



### **(Progress of Disclosed Matters)**

#### **F351 Phase III Clinical Trial Roadmap in China**

**January 31, 2022** – GNI Group Ltd., (TSE Mothers listed code: 2160) is pleased to announce the following update to our previous Press Release on January 17, 2022, “First Patient Enrollment of F351 Phase III Clinical Trial in China.”

For this Phase III clinical trial, we expect to enroll 248 patients and aim to enroll the last patient in the first half of 2023. At that point assuming all is in good order, we further expect to complete the primary study before or in the second quarter of 2024, as disclosed in the previous release. However, this may take until the third quarter of 2024 subject to factors such as the COVID-19 pandemic out of our control.

Topline data are projected to be released around November 2024 after consultation with the NMPA (National Medical Products Administration, the Chinese agency for regulating drugs and medical devices). We expect the commercial launch of the product within 2-3 years after the last patient enrollment (launch around 2025), subject to data quality and NMPA approval. Within the first quarter of 2022, our subsidiary Beijing Continent is aiming to publish important and detailed guidelines on all R&D programs including F351 based on stock exchange regulations for IPO preparations, and we will publish further updates as they become available accordingly.

#### **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.

---

#### **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.gnipharmaceutical.com](http://www.gnipharmaceutical.com).

#### **For further inquiries**

Email: [infojapan@gnipharmaceutical.com](mailto:infojapan@gnipharmaceutical.com)

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.