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GENFIT: A HOSPITAL-BASED CLINICAL STUDY DEMONSTRATES THE ACTION OF GFT505 ON THE LIVER

- **Necessary elements are in place to proceed with a Phase IIb study in NAFLD/NASH.**

Lille (France), Cambridge (Massachusetts, United States), October 19th, 2011 – 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 reveals highly significant partial results for a pharmaco-clinical study that demonstrate a hepatic mechanism of action for GFT505 in insulin-resistant patients.

GFT505-210-6**, an exploratory single-blind pharmaco-clinical trial, that can only be performed under medical control within a hospital setting, aims to precisely describe the mechanism of action of GFT505 on its target organs, and in particular the liver, by the "glucose clamp" technique.

Partial results for 19 of the 22 patients included in the study (3 patients are still being treated) already show that GFT505 very significantly increases the response of the liver to insulin action. At the end of the treatment period, the decrease in hepatic glucose production (HGP) induced by insulin was -51±5% after GFT505 vs -34±4% % after placebo (p=0.0014).

The insulin sensitivity of the muscles and other peripheral tissues was also increased by 30% with a significant effect on the glucose infusion rate (GIR, 3.71±0.3 mg/kg/min after GFT505 vs 3.2±0.3 mg/kg/min after placebo, p=0.025).

The beneficial effects of GFT505 on the liver confirm the findings of previous studies conducted by GENFIT, with a very significant decrease in hepatic dysfunction markers. The observed reductions in circulating levels of γGT (-35±4% after GFT505 vs +3±4% after placebo, p<0.001) and ALAT (-17±5% after GFT505 vs +7±6% after placebo, p<0.001) are particularly marked, while the level of ASAT is unchanged (-1±4% after GFT505 vs +6±4% after placebo, p=0.16).

Commenting on these first analyses, **Rémy Hanf, EVP, Product Development**, declared: « *These results concerning more than 80% of the patients in the study are such that they already provide us with the key mechanistic elements required by experts for the initiation of a Phase IIb study in NAFLD/NASH*. It is clear that the mixed PPARα/δ activity of GFT505, combined with this hepatic tropism, give it a unique potential in NAFLD/NASH, a medical need that is today unmet by lipid-lowering or oral anti-diabetic medicines.* »

Jean-François Mouney, CEO & Chairman of GENFIT's Management Board, added: « *These new results are extremely important and were eagerly awaited by our experts. Thanks to those meaningful first results, we are proceeding with the initiation of an international multi-center Phase IIb study for which the first patient should be recruited at the beginning of the second trimester of 2012.* »

***About NAFLD and 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 diabetic pathophysiological process. NAFLD is believed to affect between 80 and 100% 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 the GFT505-210-6 study**

The GFT505-210-6 study is based on the gold standard "hyperinsulinemic euglycemic clamp", with two levels of insulin and using a deuterated tracer to measure hepatic glucose production. The two principal parameters measured by this method are:

- The insulin sensitivity of the liver (the decrease in hepatic glucose production, HGP, induced by the first insulin level).
- The insulin sensitivity of the muscles and other peripheral tissues (measure of the glucose infusion rate, GIR, at the end of the second insulin level).

The single-blind GFT505-210-6 study included a total of 22 insulin-resistant patients in a specific crossover design that optimizes the statistical power of the study. Each patient underwent two successive 2-month treatment periods (Group 1: GFT505 80 mg/d then Placebo, Group 2: Placebo then GFT505 80 mg/d) with a treatment-free period of 4 weeks between treatments. The “clamp” procedure was performed on all patients at the end of each treatment period, and the data obtained after GFT505 and after placebo are compared. Markers of hepatic dysfunction, plasma lipids, and inflammation markers are also measured at the beginning and the end of each treatment period.

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 (SANOFI, SERVIER, …), 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 100 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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