



Update On Progress Of F647 NDA Filing

TOKYO, February 23, 2010 - GNI Ltd., a clinical-stage biopharmaceutical company, announced today that Shanghai Food and Drug Administration (Shanghai FDA) has completed the review of F647 New Drug Application filed by its fully owned subsidiary in China, Shanghai Genomics in December, 2009. After passing the Shanghai FDA examination, the NDA file will now be transferred to the State Food and Drug Administration (SFDA) at Beijing for the second phase of review. The second phase review will take five months or longer, as previously announced in December, 2009.

As an important first step in the NDA review process, in the last six weeks, Shanghai FDA and its delegated government agencies have inspected several sites in China, including hospitals, research institutes, and manufacture sites which participated or provided contract services in the clinical trial of F647. The Company is now actively preparing for the second phase of review by SFDA. At the meantime, Shanghai Genomics is also preparing for the manufacturing site selection.

"Recently, we have completed a round of financing through Orix Securities. This gives us more alternatives to make the best manufacture decision for our company. We will use every penny carefully," said 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 SFDA of China may approve the Company's NDA application. GNI does not undertake any obligation to update forward-looking statements.