China SFDA Approves F647/Pirfenidone for the Treatment of Idiopathic Pulmonary Fibrosis

TOKYO, September 22, 2011 – GNI Group Ltd. an international biopharmaceutical company, announced today that the China State Food and Drug Administration has issued New Drug Certificate for F647 (pirfenidone) to Shanghai Genomics, the wholly owned subsidiary of GNI Group. F647 is indicated for the treatment of idiopathic pulmonary fibrosis (IPF) in adults, a progressive and fatal lung disease. This approval finally gives the estimated 182,000~550,000 IPF patients in China an effective treatment.

"GNI is very proud to bring the first IPF medicine to Chinese patients," said Dr. Ying Luo, CEO and President of GNI Group. "IPF is a deadly disease with estimated survival of only 20% after 5 years. Patients in China are told by their physician that it is more lethal than lung cancer. In the last 10 years, F647 had been our lead product under development. Even at the most difficult time, we never gave up our hope to bring F647 to these patients some day. Today's milestone can not be achieved without dedication by many executives, scientists, and staffs in the past.

GNI has separately announced that it has received government approval to acquire 51% of Beijing Continent as the future manufacture site for F647 in Beijing. Beijing Continent has almost completed renovating works for its GMP-compliant factory to meet requirements for the application for manufacture permit. The sales and marketing team within Beijing Continent is also working diligently to make this product accessible to Chinese patients as soon as it becomes available.
Mr. Takashi Kataoka, COO of GNI Group, said, "I am very pleased as this approval opens a new chapter in GNI Group's history and marks a transition point for our company from a R&D organization to become a real pharmaceutical company."

About F647 (pirfenidone)

F647 is an orally active, small molecule drug that inhibits the synthesis of TGF-β, which plays a key role in fibrosis. The approved formulation is capsule. In laboratory studies, F647 also inhibits the synthesis of TNF-alpha, a cytokine that is known to have an active role in inflammation. In late 2008, pirfenidone has been approved in Japan as Pirespa(R) by Shionogi. In March, 2011, pirfenidone is also approved in Europe as Esbriet(R) by Intermune. In USA, pirfenidone is still under clinical trial for the treatment of IPF.

About GNI Group

GNI Group, Ltd. is an international pharmaceutical company with its headquarters in Tokyo, Japan, research operations in Shanghai, China, and manufacture/sales operation in Beijing, China. GNI Group focuses on the research, development, and commercialization of innovative therapies in the field of pulmonary, liver and kidney diseases. For further information, please visit www.gnipharma.com and www.shanghaigenomics.com.

For further inquiries

Shinobu Tanaka Tel: +81 (03) -5326-3097
Email: ir@gene-networks.com
Ying Luo Tel: +86 1381-769-8961

Email: bd@shanghaigenomics.com

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.