GNI Announces Strategy for Seeking Early Conditional Approval of F647 for the treatment of Idiopathic Pulmonary Fibrosis in China

TOKYO, September 25, 2008 - GNI Ltd. a clinical-stage biopharmaceutical company, announced its regulatory strategy for its leading product F647 (Pirfenidone) in China. A randomized, double-blind, and multi-centered Phase II Clinical trials of F647 for an orphan but fatal disease, Idiopathic Pulmonary Fibrosis (IPF), was started in early 2006 and finished in May, 2008. The Company has previously disclosed favorable safety and statistically significant positive efficacy results which met the primary end points for the trial.

On August 29, 2008, Japan PMDA approved Pirfenidone for the therapy of IPF. Based on the orphan drug status of Pirfenidone granted in US/Japan, the unmet medical need, and the results from our independent Phase I and Phase II IPF trials, the Company will temporarily halt the preparation for its Phase III IPF trial and apply for conditional early approval of F647 (NDA) for the treatment of IPF in China. This decision is subject to further consultation with SFDA, the regulatory agency of China. The Company anticipates scheduling meetings with the SFDA to review the trial results and the its revised strategy in the near future.

“F647/Pirfenidone may provide a promising hope for thousands of IPF patients to improve their life quality and extend their life,” said Dr. Ying Luo, GNI’s President and CEO. “We are pleased that we can dedicate our limited capital resources to the development of this important product in the past 6 years. Medical doctors in China have been eagerly searching for safe and efficacious therapies for IPF for a long time. We will cooperate with SFDA regarding the potential for accelerated and conditional approval of F647 so that it can reach IPF patients sooner.”

F647/Pirfenidone is a small molecule compound inhibiting collagen synthesis and deposit. In the previous clinical studies, the Company has demonstrated that it helps stabilize and improve pulmonary functions of IPF patients as measured by oxygen level in the blood (SaO2 and SpO2) and gas exchange capacity of the lung (DLCo).

About GNI

Founded in 2001, GNI, Ltd. is a clinical-stage international drug development company with its headquarters in Tokyo, Japan, and major operations in Shanghai, China. In June 2005, GNI acquired Shanghai Genomics, which was also founded in 2001, and currently operates an integrated drug discovery and development platform in Shanghai. The combined strengths of GNI and Shanghai Genomics have resulted in research collaborations with major international pharmaceutical companies. GNI has offices in Beijing, Tianjin, and Zhengzhou, China. For further information, please visit www.gnipharma.com, wap.gnipharma.com and www.shanghaigenomics.com.

For further inquiries

Shinobu Tanaka	Tel: +81 (03) 3580-0751
	Email: ir@gene-networks.com
Ying Luo	Tel: +86 1381-769-8961
	Email: bd@shanghaigenomics.com

similar expressions are intended to identify these forward-looking statements. There are a number of important factors that could cause GNI's results to differ materially from those indicated by these forward-looking statements, including risks associated with the timing and success of clinical trials and the commercialization of product candidates. GNI does not undertake any obligation to update forward-looking statements.