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Completion of Phase 1 Clinical Trial and Positive Results of CG001419, a Novel Non-Opioid Pain Product Candidate Developed by Key Subsidiary Cullgen

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GNI Group Ltd. (the "Company") announces that its key subsidiary, Cullgen Inc. ("Cullgen"), has completed a Phase 1 clinical trial of CG001419, its lead product candidate.
Currently, opioid dependence and misuse have become a serious social issue worldwide, particularly in the United States. Against this backdrop, the medical need for safer non-opioid analgesics continues to grow.
CG001419, developed by Cullgen, has the potential to be a first-in-class oral pan-TRK protein degrader for the treatment of pain.

Cullgen's press release is available at the following URL:
Cullgen Reports Positive Results from Phase 1 Study — Cullgen

Cullgen's Phase 1 study was a single-center, randomized, placebo-controlled, double-blind, single-ascending-dose/food-effect (with or without food) and multiple-ascending-dose trial evaluating the safety, tolerability, and pharmacokinetic characteristics of CG001419 in 78 healthy volunteers conducted in Australia. The results demonstrated that CG001419 was well tolerated across all dose levels, with no drug-related serious adverse events observed.

Ying Luo, Ph.D., Chief Executive Officer of both the Company and Cullgen, commented as follows:
"We are very pleased with the positive outcome of this Phase 1 study. CG001419 is an important program as it could provide a new, non-opioid, non-NSAID analgesic therapy option for patients suffering from acute and chronic pain."

Based on the favorable results of this study, Cullgen plans to submit an IND (Investigational New Drug application) to FDA in early 2026 to support the initiation of a Phase 2 clinical trial of CG001419.
Subject to FDA clearance of the IND, Cullgen plans to initiate a Phase 2 clinical trial in the United States in the first half of 2026 in patients with acute pain following bunionectomy surgery.
In addition to its development for pain indications, CG001419 is also being studied in a separate Phase 1 clinical trial in PRC in patients with solid tumors.

The impact of this matter on the Company's consolidated financial results for the current fiscal year is expected to be immaterial.