



(Progress of Disclosed Matters)

First Patient Enrollment of F351 Phase III Clinical Trial in China

January 17, 2022 – GNI Group Ltd., (TSE Mothers listed code: 2160) today announced that the first patient had been enrolled in a Phase III clinical trial to evaluate F351 as a potential treatment for HBV-induced liver fibrosis in China.

“Prevention of liver fibrosis advancing to cirrhosis, which is associated with reduced survival and increased incidence of hepatocellular carcinoma, still represents a major unmet medical need globally,” said Dr. Ying Luo, Ph.D., CEO of GNI Group. “The initiation of patient enrollment in this study represents an important step in our efforts to bring new medicines to liver disease patients based on our encouraging Phase II clinical trial results.”

The Phase III study is a randomized double-blind, placebo-controlled multicenter study evaluating the efficacy and safety of F351 for the treatment of HBV-induced liver fibrosis (ClinicalTrials.gov identifier: NCT05115942). The study is sponsored by Beijing Continent Pharmaceutical Co., Ltd. and will be conducted in approximately 42 clinical research hospitals in China. It is expected to enroll 248 patients and to be completed in Q2, 2024. As previously disclosed, China National Medical Products Administration (NMPA) designated F351 as a “Breakthrough Therapy.”

About F351 (Generic name: Hydronidone)

F351 is a New Chemical Entity (NCE) derivation of Etuary®, which inhibits hepatic stellate cell proliferation and TGF- β signaling pathway, both of which play major roles in the fibrosis of internal organs. GNI Group has the key global patent rights for F351 in a number of countries and regions including China, Japan, Australia, Canada, the United States and Europe.