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GENFIT: ANNUAL RESULTS FOR 2011

- **MAJOR INVESTMENTS IN THE DEVELOPMENT OF THE DRUG CANDIDATE GFT505 REWARDED BY PROMISING CLINICAL RESULTS**
- **ACHIEVEMENT OF IMPORTANT MILESTONES WITHIN INDUSTRIAL COLLABORATIVE PROGRAMS AND SIGNING OF AN UNPRECEDENTED CONTRACT WITH SANOFI**
- **SIGNIFICANT PROGRESS IN TWO PROPRIETARY PROGRAMS TO PREPARE FOR NEW INDUSTRIAL ALLIANCES**

Lille (France), Cambridge (Massachusetts, United States), April 25, 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 its consolidated financial statement for the year ending December 31st, 2011.

Jean-François Mouney, Chairman and CEO of GENFIT, stated: *"The major investments accorded in 2011 to GFT505, our leading proprietary drug candidate, for Phase IIa efficacy studies and studies to confirm its safety, impacted our operating result to a similar extent as for the 2010 financial year. Today, these investments are rewarded since all the studies have achieved their objectives. The totality of the assembled data now enables GENFIT to present GFT505 as a molecule with an excellent efficacy/safety ratio that places it in a highly strategic position in its therapeutic field.*

The most recent results enable us to prepare the launch of a Phase IIb study in NASH, an increasingly widespread hepatic complication of the metabolic syndrome for which hepatologists currently have no satisfactory therapeutic solution. Such a study does not preclude the possibility for the future owner of the GFT505 commercialization rights to pursue its development in the prevention of cardiovascular events, particularly in high-risk prediabetic and diabetic patients.*

In parallel, 2011 was marked by the achievement of important scientific milestones as part of our industrial collaborative programs, and by the progress made in two of our proprietary research programs, in the wake of which we hope to sign new industrial co-development alliances in 2012 and 2013."

Consolidated financial statement (IFRS standards) *(million EUR)*	**31/12/2011**	**31/12/2010**
Total income	6.78	7.63
Current operating result	(7.67)	(7.43)
Financial result	(0.05)	(0.19)
Net result	(9.68)	(9.38)
End-of-year cash situation (gross)	12.80	13.92

CONSOLIDATED FINANCIAL RESULTS FOR 2011

From a financial point of view, the year ending December 31st, 2011 was marked by the following elements:

- Total revenues amounted to € 6.78 million, compared to € 7.63 million in 2010. Of this total, industrial

revenues accounted for € 2.36 million (€ 3.76 million in 2010), and public research funding made up of operational grants and Research Tax Credit accounted for € 4.41 million.

- Despite considerable investment in clinical trials and toxicological studies for the drug candidate GFT505, the concentration of efforts on the most readily exploitable therapeutic programs and on biomarker programs, enabled operating charges for 2011 to be decreased by 4.12% to € 14.45 million (€ 15.07 million in 2010).

- Personnel costs decreased by 11.14% to € 5.94 million versus € 6.69 million in 2010. The average number of employees over the 2011 financial year was 92, compared to 104 during 2010.

- The operating result shows a loss of € 7.67 million for the 2011 financial year versus € 7.43 million for 2010.

- The consolidated net result for 2011, according to international IFRS standards and including a deferred tax liability of € 1.98 million linked to income tax regulations adopted in 2011 that considerably prolong the period over which deferred taxes can be absorbed, shows a loss of € 9.68 million (- € 9.38 million in 2010).

- On December 31st, 2011, the cash and cash equivalents of the Company amounted to € 12.80 million, compared to € 13.92 million on December 31st, 2010.

MAJOR ACHIEVEMENTS FOR 2011

Significant progress for GFT505

Phase IIa clinical trial GFT505-210-5: this study performed in 97 treatment-naïve diabetic patients demonstrated the efficacy of 3 months of treatment with GFT505 (80 mg/day) on glucose homeostasis. The study also confirmed in this population the beneficial effects of GFT505 on plasma lipids previously observed in other Phase II trials, and showed an improvement in markers of hepatic dysfunction, with notably a highly significant decrease in gammaGT levels. The excellent safety profile of GFT505 was also confirmed in this 3-month study.

Clinical trial GFT505-210-6: this mechanistic study performed in 22 insulin-resistant patients with abdominal obesity achieved all its primary and secondary efficacy objectives with no adverse side-effects. The results demonstrated that 8 weeks of treatment with GFT505 (80 mg/day) improves the insulin sensitivity of the liver and peripheral tissues, improves dyslipidemia, and reduces markers of hepatic dysfunction and inflammation.

Preclinical results obtained in NAFLD/NASH*: several series of preclinical studies in recognized animal models have demonstrated the efficacy of GFT505 to reduce hepatic steatosis (fat accumulation in the liver that is a characteristic feature of NAFLD) and to combat the profibrotic mechanisms responsible for NASH. These findings open the possibility of evaluating GFT505 in other hepatic diseases associated with fibrosis, such as primary biliary cirrhosis, viral hepatitis, or drug-induced hepatitis

TGFTX1 and TGFTX3 programs: good prospects for new industrial alliances

The proprietary research programs **TGFTX1** and **TGFTX3** target two nuclear receptors that are at the interface between cardiometabolic and inflammatory diseases.

