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GFT505 REDUCES THE RISK OF CARDIOVASCULAR EVENTS THROUGH ITS ACTION ON REMNANT CHOLESTEROL

Lille (France), Boston (Massachusetts, United States), May 15, 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 GFT505 reduces a new component of cardiovascular risk: the cholesterol contained in lipid particles other than LDL and HDL, also known as ‘remnant cholesterol’.

All the Phase II clinical studies performed to date have shown that GFT505 improves classical lipid risk factors. It lowers the level of LDL-cholesterol (‘bad cholesterol’), increases the level of HDL-cholesterol (‘good cholesterol’), and lowers the level of non-HDL-cholesterol and triglycerides in the blood.

A recently published study (Varbo et al. J Am Coll Cardiol 2013; 61: 427–36) of more than 70,000 subjects shows that the level of cholesterol not contained in LDL or HDL particles, also known as ‘remnant cholesterol’, is directly and causally associated with an elevated risk of ischemic heart disease. According to this study, subjects with increased levels of remnant cholesterol have a two- to three-fold greater risk of developing ischemic heart disease than subjects with low levels of remnant cholesterol.

The data from the Phase IIa studies, GFT505-209-4 in pre-diabetic patients and GFT505-210-5 in diabetic patients, have been analyzed. This analysis demonstrates that treatment with GFT505 (80 mg/day) significantly reduces the level of ‘remnant cholesterol’ in these two patient populations. In the GFT505-209-4 study, the effect of GFT505 on measured remnant cholesterol was -24% (p=0.0046) compared to the placebo group after 28 days of treatment. Consistently, after 3 months of treatment in diabetic patients (study GFT505-210-5), the effect of GFT505 on calculated remnant cholesterol compared to the placebo group was -46% (p=0.01).

Two experts commented these results.

Professor Gerald Watts (University of Western Australia) declared: *“GFT505, when administered as monotherapy to patients with pre-diabetes or diabetes, leads to a significant fall in plasma triglyceride and triglyceride-rich lipoprotein remnants. The 10-15% reduction in non-HDL cholesterol could be clinically significant in terms of a proportional reduction in cardiovascular events in patients with the metabolic syndrome.”*

Professor Bart Staels, University of Lille 2 and President of the Scientific Advisory Board, precised: *“NAFLD/NASH* is considered to be the hepatic complication of the metabolic syndrome. Overall, the results of large outcome trials show that statin treatment decreases the cardiovascular risk by only 30%, the remaining 70% representing a high residual cardiovascular risk. Given Varbo et al’s demonstration of the causal link between the level of remnant cholesterol and cardiovascular risk, the beneficial effects of GFT505 on remnant cholesterol further strengthen its cardioprotective profile.”*

***About NAFLD/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 pathophysiological process of insulin resistance in patients that are overweight and/or diabetic. NAFLD is believed to affect 70-80% 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 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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