GENFIT: A NEW POTENTIAL INDICATION FOR GFT505, DIABETES ASSOCIATED FATTY LIVER DISEASES

- **OVERWEIGHT OR OBESE PATIENTS WITH ATHEROGENIC DYSLIPIDEMIA ARE AT RISK OF DEVELOPING LIVER DISEASES.**
- **NEW CLINICAL RESULTS OF GFT505 IN THIS PATIENT POPULATION OFFER NEW PERSPECTIVES FOR THE TREATMENT OF NON-ALCOHOLIC FATTY LIVER DISEASE (NAFLD) AND NON-ALCOHOLIC STEATO-HEPATITIS (NASH).**

Lille (France), Cambridge (Massachusetts, United States), November 26, 2009 – 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 diseases, today revealed complementary beneficial effects of its most advanced proprietary drug candidate GFT505 in prediabetic patients suffering from atherogenic dyslipidemia. In addition to its effects on plasma lipids and specific apolipoproteins, GFT505 significantly improved markers of liver dysfunction in these patients at risk of developing non alcoholic liver disease and steatohepatitis (NAFLD and NASH).

As recently communicated, patients treated with GFT505 demonstrated a statistically significant reduction in plasma triglycerides and an increase in plasma level of "good cholesterol" (HDL-C). Concomitantly, significant reductions vs placebo were observed in apolipoproteins associated with pro-atherosclerotic particles ApoCIII ($p=0.04$) and ApoB ($p=0.02$). Furthermore, GFT505 significantly increased plasma levels of ApoA1 ($p=0.002$) and ApoA2 ($p<0.0001$), two important constituents of HDL anti-atherosclerotic particles.

Importantly, GFT505 had clear statistically significant beneficial effects on two hallmarks of fatty-liver dysfunction, alanine amino transferase (ALAT: 15% decrease vs placebo, $p=0.02$) and Gamma glutamyl transpeptidase (gGT: 20% reduction vs placebo, $p<0.0001$) while it did not affect plasma level of aspartate amino transferase (ASAT). Relative to exisiting lipid lowering drugs, these effects on markers of liver dysfunction are clear assets for the management of overweight prediabetic and diabetic patients, whom the majority is known to have fatty liver disease and is at risk of developing steatohepatitis.

Pr. Bart Staels, President of the Scientific Advisory Board stated: "The GFT505-2083 trial supports GFT505 as an original drug candidate for simultaneously managing multiple co-morbidities related to (pre)diabetes. Furthermore, these latest results clearly offer new perspectives for GFT505 in the prevention/treatment of NAFLD and NASH which merit specific studies through dedicated clinical trials."

Rémy Hanf, Vice-President of Product Development added: "In addition to the demonstrated efficacy on lipids and the good safety of use, these results on liver enzymes further strengthen our confidence for the next steps of GFT505 development. Furthermore, complementary data on oxidative-stress and renal function are still expected within the next weeks which may extend the spectrum of action of GFT505. Together with the results

of the ongoing pharmaco-clinical trial (GFT505-2084) in subjects with impaired glucose tolerance, we will have a very large dataset to support effectiveness of GFT505 on multiple prediabetes associated disorders."

About Phase II clinical study (GFT505-2083):
This phase IIa pilot trial included a total of 97 patients suffering from atherogenic dyslipidemia (plasma triglycerides >150mg/dL and HDL-C <40mg/dL for men and <45mg/dL for women) and abdominal obesity (>102cm for men and >88cm for women). This randomized, double blind, placebo controlled pilot trial assessed the safety and efficacy of 80mg/d oral administration of GFT505 for 28 days. The activity was assessed by comparing changes in plasma triglycerides and HDL-C in GFT505 treated patients (n=63) vs placebo treated patients (n=31). Secondary end-points included apolipoproteins, oxidative-stress, inflammation markers, renal and liver function markers. The efficacy to safety ratio was assessed by measuring biological markers associated with safety concerns of PPAR related drugs.

About NAFLD and NASH:
NAFLD (non-alcoholic fatty liver disease) refers to a wide spectrum of liver damage, ranging from simple steatosis to NASH (non-alcoholic steatohepatitis), advanced fibrosis and cirrhosis. NAFLD is strongly associated with insulin resistance and is defined by accumulation of liver fat. In certain subgroups of patients, such as those with Type 2 diabetes, the prevalence of NAFLD, may be as high as 70%. NASH is an important subgroup within the spectrum of NAFLD that progresses over time with worsening fibrosis and cirrhosis, and is associated with increased risk for cardiovascular disease and liver cancer. Limited results suggest that the prevalence of NASH could be as high as 11% in the general population, suggesting there is a worsening future public health problem in this field of medicine. With a burgeoning epidemic of diabetes in an aging population, it is likely that the prevalence of NASH will continue to increase over time as both factors are important risk factors for liver fibrosis. Up to now, there is no treatment approved for NASH and there is an urgent need for new classes of drugs for treating this pathological condition.

About GENFIT:

GENFIT is a biopharmaceutical company focused on the Discovery and Development of drug candidates in strategic therapeutic fields linked to cardiometabolic and neurodegenerative disorders (prediabetes/diabetes, atherosclerosis, dyslipidemia, obesity, Alzheimer's…). GENFIT uses a multi-pronged approach based on early diagnosis, preventive solutions, and therapeutic treatments to address these major public health concerns and their unmet medical needs. GENFIT's proprietary research programs and its partnerships with leading pharmaceutical companies, including SANOFI-AVENTIS, SOLVAY GROUP, and SERVIER, have resulted in the creation of a rich and diversified pipeline of drug candidates at different stages of development. GENFIT's lead proprietary compound, GFT505, is currently in Phase II and two other compounds, in partnership with SANOFI-AVENTIS (AVE0897) and SOLVAY (SLV341), are in the advanced stages of Phase I.
With facilities in Lille, France, and Cambridge, MA (USA), the Company has about 130 employees, including over 100 scientists. GENFIT is a public company listed on the Alternext trading market by Euronext™ Paris (Alternext: ALGFT; ISIN: FR0004163111).
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