Notice of Investigational New Drug (IND) Application Updates

May 15, 2017 - GNI Group Ltd. announced today the following clinic trial updates for its IND applications for drug candidates F351 and Hydrocortisone Butyrate Temperature-Controlled Foam Formulation.

1. **F351**
   The third party contract research organization engaged by GNI Group Ltd. has successfully completed its 8-day toxicology study under US GLP regulations for F351 (chemical name: Hydronidone). This US GLP study was requested by the U.S. FDA in support of the Investigational New Drug (IND) application for F351, as a supplement to the previously completed China GLP toxicology studies. The IND application for initiation of U.S. clinical trials for F351 in the treatment of liver fibrosis was filed with the FDA in March 2016 and is currently on hold. GNI Group Ltd. intends to submit the US GLP toxicology study, in addition to other nonclinical requested information, to the FDA as soon as feasible as a subsequent submission for the F351 IND application.

2. **Hydrocortisone Butyrate Temperature-Controlled Foam Formulation**
   Beijing Continent Pharmaceutical Co. Ltd., (Beijing Continent), a consolidated subsidiary of the GNI Group Ltd., received notification from the Beijing Food and Drug Administration (Beijing FDA) that current IND lacks certain data and additional data is required in support of the Investigational New Drug (IND) application for Hydrocortisone Butyrate Temperature-Controlled Foam Formulation originally submitted by Beijing Continent on December 24, 2015. The additional material requested in the notification includes impurity analysis methods, long-term stability studies, etc. Beijing Continent will prepare the requested material and expects to resubmit the IND application in a timely basis.

GNI Group Ltd.'s consolidated financial forecasts for fiscal year 2017 (January 1, 2017 to December 31, 2017) revised on April 18, 2017, will not be affected by this announcement.

About GNI

GNI Group Ltd. is a multinational biopharmaceutical company focused on research, development, manufacture, and commercialization of therapeutic agents for endemic diseases in Asia and worldwide. In addition to its CFDA Class 1.1 approved drug Etuary®, the only approved therapy for Idiopathic Pulmonary Fibrosis in China, GNI Group Ltd. 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 acute promyelocytic leukemia (APL). GNI Group Ltd. 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.

For further inquiries

+81 (03) -6214-3600

Email: infojapan@gnipharma.com

This press release contains "forward-looking" statements, including statements related to our group'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 our group'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. Our group does not undertake any obligation to update forward-looking statements.