F351 Liver Fibrosis Trial Shows Positive Efficacy

September 25, 2018 – GNI Group Ltd., ("GNI Group": TSE Mothers 2160) today announced receiving a recommendation from the independent data monitoring committee (IDMC) reviewing the F351 drug candidate’s Phase II liver fibrosis trial in China to end the enrollment of new patients in the trial based on positive efficacy results achieved to date. Currently, 175 patients out of an original 240 patient target have been enrolled in the trial.

In 2015 GNI Group initiated the Phase II trial to study the safety and efficacy of F351 in the treatment of liver fibrosis caused by chronic Hepatitis B virus infection, with a randomized, double-blind, placebo-based multi-dose, multi-center dosage exploration involving 13 Class AAA hospitals throughout China. The primary endpoint of the trial is the improvement of ratio of Ishak score of liver fibrosis by one grade. On Sunday September 23rd, the IDMC disclosed its review of the interim safety and efficacy outcomes in the trial. The Committee found that F351 demonstrated in general a favorable safety profile. Dose-response had been observed, with the best efficacy in the 270 mg/day arm (90 mg/tid). The IDMC recommended the continuation of monitoring the remaining 36 patients undergoing treatment through the 52 week regime prior to completing the trial.

The recommendation to end enrollment of additional patients is a significant and positive development for GNI Group, its shareholders and the patients with liver fibrosis. Based on the recommendation, the China Phase II trial is expected to be completed mid-summer 2019 and the final results data from the trial will be disclosed and presented to the international scientific community thereafter. In the meantime, GNI Group will proceed with its preparation for a Phase III trial for F351 in China and the review of the final U.S. Phase I trial data in the 4th quarter of this year.

GNI Group does not expect the aforementioned study will materially impact financial results for the year ending December 31, 2018.

About F351
F351 is a New Chemical Entity (NCE) derivation of Etuary®, which inhibits hepatic stellate cell proliferation and also the TGF-β signaling pathway, both of which play major roles in the fibrosis of internal organs. Multiple animal model studies conducted by GNI Group have indicated the efficacy of F351 as a treatment for fibrosis, and in particular as a treatment for both liver and kidney fibrosis. GNI Group has obtained key global patent rights for F351 in a number of countries and regions including China, Japan, Australia, Canada, the United States and Europe.
About GNI Group Ltd.
GNI Group Ltd. is a multinational pharmaceutical company listed on the Tokyo Stock Exchange Mothers Market, Code 2160. The Group is headquartered in Tokyo, with primary business units of pharmaceuticals and medical devices with subsidiaries in Hong Kong, Shanghai, Beijing and the United States. For further information about GNI Group Ltd., please visit www.gnipharma.com.

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This press release contains “forward-looking” statements, including statements related to the 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 the 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. The Group does not undertake any obligation to update forward-looking statements.