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GENFIT Launches a Phase 2 Trial Evaluating Elafibranor on Hepatic Lipid Composition for NAFL

- **Study objective to determine the effect of elafibranor, a dual PPAR alpha/delta agonist, on fatty acid saturation**
- **Phase 2 study to evaluate the effect of a 6-week, once daily treatment of elafibranor (120mg) vs. placebo on hepatic lipid composition in patients with Nonalcoholic Fatty Liver (NAFL)**
- **State of the art non invasive techniques (H-MRS) to be used to provide indications on both quantitative and qualitative evolution of liver fat**

Lille (France), Cambridge (Massachusetts, United States), June 04, 2019 – GENFIT (Nasdaq and Euronext: GNFT), a late-stage biopharmaceutical company dedicated to the discovery and development of innovative therapeutic and diagnostic solutions in metabolic and liver related diseases, today announced the launch of a P2 clinical trial evaluating elafibranor's activity on liver fat quantity and – most importantly – fat composition in nonalcoholic fatty liver disease (NAFLD) patients.

NAFLD is a common disorder referring to a condition associated with an accumulation of fat in the liver. Although persistent fat in the liver is common and can remain static, NAFLD is known to be a precursor for a much more serious condition, non-alcoholic steatohepatitis or NASH, which is associated with liver cell damage, inflammation, and scarring of the liver, and potentially severe outcomes including cardiovascular events, cirrhosis, liver failure or liver cancer. The composition of hepatic lipids is altered in NASH, especially in patients with diabetes, where polyunsaturated fatty acids are more prominent and give rise to toxic lipid species, such as ceramides. It is therefore crucial for NASH-targeted drugs to preferentially eliminate lipid species that are substrates for toxic lipid production.

The phase 2 is a randomized, placebo-controlled, double-blind, cross-over study in sixteen patients with NAFL as identified with magnetic resonance spectroscopy (H-MRS). The primary objective will evaluate the effects of treatment with elafibranor (120mg/daily) for 6-weeks vs. placebo on changes in hepatic lipid composition in subjects with fatty liver. Secondary measurements include impact on hepatic glucose production (HGP), glucose homeostasis, lipid metabolism, inflammatory markers and liver function, as well as safety. The trial will be conducted in The Netherlands.

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TOWARDS BETTER MEDICINE

PRESS RELEASE

Elafibranor, a PPAR alpha/delta agonist, is currently the only late-stage, Phase 3 (RESOLVE-IT) therapy undergoing investigation for "NASH resolution without the worsening of fibrosis" (approved regulatory endpoint for Phase 3 trials), and could be the first therapy able to eliminate the underlying cause of NASH disease progression. The results from the P2b GOLDEN trial showed elafibranor's unique ability to address NASH resolution, and beneficial effects on cardiometabolic lipids (LDL decrease, HDL increase, and TG decrease), glucose metabolism (HbA1c, HOMA-IR, FPG, FFA, C-peptide), in addition to a favorable safety and tolerability profile. Therefore, elafibranor's superior, pluripotent mechanism of a PPAR alpha and delta, could be beneficial by improving quantity and quality of fat in the liver, specifically targeting the more harmful, lipotoxic fat subtypes that buildup in NAFLD and drive progression to NASH.

Dean Hum, Chief Operating Officer and Chief Scientific Officer at GENFIT said: "*From GENFIT's twenty years of research, we have seen that the synergistic combination of PPAR alpha and delta results in a pleiotropic impact resulting in benefits for many of the characteristics of NAFL and NASH. The significant benefit is due largely to the pluripotent effects on the disease cascade, including driving on-target liver directed activity at the hepatocyte level, providing increased oxidation of fatty acids, thereby reducing the injury to the liver. The reduction of fat has shown significant benefit in NAFL, and in certain patients, prevents the progression to NASH. Assessing liver fat with non-invasive tools is helpful in understanding the way in which elafibranor's mechanism positively affects the fat composition, specifically, fatty acid saturation.*"

Pr Vlad Ratziu, Hepatologist, Hôpital Universitaire Pitié Salpêtrière, Paris, added: *"One of the greatest challenges for NAFL patients is understanding the underlying drivers that cause progression to NASH. The data GENFIT will generate from this trial will be supportive for defining the relationship between different types of lipids and their roles. MRI-PDFF is an informative tool used to address fat quantity, but is still unable to differentiate between saturated and unsaturated fatty acids, all which produce different pathophysiological outcomes. This is why using H-MRS is important to gain precious insights on the quality of intrahepatic fat. With that said, it's also important to remember that ballooning and inflammation remain the only NASH lesions recognized by regulators in Phase 3 trials."*

