



## Shanghai Genomics Issued US Patent Covering F351

**TOKYO, September 17, 2010** - GNI Ltd. a clinical-stage development biopharmaceutical company announced today that its fully owned subsidiary in China, Shanghai Genomics, has received Notice of Allowance from the United States Patent and Trademark Office (PTO), covering the pharmaceutical composition of F351 in the treatment of fibrotic diseases. The United States is the fourth country, after China, Australia, Canada, to grant such allowance on the Company's F351 patent application. Applications in Japan, Europe, and India are still pending. GNI employed US IP law firm, Wilson Sonsini, to prosecute the patent applications in US.

As the single largest healthcare market worldwide, nearly 500,000 HCV-infected patients are at the risk of progression to liver fibrosis in the United States alone. Also in light of the growing obesity epidemic, approximately 12.2 million NASH (nonalcoholic steatohepatitis) patients worldwide could also benefit from this anti-fibrotic therapy. In addition, renal fibrosis is central to the progression of Diabetic Nephropathy disease which affects nearly 57 million people worldwide. Fibrosis of internal organs all share similar mechanism.

US patent allowance provides the Company with strong incentive to explore F351's therapeutic use in various types of fibrosis. Like the previous announced joint development program with EPS in China and Japan, GNI will actively look for additional strategic partners in North America, in the disease areas of liver fibrosis, lung fibrosis, and kidney fibrosis. The Company already has a New Drug Application (NDA) of F647 pending for review in the China State Food and Drug Administration for Idiopathic Pulmonary Fibrosis.

"As a biotech company, patent is one of our valuable core assets. This patent allowance demonstrates that our IP strategy is well executed," said Dr. Ying Luo, Chief Executive Officer of GNI and Shanghai Genomics. "Today, we are actively preparing for Phase II clinical trial of F351 for liver fibrosis therapy in China. Together with F1013, our pre-IND drug candidate for acute-on-chronic liver failure, GNI has gradually built a promising pipeline in liver diseases."

### **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](http://www.gnipharma.com) and [www.shanghai-genomics.com](http://www.shanghai-genomics.com).

### **For further inquiries**

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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. GNI does not undertake any obligation to update forward-looking statements.