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# CONCLUSIVE RESULTS OF REGULATORY TOXICOLOGY STUDIES WITH GFT505

- **The complete regulatory toxicology package of GFT505 confirms its safety in long-term treatment.**

**Lille (France), Cambridge (Massachusetts, United States), February 8th, 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 the results of long-term animal toxicology studies involving up to two years of treatment. At the highest doses tested, GFT505 has no major adverse effect relevant to humans. In particular, none of the adverse effects previously observed in similar studies with the different classes of oral anti-diabetes drugs has been observed.

In accordance with the regulatory requirements of official health agencies (FDA, ICH, and EMA) for the initiation of clinical trials involving more than 6 months of treatment, GFT505 has been tested in rats for 6 months at up to 100 mg/kg/day and in monkeys for one year at up to 50 mg/kg/day. At these high doses and in both species, GFT505 induced no toxic effect relevant to humans. In particular, GFT505 showed no adverse effect on cardiac function, in contrast to oral anti-diabetes drugs of the PPARγ class (glitazones and glitazars), that provoke cardiac hypertrophy and increase cardiac mortality at high doses in the same type of studies. Moreover, in contrast to PPARγ activators, long-term GFT505 treatment did not result in increased weight gain or edema.

In parallel, and to further satisfy the regulatory requirements for long-term treatment, GFT505 has also been tested in rats and mice with daily administration for a period of two years. These complementary studies were designed to identify any potential carcinogenic risk of the product. Up to the highest dose tested, GFT505 did not show any carcinogenic effect relevant to humans. Again, the results contrast with those reported for certain oral anti-diabetes drugs in similar studies.

Commenting on these new results, **Dr. Rémy Hanf, EVP, Product Development**, declared: « *The regulatory toxicology package of GFT505 for Phase IIb/III clinical studies is now complete. All the animal toxicology data strongly confirm the security of long-term treatment with GFT505 and provide a comfortable safety margin compared to the therapeutic doses in humans. Moreover, a 14-day clinical trial in healthy overweight volunteers is currently in progress to confirm the safety of GFT505 in humans at doses up to 3-fold higher than the current therapeutic dose of 80 mg/day* ».

**Jean-François Mouney, Chairman and Chief Executive Officer of GENFIT**, added: « *In a context where the security of treatments for metabolic disorders is particularly monitored by the health authorities, the results of these chronic toxicology studies were eagerly awaited. They confirm the safety of GFT505 for the long-term treatment of NAFLD/NASH*, chronic liver disorders with major unmet medical needs* ».

***About NAFLD and 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 (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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