



## **GNI Receives Patent Allowance on F351 and F647**

**Tokyo, August 2, 2011** – GNI Group Ltd, a leading biopharmaceutical company in Japan and China, is pleased to announce that its wholly owned subsidiary, Shanghai Genomics, has received patent allowance on its major drug candidates: F351 and F647 (pirfenidone). The first US patent allowance covers the use of F351 in the treatment of fibrotic disease. The second European patent allowance covers the use of F647 and F351 in the treatment of radiation pneumonitis.

Currently, F647's New Drug Application (NDA) for the treatment of Idiopathic Pulmonary Fibrosis (IPF) is still under review by SFDA. In anticipation of its approval, GNI Group has recently signed agreement to acquire a majority stake in a pharmaceutical production company in China. Shanghai Genomics has also completed Phase II study of F647 for the treatment of radiation pneumonitis in China. Pirfenidone, developed by US company Intermune, had been approved in Europe to treat IPF in March, 2011. This important patent allowance to Shanghai Genomics for treatment of radiation pneumonitis protects the company's intellectual positions in Europe.

F351 Phase I clinical trial has been completed in China. The Company is waiting for SFDA's review result and then decide on how to continue further development of F351 for the treatment of liver and renal fibrosis in both China and worldwide.

Similar to liver fibrosis, renal fibrosis also represents an area of significant unmet medical need. It is estimated that 13% of Americans have chronic kidney disease (CKD). Fibrosis is the final common path which eventually leads to renal failure. Currently, Shanghai Genomics has initiated several animal studies to verify the efficacy of F351 in renal fibrosis model with a plan to add renal fibrosis indication in future clinical trials. Initial results demonstrated that F351 was superior to F647 in both liver and renal fibrosis treatment in various animal models.

"New drug development takes 10-15 years in North America. We are making solid progress down this road in the last 10 years," said, Ying Luo, CEO of GNI Group and Shanghai Genomics.

### **About GNI**

Founded in 2001, GNI Group, Ltd. is a clinical-stage international drug development group 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).

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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.