GNI Reports Human Phase II Trial Results of F647 for Radiation Pneumonitis and Future Plan for Idiopathic Pulmonary Fibrosis

Tokyo, January 21, 2009 – GNI Ltd, a clinical-stage biopharmaceutical company in China and Japan, today announced the results of a Phase II clinical trial of F647 (generic name: pirfenidone) for Radiation Pneumonitis (RP). The results demonstrated a positive trend in efficacy of F647 in reducing the incidence of lung injury of grade II or above induced by radiation therapy. This trial had been conducted in six major cancer centers in China by Shanghai Genomics, Inc., a wholly owned subsidiary of GNI.

The human trial is randomized, double-blind, multi-dose (including placebo), and multi-centered. A total of 107 patients received concurrent or sequential chemotherapy and conformal/intensity -modulated radiation therapy for non-resectable stage Ⅲ non-small cell lung cancer or restricted small cell lung cancer. The total radiation dosage is no less than DT 50 Gy. Patients were randomly assigned to high dose (1,200 mg/day, orally, three times daily) of group (H), low dose (600 mg/day, orally, three times daily) of group (L), and the placebo group (0 mg/day, orally, three times daily) (P) (H: L: P = 35: 36: 36). The first dosage of F647 was given 3 days prior to the beginning of the radiation therapy. The treatment period was 12 weeks and the observation period was 6 months after the completion of radiation therapy.

The key primary end point was the incidence of radiation-induced lung injury with grade II or above (NCI CTC AE v3.0) in the H, L, and P group of patients. The incidences of different group of patients were 20% (H), 27.78% (L), 25% (P) based on full analysis set (FAS). The incidences were 21.43% (H), 30% (L), 31.03% (P) based on per protocol set (PPS). Although there is no statistical significance among the three groups due to the small trial size, it already demonstrated a positive trend of potential efficacy of F647 in preventing the occurrence of severe lung injury induced by radiation therapy. The study also showed that F647 was well tolerated by patients. A much larger human Phase III is being planned to start in mid 2009 to provide further confirmation of safety and efficacy.

Dr. Ying Luo, Chief Executive Officer and Representative Director of GNI, said, "We are very encouraged to see F647's promising effect on preventing radiation-induced lung injury. Nowadays when more and more lung cancer patients are undergoing chemotherapy and radiation therapy, there is an increasing urgency to develop a preventive medicine for this unmet medical need. Facing the current financial market turbulence, the Company's priority is to push its clinical programs forward for early commercialization, while reducing spending on other programs."

In June, 2008, GNI also reported positive Phase II results of F647 in treatment of a rare but fatal disease, Idiopathic Pulmonary Fibrosis (IPF). Following the consultation with the Chinese regulatory agency, SFDA, the Company decided to suspend the preparation of Phase III trial of IPF and seek a fast-track conditional approval for an orphan treatment of IPF (disclosed in September, 2008). The company is currently working with a third party GMP manufacturing and formulation facilities to prepare necessary supporting materials and documents for the NDA filing. The Company expects to submit a New Drug Application (NDA) specifically for IPF to SFDA in the fall of 2009.

About Radiation Induced Lung Injury
Radiation therapy is an important treatment for multiple thoracic malignancies, including lung cancer, breast cancer, lymphoma, or thymoma. Injury to lungs, which are particularly

susceptible to radiation, is unavoidable and is a dose-limiting factor for radiation therapy. Acute pneumonitis and/or subsequent fibrosis are common severe sides effect with morbidity rate about 30-50% in patients undergone thoracic radiation therapy.

Radiation pneumonitis occurs within 1-6 months following treatment. Symptoms can include low-grade fever, cough, and fullness in the chest. Severe reactions can result in dyspnea, pleuritic chest pain, hemoptysis, acute respiratory distress, and death. Fibrosis can occur without previous pneumonitis. Once pneumonitis occurs, fibrosis is almost certain to follow. Fibrosis causes lung tissue to become hard and stiff, hindering air exchange ability of lung and causing shortness of breath. There is currently no effective preventive measure for this irreversible, permanent and often fatal disease.

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. For further information, please visit www.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

This press release contains "forward-looking" statements, including statements related to GNI's plans to pursue development of product candidates and the timing thereof. Any statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Words such as "continue," "could," "may," and 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.