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Announcement of First Dosing in Phase 1 Clinical Trial of F230 for Pulmonary Arterial Hypertension (PAH) by Gyre Therapeutics

(Note) This document has been translated from the Japanese original for reference purposes only. In the event of any discrepancy between this translated document and the Japanese original, the Japanese original shall prevail.

GNI Group Ltd. (“the Company", and together with its subsidiaries and affiliates, “the Group") announces that its key subsidiary, Gyre Therapeutics, Inc.(“GYRE”), has commenced dosing of the first volunteer in China in a Phase 1 clinical trial of F230, a treatment candidate for pulmonary arterial hypertension (PAH).

This development marks GYRE’s entry into the PAH field—an area characterized by a rare, progressive, and life-threatening cardiovascular disease with limited treatment options. PAH is designated as a rare disease in China. According to Frost & Sullivan, the PAH drug market in China was valued at USD 370 million in 2023 and is projected to reach USD 480 million by 2031.

F230, a novel endothelin A (ETA) receptor-selective antagonist, was initially developed by the Japanese pharmaceutical company Eisai Co., Ltd. In March 2020, the Group obtained exclusive rights for the manufacturing, development, and commercialization of F230 for the treatment of PAH in China from Eisai. F230 is a small molecule compound designed to selectively block the ETA receptor. By targeting this pathway, it may suppress pulmonary vascular remodeling and reduce pulmonary arterial pressure, potentially preventing the progression of PAH.

The Phase 1 clinical trial aims to evaluate the safety, tolerability, and pharmacokinetics (PK) of F230 in healthy volunteers. This trial represents an expansion of GYRE’s fibrosis-first strategy beyond liver diseases and leverages the Group’s robust platform and commercial foundation in China.

This matter will have no impact on the Group’s consolidated earnings forecast for the current fiscal year.

F230 joins Gyre’s pipeline alongside lead candidate Hydronidone (F351), which met the primary endpoint in a

pivotal Phase 3 trial for CHB-fibrosis. A New Drug Application ("NDA") submission to China's National Medical Products Administration ("NMPA") is planned for Q3 2025, and a pre-IND meeting with the U.S. Food and Drug Administration is being planned for an expected Phase 2 trial in metabolic dysfunction-associated steatohepatitis ("MASH") fibrosis.