

GENFIT: GFT505 POSITIONED AS A LEADING

DRUG CANDIDATE IN ITS THERAPEUTIC AREA

NEW CLINICAL EFFICACY RESULTS DEMONSTRATE THAT GFT505:

- REDUCES GLOBAL CARDIOVASCULAR RISK FACTORS IN PREDIABETIC PATIENTS WITH IMPAIRED GLUCOSE TOLERANCE
- DECREASES FASTING GLUCOSE LEVELS AND IMPROVES INSULIN SENSITIVITY
- HAS A POSITIVE IMPACT ON LIPID PARAMETERS (TRIGLYCERIDES AND CHOLESTEROL)
- HAS ANTI-INFLAMMATORY EFFECTS

Lille (France), Cambridge (Massachusetts, United States), January 28, 2010 – 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 neurodegenerative diseases, today announces positive results from a recently completed clinical trial demonstrating the activity of GFT505 on glucose homeostasis. Results from the clinical trial (GFT505-2094) clearly demonstrate the potential of the drug candidate to reduce global cardiovascular risk in prediabetic patients who suffer from impaired fasting plasma glucose, impaired glucose tolerance, and abdominal obesity.

Following treatment with GFT505 (80mg/day) for 28-days, the main objective of the study which was demonstration of efficacy of the compound on glucose homeostasis was attained. GFT505 led to a significant reduction in fasting plasma glucose levels in the treated group in comparison to the placebo treated group (-5% vs placebo, p=0,03). In parallel, significant reductions in fasting plasma insulin (-25% vs placebo, p=0,009) and C-peptide (-11% vs placebo, p=0,03) were also obtained. In addition, the ability of GFT505 to increase insulin sensitivity was observed, which was assessed by the HOMA insulin-resistance index (HOMA: -31% vs placebo, p=0,0027).

In addition to the effects of GFT505 on glucose homeostasis and parallel to results from the previous study (GFT505-2083), the new results from the GFT505-2094 study clearly reaffirm the beneficial effects of the compound on plasma lipids and demonstrate an additional effect on LDL-C. Patients treated with GFT505 had a significant reduction of bad cholesterol (LDL-C, -11% vs placebo, p=0,0049) in parallel with a reduction in triglycerides (-25%, p=0,0003) and an increase in good-cholesterol (HDL-C, +9% vs placebo, p=0,003). Finally, treatment with GFT505 also led to a significant reduction in markers of inflammation (fibrinogen, -10%, p=0,0128; haptoglobin, -16%, p=0,007).

Taken together, the effects of GFT505 on plasma glucose, lipids, and inflammation, are expected to strongly reduce the risk of macrovascular events and microvascular complications found in prediabetic patients. The present study also confirms the favorable efficacy/safety ratio of GFT505, considering that no specific side effects were observed between the treated and placebo groups. In particular, treatment with GFT505, in contrast to fenofibrate, did not increase the level of circulating homocysteine which is considered a marker of cardiovascular risk.



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Jean-François Mouney, CEO of GENFIT, stated: "Together with the results from the GFT505-2083 trial communicated in December 2009, the results of the present study demonstrate the strong potential of GFT505 as a therapy to address the existing unmet needs in prediabetic and diabetic patients. An extremely important point about GFT505 is obtaining the therapeutic effects without any identifiable undesirable side effects. Therefore, we consider the efficacy/safety profile of GFT505 unparalleled in this indication, in comparison to products on the market, as well as, to those under development. Of course, these results reinforce our conviction to be able to partner this program with a major pharmaceutical company to further advance the clinical development into Phase IIb and ultimately completion of Phase III studies and the marketing of GFT505."

Dr. Dean W. Hum, CSO and Dr. Rémy Hanf, Vice-president of product development at GENFIT, added: "The Phase IIa program with the objective to provide proof of efficacy of GFT505 is now complete. The effect of the compound on glucose homeostasis is of course very important considering that it clearly differentiates GFT505 from its competitors. Following our complete analysis of the present study and in combination with the data from previous studies, Genfit will design the pivotal phase IIb study to optimize the future development plan of GFT505. Genfit is assembling a dedicated Steering Committee presided by Professor Bart Staels to oversee the advancement of GFT505. This committee will be composed of experts in the field and is scheduled to meet during the first quarter of 2010. In light of the recent results, several internationally renowned experts have already accepted to participate in this committee and to guide the development of GFT505."

About the phase II clinical trial (GFT505-2094):

This pilot phase II clinical trial included 47 prediabetic patients with impaired fasting plasma glucose (>100 and <126 mg/dL), impaired glucose tolerance (2-hour plasma glucose >140 and <200 mg/dL during OGTT) and abdominal obesity (waist circumference >94 cm for men and >80 cm for women). This was a double blind, randomized, placebo controlled study for assessing the safety and efficacy of 35 days oral treatment with GFT505 at 80mg/d. Efficacy was assessed by comparing changes in glucose metabolism (fasting plasma glucose, insulin, C-peptide...), plasma lipids (triglycerides, HDL-C, LDL-C, apolipoproteins...) and inflammation markers in the GFT505 treated group (n=23) and in the placebo treated group (n=24). Additional analyses were performed at the end of the treatment period.

About treatment of prediabetes, diabetes:

The worldwide epidemic of obesity forecasts a parallel increase in the prevalence of type 2 diabetes and associated complications. According to the WHO, this "epidemic disease" could affect up to 300 million people by 2025 whereas they were only 30 million in 1985. Thus, the prevention and treatment of micro and macro-vascular diseases associated with prediabetes and diabetes are considered as worldwide public health issues by both academic societies (IAS, ADA, EASD) and health organizations (WHO, FDA, EMEA). The prediabetic and diabetic patients suffer from overlapping disorders (high blood pressure, dyslipidemia, insulin resistance, inflammation...) which increase the risk of developing type II diabetes as well as related micro and macro-vascular diseases: myocardial infarction, stroke, retinopathy, kidney disease, diabetic foot or arteritis... The weaknesses of diagnosis tools and current treatments do not totally cover this global medical need. At present, even treated patients remain at high risk of developing vascular diseases. In particular, atherogenic dyslipidemia (characterized by low plasma concentration of good cholesterol (HDL-C) and high level of triglycerides), the pro-inflammatory and oxidative states and alteration of glucose metabolism are promising therapeutic targets for the medical management of prediabetic and diabetic populations.



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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). www.genfit.com

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