



Company Name: GNI Group Ltd.

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## **Subject Enrollment Completed in F351 Phase III Clinical Trial**

GNI Group Ltd., (TSE Growth listed code: 2160; "GNI" or "the Company"; "we" or "the Group" including our subsidiaries and affiliates) today announced that Beijing Continent Pharmaceuticals Co., Ltd. ("BC"), one of its core subsidiaries, completed the subject enrollment of Phase III clinical trial in China of F351 (generic name: Hydronidone) for HBV-induced liver fibrosis. The clinical study aims to confirm the efficacy of F351 in treating liver fibrosis associated with chronic hepatitis B (CHB) and to continue to observe its safety. 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 completion of the registration was achieved more than two months ahead of our initial expectation, thanks to the cooperation of not only the Group but also many others, and we believe that this shows the high expectations for F351 in China.

The completion of this registration is very important for the commercial launch of F351, and the entire group will work together to bring the product to market as soon as possible.

As disclosed on October 24, 2023, BC will become a subsidiary of Catalyst Biosciences, Inc. ("CBIO"). After becoming a subsidiary of CBIO, there will be no change to the fact that it will continue to be fully consolidated by the Group.

Please refer to BC's press release below for more details.

## https://www.bjcontinent.com/en/news

After a 52-week data collection period, Beijing Continent plans to publish top-line data and, if the results are as favorable as expected, submit an application to the Chinese authorities for marketing in China. The safety profile of the drug has so far been satisfactory and comparable to that of the Phase II clinical trial in China.

The impact of this news on the Company's consolidated financial results for the current fiscal year is immaterial.

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.

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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