Shanghai Genomics Reports Human Phase I Trial Data of F351

TOKYO, July 26, 2010 - GNI Ltd., a clinical-stage biopharmaceutical company, announced today that its fully owned subsidiary in China, Shanghai Genomics has completed human Phase I study of F351 for liver fibrosis in Beijing, China. The results of the study indicate that F351 has an excellent safety and tolerability profile at all doses administered.

The human Phase I trial started in 2009 was designed as a randomized, double-blind, placebo controlled, ascending dose study to assess the safety, tolerability and pharmacokinetic parameters of F351. In total, 101 healthy male and female volunteers received between 100 to 800 micrograms of F351 or placebo via oral administration. All doses of F351 were safe and well tolerated. In addition, no serious adverse events were observed. Most frequently reported minor adverse events of the 800 mg tid group included unspecific dizziness, headache, constipation, nausea, distension, heart burn, rash, hyperlipidemia, and abnormal liver function, etc. Observed adverse events were generally mild and resolved spontaneously.

Analysis of pharmacokinetic properties of F351 revealed maximal plasma concentrations within one hour of administration and a proportional increase of exposure with dose. $T_{1/2}$ is nearly 3 times of F647, the anti-lung fibrosis drug being developed for Idiopathic Pulmonary Fibrosis.

In China, there are currently about 93 million people infected by Hepatitis B virus and 30 million hepatitis patients. Chronic hepatitis will lead to liver fibrosis and at severe stage, liver cirrhosis. In addition, with economy development in China, alcohol abuse and fatty liver also increasingly lead to liver fibrosis. In China alone, it is estimated that up to 18 million patients seeks liver fibrosis therapy per year (http://hbv.39.net/hbv/szjd/222666.html). Other than herb medicine, there is no existing proven drug.

Dr. Ying Luo, Chief Executive Officer of GNI Ltd. and Shanghai Genomics, Inc. commented: “The results of this Phase I study strongly support our working hypothesis that F351 has a superior safety and tolerability profile in human. In addition, favorable pharmacokinetic profile for F351 indicates that it is suitable for the treatment of chronic disease such as liver fibrosis. In combination with our previous pre-clinical animal studies, these Phase I study results provide a solid basis for further development of F351 in Phase II human trial. We intend to ask SFDA for permission to start Phase II trial in the coming fall or later.”

About GNI

Founded in 2001, GNI, Ltd. is a clinical-stage international drug development company with its headquarters in Tokyo, Japan, and research 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.

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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 "will," "intend to," 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.