PRESS RELEASE

Data from Phase 2b trial of GENFIT's Elafibranor published in *Gastroenterology*

- **The peer-review publication highlights the resolution of NASH without fibrosis worsening with 120mg Elafibranor**
- **This result is confirmed both in intention-to-treat population as well as in subgroups of moderate/severe NASH patients, based on the recommended definition of "NASH resolution" now used for clinical trials**
- **In addition, the publication confirms that Elafibranor significantly improved the cardiometabolic risk profile and was safe, well-tolerated**

Lille (France), Cambridge (Massachusetts, United States), February 11, 2016 – 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 that detailed results from the Phase 2b clinical trial evaluating GFT505 in NASH, the company's investigational once-daily oral drug (first-in-class), have been published online in *Gastroenterology*, in advance of appearing in print in the May isssue. Key elements of context and content below :

- The GOLDEN-505 clinical trial was the first international trial on NASH, conducted in 56 centers spread across 9 countries, with the ambition to address the NASH burden using "resolution of NASH without worsening of fibrosis" as primary endpoint.
- The detailed results of the GOLDEN-505 trial represent an essential contribution to the global effort to address this disease related to the obesity and diabetes epidemics (and for this reason considered a priority by the regulatory agencies, as confirmed by the fast-track designation granted to Elafibranor, as well as by the Subpart H process applied to its Phase 3 trial).
- In the Phase 2b trial, GFT505/Elafibranor or a placebo was administered to patients with a histological diagnosis of NASH. The treatment was taken for 52 weeks. The inclusion and end-of-treatment biopsies were all read centrally in a blinded manner. At end of study, all slides (baseline and end-of-study) were read in scrambled order.
- The conclusions of the scientific publication take into account the new recommended definition of "NASH resolution", which focuses on the necroinflammation, considered as the key driver of disease activity and progressive fibrosis towards cirrhosis (necroinflammation is defined as the combination of two important lesions in the liver : hepatocellular ballooning, and lobular inflammation).
- A key conclusion of the work carried out by the large team of worldwide specialists in the field of hepatology is that 120mg Elafibranor achieved resolution of NASH without fibrosis

worsening, in both intention-to-treat population and subgroups of moderate/severe NASH patients, based on the recommended definition of "NASH resolution" now used for clinical trials.

- Key results can be summarized as follows :
    - 120mg Elafibranor significantly increased resolution of NASH without fibrosis worsening (19% vs. 12%, OR=2.31, 95% CI [1.02,5.24], p=0.045) on the whole study population, in an analysis based on the new recommended definition for "NASH resolution".
    - In a subgroup of NAS≥4 patients (N=234), 120mg Elafibranor performed better than placebo, regardless of the definition used for "NASH resolution" (20% vs. 11%, OR=3.16, 95% CI [1.22-8.13], p=0.018 ; and 19% vs. 9%, OR=3.52, 95% CI [1.32-9.40], p=0.013; for the predefined protocol definition and for the new recommended definition, respectively).
    - Patients with NASH resolution on 120mg Elafibranor improved liver fibrosis (mean reduction of the fibrosis score -0.65±0.61 in responders vs. increase 0.10±0.98 for non-responders, p<0.001).
    - In the 120mg Elafibranor group, liver enzymes and inflammatory markers have been reduced significantly; lipid and glucose profiles have also been improved.
    - Elafibranor was well tolerated, without weight gain, without cardiac events, and with a mild and reversible increase in serum creatinine.

