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### **(Update to a previous disclosure) F351 Phase III Clinical Trial Status**

GNI Group Ltd., (TSE Growth listed code: 2160; “the Company” or “we”) today announced the latest update on Phase III clinical trial in China of F351 (generic name: Hydronidone) for HBV-induced liver fibrosis conducted by one of our main subsidiaries, Beijing Continent Pharmaceuticals Co., Ltd. (“BC”).

As disclosed on May 9, 2023, due in part to BC’s addition of several clinical trial sites, 63 subjects were enrolled during the second quarter. This brings the total number of enrolled subjects to 157 as of the end of the second quarter, with 91 remaining to reach the target of 248, and we are on track to complete enrollment by the end of 2023. Regarding safety, the results so far have been as good as those in the Phase II clinical trial.

The impact of this news on the Company’s consolidated financial results for the current fiscal year is immaterial. As previously disclosed, China National Medical Products Administration (NMPA) designated F351 as a “Breakthrough Therapy” in 2021, and F351 forms a core of our future drug pipeline.

#### **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. BC holds the key patent rights for F351 in mainland China, while Catalyst Biosciences, Inc., an equity method affiliate of the Company, holds its rights in the other countries.

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#### **About GNI Group Ltd.:**

The Company is a holding company of global healthcare company listed on the Growth Board of the Tokyo Stock Exchange and engaged in drug discovery, pharmaceutical development, biomaterial development, clinical studies, manufacturing, and sales in both the United States and China. For more information, please visit our website below:

<https://www.gnipharma.com/>

**About Beijing Continent Pharmaceuticals Co, Ltd:**

Continent is a profitable fully integrated specialty biopharmaceutical company with a focus in the organ fibrosis market. With global research and development capabilities, commercial-scale manufacturing facilities, a deep distribution network across China, and a sales and marketing team of 300 people, Continent is a leading company in China of the idiopathic pulmonary fibrosis (IPF) treatment with its flagship medicine ETUARY®. The company has a rich pipeline of potential assets, including F351 for HBV associated liver fibrosis which is in Phase 3 study in China. For more information, please visit Continent's website below:

<https://www.bjcontinent.com/en/>

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