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GFT505: PATIENT SELECTION FOR THE PHASE IIB STUDY IS SUCCESSFULLY COMPLETED

- **The inclusion of patients at the dose of 120 mg/d of GFT505 was initiated in October 2013 following the approval of the independent Data Safety and Monitoring Board (DSMB)**
- **All the patients of the second recruitment phase (GFT505 120 mg/d versus placebo) have given their consent for participation in the study**
- **The first patients of the first recruitment phase (GFT505 80 mg/d versus placebo) have completed their end-of-treatment visit after one year of treatment**

Lille (France), Boston (Massachusetts, United States), November 22, 2013 – 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 all the patients of the second phase of the study GFT505-212-7 that aims to demonstrate the efficacy of GFT505 on NASH have given their consent for participation in the study.

The GFT505-212-7 study set up by GENFIT is one of the largest interventional studies ever conducted in NASH. A total of 56 centers of clinical excellence in the United States and in multiple European countries (France, Belgium, The Netherlands, Italy, United Kingdom, Germany, Spain, and Romania) actively participate in this study.

One hundred and thirty-nine (139) patients were recruited during the first recruitment phase for treatment with 80 mg/d of GFT505 or placebo. More than half of the patients from this first phase have been under treatment for more than 6 months, and the first patients recruited in October 2012 have already completed their end-of-treatment visit after one year of treatment.

In accordance with the study protocol, GENFIT initiated in October 2013 the second recruitment phase at the dose of 120 mg/d after having received the unrestricted approval of the independent Data Safety and Monitoring Board (DSMB) following its evaluation of the safety data at the dose of 80 mg/d GFT505. In less than one month, more than 150 patients have been selected (50% in the United States), and more than 90 patients are currently under treatment at the dose of 120 mg/d. Given the rapid recruitment rate, the first results on GFT505 efficacy will be available as planned at the end of 2014.

In this context, **Dr. Sophie Mégnien, Chief Medical Officer of GENFIT, declared:** « *The remarkably rapid recruitment rate bears witness to the enthusiasm of NASH patients to participate in this study. It reflects the major hope that GFT505 represents for the patients and their physicians, who currently have no efficient treatment for NASH.* »

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 IIb.
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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