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Press release



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GENFIT ANNOUNCES TOPLINE RESULTS FROM THE GOLDEN-505 TRIAL IN NASH

- GFT505 DEMONSTRATES DOSE-DEPENDENT EFFICACY ON THE PRIMARY ENDPOINT, AFTER CONTROLLING FOR BASELINE SEVERITY AND HETEROGENEITY (P=0.027)
- TREATMENT WITH GFT505 LEADS TO SIGNIFICANT CARDIO-METABOLIC BENEFITS
- GFT505 WAS SAFE AND WELL TOLERATED IN THIS 1-YEAR TRIAL

Lille (France), Boston (Massachusetts, United States), March 26, 2015 – GENFIT (Euronext: GNFT; ISIN: FR0004163111), today announces topline results of the phase 2 GOLDEN-505 trial in NASH.

Due to the unexpected rate of resolution of NASH in patients randomized to placebo who had early NASH (NAS of 3, placebo response rate >57%), along with the high number of sites for a limited sample size, the study as initially designed did not enable the trial to meet directly the primary endpoint. With correction for this baseline severity and site heterogeneity by a standardized statistical analysis, GFT505 120mg meets the primary endpoint: Reversal on NASH without worsening of fibrosis, as detailed below.

Treatment with GFT505 provides a significant beneficial effect on the primary endpoint (GFT505 120mg vs placebo, $p=0.016$, $RR=2.03$) in the global randomized population ($n=274$, full analysis set), where patients without an end of treatment biopsy were considered as non-responders. The primary endpoint was also achieved in the evaluable population of patients who underwent both baseline and end of study liver biopsies ($n=237$, ITT; $p=0.027$ vs placebo; $RR=1.94$). In the evaluable patient population, GFT505 120mg also has a beneficial effect of a decrease of NAS-score ≥ 2 ($p=0.04$ vs placebo).

Early NASH patients with NAS=3 were not included in other recent NASH trials. If the same is done in the GOLDEN-505 study, keeping patients with more severe disease defined by $NAS \geq 4$ ($n=202$), GFT505 120mg demonstrates a doubling of responders on the primary endpoint (22.4% vs 12.7%, $p=0.046$, $RR=1.9$), thus providing evidence of a clinically meaningful benefit in patients with more advanced disease.

This 52-week phase 2b trial evaluated the efficacy and safety of GFT505 in 274 subjects (double blind, placebo-controlled; three arms: placebo, 80mg, 120mg) with centrally-read, liver biopsy proven NASH across 56 centers in nine countries in North America and Europe.

Study criteria required patients to have all three histological components of NASH. The patients' NAFLD Activity Score, or NAS, ranged from those with early disease with NAS=3 to severe disease of NAS=8. The primary endpoint was defined as "resolution of NASH without worsening of fibrosis" which requires reaching a NAS of zero on any one of the three histological components. This trial also assessed a comprehensive set of safety and secondary efficacy endpoints.

The evaluation of various biomarkers confirms the beneficial biological activity of GFT505 120mg. Specifically, using the initial protocol analysis, statistically significant improvement of the following liver related biomarkers was noted: decrease of ALT, GGT, ALP, and improvement on various NAFLD composite scores (Steatotest, Fibrotest, Fatty Liver Index, NAFLD Fibrosis score).

Even on top of various standard of care therapies, GFT505 provides additional improvements vs placebo on cardio-metabolic risk factors, commonly found in NASH patients:

- lipid profile: TG, LDL-C, HDL-C
- glycemic indices/insulin resistance in Diabetics: HbA1c, FPG, Fasting insulin
- inflammatory markers: Haptoglobin, Fibrinogen, CRP

Taken together, these beneficial effects on cardio-metabolic parameters are very important for the treatment and management of NASH patients, in whom cardiovascular disease is the leading cause of mortality.

