F351 Phase II Clinical Trials in China Initiated

June 10, 2015 - GNI Group Ltd. (GNIG), a leading multinational biopharmaceutical company, announced today the initiation of the Phase II clinical trials in China for the Company’s milestone drug candidate F351 for the treatment of liver fibrosis. GNIG received approval from the China Food and Drug Administration (CFDA) for the Phase II trial in July 2014 and subsequently completed the CFDA preliminary consultation and necessary preparations for the significant “proof-of-concept” (POC) trial. The trial, with the goal to study the safety and efficacy of F351 in the therapy of liver fibrosis caused by chronic HBV infection, will be a randomized, double-blind, placebo-controlled, multi-dose, multi-center dosage exploration with 240 subjects. Thirteen Class AAA hospitals throughout China will participate in the trial and the treatment period will be 52 weeks. The principal investigators and hospitals for the study will be Dr. Lu Lungen of the Shanghai First People’s Hospital and Dr. Cheng Jun of the Beijing Ditan Hospital. Both Dr. Lu, Vice Chairman of the China Gastrointestinal Disease Society, and Dr. Cheng, Vice Chairman of the China Infectious Disease Society are leaders in their respective fields and the Chinese medical profession.

In addition, a separate clinical study for drug metabolism and drug interactions study will be undertaken in Wuhan, China, with up to 16 patients.

Hepatitis B, a major cause of liver diseases, is estimated to have infected approximately 93 million people in China, of which one one-third are currently hepatitis patients. In addition to Hepatitis B, other significant causes of liver disease such as alcohol abuse and “fatty liver” are increasing as a result of changes in lifestyles of China’s rising affluent society. Among the chronic hepatitis patient population, it is estimated the development of liver fibrosis and subsequent decrease in liver function affects more than 18 million people a year in China (http://hbv.39.net/_has_szjd/222666.htm). At present, there is no proven pharmaceutical therapy for liver fibrosis in the world. As GNIG holds global patents for F351, the Company seeks to provide this drug therapy to liver fibrosis patients through the world. Currently GNIG is in the process of filing an IND for F351 with the U.S. FDA.

F351 is a New Chemical Entity having similar mechanism of action to Etuary®, our pirfenidone drug approved by the CFDA for treatment of idiopathic pulmonary fibrosis (IPF) and currently sold in the China market. F351 is a small molecule drug in the same class as Etuary®, however in comparison studies F351 has shown superior efficacy in vivo and in vitro animal experiments for liver, kidney, cardiac disease and skin fibrosis. Through our clinical development in China, F351 has demonstrated favorable safety profile in Phase 1a and 1b human trials.
We believe that there is no impact on the Company's Forecasts of Consolidated Financial Results for Fiscal 2015 (January 1, 2015 to December 31, 2015) issued on February 13, 2015. The revised forecasts will be published as soon as it is recognized.

**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](http://www.gnipharma.com).

**For further inquiries**

+81 (03) -6214-3600  
Email: infojapan@gnipharma.com

This press release contains “forward-looking” statements, including statements related to GNI’s plans to pursue development of product candidates and the timing thereof. Any statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Words such as “continue,” “expected to”, “will” and similar expressions are intended to identify these forward-looking statements. There are a number of important factors that could cause GNI's results to differ materially from those indicated by these forward-looking statements, including risks associated with the timing and success of clinical trials and the commercialization of product candidates. GNI does not undertake any obligation to update forward-looking statements.