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GENFIT: Recruitment of the 100th patient to the pivotal GFT505 study in NASH

- **The international study GFT505-212-7 that evaluates GFT505 in NASH is in the active recruitment phase.**
- **More than 100 patients have been recruited to the study.**
- **The first patients have been under treatment since October 2012, with no serious adverse event reported.**

Lille (France), Boston (Massachusetts, United States), March 7th, 2013 – 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 announces that more than 100 patients (110 as of March 7th, 2013) have been recruited to the GFT505-212-7 study that aims to demonstrate the efficacy of a one year treatment with GFT505 on histological parameters of non-alcoholic steatohepatitis (NASH*).

The GFT505-212-7 study set up by GENFIT will be one of the largest interventional studies ever conducted in NASH. A total of 75 to 80 centers of clinical excellence in the United States and in multiple European countries (France, Belgium, The Netherlands, Italy, United Kingdom, Germany, Spain, and Romania) will participate in this study and recruit a total of 270 patients.

After having obtained the authorization of the national health agencies of each country and of the corresponding ethical committees, and having initiated more than half of the clinical investigation centers, more than 100 patients (110 as of March 7th, 2013) have already been recruited to the GFT505-212-7 study. At this rate, and given the low screening failure rate observed, the planned total of 270 patients for this study will easily be reached and the first results should be disclosed as expected at the end of 2014 or beginning of 2015.

The first patients were recruited in October 2012 and have been under treatment for 4-5 months. To date, no serious adverse event has been noted by a committee of independent experts responsible for evaluating patient safety throughout the study. As planned, an intermediate safety data review will be carried out by this committee in the Fall of 2013.

Dr. Sophie Mégnien, Chief Medical Officer of GENFIT, declared: "*The protocol is welcomed by NASH patients, the vast majority of whom wished to participate in the study. The hepatic biopsies necessary for the protocol are well accepted thanks to the high quality support provided by the clinical investigators. This very dynamic recruitment reflects the major hope that GFT505 represents for the patients and their physicians, who currently have no efficient treatment for NASH.*"

***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 IIb.
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

Contacts:

GENFIT
Jean-François Mouney – CEO & Chairman of the Management Board
Ph. +333 2016 4000

MILESTONES – Press Relations
Bruno Arabian
Ph. +331 7544 8740 / +336 8788 4726 – barabian@milestones.fr