PRESS RELEASE

GENFIT: FDA has officially cleared the IND to proceed with Phase II trial and evaluate elafibranor in PBC

- **Investigational New Drug (IND) application cleared by the FDA for the new indication of elafibranor in Primary Biliary Cholangitis (PBC), a rare disease with unmet need and only two orphan products approved to date**

Lille (France), Cambridge (Massachusetts, United States), November 4, 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 the FDA has cleared the IND to proceed with the Phase II trial aimed at evaluating elafibranor in PBC.

As previously announced, this trial is designed to be a multicenter, double-blind, randomized, placebo-controlled, Phase II 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, CEO, Co-founder, and Chairman of the board of GENFIT commented: "*We are satisfied with the progress made on the regulatory side in PBC. Our presence in this field is highly relevant given the profile of elafibranor, our proprietary molecule. We soon hope to be able to provide patients with a new, safe and well-tolerated therapeutic solution. Our involvement in PBC will continue to enrich our medical network thanks to our broad discussions and interactions we have with hepatologists. We value and cultivate a high level of collaboration with the medical community as it's a way for us to ensure that the best decisions are made to address unmet medical needs in this field.*"

PRESS RELEASE

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. The drug will also be evaluated in Primary Biliary Cholangitis (PBC).

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 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 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 7 "Main Risks and Uncertainties"of the Company's Half Year 2016 Business and Financial 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