Filing of IND for Connective Tissue Disease Associated Interstitial Lung Disease

GNI Group, a leader in fibrotic disease drug development, today announced the IND filing for its Etuary® (pirfenidone) drug's therapeutic treatment of Connective Tissue Disease Associated Interstitial Lung Disease (CTD-ILD). This is the third additional new indication under development for Etuary®, in addition to Radiation Pneumonitis (under Phase II) and Diabetic Nephropathy (IND filed). Additionally, GNI Group has F351, a new chemical entity derivation of Etuary®, in Phase II clinical development for liver fibrosis.

Connective Tissue Disease-Associated Interstitial Lung Disease (CTD-ILD) is a lung condition that affects patients with a connective tissue disease, including system sclerosis (SSc or scleroderma), rheumatoid arthritis (RA), systemic lupus erythematosus (SLE), polymyositis (PM), and dermatomyositis (DM), Sjögren's syndrome (SjS), mixed CTD (MCTD), etc. In addition, patients who have one or several features of systemic autoimmune disease but do not fulfill American College of Rheumatology (ACR) classification criteria for defined CTD are considered to have undifferentiated connective tissue disease (UCTD). ILD in UCTD patients are called UCTD-ILD.

Sjögren's syndrome has the highest prevalence ranging between 0.5 and 3% of population. The prevalence of systemic lupus erythematosus (SLE) is estimated between 15 and 50 per 100,000 individuals. The prevalence of SSc is lower, however, varying significantly between different studies and countries. The prevalence of MCTD is unknown, and PM and DM are regarded as very rare rheumatic diseases.

CTD-ILD causes inflammation and/or fibrosis of the lungs. The exact cause of lung damage is unknown. It was reported that among a group of ILD patients in China, 37% had IPF and 63% had CTD-ILD/UCTD-ILD. Therefore, CTD-ILD/UCTD-ILD has a higher incidence and prevalence rate than IPF.

Clinical Trial Permit application (Class 1.6 in China) has been filed with Beijing FDA by Beijing Continent Pharmaceutical Co, Ltd.. Since there is no approved therapy for CTD-ILD in the world, the IND for new indication trial is categorized as Class 1.6 by CFDA. Phase I may be exempted since Etuary® is already approved for IPF therapy, subject to CFDA's evaluation.