Pre-IND Studies of F1013 For Liver Failure Initiated In China And Update On Drug Pipeline Development

TOKYO, March 15, 2010 - GNI Ltd. a clinical-stage biopharmaceutical company, announced today that its fully owned subsidiary in China, Shanghai Genomics has initiated pre-IND (Investigational New Drug) preparation of F1013 (EP1013) for the therapy of acute-on-chronic liver failure. In July, 2008, GNI signed a collaboration agreement with US-based Epicept (NASDAQ: EPCT) to license-in a new chemical entity, EP1013, for the therapy of liver disease in Asia. In the last 1 1/2 years, Shanghai Genomics has been working on chemistry synthesis and animal models to finalize industrial scale synthesis protocol and to test F1013's safety and efficacy. IND filing is expected by the end of 2010.

Apoptosis is an important type of human cell death. It plays critical roles in human diseases such as cancer, cerebral infarction, myocardial infarction, and liver failure. Induction of apoptosis may increase cancer cell death and lead to novel cancer therapy. At the meantime, inhibition of apoptosis may prolong the life of liver, brain, or cardiac cells when such organs are experiencing viral infection, toxic substances, or loss of oxygen supply. Caspases are a class of intra-cellular enzymes executing the apoptosis process. F1013 is an irreversible pan-caspase inhibitor. In animal model studies, Company's scientists have found that F1013 is able to inhibit liver cell death caused by various types of chemicals and significantly lower the blood level of ALT and AST, two key biochemical indicators of liver function.

With the new addition, the Company builds up a pipeline of new drugs including F647, F351, and F1013, from pre-IND to NDA stage. In December, 2009, the Company has announced that it had filed NDA for its lead compound, F647/pirfenidone, for the therapy of Idiopathic Pulmonary Disease (IPF) in China. On March 9, 2010, US-based Intermune (NDASDA: ITMN) has disclosed that US FDA advisory panel has recommended approval of pirfenidone for the therapy of IPF. The Company believes that the US FDA action will also positively affect the current NDA review at China SFDA, although China SFDA makes decision independently. It is estimated that there are up to 200,000 IPF patients in US and Europe. In China, up to 550,000 patients are affected by IPF.

F351, a new chemical entity derived from pirfenidone, has also completed Phase I clinical studies in Peking Union Hospital of China in January, 2010. F351 may work in a similar molecular mechanism to F647 to inhibit collagen production and deposition in human organs. Furthermore, in the Phase I human studies, F351 demonstrates more favorable safety profile and pharmacological profile than pirfenidone. The final results of the F351 Phase I trial will be disclosed within 4-6 weeks. The Company is developing F351 for the therapy of liver fibrosis. Phase II clinical trial is expected to start by summer, 2010 after SFDA reviews the Phase I result. Liver fibrosis healthcare market is much larger than IPF's, although the design and execution of clinical trial is also more complicated. In China alone, millions of people are affected by liver fibrosis. Worldwide market is even bigger. Because of F351's global potential, the Company has secured F351 patent in China and Australia. Patents in US, Europe, Canada and Japan are pending. The Company is also seeking global partners for the development of F351 in the rest of the world.

Dr. Ying Luo, President and CEO of GNI and Shanghai Genomics, said, "We are very delighted to hear the news that US FDA review panel recommends the approval of pirfenidone developed by Intermune. This approval is important not only for our NDA of F647, but also for the future of F351 because both drugs share the similar molecular mechanism of action inside cell. With the addition of F1013, we are gradually building a leading biotech company focusing on pulmonary and 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 and www.shanghaigenomics.com.

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