- The online version is available here :

  Elafibranor, an Agonist of the Peroxisome Proliferator-activated Receptor-α and -δ, Induces Resolution of Nonalcoholic Steatohepatitis Without Fibrosis Worsening
  http://www.gastrojournal.org/article/S0016-5085(16)00140-2/abstract

Professor Vlad Ratziu, Principal Investigator of the GOLDEN-505 study, and Professor of Hepatology Hôpital Pitié Salpêtrière and Université Pierre et Marie Curie Paris, France, commented: "*There is an urgent unmet medical need for a significant and increasing part of the population suffering from NASH, also known as nonalcoholic steatohepatitis. The large amount of data gathered in this first international trial has provided a breadth of information that the scientific community has already been able to use to discuss and define the future directions research should take in the field of NASH. The fact that these results get published today in* Gastroenterology *demonstrates how important this trial has been for the scientific and medical community, and how significant and positive Elafibranor's activity could be for NASH patients.*"

COL (Dr.) Stephen Harrison, Hepatologist at Brooke Army Medical Center in San Antonio and Professor of Medicine, Uniformed Services University of the Health Sciences, commented: "Gastroenterology *is a high impact journal and this publication represents a major milestone within the field of NASH. The data derived from this clinical trial showing improvement in both histopathology and cardiometabolic parameters, particularly in those patients with more advanced disease, have generated significant enthusiasm for an upcoming Phase 3 trial with Elafibranor. We are hopeful that NASH patients, who are already exposed to cardiometabolic risk,*

might soon have a real option to tackle both their liver problem and their cardiometabolic problems."

Dean Hum, Chief Scientific Officer (CSO) of GENFIT, reacted: "*We are pleased to see that the scientific community is fully aligned with the FDA and the EMA when it comes to the importance of managing the cardiometabolic dimension of the disease, as cardiovascular events are the leading cause of mortality in NASH patients. It is also important that the more stringent definition of NASH resolution is now being applied in clinical trials, as this endpoint is particularly well suited to demonstrate the efficacy of Elafibranor. This publication is a milestone which will likely increase awareness about NASH, and accelerate the process of providing safe and effective therapies to patients who are in high need for a treatment."*

About *Gastroenterology*:

Gastroenterology is the most prominent journal in the field of gastrointestinal disease. As the official journal of the AGA Institute, *Gastroenterology* delivers up-to-date and authoritative coverage of both basic and clinical gastroenterology. Regular features include articles by leading authorities and reports on the latest treatments for diseases. Original research is organized by clinical and basic-translational content, as well as by alimentary tract, liver, pancreas, and biliary content. *Gastroenterology* also bridges the gap between basic and clinical science by publishing comprehensive reviews and perspectives on important topics. http://www.gastrojournal.org/

About Elafibranor:

Elafibranor (GFT505) is GENFIT's lead pipeline product. It's an oral once-daily treatment, positioned as a first-in-class drug to treat nonalcoholic steatohepatitis (NASH). Based on the beneficial activities that it demonstrates on the different features of the pathology, Elafibranor represents a promising drug for NASH patients, including those suffering from the most severe forms of the disease.

About NASH:

"NASH", or nonalcoholic steatohepatitis, is a liver disease characterized by an accumulation of fat (lipid droplets), along with inflammation and degeneration of hepatocytes. Once installed, the disease is accompanied with a high risk of cirrhosis, a state where the liver functions are altered and can progress to liver insufficiency. Thereafter, the NASH often progresses to liver cancer.

About GENFIT:

GENFIT is a biopharmaceutical company focused on the discovery and development of drug candidates in areas of high unmet medical needs corresponding to a lack of suitable treatment and an increasing number of patients worldwide. GENFIT's R&D efforts are focused on bringing new medicines to market for patients with metabolic, inflammatory, autoimmune and fibrotic diseases, that affect the liver (such as NASH – Nonalcoholic steatohepatitis) and more generally the gastro-intestinal arena. 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, Elafibranor (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 Cambridge, MA (USA), the Company has approximately 100 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. Items in this press release may contain forward-looking statements involving risks and uncertainties. The Company's actual results could differ substantially from those anticipated in these statements owing to various risk factors which are described in the Company's prospectus. This press release has been prepared in both French and English. In the event of any differences between the two texts, the French language version shall supersede.

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