Initiation of Postmarketing Surveillance Studies of Etuary®

Tokyo, April 27, 2015 – GNI Group Ltd., a leading biopharmaceutical company in Asia, today announced the initiation of the Postmarketing Surveillance Studies (PMS or Phase IV) for Etuary® in Chengdu, China via its majority controlled subsidiary company, Beijing Continent Pharmaceuticals Co, Ltd.

As part of the manufacture permit for Etuary® received from the China Food and Drug Administration (CFDA) in December 2013, the Company is required to undertake PMS or Phase IV clinical trials to further refine the safety, efficacy, or optimal use of Etuary® or to ensure the consistency and reliability of product quality. The trial will enroll up to 500 patients from as many as 20 hospitals. The Principal Investigator (PI) for the PMS will be Dr. Dai Huaping, Chairwoman of Interstitial Lung Disease Study Group of the Chinese Thoracic Society.

The PMS trial will be beneficial as it will provide additional safety and efficacy data for a significantly larger number of Idiopathic Pulmonary Fibrosis (IPF) patients than the pre-approval clinical trials. New scientific knowledge about the efficacy of Etuary® in patients with different underlying diseases or concomitant medication will be obtained. It will also enable medical doctors who never participated in IPF clinical trials before to gain critical knowledge on how to treat the deadly disease.

Through the IPF PMS and other pending new indication clinical trials for Etuary® including Radiation Pneumonitis (RP), Diabetic Nephropathy (application under review at CFDA), and Connective Tissue Disease Associated Interstitial Lung Disease or CTD-ILD (application under review at CFDA), the GNI Group will become a global leader in fibrotic disease therapy. While GNI will fully support the PMS of Etuary®, the project is expected to be revenue neutral for the Company in 2015.

About GNI

GNI Group Ltd. is a vertical integrated pharmaceutical company focused on research, development, manufacture, and commercialization of therapeutic agents for endemic diseases in Asia. In addition to its CFDA Class 1.1 approved drug Etuary®, the only approved therapy for Idiopathic Pulmonary Fibrosis, GNI has a robust drug development pipeline focused on innovative therapeutic agents for diseases including radiation pneumonitis, diabetic nephropathy, liver fibrosis (cirrhosis), acute-on-chronic liver failure (ACLF) and chronic obstructive pulmonary disease (COPD). GNI is listed on the Tokyo Stock Exchange Mothers Market, Code 2160, with headquarters in Tokyo and subsidiaries in Hong Kong, Shanghai, Beijing and the United States. For further information, please visit www.gnipharma.com.

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