GNI Group Receives Manufacture Approval for F647 from China FDA for First Idiopathic Pulmonary Fibrosis Drug in China

Tokyo, Japan – January 6, 2014: GNI Group Ltd. (“GNIG”) has announced that its majority owned subsidiary, Beijing Continent Pharmaceuticals (“BC”), received approval from the China Food and Drug Administration (”CFDA”) for the manufacture and commercialization of F647 on December 31, 2013. F647 is the only drug approved by the CFDA for the treatment of Idiopathic Pulmonary Fibrosis (“IPF”).

IPF is a progressive and fatal respiratory disease characterized by scarring of the lungs, restricting the ability of the tissue to transport oxygen and the patient’s ability to breath. IPF has no known cause and it is estimated over 550,000 patients may suffer from the disease in China. Other than the pirfenidone antifibrotic agent such as F647, there is no other approved therapy for this lethal disease.

“As the first Class 1.1 drug researched and developed by our Shanghai Genomics facilities in China, we are extremely pleased to offer F647 to meet the unmet medical needs of IPF patient community in the Chinese market. As the mission of GNI Group, we will continue to bring new and innovative drugs for first line treatment of other major inflammatory diseases in the Asian markets.” said Dr. Ying Luo, Chief Executive Officer of GNIG.

GNIG, through its BC subsidiary, will market F647 in China pending final sale price and commercial name approval by the CFDA of 艾思瑞 (ài sī ruì, English trademark name “Etuary”). Sales and distribution will be managed through a network of selected distributors, with the launch of sales as soon as possible. For sales outside of China, a licensing agreement has been concluded with AFT Pharmaceuticals Limited for the commercialization of F647 under the Etuary trademark in Australia, New Zealand, ASEAN countries, Hong Kong, Russia and the CIS countries.

As a Class 1 drug, F647 will have a five year monitoring/administrative protection period in China based on the current CFDA regulation, during which post-marketing research will be conducted among F647 patients to ensure its safe usage and monitor potential adverse drug reactions, if any.

Furthermore, as disclosed on January 23, 2013, GNIG has applied for an IND (Investigational New Drug) application for F647 for the treatment of diabetic nephropathy, which is currently under review and site-inspection by the Shanghai Food and Drug Administration. Initial clinical studies by US institutes have indicated pirfenidone to have clinical benefits for diabetic nephropathy, of which it is estimated to affect up to 30 million patients in China.

GNI Group Ltd. is a vertical integrated pharmaceutical company engaged in drug discovery of therapeutic agents for endemic diseases in Asia. Its drug pipeline, in addition to F647 for IPF, radiation pneumonia and diabetic nephropathy, includes F351 for liver fibrosis (cirrhosis), F573 for acute hepatic insufficiency and acute-on-chronic liver failure (“ACLF”) and F200 for chronic obstructive pulmonary disease (“COPD”). GNIG is listed on the Tokyo Stock Exchange Mothers Market, Code 2160, with headquarters in Tokyo and subsidiaries in Hong Kong, Shanghai and Beijing.