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## PRESS RELEASE

### **GENFIT: Launch of a U.S. Phase 2 investigator-initiated study with nitazoxanide in patients with NASH-induced fibrosis**

- **Phase 2 study targeting a patient population with NASH-induced Stage 2 or 3 fibrosis**
- **Anti-fibrotic effect of nitazoxanide to be evaluated by several approaches including an innovative method to quantify hepatic fibrogenesis flux rates**

**Lille (France), Cambridge (Massachusetts, United States), December 3, 2018** – GENFIT (Euronext: GNFT - ISIN: FR0004163111), a biopharmaceutical company focused on discovering and developing drug candidates and diagnostic solutions targeting liver diseases, in particular those of metabolic origin, and hepatobiliary diseases, today announced the initiation of a Phase 2 proof-of-concept clinical trial evaluating nitazoxanide (NTZ) in patients with non-alcoholic steatohepatitis (NASH)-induced fibrosis, following submission of the study protocol by Pinnacle Clinical Research to the U.S. Food and Drug Administration (FDA).

Dr Stephen Harrison, Medical Director of Pinnacle Clinical Research, San Antonio, Texas, USA, Visiting Professor of Hepatology at the Radcliffe College of Medicine, University of Oxford, will conduct this investigator-initiated single-center, open-label trial to evaluate the safety and efficacy of nitazoxanide in patients with NASH-induced Stage 2 or Stage 3 fibrosis.

The objectives of this proof of concept trial include evaluating the anti-fibrotic effect of nitazoxanide by several approaches including an innovative method to quantify hepatic fibrogenesis flux rates. Using heavy water labeling, *de novo* collagen-associated protein synthesis will be determined through Fractional Synthesis Rate (FSR) of circulating proteins at baseline and at the end of treatment to assess the effect of daily oral administration of nitazoxanide. Other non-invasive methods including Magnetic Resonance Elastography (MRE) and FibroScan® will be used to evaluate the liver stiffness changes after nitazoxanide treatment.

Nitazoxanide, currently marketed and prescribed in the United States and other territories as an anti-parasitic drug, was discovered by Genfit scientists to have novel anti-fibrotic properties that were confirmed in preclinical liver fibrosis models. Genfit presented the results of this research in April 2017 at the European Association for the Study of the Liver (EASL) International Liver Congress, supporting the efficacy of nitazoxanide in two *in vivo* disease models of liver fibrosis.

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Genfit observed that administration of nitazoxanide significantly attenuated liver fibrosis development. Additional preclinical data presented in April 2018 at EASL on combination therapy with a low dose of elafibranor and nitazoxanide indicate that nitazoxanide could be a good candidate for combination therapy with elafibranor, in addition to an anti-fibrotic monotherapy.

Genfit has been granted a U.S. patent for use of nitazoxanide in NASH-induced liver fibrosis.

**Dr Stephen Harrison of Pinnacle Clinical Research** stated: *"Genfit's exciting discovery of the anti-fibrotic properties of nitazoxanide in a preclinical model has the potential to bring a new and interesting treatment option to NASH patients with fibrosis. I look forward to seeing the results in patients and contributing to Genfit's promising development plans for nitazoxanide."*

**Jean-François Mouney, Chairman and CEO of GENFIT** added: *"We are pleased that this trial has been initiated, further contributing to Genfit's pipeline of clinical stage programs. Dr. Harrison is a world-renowned hepatologist and expert in NAFLD and we are delighted that we can collaborate with him and Pinnacle Clinical Research to perform this study in patients with high unmet needs. We very much look forward to seeing the results of this study which, if positive, will enable the further development of nitazoxanide for the treatment of NASH patients both as a monotherapy as well as in combination with elafibranor."*

### 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 PINNACLE CLINICAL RESEARCH

Pinnacle Clinical Research is dedicated to conducting late stage clinical trials in the areas of hepatology and gastroenterology, with a special focus on fatty liver disease. Pinnacle prides itself on conducting high-quality research as a complement to the medical care that its volunteers receive from their routine care center.

### ABOUT GENFIT

GENFIT is a biopharmaceutical company focused on discovering and developing drug candidates and diagnostic solutions targeting liver diseases, in particular those of metabolic origin, and hepatobiliary diseases. GENFIT concentrates its R&D efforts in areas of high unmet medical needs corresponding to a lack of approved treatments. GENFIT's lead proprietary compound,

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elafibranor, is a drug candidate currently being evaluated in one of the most advanced Phase 3 studies worldwide (“RESOLVE-IT”) in nonalcoholic steatohepatitis (NASH), considered by regulatory authorities as a medical emergency because it is silent, with potentially severe consequences, and with a prevalence on the rise. Elafibranor is also being evaluated in a Phase 2 study in Primary Biliary Cholangitis (PBC), a rare liver disease. As part of its comprehensive approach to clinical management of NASH patients, GENFIT is conducting a discovery and development program aimed at providing patients and physicians with a non-invasive blood-based diagnostic test for NASH. With facilities in Lille and Paris, France, and Cambridge, MA (USA), the Company has approximately 150 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 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 from, its ongoing and planned clinical trials, review and approvals by regulatory authorities, such as the FDA or the EMA, of its drug and diagnostic candidates, the success of any inlicensing strategies, the ability of the Company to maintain, protect and enhance its intellectual property rights in nitazoxanide without infringing the rights of other companies, 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 in Section 4 “Main Risks and Uncertainties” of the Company’s 2017 Registration Document registered with the French Autorité des marchés financiers on April 27, 2018 under n° R.18-032, which is available on GENFIT’s website ([www.genfit.com](http://www.genfit.com)) and on the website of the AMF ([www.amf-france.org](http://www.amf-france.org)) and as updated by the 2018 Half Year Business and Financial Report and available on the Investors page of GENFIT’s website. 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.

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### CONTACT

#### **GENFIT** | Investors

Naomi EICHENBAUM - Investor Relations | Tel: +1 (617) 714 5252 | [investors@genfit.com](mailto:investors@genfit.com)

#### **PRESS RELATIONS** | Media

Hélène LAVIN - Press relations | Tel: +333 2016 4000 | [helene.lavin@genfit.com](mailto:helene.lavin@genfit.com)