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## **GENFIT: THE GFT505-210-5 CLINICAL TRIAL CONFIRMS THE BROAD SPECTRUM OF ACTION OF GFT505 IN DIABETIC PATIENTS**

- **An independent committee of international experts strongly recommends continuing the clinical development of GFT505 into Phase IIb for two major indications: NAFLD/NASH and the prevention of cardiovascular risk in diabetic patients.**
- **The Company today announces the launch of a private placement in order to reinforce its equity position.**

**Lille, France, and Cambridge, Mass., July 12<sup>th</sup>, 2011** – GENFIT (Alternext: ALGFT; ISIN: FR0004163111), a biopharmaceutical company at the forefront of drug discovery and development, focused on the early diagnosis and preventive treatment of cardiometabolic and associated disorders, today announces the first results of the GFT505-210-5 clinical trial, confirming the broad spectrum of action of GFT505 in diabetic patients. A scientific committee of independent international experts has studied the results and strongly encouraged GENFIT to pursue the development of GFT505 for two indications: NAFLD/NASH (non-alcoholic hepatic steatosis and fibrosis) and the prevention of cardiovascular risk in diabetic patients.

The GFT505-210-5 Phase II trial, that studied the effect of 12 weeks of GFT505 treatment versus placebo in 97 treatment-naïve diabetic patients, is part of GENFIT's program for the evaluation of the therapeutic potential of GFT505 in different target populations. These first results confirm and reinforce the multifaceted activity of GFT505 on several metabolic parameters:

- In the GFT505-treated group, glucose homeostasis is improved. Compared to baseline values, there is a significant reduction in HbA1c levels (-0.4%,  $p=0.01$ ), in 2 hour glycemia upon OGTT (-38 mg/dL ;  $p<0.001$ ), and in the area under the curve for glycemia upon OGTT (-39 mg/dL\*h ;  $p<0.001$ ). There is also a reduction in fasting glycemia in the GFT505 group (-8.01 mg/dL,  $p=0.08$ ), while this parameter is not altered in the placebo group. A non-significant improvement observed for the other glycemic parameters of the placebo group limits inter-group statistical significance.
- GFT505 treatment strongly lowers plasma triglyceride levels (-34% vs placebo,  $p<0.0001$ ). It also significantly lowers non-HDL-C (-12%,  $p<0.001$ ), LDL-C (-8%,  $p<0.05$ ), and total cholesterol (-8%,  $p<0.01$ ). The level of HDL-C is increased by +15% ( $p<0.0001$ ) compared to baseline values, but a significant effect is also observed in the placebo group (+11%,  $p<0.01$ ).
- Markers of hepatic dysfunction are improved upon GFT505 treatment, with a highly significant reduction in gamma GT levels (-28% vs placebo,  $p<0.0001$ ). Moreover, the excellent safety profile of GFT505 is confirmed over a prolonged period of 3 months. GFT505 has no undesirable effect on arterial pressure or cardiac rhythm, and no weight gain, edema, or hemodilution were observed.

**Pr. Bertrand Cariou, Principal Investigator of the study declared:** « *Based on the results of the different studies conducted by GENFIT, the scientific expert committee strongly recommended continuing the clinical development of GFT505 and the initiation of a Phase IIb trial. This next study, that will pave the way for Phase III, will enable the confirmation of the beneficial properties of GFT505 in cardiovascular prevention and its*

*positive effects in NAFLD/NASH. This study will target a high risk population, including diabetics, pre-diabetics, and patients with the metabolic syndrome ».*

The detailed study results, as well as a poster focused on NASH, will be presented at the 47<sup>th</sup> EASD congress in Lisbon (September 12-16, 2011).

**Jean-François Mouney, Chairman of GENFIT's Management Board, added:** *« The scientific expert committee has convinced us to move forward with the development of GFT505 with a focus on NASH, a major unmet therapeutic need, and on cardiovascular protection in high-risk patients, rather than competing with oral anti-diabetic drugs (OAD). In order to pursue these strategic directions, GENFIT is today launching a limited private placement ».*

The amount of this placement, that will be closed on Wednesday July 13<sup>th</sup> 2011, is in keeping with the delegations accorded to the Management Board by the General Meeting held on June 28<sup>th</sup> 2011.

According to the International Diabetes Federation, approximately 250 million people are currently estimated to suffer from type 2 diabetes, a figure which is expected to rise to 450 million by 2030. The global management of diabetes and its associated disorders is thus a major public health issue.

The diabetic patient is 2-4 times more likely to develop cardiovascular disease than non-diabetics. Heart disease and stroke are the leading causes of death and invalidity in diabetic patients. Today, 65% of diabetics die of cardiovascular disease in spite of treatment with OADs and with statins.

In parallel, there is currently an increase in the incidence of non-alcoholic fatty liver disease (NAFLD) linked to diabetes. The hepatic steatosis that occurs in 80-100% of diabetic patients can progress to chronic liver disease (NASH) in 20-50% of cases. NAFLD/NASH can progress to cirrhosis and even liver cancer. Mortality linked to hepatic disease is 2-3 times higher in the diabetic population compared to the non-diabetic population. Today, no treatment for NASH exists; many products are in development, but the vast majority are at earlier stages than GFT505.

#### **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, 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](http://www.genfit.com)

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