



www.genfit.com

GENFIT: THE FDA GRANTS FAST TRACK DESIGNATION TO GFT505 IN NASH

Lille (France), Boston (Massachusetts, United States), February 17, 2014 – 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 the Food and Drug Administration (FDA) has granted Fast Track designation to the GFT505 development program in NASH, with effect from February 14, 2014.

The FDA's Fast Track program is designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions, and that demonstrate the potential to address unmet medical needs. The aim is to ensure that new therapies for serious conditions are approved and available to patients as soon as possible. This designation permits close and regular contact between GENFIT and the FDA, thus enabling the joint definition of the most efficient development plan through frequent meetings and an accelerated review process.

GENFIT is currently conducting the Phase IIb study GFT505-212-7, for which the primary objective is to demonstrate the efficacy of one year of treatment with GFT505 (80 mg/d and 120 mg/d versus placebo) on the reversion of biopsy-diagnosed NASH. This international study involves a total of 56 centers of clinical excellence in the United States and in multiple European countries. All patients (a total of 270) have been recruited, more than half have been under treatment for more than 6 months, and the first patients have completed one year of treatment. The results should be announced at the end of 2014.

Commenting on the FDA's Fast Track designation for GFT505, **Jean-François MOUNEY, Chairman and Chief Executive Officer of GENFIT**, declared: *«All the preclinical and clinical data obtained to date show that GFT505 has the ideal profile for NASH treatment. The granting of the Fast Track designation will enable us to accelerate the development of GFT505 and reduce the time to market.»*

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

Contacts:

GENFIT

Jean-François Mouney – CEO & Chairman of the Management Board - Ph. +333 2016 4000

MILESTONES – Press Relations

Bruno Arabian Ph. +331 7544 8740 / +336 8788 4726 – barabian@milestones.fr