ABOUT ELAFIBRANOR

Elafibranor is GENFIT's lead pipeline product candidate. Elafibranor is an oral, once-daily, first-in-class drug acting via dual peroxisome proliferator-activated alpha/delta pathways developed to treat, in particular, nonalcoholic steatohepatitis (NASH), for which it has been granted Fast Track Designation. GENFIT believes, based on clinical results to date, that elafibranor has the potential to address multiple facets of NASH, including inflammation, insulin sensitivity, lipid/metabolic profile, and liver markers. Phase 2 clinical trial results have also shown that elafibranor may be

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PRESS RELEASE

an effective treatment for PBC, a severe liver disease. Elafibranor was granted a Breakthrough Therapy Designation in this indication.

ABOUT NASH

NASH 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 failure, and also progression to liver cancer.

ABOUT GENFIT

GENFIT is a late-stage biopharmaceutical company dedicated to the discovery and development of innovative therapeutic and diagnostic solutions in metabolic and liver related diseases where there are considerable unmet medical needs, corresponding to a lack of approved treatments. GENFIT is a leader in the field of nuclear receptor-based drug discovery with a rich history and strong scientific heritage spanning almost two decades. Its most advanced drug candidate, elafibranor, is currently being evaluated in a pivotal Phase 3 clinical trial ("RESOLVE-IT") as a potential treatment for NASH, and GENFIT plans to initiate a Phase 3 clinical trial in PBC later this year following its positive Phase 2 results. As part of GENFIT's comprehensive approach to clinical management of NASH patients, the company is also developing a new, non-invasive and easy-to-access blood-based *in vitro* diagnostic test to identify patients with NASH who may be appropriate candidates for drug therapy. With facilities in Lille and Paris, France, and Cambridge, MA, USA, the Company has approximately 160 employees. GENFIT is a public company listed on the Nasdaq Global Select Market and in compartment B of Euronext's regulated market in Paris (Nasdaq and Euronext: GNFT). www.genfit.com

FORWARD LOOKING STATEMENTS

This press release contains certain forward-looking statements, including those within the meaning of the Private Securities Litigation Reform Act of 1995, with respect to GENFIT, including the potential benefits of evaluating elafibranor's effect on hepatic fat composition, on the ability of elafibranor to eliminate the underlying cause of NASH disease progression and its potential to be approved for the treatment of NASH and the timing thereof, by regulatory authorities. The use of certain words, including "believe," "potential," "expect" and "will" and similar expressions, is intended to identify forward-looking statements. Although the Company believes its expectations are based on the current expectations and reasonable assumptions of the Company's management, these forward-looking statements are subject to numerous known and

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PRESS RELEASE

unknown 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 safety, biomarkers, progression of, and results from, its ongoing and planned clinical trials, review and approvals by regulatory authorities of its drug and diagnostic candidates and the Company's continued ability to raise capital to fund its development, as well as those risks and uncertainties discussed or identified in the Company's public filings with the French Autorité des marchés financiers ("AMF"), including those listed in Section 4 "Main Risks and Uncertainties" of the Company's 2018 Registration Document filed with the AMF on February 27, 2019 under n° D.19-0078, which is available on GENFIT's website (www.genfit.com) and on the website of the AMF (www.amf-france.org) and public filings and reports filed with the U.S. Securities and Exchange Commission ("SEC"), including the Company's final prospectus dated March 26, 2019, and subsequent filings and reports filed with the AMF or SEC, or otherwise made public, by the Company. In addition, even if the Company's results, performance, financial condition and liquidity, and the development of the industry in which it operates are consistent with such forward-looking statements, they may not be predictive of results or developments in future periods. These forward-looking statements speak only as of the date of publication of this document. Other than as required by applicable law, the Company does not undertake any obligation to update or revise any forward-looking information or statements, whether as a result of new information, future events or otherwise.

CONTACT

GENFIT | Investors

Naomi EICHENBAUM – Investor Relations | Tel: +1 (617) 714 5252 | investors@genfit.com

PRESS RELATIONS | Media

Hélène LAVIN – Press relations | Tel: +333 2016 4000 | helene.lavin@genfit.com