PRESS RELEASE

GENFIT: First patient enrolled in a phase 2 trial recruiting adults with Primary Biliary Cholangitis (PBC), a rare liver disease

› **First patient randomized in a Phase 2a clinical trial evaluating efficacy and safety of elafibranor in PBC (Primary Biliary Cholangitis)**

› **Target population: patients with inadequate response to ursodeoxycholic acid**

› **Primary outcome measure: relative change from baseline in serum alkaline phosphatase (ALP) compared to placebo after 12 weeks**

Lille (France), Cambridge (Massachusetts, United States), May 5, 2017 – 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 the first patient has been enrolled in the Phase 2a trial evaluating elafibranor in PBC.

This trial is designed to be a multicenter, double-blind, randomized, placebo-controlled, Phase 2a study to evaluate the efficacy and safety of elafibranor in adult patients with PBC and inadequate response to ursodeoxycholic acid (UDCA). The trial is designed as follows:

- 3 arms (80mg, 120mg, placebo)
- 45 patients (15 patients per arm)
- 12 weeks treatment
- Clinical centers in the U.S. and in 3 European countries

The primary objective is to determine the effect of daily oral administration of elafibranor on serum alkaline phosphatase (ALP) in these patients, based on relative change from baseline to end of treatment compared to placebo.

Secondary endpoints include:

- ALP < 1.67 × upper limit of normal (ULN) and total bilirubin within normal limit and > 15% decrease in ALP
- Paris, Toronto, UK PBC scores
- Pruritus and QoL (Quality of Life)
- Safety of elafibranor in a PBC population

Dr. Velimir A. Luketic, MD, Division of Gastroenterology, Hepatology and Nutrition Virginia Commonwealth University School of Medicine, Richmond, VA (USA), commented: *"PBC is a chronic progressive liver disease characterized by immune mediated destruction of the small intrahepatic bile ducts that if untreated progresses to end-stage liver disease and liver*

failure. A substantial number of patients do not benefit from the currently available therapies – UDCA or OCA – either because of lack of response or intolerable side effects. This represents a major unmet need for this population. In the literature, targeting PPAR receptors have shown to reduce the synthesis of bile acids and to improve detoxification of bile in the bile duct. In clinical trials, PPAR targeting drugs have shown significant decrease in ALP, and improved biochemical profiles and pruritus in PBC patients."

Sophie Mégnien, Chief Medical Officer of GENFIT, added: *"We are excited to have this first randomized PBC patient in this Phase 2 trial and advance our PBC program. Elafibranor, a dual PPAR alpha & delta agonist, is an attractive candidate for PBC patients due to its impact on lowering alkaline phosphatase levels, as shown in previous studies, on other populations. This attribute, along with what PPARs have consistently demonstrated on ALP reduction, provides a strong rationale for elafibranor in PBC. Starting randomization in such a rare disease is a key milestone, and we hope elafibranor will provide a meaningful benefit to patients, and will ultimately address the unmet need."*

ABOUT ELAFIBRANOR

Elafibranor 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 developed to treat, in particular, nonalcoholic steatohepatitis (NASH). Elafibranor is believed to address multiple facets of NASH, including inflammation, insulin sensitivity, lipid/metabolic profile, and liver markers.

ABOUT PBC

"PBC", or Primary Biliary Cholangitis, is a chronic disease in which bile ducts in the liver are gradually destroyed. The damage to bile ducts can inhibit the liver's ability to rid the body of toxins, and can lead to scarring of liver tissue known as cirrhosis.

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's approach combines novel treatments and biomarkers. Its lead proprietary compound, elafibranor, is currently in a Phase 3 study. With facilities in Lille and Paris, France, and Cambridge, MA (USA), the Company has approximately 130 employees. GENFIT is a public company listed in compartment B of Euronext's regulated market in Paris (Euronext: GNFT - ISIN: FR0004163111). www.genfit.com

PRESS RELEASE

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 those expressed in, or implied or projected by, the forward-looking statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, including related to biomarkers, progression of, and results of clinical data from, the RESOLVE-IT trial, review and approvals by regulatory authorities, such as the FDA or the EMA, regarding in particular, elafibranor in NASH and PBC, as well as other indications, and biomarkers, the success of any inlicensing strategies, the Company's continued ability to raise capital to fund its development, as well as those discussed or identified in the Company's public filings with the AMF, including those listed under Section 4 "Main Risks and Uncertainties" of the Company's 2016 Registration Document registered with the French Autorité des marchés financiers on April 28, 2017 under n° R.17-034, which is available on GENFIT's website (www.genfit.com) and on the website of the AMF (www.amf-france.org). Other than as required by applicable law, the Company does not undertake any obligation to update or revise any forward-looking information or statements.

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. 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.

CONTACT

GENFIT | Jean-François Mouney – Chairman & CEO | +333 2016 4000
MILESTONES – Press Relations | Bruno Arabian | +331 8362 3484 / +336 8788 4726 – barabian@milestones.fr