2015
Press Release

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GENFIT ANNOUNCES PIVOTAL PHASE 3 CLINICAL TRIAL OF ELAFIBRANOR IN NASH FOLLOWING REGULATORY INPUT

- **Initial approval to be based on analysis of first 900 patients, after 72 weeks treatment, based on a single histological surrogate endpoint**

- **Additional GOLDEN 505 trial data presented at AASLD further demonstrate efficacy, cardiometabolic benefit, safety and good tolerability of Elafibranor**

Lille (France), Cambridge (Massachusetts, United States), November 16th, 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, today announces the design of the global phase 3 trial to evaluate the benefits of Elafibranor treatment on NASH patients.

The pivotal trial will be a randomized, double-blind, placebo-controlled (2:1) Phase 3 trial, conducted in approximately 1800 patients, at 200 centers worldwide. The study population will include NASH patients (NAS≥4) with F2 or F3 fibrosis. Elafibranor 120 mg and placebo will be administered once daily. An interim analysis, for initial market approval under Subpart H, will be performed after 72 weeks in order to evaluate the beneficial effect of Elafibranor on the liver histology of the first 900 patients. To support full approval, the trial will continue in order to demonstrate the impact of Elafibranor on the prevention of cirrhosis and other liver related outcomes on the full study population. A group of patients with F1 fibrosis and concomitant cardiometabolic comordities, which are associated with rapid progression of the disease, will also be enrolled.

Initial approval will be based on the interim analysis (72 weeks / 900 patients) of the following surrogate histological primary endpoint : NASH resolution without worsening of the fibrosis, corresponding to ballooning=0,

inflammation=0-1. This criteria defining disease activity, and based on a centralized histological reading, is considered by the regulatory authorities as well as NASH experts as a surrogate endpoint for approval.

In order to confirm the long-term clinical benefits of NASH resolution induced by Elafibranor 120mg, the trial will continue post-marketing and remain blinded after the interim analysis. All patients will be followed until the occurrence of a pre-defined number of progressions to cirrhosis and other liver related events.

The trial will evaluate key secondary histological endpoints, including an improvement on fibrosis, and non-invasive markers of steatohepatitis. In addition, the trial will assess the improvement of cardiometabolic profile, including plasma lipids, glucose homeostasis and inflammatory markers.

The trial initiation is anticipated in fourth quarter of 2015.

Jean-François Mouney, Chairman and Chief Executive Officer of GENFIT commented: *"After constructive discussions with KOLs and regulatory authorities, we are proud to announce our Phase 3 trial in NASH, where there remains a significant unmet need and no available treatment options. Based on our recent discussions with agencies, we agreed that approval may be obtained after an interim analysis at 72 weeks of treatment based on a histological endpoint of NASH resolution. The new consensual definition of resolution of NASH, which corresponds to the absence of ballooning and the absence or mild inflammation, is well aligned with the efficacy of Elafibranor on these two lesions. As a result of Elafibranor's remarkable safety profile, GENFIT is on track to provide a safe first-line therapy for the management of a large population of NASH patients with established fibrosis. Alongside the development of Elafibranor, GENFIT will validate, within the phase 3, its new non invasive proprietary diagnostic algorithm for the identification of NASH patients who should be treated, reflecting our commitment to provide a comprehensive approach to managing this silent killer."*

Professor Arun Sanyal, Division of Gastroenterology, Hepatology and Nutrition, Virginia Commonwealth University School of Medicine, Richmond, VA, commented: *"The Phase 2b GOLDEN-505 study demonstrated that, in patients with clearly established NASH with high disease activity, Elafibranor safely led to resolution of steatohepatitis as well as improvement in cardiometabolic risk factors. Of particular importance is the efficacy of Elafibranor on the new consensual definition of resolution of NASH without worsening of fibrosis. Using this new consensual definition which emphasizes the role of cell injury and inflammation as the main drivers of fibrosis evolution, the GOLDEN-505 trial demonstrated that Elafibranor-treated patients who cleared their NASH also experienced a significant reduction in liver fibrosis. Thus, the design of the Phase 3 trial is optimal to confirm the good efficacy/safety ratio of Elafibranor on resolution of NASH at an interim analysis after 72 weeks, and on prevention of cirrhosis in the long-term."*

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GENFIT presence at American Association for the Study of the Liver Disease 2015:

Results from the GOLDEN-505 trial will be presented at the AASLD Liver Meeting demonstrating the efficacy, safety, good tolerability, and beneficial cardiometabolic protection profile of Elafibranor, during two oral presentations, including a presidential plenary session, and a poster.

At this occasion, GENFIT will host two separate events on Monday, November 16th:

- Analyst and investor event (6:45pm PT) with Professor Vlad Ratziu - Division of Hepato-Gastroenterology, Pitié-Salpêtrière Hospital, Paris, France,
- Investigator event (8:30pm PT) with Professor Vlad Ratziu ; Professor Arun Sanyal - Division of Gastroenterology, Hepatology and Nutrition, Virginia Commonwealth University School of Medicine, Richmond, VA

In addition, GENFIT will be present at the Liver Meeting and will:

- co-chair a working group of the Liver Forum which aims to optimize drug development for the treatment of NASH patients in collaboration with regulators, learned societies, academic and industry stakeholders,
- host a booth (#219) in the exhibitor hall of the Moscone Center.

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/Elafibranor, that has completed a positive Phase 2b study in NASH and is currently launching a Phase 3 study. With facilities in Lille, France, and Cambridge, MA (USA), the Company has approximately 90 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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