The safety assessment of this one-year study demonstrates a very favorable profile, which is consistent with the conclusions of the DSMB reviews throughout the study. There were no cardiac events, signal on cancer, nor death in the GFT505 treatment groups. Weight remained stable, and no signal for edema was observed. A mild dose dependent increase in creatinine was noted (< 5%; GFT505 120mg vs placebo), which is a known reversible effect of GFT505. The most common adverse events were of gastrointestinal nature of mild intensity.

GENFIT is fully satisfied by this phase 2 study, in consensus with its key NASH experts, that this study provides, as expected, all the information needed to move forward and design the upcoming phase 3 trials. These data will be presented in the next weeks to Regulatory Agencies (FDA, EMA) as a basis for phase 3 launch. The preparation of the manuscript in a major scientific journal is ongoing.

- "This is the first truly international trial in NASH across multiple sites, and over 2 continents. This study was performed according to FDA and EMA standards, using rigorous quality in all operational aspects of the trial conduct (notably centralized procedures for biopsy reading, laboratory analyses)" **said Dr Sophie Mégnien, CMO.**

She added "Design, methodology and analysis were elaborated in close contact with Authorities, key NASH experts, independent renowned experts for Safety assessment (DSMB). The design of phase 3 will be optimized through in-depth analysis of these results, and with the continuous support of our experts."

“This critical trial demonstrates that GFT505 is safe and produces a dose-dependent improvement in liver histology in patients with NASH. Beyond its clear safety profile, GFT505 improves cardio-metabolic risk factors frequently present in these patients.” **said Prof Vlad Ratziu, Principal Investigator and International Coordinator of the GOLDEN-505 study.** “This study validates the modulation of PPAR α and PPAR δ as pharmacological targets for treating NASH. In my opinion, these data should encourage the further development of GFT505 for the treatment of NASH.”

Jean-François Mouney, CEO of GENFIT added “This study demonstrating the efficacy and safety of GFT505 brings us a major step forward towards the first line therapy for the treatment of NASH, which remains a major unmet medical need. GENFIT, along with key experts in the field of NASH, are convinced by these results, and we are preparing together a manuscript for a detailed publication in international major peer reviewed scientific journal. Following the advice of its experts, GENFIT is preparing for the phase 3 of GFT505 in NASH, and is planning for the next meetings with the FDA and EMA to discuss the design of the pivotal trials. During the EASL conference which will be held in Vienna in April, we will organize 2 events, one with investors and analysts, and another for the investigators of the GOLDEN-505 trial.”

Conference Call and Webcast

GENFIT management will discuss these topline Phase 2b results in a live webcast and conference call today, March 26, 2015 at 2:30pm EDT / 7:30pm CET. The webcast may be accessed live at <http://genfit.equisolvewebcast.com/phase2b> (or www.genfit.com), and will be archived there for 30 days. To access the call via dial-in, please dial (877) 407-3979 (U.S. toll free), (412) 902-0042 (international) or 0 800 912 848 (French toll free).

Management will also provide a live webcast today at 4:00pm EDT / 9:00pm CET, where they will rebroadcast the call in French. The French webcast may be accessed at <http://genfit.equisolvewebcast.com/phs2b-french> (or www.genfit.com), and will be archived for 30 days.

This press release is available on GENFIT website (www.genfit.com) as well as on the Euronext website.

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 is completing a Phase 2b study in NASH.

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

Disclaimer:

This press release contains certain forward-looking statements. Although the Company believes its expectations are based on reasonable assumptions, these forward-looking statements are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those anticipated. For a discussion of risks and uncertainties which could cause the Company's actual results, financial condition, performance or achievements to differ from those contained in the forward-looking statements, please refer to the Risk Factors ("Facteurs de Risque") section of the Listing Prospectus upon the admission of Company's shares for trading on the regulated market Euronext of Euronext Paris filed with the AMF, which is available on the AMF website (www.amf-france.org) or on GENFIT's website (www.genfit.com).

This press release and the information contained herein do not constitute an offer to sell or a solicitation of an offer to buy or subscribe to shares in GENFIT in any country.

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