



# **GENFIT ANNOUNCES**

# **ITS DEVELOPMENT PLAN FOR GFT505**

Lille (France), Cambridge (Massachusetts, United States), June 28, 2010 – 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 plans to advance the development of GFT505, its leading drug candidate, following the completion of several clinical studies demonstrating its efficacy and safety in different patient populations.

In a double-blind, placebo-controlled<sup>(\*)</sup> Phase IIa clinical trial (GFT505-2094) conducted in 47 pre-diabetic patients with elevated fasting glucose, impaired glucose tolerance, and abdominal obesity, treatment with GFT505 (80 mg/day) for 28 consecutive days led to a significant decrease in fasting plasma glucose, fasting plasma insulin, and consequently an improvement of the HOMA insulin resistance index. In parallel, patients treated with GFT505 experienced a significant reduction of LDL-C with a reduction in triglycerides and an increase in HDL-C. In addition, GFT505 significantly reduced the pro-atherogenic apolipoproteins (ApoCIII, ApoB) and increased anti-atherogenic apolipoproteins (ApoAI and ApoAII).

In another double-blind, placebo-controlled Phase IIa clinical trial (GFT505-2083) conducted in 98 patients with atherogenic dyslipidemia (high triglycerides, low HDL-C) and abdominal obesity, treatment with GFT505 (80 mg/day) for 28 consecutive days led to a significant reduction in plasma triglycerides and a significant increase in HDL-C levels. Parallel decreases in pro-atherogenic apolipoproteins (ApoCIII, ApoB) and increases of anti-atherogenic apolipoproteins (ApoAI, ApoAII) were also observed.

In both studies, the anti-inflammatory effects of GFT505 were demonstrated by significant and similar reductions in plasma fibrinogen and haptoglobin. Importantly, GFT505 had clear statistically significant beneficial effects on two indicators of fatty-liver dysfunction, Alanine Amino Transferase and Gamma Glutamyl Transpeptidase, while it did not affect the plasma level of Aspartate Amino Transferase.

These Phase IIa trials confirm the safety of use of GFT505, with no safety concern identified. Notably, at an effective dose of 80 mg/day, GFT505 did not increase plasma homocysteine, a cardiovascular risk factor known to be increased by pure PPAR $\alpha$  agonists.

These results will be presented during the poster session scheduled from 12:00 p.m. to 2:00 p.m. EDT on Monday, June 28 at the American Diabetes Association's 70th Scientific Sessions in Orlando, Florida.

In multiple phase I trials that included a total of 168 healthy volunteers treated with single or repeated (14 days) oral doses, GFT505 was well tolerated up to the maximal dose tested (100 mg/day), with no clear treatment emergent adverse event. Moreover, there was no clinically significant pharmacokinetic interaction between GFT505 and simvastatin as determined in a specific Phase I trial.

GENFIT has held advisory panel meetings specifically on the GFT505 program with internationally renowned experts in the field of cardiometabolic diseases, which have acknowledged the wide spectrum of action of GFT505 and its safety of use in human, thus supporting the further development of GFT505 in cardiometabolic indications. According to their recommendations, the anti-diabetic efficacy of GFT505 on plasma glucose and HbA1C will be evaluated in a new phase II trial on patients with Type 2 Diabetes at inclusion. Its potential to address associated liver disorders could be assessed in another specific trial in patients suffering from Non-Alcoholic Fatty Liver Disease (NAFLD).



Prof. Bart Staels, Chairman of GENFIT's Scientific Advisory Board, stated: "We are very pleased with the meetings we had on the GFT505 program with the different clinical experts. The discussions were constructive, and by including renowned clinicians with complementary expertise in the cardiometabolic disease area, we have obtained important insights to continue with the development of GFT505 in specific patient populations."

Jean-François Mouney, CEO of GENFIT concluded: "We are excited to launch the next steps in advancing the development of GFT505. The clinical results obtained thus far which demonstrate the efficacy and safety of the product confirm the strong potential of this drug candidate to treat Diabetes. It is clear that innovative therapies are and will be required to address the increasing population of individuals at high risk of developing Type 2 Diabetes. The completion of the upcoming studies will complement the results we have already obtained and will provide a comprehensive understanding on the potential of GFT505 in specific cardiometabolic disease indications."

### About the American Diabetes Association's 70th Scientific Sessions:

The ADA's 70th Scientific Sessions is the world's most prominent diabetes meeting. The meeting will held in Orlando, Florida, on June 25-29, at the Orange County Convention Center in the West Building. This meeting provides the most recent education and information for those who are involved in the diabetes community.

#### (\*) <u>Double blind-placebo controlled</u>

A randomized controlled trial involves the random allocation of different interventions (treatments or conditions) to subjects. In a double blind placebo-controlled clinical trial, neither the patients nor the researchers know who is getting the placebo and who is getting the treatment.

### About GENFIT:

GENFIT is a biopharmaceutical company focused on the Discovery and Development of drug candidates in strategic therapeutic fields linked to cardiometabolic and neurodegenerative disorders (prediabetes/diabetes, atherosclerosis, dyslipidemia, obesity, Alzheimer's...). GENFIT uses a multi-pronged approach based on early diagnosis, preventive solutions, and therapeutic treatments to address these major public health concerns and their unmet medical needs. GENFIT's proprietary research programs and its partnerships with leading pharmaceutical companies, including SANOFI-AVENTIS, SOLVAY GROUP, and SERVIER, have resulted in the creation of a rich and diversified pipeline of drug candidates at different stages of development. GENFIT's lead proprietary compound, GFT505, is currently in Phase II and two other compounds, in partnership with SANOFI-AVENTIS and SOLVAY, are in the advanced stages of Phase I.

With facilities in Lille, France, and Cambridge, MA (USA), the Company has approximately 120 employees. GENFIT is a public company listed on the Alternext trading market by Euronext<sup>™</sup> Paris (Alternext: ALGFT; ISIN: FR0004163111). <u>www.genfit.com</u>

#### **Contacts:**

**GENFIT** Jean-François Mouney – Chairman of the Management Board +33 (0)3 2016 4000

MILESTONES – Press Relations Bruno Arabian +33 (0)1 75 44 87 40 / +33 (0)6 87 88 47 26 – <u>barabian@milestones.fr</u>

## MEDIA CONTACTS: RUSSO PARTNERS, LLC, ON BEHALF OF GENFIT

Chantal Beaudry Phone: (212) 845-4272 - chantal.beaudry@russopartnersllc.com