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GENFIT: GFT505 ELIMINATES NASH AND FIBROSIS IN A CLINICALLY RELEVANT DISEASE MODEL

Lille (France), Boston (Massachusetts, United States), March 19, 2014 – 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 data from Professor Isabelle Leclercq of Université Catholique de Louvain (Belgium) demonstrating the curative effects of GFT505 in an experimental model of NASH associated with metabolic disorders.

The NASH model used in this study (*foz/foz* mice subjected to a high-fat diet) accurately reproduces the natural evolution of the disease in man. Thus, several metabolic disorders (obesity, insulin resistance, diabetes, dyslipidemia) lead to the establishment of NASH (steatosis with inflammation and hepatocyte ballooning) and the progressive development of hepatic fibrosis.

The experimental protocol therefore reproduces the ongoing Phase IIb clinical study (GFT505-212-7). After a period of establishment of the disease by a high-fat diet, the animals were as expected obese, insulin resistant, and dyslipidemic, and had NASH associated with hepatic fibrosis upon microscopic examination of the liver. These animals with established NASH (average NAS score of 5) were then maintained on the high-fat diet for a further 18 weeks, one group under GFT505 treatment and one group under placebo.

The results show that GFT505 eliminates NASH and improves fibrosis. Thus, there was almost no NASH remaining in the group treated with GFT505, while the pathology continued to develop in the placebo group. The three major NASH parameters (steatosis, ballooning, and inflammation) all improved in parallel. More importantly, the animals treated with GFT505 were almost free of fibrosis. Finally, compared to the placebo group, the mice treated with GFT505 showed a significant weight loss in spite of unchanged food intake, and an improvement in diabetes parameters and plasma lipids.

The full results of the study will be presented at the American Association for the Study of Liver Diseases (AASLD) congress to be held in Boston in November 2014.

Commenting on this data, **Dr. Dean W. Hum, Chief Scientific Officer at GENFIT**, declared: «*The model used in this study is one of the few experimental models that accurately reproduces the natural evolution of NASH related to metabolic disease in obese and diabetic patients. These preclinical results exemplify all the expected therapeutic effects of GFT505 in the GFT505-212-7 study. Indeed, the primary objective of this Phase IIb study is the treatment of NASH without worsening of fibrosis, the results of which are expected at the end of 2014.*»

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

Contacts:

GENFIT
Jean-François Mouney – CEO & Chairman of the Management Board
Ph. +333 2016 4000

MILESTONES – Press Relations
Bruno Arabian
Ph. +331 7544 8740 / +336 8788 4726 – barabian@milestones.fr