PRESS RELEASE

GENFIT is Filing for IND Submission for New Indication of Elafibranor in Primary Biliary Cholangitis (PBC)

- **Filing of Investigational New Drug (IND) application for a new indication of elafibranor in Primary Biliary Cholangitis (PBC), a rare disease with unmet need and only two orphan products approved to date**
- **Launch of a Phase 2 study to evaluate the efficacy and safety of elafibranor in PBC adult patient population: 3 month treatment; 30 patients; evaluation of ALP decrease vs placebo; sites in both the United States and Europe**

Lille (France), Cambridge (Massachusetts, United States), September 27, 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 is filing an IND submission for a Phase 2 trial in Primary Biliary Cholangitis (PBC), aimed at evaluating decrease in alkaline phosphatase (ALP) with elafibranor vs placebo.

This trial is designed to be a multicenter, double-blind, randomized, placebo-controlled, phase 2 study to evaluate the efficacy and safety of elafibranor after 12 weeks of treatment in patients with PBC and inadequate response to ursodeoxycholic acid.

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 versus placebo.

Secondary endpoints will 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

PBC is a rare disease with unmet need. Current treatments only cure a fraction of the patient population, and/or generate important side-effects such as pruritus, which is a major and well-known symptom already affecting most PBC patients.

Jean-François Mouney, Chairman & CEO of GENFIT, said: *"As announced earlier this year, we are now in the process of launching a Phase 2 in PBC with our lead compound elafibranor. This strategic move is the result of the interactions we've had over the last year with key opinion*

leaders in PBC, who believe that PBC patients are still in need of alternative and appropriate treatments for their disease. The fact that the ALP-related surrogate endpoint has been clearly accepted by regulatory agencies as a valid endpoint for registration has been an important step, and a key element in our decision. We are encouraged by the literature on fibrates that seems to indicate a real potential for a PPARα like elafibranor to have a positive effect on ALP. We have designed a short trial, with only 3 months treatment, which means we should be able to readout on data in a relatively short timeframe."

Dr. Sophie Mégnien, Chief Medical Officer of GENFIT Corp., commented: *"There is a real unmet need for many PBC patients who do not respond well enough to their UDCA treatment, i.e. do not reach the targeted level of serum alkaline phosphatase, and who – as such – remain at risk. We are pleased to be able today to take a step in a direction that represents a new hope for patients and a potentially safer alternative to currently available treatments. Based on its mechanism of action, we are confident in the potential of elafibranor to hit the appropriate target with a good level of efficacy, safety, and tolerability."*

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, France, and Cambridge, MA (USA), the Company has approximately 110 employees. GENFIT is a public company listed in compartment B of Euronext's regulated market in Paris (Euronext: GNFT - ISIN: FR0004163111). 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 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 review and approvals by regulatory authorities of the planned IND submission for Elafibranor in PBC, progression of recruitment, and the timing and results of clinical data from, a trial in PBC, when approved and the RESOLVE-IT trial generally, 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 7 "Main Risks and Uncertainties" of the Company's Half Year 2016 Business and Finanial Report, 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 | Ph. +333 2016 4000
MILESTONES – Press Relations | Bruno Arabian | Ph. +331 8362 3484 / +336 8788 4726 – barabian@milestones.fr