GENFIT: POTENTIAL FOR COMBINATION OF GFT505 WITH STATINS

- **A NEW CLINICAL STUDY (GFT505-1095) SHOWS THAT THE MAJOR SAFETY ISSUES ASSOCIATED WITH SOME FIBRATE-STATIN CO-PRESCRIPTIONS SHOULD BE AVOIDED WITH GFT505.**
- **GENFIT IS PLANNING TO DEVELOP A GFT505/SIMVASTATIN COMBINATION THERAPY.**
- **GFT505 ACQUIRES A NEW COMPETITIVE ADVANTAGE FOR THE TREATMENT OF PRE-DIABETIC AND DIABETIC POPULATIONS.**

Lille (France), Cambridge (Massachusetts, United States), January 13, 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 the absence of a safety risk due to pharmacokinetic drug-drug interaction when GFT505 is co-administered with a statin (GFT505-1095 clinical study). These results prepare the launch of Phase IIb and Phase III trials in patients already treated with a statin (on-top of statin trials). Furthermore, GENFIT is now evaluating the opportunity to develop a combination therapy associating GFT505 with a generic statin in the same pill.

Certain fibrates are associated with an increased risk of serious muscular side-effects when they are co-administered with a statin. Indeed, these drugs significantly increase the plasma concentration of certain statins (including simvastatin) and/or their active metabolites. This pharmacokinetic drug-drug interaction increases the risk of muscular side-effects associated with hypolipidemic agents.

To assess the safety of use of GFT505 in co-administration of a therapeutic dose of GFT505 (80 mg/d) with a usual dose of simvastatin (20 mg/d), the study GFT505-1095 was conducted in two parallel groups of healthy volunteers.

In the first group, a repeated daily administration of GFT505 for 14 days did not increase the plasma exposure of simvastatin and its active metabolite. On the contrary, a modest but statistically significant decrease in this plasma exposure was observed.

In the second group, a repeated daily administration of simvastatin for 14 days did not affect the plasma exposure of GFT505 and its active metabolite GFT1007.

No adverse side-effect was observed when either drug was administered for 14 days. As expected, simvastatin treatment resulted in a reduction in the plasma levels of LDL-cholesterol, and GFT505 treatment resulted in a reduction in plasma triglyceride levels. Moreover, no adverse reaction was observed when GFT505 and simvastatin were co-administered at the end of the 14-day treatment periods.

Dr. Rémy Hanf, Vice-President of Product Development, stated: "These new data are of vital importance, since GFT505 targets the residual cardiovascular risk that persists in patients treated with statins. These patients make up a substantial proportion of the target pre-diabetic and diabetic population. In sharp contrast to the demonstrated pharmacokinetic interaction of certain fibrates with statins, GFT505 could potentially be prescribed to the entire pre-diabetic and diabetic population, irrespective of whether patients are already under statin treatment or not."

Jean-François Mouney, CEO of GENFIT, added: "We were awaiting the results of this clinical study with impatience, since the information it provides substantially increases the intrinsic value of GFT505. The absence of a pharmacokinetic interaction between GFT505 and statins provides GFT505 with an undeniable competitive advantage that is of critical importance for the pharmaceutical groups with which we are discussing."

About the clinical trial GFT505-1095:
This is an open label randomized phase I study in two parallel groups of healthy volunteers to evaluate the potential pharmacokinetic interaction between GFT505 80 mg and simvastatin 20 mg. In group 1, fourteen volunteers were treated from D2 to D15 with GFT505 80 mg/d. Simvastatin (20 mg) was administered alone at D0 and co-administered with GF505 (80 mg) at D16 for pharmacokinetic analysis of native simvastatin and beta-hydroxyacid simvastatin (active metabolite). In group 2, fourteen healthy volunteers were treated from D2 to D15 with simvastatin 20 mg/d. GFT505 (80 mg) was administered alone at D0 and co-administered with simvastatin (20 mg) at D16 for pharmacokinetic analysis of native GFT505 and GFT1007 (active metabolite).

About the treatment of prediabetes and diabetes:
The worldwide obesity epidemic 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 to be worldwide public health issues by both academic societies (IAS, ADA, EASD) and health organizations (WHO, FDA, EMEA). 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… Current diagnostic tools and treatments do not sufficiently 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

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