GNI's F647 Shows Positive Results in Phase II Human Clinical Trial of Idiopathic Pulmonary Fibrosis

Tokyo, June 18, 2008 – GNI Ltd, a leading biopharmaceutical company in China and Japan, today announced the results of a Phase II clinical study of F647 (generic name: pirfenidone), showing a positive efficacy trend of F647 in slowing progression of Idiopathic Pulmonary Fibrosis (IPF). This trial was conducted in China by Shanghai Genomics, Inc., a wholly owned subsidiary of GNI

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The clinical trial was a randomized, double-blind, placebo-controlled multi-center clinical trial with concomitant therapy with prednisone. A total of 72 patients were randomly assigned to high dose (1800 mg/day, orally, three times daily) of pirfenidone group (H), low dose (1200 mg/day, orally, three times daily) of pirfenidone group (L), and the placebo group (0 mg/day, orally, three times daily) (P) (H: L: P = 1: 1: 1). The dosage regime for prednisone was 0.5mg/kg/day initially for 2 weeks, followed by a series of decreasing dosages in the sequence of 0.4mg/kg/day for 1 week, 0.3mg/kg/day for 1 week, 0.25mg/kg/day for 8 weeks, and the final maintenance dosage of 0.125mg/kg/day or 0.25mg/kg qod (every other day) till the end of the trial. The clinical trial was conducted over a 12-month treatment period in patients who diagnosed with IPF.

One of the primary end points, mean changes of SaO2 (arterial oxygen saturation) from baseline before the treatment to12 months after the treatment commencement, was -2.57% (group H), -0.30% (group L) and -3.83% (group P), with a statistical significance between group L and group P ($P<0.05$). Mean changes of SpO2 (peripheral oxygen saturation) after 6 minute walk test during the same period was -5.17% for group H, 0.22% for group L and -9.08% for group P, with a statistic significance between group L and group P ($P<0.05$). Other favorable parameters demonstrating a positive efficacy trend of F647 in treatment of IPF include pulmonary function effective rate (including improved or stable lung function test results), which was 62.5% (group H), 56.52% (group L) and 41.67% (group P); the change of walking distance of 6 minute walk test, which was -120.44 meters (group H), -116.47 meters (group L) and -164.62 meters (group P). The study also showed that F647 was well tolerated by patients.

This clinical study has demonstrated that F647 treatment can achieve favorable efficacy response in IPF patients with good tolerability. GNI plans to initiate Phase III clinical trial with F647 for IPF patients in the second half of 2008. Currently, GNI is conducting another Phase II trial of F647 in prevention and therapy of radiation pneumonitis (radiation therapy-induced lung injury) in lung cancer patients in China.

Dr. Ying Luo, Chief Executive Officer and Representative Director of GNI said, "We are excited to see improvement in patients taking F647. This is a pivotal achievement in our company's drug development history. F647 as a potential new therapy for hundred thousands IPF patients is very promising. We will continue to focus more of our resource on late-stage development of novel therapeutic products for Asian population."

About IPF

Idiopathic pulmonary fibrosis (IPF) is a medical condition of unknown etiology with extremely poor prognosis. It causes inflammation and scarring (fibrosis) in the lungs, hindering a person's ability to process oxygen and causing shortness of breath (dyspnea) and cough.

The patients suffer abnormal pulmonary function (reduced vital capacity) and impaired gas exchange (increased alveolar-arterial pressure differences for O2 and decreased arterial O2 saturation at rest or after exercise). IPF is a progressive and fatal disease, with an average survival time between two to five years following diagnosis. There is currently no efficacious treatment for IPF.

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 and Fukuoka, Japan. For further information, please visit www.gnipharma.com and www.shanghaigenomics.com.

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