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GFT505: A NEW CLINICAL TRIAL

TO CONSOLIDATE ITS ANTI-DIABETIC POTENTIAL

AN INTERNATIONAL PHASE II TRIAL IS LAUNCHED TO ASSESS THE ANTI-DIABETIC EFFICACY OF GFT505 ON THE SURROGATE MARKER APPROVED BY THE FDA AND EMEA FOR REGISTRATION: GLYCATED HEMOGLOBIN (HBA1C).

Lille (France), Cambridge (Massachusetts, United States), September 17th, 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 associated disorders, today announces the launch of a new Phase II clinical trial to assess the HbA1c-lowering potential of a 12-week treatment with GFT505 at 80 mg/d in type 2 diabetic patients.

Based on the favorable results obtained in the GFT505-209-4 and GFT505-109-6 studies, demonstrating the insulin-sensitizing effects of GFT505 in non-diabetic subjects, an international expert panel chaired by Pr. Bart Staels, President of the Scientific Advisory Board, encouraged GENFIT to launch a new clinical trial to assess the anti-diabetic efficacy of GFT505 in patients with HbA1c levels between 7.0 and 9.5% at inclusion. This placebo-controlled study (GFT505-210-5) carried out in 6 European countries will include a total of 120 patients (2x60). Results should be available by mid-2011.

Pr. Bertrand Cariou, International Scientific Coordinator of the trial, commented: "All the clinical data obtained to date suggest that GFT505 should be efficacious in reducing fasting glycemia and HbA1c in type 2 diabetic patients in addition to its proven beneficial effects on diabetic dyslipidemia and the pro-inflammatory state. Thus, if the safety and efficacy of GFT505 are confirmed, this Phase II trial should give the drug candidate a unique positioning in the management of type 2 diabetes through its wide spectrum of action."

Dr. Rémy Hanf, Vice President Product Development at GENFIT, added: "The scientific experts are unanimous in acknowledging the intrinsic medical value of GFT505 in the treatment of type 2 diabetes. Their opinion is primarily based on the proof of efficacy in humans, but also on experimental results obtained in diabetic animals. Indeed, the latest pre-clinical data further strengthen the anti-diabetic efficacy of GFT505, since they show highly significant beneficial effects of GFT505 on HbA1c, while shedding new light on its original mechanism of action."

About the GFT505-210-5 clinical trial:
This phase II clinical trial will include 120 newly-diagnosed type 2 diabetic patients, naïve of all anti-diabetic treatment, with HbA1c levels between 7.0% and 9.5% at inclusion. This is a parallel group (2x60 patients), placebo-controlled, double-blind study to assess the safety and efficacy of a 12-week oral treatment with GFT505 at 80mg/d. Efficacy will be evaluated by comparing changes in HbA1c levels in the two groups at the end of the treatment period. Other efficacy criteria include changes in glucose homeostasis (fasting plasma glucose, insulin, HOMA-IR, pro-insulin, C-peptide, OGTT…), changes in plasma lipids (triglycerides, HDL-C, LDL-C, apolipoproteins…), and inflammation markers. Results are expected by mid-2011.

About the treatment of prediabetes and 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 worldwide public health issues by

both academic societies (IAS, ADA, EASD) and health organizations (WHO, FDA, EMEA). Prediabetic 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… Insufficient diagnostic 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, beyond the improvement of glucose metabolism, atherogenic dyslipidemia (characterized by low plasma concentration of good cholesterol (HDL-C) and high level of triglycerides), the pro-inflammatory and oxidative states are promising therapeutic targets for the medical management of pre-diabetic and diabetic populations.

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-AVENTIS, 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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