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### **GENFIT announces enrollment of first patient in RESOLVE-IT, the pivotal Phase 3 clinical trial of Elafibranor in NASH**

**Lille (France), Cambridge (Massachusetts, United States), March 10, 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 announced that it has enrolled the first patient in its Phase 3 clinical trial RESOLVE-IT, evaluating Elafibranor as a treatment against NASH.

**The coordinating Steering Committee members, Professor Vlad Ratziu, Professor of Hepatology Hôpital Pitié Salpêtrière and Université Pierre et Marie Curie Paris, France, COL (Dr.) Stephen Harrison, Hepatologist at Brooke Army Medical Center in San Antonio and Professor of Medicine, Uniformed Services University of the Health Sciences, USA, and Professor Arun Sanyal, Division of Gastroenterology, Hepatology and Nutrition, Virginia Commonwealth University School of Medicine, Richmond, VA, USA,** commented: *"All centers participating to this ultimate phase of clinical development in NASH are excited to see the first patients enrolled so quickly. Despite a large recognition of the unmet need by regulatory agencies and experts alike, our NASH patients still have no approved treatment option today. It is therefore important for all of us to be at the forefront of the research in this field, and to have access to a molecule that has a proven activity against the disease. Elafibranor's pluripotent profile is interesting as it helps to address NASH from a global clinical management perspective, with the potential to improve both liver histology as well as cardiometabolic parameters."*

**Sophie Mégnien, Chief Medical Officer (CMO) of GENFIT Corp., Boston, MA, USA,** commented: *"We are extremely satisfied by the fast launch of RESOLVE-IT. Having our first patients on-board is an important milestone, and a real performance: it has indeed been only one year since the read-out of Phase 2b. We are proud of the excellent work done by the clinical team, especially on the integration into the Phase 3 protocol of all key adjustments required by the authorities to reflect the new definition of NASH resolution, which we consider a positive development. The enthusiasm from clinical centers worldwide is stronger than ever, particularly following the Gastroenterology publication. We are on track to finalize the recruitment on time."*

#### **About RESOLVE-IT:**

RESOLVE-IT is a randomized, double-blind, placebo-controlled (2:1) Phase 3 clinical trial targeting approximately 2,000 patients, and involving about 200 centers worldwide. The study population includes NASH patients (NAS $\geq$ 4) with F2 or F3 fibrosis who will be administered Elafibranor 120mg or placebo once daily.



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An interim analysis, targeting initial regulatory application under Subpart H, will be performed after 72 weeks of treatment on the first ~1,000 patients, evaluating the effect of Elafibranor based on the following surrogate histological primary endpoint (with centralized histological reading): NASH resolution (corresponding to ballooning=0, inflammation=0-1) without worsening of the fibrosis.

In order to measure the long-term clinical benefit of NASH resolution induced by Elafibranor 120mg, the trial will continue on a blinded-basis following 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.

### **About Elafibranor:**

Elafibranor (GFT505) is GENFIT's lead pipeline product. Elafibranor is an oral once-daily treatment, and a first-in-class drug acting via dual peroxisome proliferator-activated alpha/delta pathways to treat nonalcoholic steatohepatitis (NASH). Elafibranor is believed to address multiple facets of NASH, including inflammation, insulin sensitivity, lipid/metabolic profile, and liver markers.

### **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. The disease is associated with long term risk of progression to cirrhosis, a state where liver function is diminished, leading to liver insufficiency, and also progression 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 gastrointestinal arena. GENFIT's approach combines novel treatments and biomarkers. Its lead proprietary compound, Elafibranor (GFT505), completed a Phase 2b study in NASH and is currently in 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](http://www.genfit.com)

### **Forward Looking Statement / 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



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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](http://www.amf-france.org)) or on GENFIT's website ([www.genfit.com](http://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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