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GFT505: GENFIT VERY SATISFIED WITH THE SCIENTIFIC ADVICE OF THE EUROPEAN MEDICINES AGENCY (EMA)

- **The EMA gives a favorable response to questions concerning GFT505 and the phase IIb study in NAFLD/NASH. EMA experts give their recommendations for the phase III development plan.**

Lille (France), Cambridge (Massachusetts, United States), April 4th, 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 it has received the official scientific opinion of the European Medicines Agency (EMA) on the efficacy/safety ratio of GFT505, the design of the upcoming phase IIb study, and the clinical development plan for GFT505 in non-alcoholic steatohepatitis (NASH*).

The EMA gave a favorable response to all the questions related to GFT505 and its efficacy/safety ratio at the proposed therapeutic doses. The opinion of the EMA experts concerning the pivotal phase IIb study that aims to demonstrate the therapeutic activity of GFT505 on the histological regression of NASH is in agreement with the study protocol submitted by GENFIT. Finally, the EMA has given its recommendations for the phase III development plan of GFT505 in this new therapeutic indication.

The positive opinion of the EMA opens the door to the initiation of the pivotal phase IIb study, pending regulatory authorization by national health agencies. At least 270 patients with NASH will be recruited for this international (Europe, US) multi-center study, one of the largest ever conducted for NASH. The objective is to provide the first proof of therapeutic efficacy for a product dedicated to the treatment of NASH (there is currently no existing treatment for NASH).

The EMA judged satisfactory GENFIT's comments on the questions raised, and opted for the 'accelerated' procedure to give its opinion. "*The delivery of the EMA's scientific advice and the concordance between our proposals and their recommendations validate the foundations and the rationale of the clinical development plan that we have implemented for GFT505 in NASH. We are currently entering similar discussions with the Food and Drug Administration to enable the opening of US clinical centers for our phase IIb study*." commented **Dr. Rémy Hanf, EVP, Product Development**.

***About NASH:**

NAFLD (non-alcoholic fatty liver disease) 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 100 employees. GENFIT is a public company listed on the Alternext trading market by Euronext™ Paris (Alternext: ALGFT; ISIN: FR0004163111).
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