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Company Name: GNI Group Ltd.
Representative: Director, Representative Executive Officer, President and CEO
Ying Luo, PhD
(Security Code: 2160, TSE Growth)
Contact Person: Director, Executive Officer, Vice President
Ryosuke Matsui
(TEL. 03-6214-3600)

Notice Regarding Enrollment of the First Patient in a Clinical Trial of Pirfenidone for a New Indication in Cancer-Related Pulmonary Complications

(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") announces that its consolidated subsidiary, Gyre Pharmaceuticals Co., Ltd. ("Gyre Pharmaceuticals"), has completed enrollment of the first patient in April 2026 in a Phase 2/3 clinical trial (evaluating its self-developed pirfenidone capsules (product name: Etuary®) for a new indication: radiation-induced lung injury (RILI) with or without immune checkpoint inhibitor-related pneumonitis (CIP).
The Group will continue to advance its clinical development efforts and strive to provide better treatment options as early as possible to this patient population with significant unmet medical needs.

This clinical trial received approval from the National Medical Products Administration of China (NMPA) in March 2025, and the enrollment of the first patient marks substantial progress in the clinical exploration of pirfenidone within the field of oncology supportive care.
RILI is a common and serious complication for patients with thoracic tumors following radiotherapy. In some cases, patients may also develop CIP. Currently, treatment options for this type of lung injury are extremely limited, representing a significant area of unmet clinical need. If left unmanaged, it can potentially develop into pulmonary fibrosis, significantly impacting patients' quality of life and prognosis.

As one of the few small-molecule drugs globally approved for the treatment of idiopathic pulmonary fibrosis (IPF), pirfenidone exhibits broad-spectrum anti-inflammatory, antioxidant, and anti-fibrotic properties. Building on its demonstrated clinical benefit in IPF, Gyre Pharmaceuticals is actively expanding its application to RILI with or without CIP, aiming to fill the current therapeutic gap in this area.
The newly initiated clinical trial will further evaluate the safety and efficacy of pirfenidone in patients suffering from RILI with or without CIP.

The impact of the progress of this clinical trial on the Company's consolidated financial results is expected to be minimal.