



Company Name: GNI Group Ltd.

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(Security Code: 2160, TSE Growth)

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## (Update to a previous disclosure) GNI's Consolidated Subsidiary Beijing Continent Achieves Mid-Point Subject Enrollment for F351 Phase III Clinical Trial in China

GNI Group Ltd., (TSE Growth listed code: 2160; "the Company" or "we") is pleased to provide an update on the subject enrollment in 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. ("Continent").

As of today, Continent has completed the enrollments of 124 subjects, which is 50% of the target enrollment.

Dr. Ying Luo, Ph.D., CEO of GNI Group, stated, "We are thrilled with the progress of Continent's enrollment efforts in spite of significant disruptions by COVID-19 pandemic in China. Continent has recently added multiple sites in 2023 to expedite the clinical trial process in order to catch up with the delay. Continent's clinical trial team has been working diligently to ensure the smooth running of the trial, and we are proud of their achievement so far despite various headwinds. We have a high confidence in Continent's capability to see to it that this clinical trial be carried out steadily to the end."

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. The Company will continue to fully support Continent's efforts in China to pursue the clinical and commercial developments of F351.

## **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<sup>(R)</sup>. 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/

## About F351 (generic name: Hydronidone):

F351 is a New Chemical Entity (NCE) derivation of ETUARY<sup>(R)</sup>, which inhibits hepatic stellate cell proliferation and TGF- $\beta$  signaling pathway, both of which play major roles in the fibrosis of internal organs. Continent holds the key patent rights for F351 in mainland China, while Catalyst Biosciences, Inc., an equity method affiliate of GNI Group Inc., holds its rights in the other countries.

This material contains statements concerning the current plans, expectations and strategies of GNI Group Ltd. ("the Company"). Any statements contained herein that pertain to future operating performance and that are not historic facts are forward-looking statements. Forward-looking statements may include, but are not limited to, words such as "believe," "plan," "strategy," "expect," "forecast," "possibility" and similar words that describe future operating activities, business performance, events or conditions. Forward-looking statements, whether spoken or written, are based on judgments made by the management of the Company, based on information that is currently available to it. As such, these forward-looking statements are subject to various risks and uncertainties, and actual business results may vary substantially from the forecasts expressed or implied in forward-looking statements. Consequently, investors are cautioned not to place undue reliance on forward-looking statements.

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