'s ClinicalTrials.gov.

PBP filed a phase 1 clinical trial application of PBP1502 in Spain. Once the application is approved, the clinical trial will be conducted in Hospital Universitario La Paz based in Madrid, Spain, in 324 of healthy volunteers. PBP's affiliate, Prestige Biologics (334970: KOSDAQ) will be providing drugs for the clinical trial.

Biosimilars are usually not required to conduct phase 2 trials as their administration and dosage have already been established by their reference drugs. PBP is also planning to conduct PBP1502's phase 3 study mid-next year once its safety has been proved through the phase 1 study. PBP1502's phase 3 clinical trial will be conducted in approximately 600 of psoriasis patients and the company plans to file Marketing Authorisation Application (MAA) in EU and US in 2023.

The world's top selling drug, Humira® is used to treat autoimmune diseases such as rheumatoid arthritis and psoriasis and it brought in close to U$20 billion for AbbVie in 2020. In response to Humira®'s US patent protection expiring in 2023, PBP is on target to launch PBP1502 in EU and US.

Lisa S. Park, CEO of Prestige BioPharma, commented: "Our Humira Biosimilar, PBP1502 will be launched with its strong price competitiveness resulting from PBP's proprietary 'non-protein A antibody purification' technology" and "PBP will accelerate the development of PBP1502 to provide better treatment for more patients with autoimmune disease".