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FIRST NASH PATIENTS TREATED WITH GFT505

IN THE USA AND IN EUROPE

- **The recruitment of patients for the key international clinical study of GFT505 in non-alcoholic steatohepatitis (NASH) has begun in the United States and in Europe.**

Lille (France), Boston (Massachusetts, United States), November 20th, 2012 – GENFIT (Alternext: ALGFT; ISIN: FR0004163111), a biopharmaceutical company at the forefront of drug discovery and development, focusing on the early diagnosis and preventive treatment of cardiometabolic and associated disorders, today announced that the first patients have been recruited and are under treatment in the pivotal phase IIb GFT505-212-7 study that aims to demonstrate the therapeutic efficacy of GFT505 in non-alcoholic steatohepatitis (NASH*).

After obtaining the approval of the Food and Drug Administration (FDA), of national health authorities in Europe, and of local ethical committees, GENFIT has entered the operational phase of the international study GFT505-212-7. The first clinical investigation centers have been opened in the United States and in Europe, and the first patients are already under treatment. This study will involve a total of more than 75 centers of clinical excellence and will include 270 patients with a histological diagnosis of NASH at recruitment. All the clinical centers will be opened by the end of January 2013, and the last patient should be recruited by October 2013 at the latest. The final results are expected in December 2014, when GFT505 should become the first dedicated drug candidate with proven therapeutic efficacy in NASH.

Based on the prior recommendations of the FDA and the European Medicines Agency (EMA) concerning the global development plan for GFT505 in NASH, the primary aim of this pivotal double-blind study is to demonstrate the efficacy of one year of treatment with GFT505 at two doses (80 mg and 120 mg) versus placebo (90 patients/group) on the reversion of NASH in diabetic and non-diabetic patients. Multiple secondary objectives, in particular the demonstration of the effects of GFT505 on steatosis, inflammation, liver cell damage, and histological fibrosis, will also be pursued. Moreover, a large panel of plasmatic efficacy markers will be measured, including lipid profile, glycemia, and markers of inflammation and liver function. Patient safety will be assured throughout the study by an independent committee (Data Safety Monitoring Board). Finally, a particular focus will be made on the validation of diagnostic markers that could be developed as companion tests.

Prof. Vlad Ratziu, Principal Investigator and International Coordinator of the GFT505-212-7 study, declared: *« The large number of US and European clinical centers and internationally-recognized NASH experts involved in the GFT505-212-7 study illustrates the significant unmet medical needs in NASH and the hopes raised by GFT505 for this therapeutic indication. This is without a doubt one of the most complete NASH studies initiated in terms of patient number, length of treatment, and the number of associated clinical and biological analyses. As the principal investigator and international coordinator of the study, I am very pleased that the first patients have been recruited, and am confident as to the organization set up by GENFIT to successfully accomplish this study ».*

Dr. Rémy Hanf, EVP, Product Development, declared: *«The initiation of this pivotal study is a key step in the vast development program that we have discussed with the health agencies. For example, during 2013, GENFIT will set up complementary clinical trials and will initiate the development of new formulations of GFT505 for Phase III studies. Moreover, studies to determine the mechanism of action of GFT505 on fibrosis have been launched, and the first results show a direct effect of the molecule on the cells that are responsible for fibrosis*

development. Overall, the investments made are in keeping with the potential of GFT505 in this new indication».

***About NAFLD/NASH:**

NAFLD (non-alcoholic fatty liver disease) and in particular NASH (non-alcoholic steatohepatitis) are serious liver diseases that can lead to cirrhosis and liver cancer. The development of NAFLD/NASH is associated with the pathophysiological process of insulin resistance in patients that are overweight and/or diabetic. NAFLD is believed to affect 70-80% of diabetic patients, and progresses to chronic liver disease (NASH) in 20-50% of cases. Mortality due to liver disease is thus 2-3-fold higher in the diabetic population than in the overall population. The NASH market was estimated at 615 $M in 2010 and should reach 2,008 $M in 2018.

About GENFIT:

GENFIT is a biopharmaceutical company focused on the Discovery and Development of drug candidates in therapeutic fields linked to cardiometabolic disorders (prediabetes/diabetes, atherosclerosis, dyslipidemia, inflammatory diseases…). GENFIT uses a multi-pronged approach based on early diagnosis, preventive solutions, and therapeutic treatments and advances therapeutic research programs, either independently or in partnership with leading pharmaceutical companies, including Sanofi, to address these major public health concerns and their unmet medical needs.
GENFIT's research programs have resulted in the creation of a rich and diversified pipeline of drug candidates at different stages of development, including GENFIT's lead proprietary compound, GFT505, that is currently in Phase II.
With facilities in Lille, France, and Cambridge, MA (USA), the Company has approximately 80 employees. GENFIT is a public company listed on the Alternext trading market by Euronext™ Paris (Alternext: ALGFT; ISIN: FR0004163111). www.genfit.com

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