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GENFIT: GFT505 REVERSES ESTABLISHED NAFLD/NASH AND BLOCKS PRO-FIBROTIC MECHANISMS

- **New pre-clinical data show that the treatment of established NAFLD/NASH by the oral administration of GFT505 completely eliminates the pathology. Similarly, the treatment of established hepatic fibrosis by GFT505 blocks pro-fibrotic mechanisms.**
- **These results open the possibility of evaluating the potential of GFT505 in other diseases associated with hepatic fibrosis, such as primary biliary cirrhosis, viral hepatitis, or drug-induced hepatitis**

Lille (France), Cambridge (Massachusetts, United States), November 24, 2011 – 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 new pre-clinical data showing that the administration of GFT505 blocks pro-fibrotic mechanisms and leads to the complete regression of the hepatic steatosis associated with NAFLD/NASH*.

After having demonstrated the clinical efficacy of GFT505 on numerous markers associated with NAFLD/NASH in pre-diabetic and diabetic patients, GENFIT is preparing to launch a major international study in this indication.

In this context, two new series of pre-clinical studies show the therapeutic efficacy of GFT505 on established hepatic disorders:

- After having induced NAFLD/NASH by feeding a diet deficient in methionine and choline (MCDD) for 4 weeks to diabetic animals, GFT505 or vehicle control were administered at the same time as the MCDD for a further 4 weeks. The macroscopic examination of the liver after treatment demonstrates that GFT505 completely eliminates the steatosis induced by the MCDD, while this finding persists in the vehicle group. In parallel, hepatic dysfunction markers are completely normalized in the GFT505-treated group.

- After having induced major hepatic fibrosis in animals by the injection of a pro-fibrotic chemical agent (carbon tetrachloride, CCl_4) for 2 weeks, GFT505 or vehicle control were administered at the same time as CCl_4 for a further 4 weeks. The microscopic examination of the liver demonstrates that GFT505 completely blocks the development of fibrosis, whereas this continues to worsen in the control group.

Commenting on these results, **Dr. Rémy Hanf, EVP, Product Development**, declared: « *These pre-clinical studies demonstrate the therapeutic efficacy of GFT505 on established NAFLD/NASH despite the continued presence of the metabolic stress that provokes the pathology. They also show that GFT505 acts directly on pro-fibrotic mechanisms, which opens the possibility of evaluating GFT505 in other diseases associated with hepatic fibrosis, such as primary biliary cirrhosis, viral hepatitis, or drug-induced hepatitis* ».

***About NAFLD and NASH:**

In parallel with the current pandemic of diabetes and obesity, the prevalence of non-alcoholic fatty liver disease (NAFLD) is increasing considerably. NAFLD is believed to affect between 80 and 100% of diabetic patients, and progresses to non-alcoholic steatohepatitis (NASH) in 20-50% of cases. This serious liver disease can further progress to cirrhosis and liver cancer. There is currently no approved treatment for NAFLD/NASH, and the portfolio of products in the advanced stages of development is limited.

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

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