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GFT505: CLINICAL MECHANISM OF ACTION

PUBLISHED IN *DIABETES CARE*

- *Diabetes Care* is the official clinical journal of the American Diabetes Association (ADA).
- The scientific article can be consulted on the *Diabetes Care* web-site.

Lille (France), Boston (Massachusetts, United States), May 30, 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 the publication in *Diabetes Care* of data on the efficacy and mechanism of action of GFT505 on hepatic insulin resistance in man.

The manuscript contains the data from a clinical study** showing that GFT505 increases the insulin sensitivity of the liver (+44%, p=0.006) and the other peripheral organs (+21%, p=0.048) in cardiometabolic patients. This increase in insulin sensitivity is essentially due to GFT505 action on the liver, since the expression of PPAR (peroxisome proliferator-activated receptor) target genes in the skeletal muscle was unaffected. GFT505 activity on the liver was characterized by a decrease in liver glucose production and in the concentration of free fatty acids in the blood (p=0.006). There were also highly significant beneficial effects on liver enzymes (γ -glutamyltranspeptidase: -30.4%, p=0.003; alanine aminotransferase: -20.5%, p=0.004). Moreover, GFT505 reduced global cardiovascular risk in these patients by improving their plasma lipid profile and by reducing inflammatory markers.

After the review of the data by independent experts selected by the journal, the manuscript is published under the title: 'Dual Peroxisome Proliferator-Activated Receptor α/δ Agonist GFT505 Improves Hepatic and Peripheral Insulin Sensitivity in Abdominally Obese Subjects', B. Cariou et al., *Diabetes Care* 2013 ; published online before print May 28, 2013, doi: 10.2337/dc12-2012. The accepted manuscript may be consulted on the *Diabetes Care* web-site (<http://care.diabetesjournals.org/content/early/2013/05/23/dc12-2012.abstract>) prior to final publication.

Diabetes Care is one of the most important scientific journals devoted exclusively to diabetes treatment, care, and prevention. The journal publishes original, peer-reviewed articles of interest to healthcare professionals, with the aim of increasing knowledge, stimulating research, and promoting better management of patients with diabetes.

Dr. Sophie Mégnien, Chief Medical Officer of GENFIT, declared: "Given the key role played by loss of liver insulin sensitivity in the pathological process leading to NASH*, this new publication in an internationally renowned scientific journal provides essential information for the understanding of the therapeutic mechanism of action of GFT505 in this clinical indication."

***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 the GFT505-210-6 study**

The GFT505-210-6 study was based on the gold standard technique of "hyperinsulinemic euglycemic clamp with two levels of insulin, using a deuterated tracer to measure hepatic glucose production". The single-blind study included a total of 22 insulin-resistant patients in a crossover design. Each patient underwent two successive 2-month treatment periods (Group 1: GFT505 80 mg/d then Placebo, Group 2: Placebo then GFT505 80 mg/d) with a treatment-free period of 4 weeks between treatments.

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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