F351 Phase II Clinical Trial Approval

TOKYO, July 01, 2014 - GNI Group Ltd. (GNIG), a leading biopharmaceutical company in Japan and China, announced today that the China Food and Drug Administration (CFDA) has approved Phase II clinical trials for its liver fibrosis treatment drug candidate F351. Preliminary consultation with CFDA is required before launching Phase III clinical trial. The content of the consultation shall be given by the authority after completion of Phase II clinical trial.

Currently, it is estimated that approximately 93 million people in China are infected with Hepatitis B, of which one-third are hepatitis patients. In addition to hepatitis B, which is a major cause of liver disease, alcohol abuse and “fatty liver” caused by changes in lifestyle due to China’s economic growth have also contributed to the increase of this “affluent” disease. It is estimated that the development of liver fibrosis among chronic hepatitis patients, causing a decrease in liver function, affects more that 18 million people in China per year (http://hbv.39.net/hbv_/_has_szjd/222666.html). At present there is no proven pharmaceutical therapy for liver fibrosis in the world. As GNIG has been granted global patents for F351, we will also seek to provide this drug to liver fibrosis patients in regions beyond China in the future.

F351 is a New Chemical Entity having similar mechanism of action to Etuary [tm], our first drug approved by CFDA for treatment of idiopathic lung fibrosis (IPF). Etuary [tm] is sold in China under the brand name Aisuryui. F351 is a small-molecule drug in the same class as Etuary [tm], 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, F351 has demonstrated favorable safety profile in Phase 1a and 1b human trials.

About GNIG

GNI Group Ltd. is a vertical integrated pharmaceutical company engaged in drug discovery of therapeutic agents for endemic diseases in Asia. It has a robust drug development pipeline, focusing on innovative therapeutic agents for endemic diseases in Asia including radiation pneumonia, diabetic nephropathy, liver and kidney 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, and Beijing.

For further inquiries

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