

GENFIT EVALUATES GFT505 ON ITS PRE-DIABETIC PATIENTS TARGET POPULATION

A new phase II study aims to assess potency of GFT505 in reducing micro and macro-vascular risks on pre-diabetic patients.

At the same time, GENFIT launches long-term regulatory toxicology studies.

Lille (France), Cambridge (Massachusetts, United States), December 11, 2008 – GENFIT (Alternext: ALGFT; ISIN: FR0004163111), a biopharmaceutical company at the forefront of research and development of drugs, focusing on early diagnosis and preventive treatment of cardiometabolic and neurodegenerative diseases, today announced the launch of a new phase II trial with GFT505, its most advanced drug candidate for the treatment of atherogenic dyslipidemia associated with pre-diabetes and diabetes.

Jean-François Mouney, GENFIT's CEO, stated: "The positive clinical data already obtained allow us to accelerate the development of GFT505 in pre-diabetic target patient population. As part of the development plan of GFT505, this new study is key for the design of the phase II/III pivotal trials and will further define the position of GFT505 for registration authorities. We have high hopes that the excellent efficacy/safety ratio will be confirmed and that this pluripotent compound will not only raise HDL-C and lower triglycerides, but will also have beneficial effects on the detrimental inflammatory/oxidative states which are encountered in pre-diabetics."

About Phase II clinical study (GFT505-2083):

The new phase II trial (GFT505-2083) will include 90 patients suffering from atherogenic dyslipidemia and abdominal obesity. This randomized, double-blind vs placebo controlled trial will assess safety and efficacy of oral administration of 80 mg/d GFT505 for 28 days. The spectrum of activity will be assessed by measuring GFT505 induced changes in numerous lipids, apolipoproteins, inflammatory, as well as, microcirculation markers. This multicentric trial will take place in France, Romania and Tunisia with 35-40 centers. Patients will be enrolled during the first half of 2009 and completed study results will be available during the second half of 2009.

Rémy Hanf, GENFIT's Vice President of Product Development, added: "In anticipation of the phase III studies without any delays, GENFIT is conducting all the pre-clinical studies requested by the regulatory agencies and authorities (AFFSAPS, EMEA, FDA) in order to authorize the start of the 1-5 years treatment trials. As part of these studies, GENFIT foresees to initiate two-year studies in two rodent species in early 2009."

About GFT505:

GFT505 is the most advanced compound of a new generation of drug candidates developed by GENFIT, involved in the treatment of micro and macro-vascular risks in overweight patients with or without associated diabetes (pre-diabetes or metabolic syndrome). This drug candidate stems from the Selective Nuclear Receptor Modulator (SNuRM) platform developed by GENFIT, for the identification of innovative drug candidates with improved efficacy and safety profiles compared to current treatments. With a novel mechanism of action, GFT505 is a pluripotent compound acting simultaneously on different risk factors associated with pre-diabetes and diabetes: the lipid triad (increasing HDL cholesterol, lowering triglycerides and LDL cholesterol), and inflammation. Moreover, preclinical studies have demonstrated effects on insulin-resistance, diabetes, and atherosclerosis.

About treatment of pre-diabetes, diabetes:

The worldwide epidemic of obesity forecasts a parallel increase in the prevalence of type II 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 pre-diabetes and diabetes are considered as worldwide public health issues by both academic societies (IAS, ADA, EASD) and health organizations (WHO, FDA, EMEA). The pre-diabetic 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 pre-diabetic and diabetic populations.

About GENFIT:

A biopharmaceutical company, GENFIT studies the regulation and function of genes implicated in many of the most widespread diseases. GENFIT’s scientists identify new therapeutic targets and develop drug candidates designed specifically for such targets. GENFIT’s programs, conducted in partnership with pharmaceutical companies which include SANOFI-AVENTIS, SOLVAY GROUP, PIERRE FABRE, MERCK AG, and SERVIER, treat the most prevalent metabolic diseases. GENFIT’s development of proprietary drugs focuses on early diagnosis, prevention and treatment of micro and macro-vascular diseases in pre-diabetes and diabetes. GENFIT is also committed in research programmes in specific neurodegenerative diseases. GENFIT possesses a rich and diversified pipeline of drug candidates at different stages of development – development carried out by GENFIT alone or in partnership. GENFIT’s lead proprietary compound, GFT505, is currently in Phase II and another compound in partnership with SANOFI-AVENTIS (AVE0897) is now completing Phase I. With facilities in Lille, France, and Cambridge, MA (USA), the company has over 130 employees on staff, including over 100 scientists. GENFIT is a public company listed on the Alternext by Euronext™ Paris (Alternext: ALGFT; ISIN: FR0004163111). www.genfit.com

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