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GENFIT: FDA APPROVAL FOR THE PHASE IIB CLINICAL DEVELOPMENT OF GFT505

- **The American Food and Drug Administration (FDA) approves the initiation of a Phase IIb clinical study in the United States.**

Lille (France), Cambridge (Massachusetts, United States), September 3rd, 2012 – 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 that the Food and Drug Administration (FDA) has approved the continuing development of GFT505 in NASH*, and the initiation of a Phase IIb clinical study in the United States.

The FDA approval follows an extensive review of the pre-clinical and clinical data obtained with GFT505 to date. The FDA experts thus confirm that GFT505 shows a favorable activity on the spectrum of biological markers associated with NASH, together with an excellent safety profile. They accepted the proposed Phase IIb protocol, and considered that it met the clinical objectives in NASH, while ensuring patient safety throughout the study. The FDA thus authorizes the immediate initation of this study on the entire US territory.

This authorization by the US agency follows on from a very positive consulting meeting that took place with the FDA at the end of May 2012. The discussions covered the acceptability of the GFT505 dossier in NASH, the protocol of the Phase IIb study concerned by the present authorization, and the entire development plan for GFT505 in the target indication, up to the final Phase III studies.

Moreover, this FDA approval reinforces the positive opinion of the European Medicines Agency (EMA), which had validated in February 2012 and confirmed in July the scientific basis and rationale for GFT505 in NASH by giving a favorable response to the submitted Phase IIb and III development plan.

The FDA authorization is an essential step in the set-up of the current international multi-center Phase IIb study that involves a total of 75 clinical investigation centers in the US and in Europe. This double-blind placebo-controlled study will recruit almost 300 patients and will evaluate the efficacy on NASH of GFT505 at two doses administered daily for one year, in particular on the improvement of histological parameters.

Jean-François Mouney, Chairman and Chief Executive Officer of GENFIT, stated: «*There is currently no targeted and efficient treatment available for NASH. In spite of this absence, the therapeutic market is expected to exceed 2 billion dollars in 2018 due to the increased prevalence of the disease. By then, GFT505 could become one of the first efficient treatments for this indication. We are delighted by the FDA's go-ahead for the launch of the international Phase IIb study. This authorization stems from the considerable progress made by GFT505 over the past two years, both in terms of efficacy and its solid safety profile.*»

***About NAFLD/NASH :**

NAFLD (non-alcoholic fatty liver diseases) and in particular NASH (non-alcoholic steatohepatitis) are serious liver diseases that can lead to cirrhosis and liver cancer. The development of NAFLD/NASH is associated with the diabetic pathophysiological process. NAFLD is believed to affect between 80 and 100% of diabetic patients, and progresses to chronic liver disease (NASH) in 20-50% of cases. Mortality due to liver disease is thus 2-3-fold higher in the diabetic population than in the overall population. The NASH market was estimated at 615 $M in 2010 and should reach 2,008 $M in 2018.

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, including Sanofi, 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 80 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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