These two receptors play key roles in the regulation of the internal clock system that enables certain biological functions (sleep/wake cycle, blood pressure, cardiac function) to be organized in a temporal fashion (circadian rhythm). Numerous epidemiological studies suggest a strong relationship between alterations in the circadian rhythm and the development of chronic pathologies such as Type 2 diabetes, obesity, and dyslipidemia. The TGFTX1 and TGFTX2 programs have thus been further developed for this therapeutic domain in 2011.

For both of these programs, GENFIT has set up appropriate medicinal chemistry and developed molecular and cellular profiling tests that led in 2011 to the identification of new chemical families of potential therapeutic interest. The most advanced of these compounds have been evaluated in preclinical models with encouraging results that notably strengthen the pharmacological validation of these two targets for the indication of Type II diabetes.

Based on these results, the continuation of the programs in collaboration with pharmaceutical partners is planned from 2012, with the goal of selecting drug candidates for preclinical and clinical development by 2016.

Biomarker programs: initiation of research funded by Oséo as part of the micro-Path consortium

Through the use of two proprietary technologies (MPrint™ and HTMP) for the capture and characterization of microparticles as circulating biomarkers of a pathological state, GENFIT is developing biomarker programs in atherosclerosis (**BMGFT01 program)** and in Type 2 diabetes (**BMGFT02 program)**, with the initial aim of providing decision-making tools to speed up the R&D process for drugs targeting these pathologies.

Since mid-2011, research on these two proprietary programs has advanced within the micro-Path consortium, of which GENFIT is the leader, and which includes several other biotechnology companies and academic clinical research groups. The global budget of this consortium is € 13.5 million over 4 years, of which € 10.3 million are invested by GENFIT. The Company is supported in this consortium by € 4.9 million from the French public organization Oséo in the form of grants and loans.

Industrial partnerships: major scientific milestones reached

An unprecedented new contract with Sanofi: following on from the positive results obtained during the previous biannual contract, Sanofi and GENFIT decided in March 2011 to extend and reinforce their historical alliance for three more years with two new research programs. GENFIT receives upfront annual payments to support its research, as well as additional milestone payments according to the progress of the preclinical and clinical development, registration, and commercialization of the resulting drug candidates. The total of these upfront and milestone payments could reach up to €39 million, in addition to royalties from future sales of products.

Continuing development of SERX1 at Servier: initiated in 2004, the industrial partnership with Servier renewed at the beginning of 2010 continued up to September 2011, and was rewarded by a further milestone payment in 2011. In the case of the continuing development of molecules discovered during the collaboration, GENFIT remains eligible for additional milestone payments according to their progression in Servier's pipeline, as well as royalties from the sales of resulting drugs.

POST-CLOSURE EVENTS AND PERSPECTIVES

GFT505

Since the end of 2011, the results of two specific long-term animal toxicology studies have become available, and confirm the safety of GFT505:

- a two-year carcinogenicity study in two animal species (rat and mouse), initiated in July 2009 ;
- a one-year toxicity study in monkeys.

Confirming the results of the 6 month rat toxicity study that were obtained before the end of the financial year, these two studies showed that GFT505 has no major adverse effect relevant to humans.

The European Medicines Agency (EMA), contacted in early 2012 by the Company for its scientific opinion on the initiation of a Phase IIb study aiming to demonstrate the therapeutic activity of GFT505 on a histological endpoint of NASH* regression, gave a favorable response on the design of the proposed study and the efficacy/safety ratio of GFT505 at the proposed therapeutic doses. Finally, the EMA gave its recommendations for the Phase III development plan of GFT505 in this new therapeutic indication.

Partnership with Sanofi: achievement of the first step towards a new treatment for metabolic diseases

The activity of several selected chemical series on a target implicated in multiple metabolic disorders has been demonstrated as part of the new research collaboration signed in March 2011 for a period of three years. A first scientific and financial milestone has thus been achieved for one of the two approaches of the research program targeting mitochondrial dysfunction. The first milestone on the other approach is due at the end of 2012.

Perspectives 2012

The scientific results obtained over the past two years strengthen the Company in its major strategic decisions:

- either transfer GFT505 commercialization rights from 2012, or maximize its value by bringing or sharing its clinical development with an industrial partner to the end of Phase II trials at the latest;
- or reinforce the Company's equity capital to finance the Phase IIb studies that will yield definitive results in the second half of 2014;
- achieve a new scientific milestone in the collaboration with Sanofi;
- sign a new industrial alliance in the wake of the progress made last year on the proprietary research programs TGFTX1 and TGFTX3;
- provide a strong validation of the microparticle approach to biomarker research.

***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 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, 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 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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