2015
Press release

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GENFIT: NEW PROOF OF EFFICACY OF GFT505 IN NASH AND POSITIVE EXPERT OPINION

- **Presentation of the challenges of NASH management, and overview of GFT505 and the results of the GOLDEN-505 study, by Professors Philippe Lehert, Vlad Ratziu and Bart Staels.**
- **Presentation of new data demonstrating a very strong anti-NASH activity of GFT505 in conditions that correspond to the target population for Phase 3.**
- **Announcement of GFT505 development plan and Phase 3 agenda.**

Lille (France), Boston (Massachusetts, United States), April 24th, 2015 – GENFIT (Euronext: GNFT; ISIN: FR0004163111), a biopharmaceutical company at the forefront of developing therapeutic and diagnostic solutions in metabolic and inflammatory diseases, that notably affect the liver or the gastrointestinal system, reveals the content of the various presentations given at today's analyst and investor event held during the EASL International Liver Congress in Vienna, Austria.

At this analyst and investor event, Professors Philippe Lehert, Vlad Ratziu, and Bart Staels present today in conjunction with members of GENFIT's management.

In introduction, Prof. Ratziu reiterates the urgency of treating NASH and in particular its most advanced forms, that currently affect 5-8% of the population in developed countries. He stresses the cardiovascular consequences of the disease, with CV events being the leading cause of death in NASH patients.

Prof. Staels continues by emphasizing the physiological roles of PPARalpha and PPARdelta, the targets of GFT505, and their implication in the resolution of liver damage, the treatment of associated metabolic disorders, and in cardiovascular protection.

During the presentation of the results of the GOLDEN-505 study, Prof. Lehert further explains the statistical analyses that demonstrate the positive effects of GFT505 on the primary endpoint of the study and on several histological secondary endpoints in the global patient population. In particular, he details

the statistical method applied, and explains that it enables the consideration of NASH severity (NAS score from 3 to 8) at randomization, and a marked center effect, linked to an imbalance in treatment groups between centers. Prof. Lehert reiterates that this methodology was discussed with the FDA prior to study completion, and that it is classically used in Phase 2 studies of metabolic diseases. These results provide strong and unequivocal evidence of the beneficial effects of GFT505 at 120mg/d on the primary endpoint: "Disappearance of NASH without worsening of fibrosis" in the global study population.

Prof. Ratziu, Principal Investigator of the GOLDEN-505 study, then presents the analyses concerning the population of NASH patients with an initial NAS score of $\geq$4, who should be treated as a priority, according to expert consensus recommendations. He points out that this population represents 85% of NASH patients.

He gives details of new data on the population of patients with an initial NAS score of $\geq$4, from centers that randomized at least one patient in each of the study treatment groups. Prof. Ratziu emphasizes that this analysis corresponds to the conditions for Phase 3, and that the statistical significance of the histological results is attained without adjustment for center effect.

In this large sub-group (120 patients in Europe and United States), the activity of GFT505 at 120mg/d is very strong and significant on both the primary endpoint (29% versus 5% for placebo; p=0.01) and on the lowering of the NAS score by at least two points (48% versus 21% for placebo; p=0.02).

These effects are mainly due to a significant improvement in ballooning (p=0.02) and liver inflammation (p=0.05).

Coming back to the global population, Prof. Ratziu presents data demonstrating a marked improvement in the fibrosis score in patients responding to GFT505 (p<0.001 vs non-responders).

Finally, Prof. Staels also emphasizes the importance of data concerning the very significant improvement in cardiometabolic risk profile induced by GFT505. He stresses in particular the decrease of LDL-cholesterol (-0.24 mmol/L, p<0.001 vs placebo) and the increase of HDL-cholesterol (+0.11 mmol/L, p<0.01 vs placebo) in the global study population, and the decrease of HbA1c in diabetic patients (-0.46%, p<0.05 vs placebo). In his opinion, the cardioprotective profile of GFT505 is a key advantage in the global management of NASH patients, in addition to its beneficial histological liver effects.

GENFIT's Medical Management presents the GFT505 development plan, the Phase 3 studies in NASH and cirrhosis, the satellite studies, as well as the patient population targeted by these studies. According to the detailed agenda presented, the Phase 3 study in NASH will be discussed shortly with the FDA and EMA, and should begin at the end of the year.

Jean-François Mouney, CEO of GENFIT, supported by the investors and renowned clinicians and scientists that accompany the Company, confirms the

continuing development of GFT505 based on the results of all the analyses performed to date and the positive data presented. He reiterates that the data cannot be entirely revealed at present due to the embargo necessary before publication in a major international scientific or medical journal. The publication of the complete data set is expected this summer.

Confident that this meeting provides convincing answers to questions arising from the announcement of the preliminary results at the end of March, he expresses the desire that they will be subject to a careful and objective review. Indeed, in the very large NASH market where the patient population to be treated is extremely heterogeneous, the mechanisms of action of the various molecules under development can be complementary for the global and personalized management of NASH patients.

About GENFIT:

GENFIT is a biopharmaceutical company focused on the Discovery and Development of drug candidates in fields of high medical need due to a lack of suitable treatment and an increasing number of patients worldwide. GENFIT's R&D efforts are focused on contributing to bringing new medicines to market for patients with metabolic, inflammatory, autoimmune and fibrotic diseases, that affect the liver (such as NASH - Nonalcoholic steatohepatitis) or the bowel (such as the inflammatory bowel disease). GENFIT implements mutually beneficial approaches that combine novel treatments and biomarkers; its research programs have resulted in the creation of a rich and diversified pipeline of drug candidates, including GENFIT's lead proprietary compound, GFT505, that has completed a positive Phase 2b study in NASH and is currently launching a Phase 3 study.

With facilities in Lille, France, and Boston, MA (USA), the Company has approximately 80 employees. GENFIT is a public company listed in compartment B of Euronext's regulated market in Paris (Euronext: GNFT; ISIN: FR0004163111). www.genfit.com

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