F647 New Drug Application (NDA) DRAFT In Review By Shanghai Food and Drug Administration

TOKYO, December 21, 2009 - GNI Ltd., a clinical-stage biopharmaceutical company, announced today that its fully owned subsidiary in China, Shanghai Genomics has submitted a New Drug Application for F647's (pirfenidone) use in Idiopathic Pulmonary Fibrosis therapy, to the Shanghai Food and Drug Administration (Shanghai FDA) for review. Shanghai FDA has done initial formality review of our NDA and has given Shanghai Genomics an official Receipt with a Priority Number. Shanghai FDA will do further review and also carry out on-site inspection of selected hospitals, contract manufacturers, and other institutions participated in the clinical trials in the past few years. After review and on-site inspection by Shanghai FDA, the NDA file will then be subject to further review by the State Food and Drug Administration (SFDA) at Beijing.

The process at Shanghai FDA may take about one and a half month or longer. Shanghai FDA may or may not also ask the Company to revise the NDA significantly. It may take another 5 months or longer for SFDA in Beijing to review and make a final decision. If our NDA is approved by SFDA, a New Drug Certificate will be issued to Shanghai Genomics. The Company must later apply for Drug Manufacture Permit before production and marketing of F647 in China. To apply for Drug Manufacture Permit, the Company must demonstrate its capability to produce both Active Pharmaceutical Ingredient (API) and formulation under Good Manufacturing Practice (GMP) conditions. The Company is actively seeking facilities meeting such SFDA requirements.

The Company has completed clinical trials in 2008 and disclosed the results in a press release of June 18, 2008. On January 7, 2009, SFDA published a set of rules of New Drug Registration Special Review Administration and Regulation (http://www.sda.gov.cn/WS01/CL0058/35157.html), with the goals to promote novel drug development and to control the risk. The Company intends to follow this regulation in our NDA filing.

"I am glad that we are taking another big step forward towards the end-goal of our multi-year development program of F647. We will continue to develop F351 and other products in our pipeline in collaboration with other partners," said, Dr. Ying Luo, President and CEO of GNI and Shanghai Genomics.

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 "continue," “expected to”, "will," "intend to," “strive 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. There is no guarantee that Shanghai FDA or SFDA of China may approve the Company’s NDA application. GNI does not undertake any obligation to update forward-looking statements.