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GFT505: STRONG EFFICACY WITH NO ADVERSE EFFECTS AT A DOSE THREE-FOLD HIGHER THAN THE CURRENT THERAPEUTIC DOSE (GFT505-111-7 STUDY)

Lille (France), Cambridge (Massachusetts, United States), May 4th, 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 the results of the GFT505-111-7** study demonstrating the safety and efficacy of increasing doses of GFT505 up to a dose three-fold higher than the current therapeutic dose of 80 mg/d.

Safety of GFT505 up to 240 mg/d :
The primary aim of the GFT505-111-7 study was to demonstrate the safety of GFT505 in obese subjects at doses higher than the current therapeutic dose of 80 mg/d used in all Phase IIa proof-of-concept studies to date. GFT505 was thus administered for 14 days at 120 mg/d, 180 mg/d, and 240 mg/d, and the results compared to those obtained under placebo.

No serious adverse event was reported in this study. Compared to placebo, there were fewer undesirable effects in GFT505-treated patients. Moreover, no adverse event was reported in the subjects treated at the dose of 240 mg/d. In all groups, biochemical safety markers were unchanged. In particular, renal safety markers (creatinine) and hematological parameters were unchanged by GFT505 treatment.

Efficacy markers up to 240 mg/d :
At all tested doses, there were strong beneficial effects on markers of hepatic dysfunction (ALP, ALT, AST and GGT). For example, at the dose of 240 mg/d, the change in GGT levels following GFT505 treatment was -22.9±4.8% (p=0.001) vs +23.2±11% (p=0.06) in the placebo group. Similarly, the change in alkaline phosphatase (ALP) levels was -18.1±1.5% (p<0.0001) vs +13.6±5.4% (p=0.03) in the placebo group. For the first time, a significant decrease in the level of bilirubin was observed under GFT505 treatment (-23.2±8.9 %, p=0.03 at 240 mg/d vs -5.4±6.8%, p=0.44 under placebo), providing further proof of the liver-protective potential of GFT505.

In parallel, at all tested doses, GFT505 strongly improved plasma lipid parameters, with a decrease in the level of triglycerides (-22.4±8.1%, p=0.02 at 240 mg/d vs +19.8±8.2%, p=0.04 under placebo) and above all a strong decrease in the level of total cholesterol (-20.5±2.8%, p<0.0001 at 240 mg/d vs +3.7±1.8%, p=0.08 under placebo) and LDL-cholesterol (-28.7±4.1%, p=0.0001 at 240 mg/d vs +4.1±4.9%, p=0.42 under placebo). Finally, in the GFT505-treated groups, there was a significant decrease in glycemia (-8.4±2.0%, p=0.002 at 240 mg/d vs -2.0±3.5%, p=0.58 under placebo), while inflammatory markers such as haptoglobin were also strongly decreased (-25.9±5.9%, p=0.0022 at 240 mg/d vs +6.2±6.5%, p=0.36 under placebo).

Dr. Rémy Hanf, EVP, Product Development, declared: « *The results of this study in subjects comparable to the population targeted by GFT505 for the treatment of NASH are very convincing. Not only the dose of 240 mg/d GFT505 shows strong efficacy on markers associated with NASH, but it maintains an excellent safety profile. Moreover, pharmacokinetic analyses (GFT505 measurement in the blood) prove that, even at strong doses in man, GFT505 has a good safety margin compared to the doses tested in long-term animal toxicology studies* ».

Jean-François Mouney, Chairman and Chief Executive Officer of GENFIT, added: « *In keeping with our development plan, the results of the GFT505-211-7 study strengthen the GFT505 dossier submitted to the FDA for the Phase IIb study. The authorizations for this pivotal study are awaited progressively from the different European and US agencies by the end of September ».*

***About 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 GFT505-111-7 study:**

One of the objectives of the phase I trial, GFT505-111-7 was to assess the safety, tolerability and pharmacokinetics of increasing daily doses of GFT505 (120, 180 and 240 mg/day) administered for 14 days in overweight or obese volunteers (BMI $\geq$28 et $\leq$35 kg/m^2).

According to the protocol, 12 subjects were included in each of the three consecutive cohorts (9 treated with GFT505 + 3 placebo) corresponding to the three dose levels. Decision to escalate to the next dose was taken after reviewing complete blinded safety and PK data collected from Day 1 to Day 15: AEs, ECG, vital signs, laboratory tests and PK results.

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 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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