GNI Seeks New Indication for F647 (Pirfenidone)

Tokyo, January 23, 2013 – GNI Group Ltd, announced today that its subsidiary, Shanghai Genomics, has filed an IND application for additional indication of diabetic nephropathy for F647. This application will be reviewed by local FDA first and then sent to SFDA.

Diabetic nephropathy (*nephropatia diabetica*) is a chronic kidney disease (CKD) caused by either type 1 or type 2 diabetes. It is the most common cause of chronic kidney failure and end-stage renal disease (ESRD). The earliest detectable change in the course of diabetic nephropathy is a thickening in the glomerulus. As diabetic nephropathy progresses, increasing numbers of glomeruli are destroyed by progressive nodular glomerulosclerosis, which is a process related to fibrosis. F647 was originally developed by the Company for Idiopathic Pulmonary Fibrosis (IPF). Treatment of patients with diabetic nephropathy include glycemic control, management of hypertension, and reducing dietary salt intake and phosphorus and potassium restriction in advanced cases.

According to various estimates, there are 23~98 million people threatened by diabetes in China. There are about 171 million diabetes patients worldwide. About 20–30% of patients with type 1 or type 2 diabetes develop evidence of nephropathy. In 2011, a diabetic nephropathy clinical trial was reported by a group of scientists in the United States. Pirfenidone has demonstrated safety and efficacy in such human trials. (http://jasn.asnjournals.org/content/early/2011/04/20/ASN.2010101049.abstract)

“After receiving NDA approval of F647 for the use in IPF therapy, we are making progress in preparing our plant for GMP inspection and manufacture approval,” said Ying Luo, President and CEO of GNI Group. “At the meantime, we continue to push our pipeline product development in other disease areas, such as liver fibrosis, liver failure and now, diabetic nephropathy. This is our consistent strategy in the last 11 years.”

About GNI

GNI Group, Ltd. is a international drug development group focused on research, development, manufacture, and commercialization of new drugs in pulmonary, kidney, and liver diseases. It was founded by scientists trained in the United States in 2001. It is currently headquartered in Tokyo and carries out research operations in Shanghai and manufacture in Beijing. In 2011, the first drug, F647 as a Class 1.1 in China, was approved as the only medicine for Idiopathic Pulmonary Fibrosis. For further information, please visit www.gnipharma.com.

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