GENFIT: EXTREMELY PROMISING GFT505

RESULTS IN PHASE II

- **THE DRUG CANDIDATE GFT505 STATISTICALLY MEETS ALL THE PRIMARY END POINTS OF THE STUDY GFT505-2083 IN PREDIABETIC PATIENTS**
- **THE STUDY CONFIRMS THE EXCELLENT EFFICACY TO SAFETY RATIO OF GFT505 IN PATIENTS SUFFERING FROM ATHEROGENIC DYSLIPIDEMIA**
- **SECONDARY EVALUATION CRITERIA REVEAL ADDITIONAL EFFECTS WHICH CAN EXTEND THE THERAPEUTIC POSITIONING OF GFT505**
- **GENFIT IS IN DISCUSSIONS WITH THREE INTERNATIONAL PHARMACEUTICAL GROUPS TO ENSURE THE FOLLOW ON DEVELOPMENT OF GFT505**

Lille (France), Cambridge (Massachusetts, United States), November 23, 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 and neurodegenerative diseases, today announced extremely positive results in Phase II with its most advanced drug candidate, GFT505, in prediabetic patients with atherogenic dyslipidemia and abdominal obesity (study GFT505-2083).

Analysis of the results of this clinical trial showed that GFT505 was very well tolerated at the dose of 80mg/day and presented a very good safety of use. No specific adverse event was observed in the GFT505 treated group relative to the placebo treated group.

All primary objectives of the study were reached. Relative to the placebo group, therapeutic efficacy of GFT505 was demonstrated with a statistically significant 21% (p=0.0027) reduction of plasma triglycerides and a 9% (p=0.003) increase in good cholesterol (HDL-C) level. These metabolic effects were comparable to those published with the best competitors (fibrates) in the same patient population.

Furthermore, GFT505 revealed a remarkable lack of effect on a known cardiovasuclar risk factor, homocysteine (5% vs 40 to 50% reported with fenofibrate) and on a marker of renal dysfunction, creatinine (non significant vs 10 to 15% reported with fenofibrate).

Finally, GFT505 showed significant effects on multiple secondary evaluation criteria related to lipid metabolism and inflammation. Notably, GFT505 significantly reduced acute phase inflammation markers such as fibrinogen (p=0.045) and haptoglobin (p=0.009).

Pr. Bart Staels, Chairman of the Scientific Advisory Board, stated: "All the data clearly argue in favor of increased therapeutic potential and safety of GFT505 relative to existing treatments. Of course, all these beneficial effects should be confirmed in additional clinical trials but they already position GFT505 as the first drug candidate of a new therapeutic class selectively and simultaneously acting on two distinct nuclear receptors."

Jean-François Mouney, CEO of GENFIT concluded: "We are highly satisfied with these results which fulfill all our expectations. The safety of use as well as efficacy results on the primary end points of the study confirm that GFT505 has the potential of becoming a top drug for the medical care of various patient populations in prediabetic states. About 50% of these patients will evolve towards overt type II diabetes over five years, a disorder which current treatments -most of which are blockbusters- fail to block. Thus, with the data already obtained, we are very confident in our capacity to find an industrial partner to pursue the clinical development of GFT505 and ensure its commercialization. We are in close discussions with three international pharmaceutical groups and are initiating a due diligence with one of them."

About the phase II clinical trial (GFT505-2083):
This phase II clinical trial included 97 patients suffering from atherogenic dyslipidemia (plasma triglycerides >150mg/dL and HDL-Cholesterol <40 mg/dL for men and <45 mg/dL for women) and abdominal obesity (waist circumference >102cm for men and >88 cm for women). This was a double blind, randomized, placebo controlled study for assessing the safety and efficacy of 28 days oral treatment with GFT505 at 80mg/d. Efficacy was assessed by comparing changes in plasma triglycerides and HDL-C in the GFT505 treated group (n=63) vs the placebo treated group (n=31).

About treatment of prediabetes, 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 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.

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

Contacts:

GENFIT
Jean-François Mouney – Chairman of the Management Board
+33 (0)3 20 16 40 00

MILESTONES – Press Relations
Bruno Arabian
+33 (0)1 75 44 87 40 / +33 (0)6 87 88 47 26 – barabian@milestones.fr