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GFT505: THE GFT505-210-6 STUDY REACHES ALL ITS EFFICACY OBJECTIVES WITH NO ADVERSE EFFECTS

Lille (France), Cambridge (Massachusetts, United States), February 3rd, 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 announces that the GFT505-210-6** Phase II clinical study has reached all its primary and secondary efficacy objectives with no adverse side-effects. Statistical analysis shows that GFT505 improves insulin sensitivity in the liver and peripheral tissues, improves dyslipidemia, and lowers markers of liver dysfunction and inflammation in insulin-resistant patients with abdominal obesity (BMI = 30±3 kg/m^2).

Insulin sensitivity:
The primary objective of the GFT505-210-6 pharmaco-clinical trial was to evaluate the effect of 8 weeks of GFT505 treatment (80 mg/day) on the insulin sensitivity of the liver and peripheral tissues by the gold standard hyperinsulinemic euglycemic clamp technique. The decrease in hepatic glucose production (HGP) induced by insulin was -0.86 ± 0.07 mg/kg/min after GFT505 vs -0.63 ± 0.07 mg/kg/min after placebo (p=0.006), equivalent to an improvement in the liver insulin response of 37%. Similarly, the insulin sensitivity of the peripheral tissues was significantly increased by GFT505 treatment (glucose infusion rate GIR, 3.8 ± 0.3 mg/kg/min after GFT505 vs 3.2 ± 0.3 mg/kg/min after placebo, p=0.019).

Liver function markers:
In this study, GFT505 strongly lowered markers of liver dysfunction associated with non-alcoholic steatohepatitis (NAFLD/NASH*), with a decrease in circulating levels of γGT (-30.4 ± 8.9% vs placebo, p=0.003), ALAT (-20.5 ± 6% vs placebo, p=0.004) and ASAT (-6.7 ± 4.7% vs placebo, p=0.18). Moreover, a significant improvement in plasma levels of alkaline phosphatase was also observed (-19 ± 3% vs placebo, p<0.0001).

Plasma lipids:
In parallel, GFT505 treatment improved all the plasma lipid parameters. GFT505 significantly lowered the levels of plasma triglycerides (-21 ± 6% vs placebo, p=0.0033), total cholesterol (-9.2 ± 2.8% vs placebo, p=0.004), LDL-cholesterol (-13 ± 3% vs placebo, p=0.0006), and non-HDL-cholesterol (-12.7 ± 3.4% vs placebo, p=0.001), while the level of HDL-cholesterol increased by +4.4 ± 3.1% (p=0.17). These effects correlated with a significant decrease in the pro-atherogenic apolipoprotein, ApoB (-14 ± 3% vs placebo, p=0.0003).

Inflammatory markers:
GFT505 treatment also lowered inflammatory markers such as fibrinogen (-15.0 ± 6.9% vs placebo, p=0.04) and haptoglobin (-10.1 ± 4.1% vs placebo, p=0.03).

Safety of use:
No secondary effect attributed to GFT505 treatment was reported by the investigators. Moreover, the safety markers analyzed during the study were not altered.

Commenting on these results, **Pr. Bertrand Cariou (Diabetiologist, Nantes University Hospital),** principal investigator of the GFT505-210-6 study, declared: « *Today, the improvement of insulin sensitivity remains a major therapeutic objective in the management of patients with the metabolic syndrome. This mechanistic study proves the insulin-sensitizing effect of GFT505. Combined with the beneficial effects of this new molecule on liver enzymes, dyslipidemia, and inflammatory markers in such patients, there is no doubt that GFT505 is an*

ideal candidate for the management of global cardiovascular risk and liver diseases (NAFLD/NASH) in (pre)-diabetic patients ».

Jean-François Mouney, Chairman and Chief Executive Officer of GENFIT, added: « *This new data obtained with all the patients included in the study confirms the wide spectrum of action of GFT505 on multiple parameters involved in the development of NAFLD/NASH. We had already observed this activity with the partial study results published in October 2011, that were positively received by the pharmaceutical and financial communities at the recent JP Morgan conference in San Francisco. We believe that the new data will strengthen the conviction of our contacts of the potential of GFT505 in the prevention and treatment of NAFLD/NASH. The absence of adverse effects, as in all the clinical studies performed to date with GFT505, is also a positive point for this therapeutic indication where the efficacy/safety ratio is particularly important for the regulatory authorities ».*

***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: Placebo then GFT505 80 mg/d, Group 2: GFT505 80 mg/d then Placebo) with a treatment-free period of 6 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

Contacts:

GENFIT
Jean-François Mouney – CEO & Chairman of the Management Board
+33 (0)3 2016 4000

MILESTONES – Press Relations
Bruno Arabian
+33 (0)1 75 44 87 40 / +33 (0)6 87 88 47 26 – barabian@milestones.fr