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GENFIT: New Preclinical Data Shows Elafibranor Inhibits Development of NAFLD/NASH-Related Cancer

- **Elafibranor administration prevented liver tumor development in NAFLD/NASH disease models**
- **Elafibranor showed direct cytostatic properties on a large selection of human tumor cell-lines**

Lille (France), Cambridge (Massachusetts, United States), June 27, 2018 – 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 new preclinical results which indicate that elafibranor has anti-tumor development activity in the context of NAFLD/NASH-induced hepatocellular carcinoma (HCC).

It is generally acknowledged that patients with NAFLD/NASH are at an increased risk for developing HCC, the most common primary liver cancer with a corresponding high fatality rate. The prevalence of NAFLD/NASH-related HCC is increasing worldwide and is projected to become the most common type of HCC globally, surpassing viral hepatitis or alcohol-related cirrhosis. Additionally, there have been multiple reports indicating that NASH-induced HCC can occur in non-cirrhotic stages of disease which further stresses the importance of treating NASH at earlier stages. Given the complexity of the disease, it would be highly advantageous for a novel NASH therapeutic to hit on multiple features of the disease pathology including resolving NASH without worsening of fibrosis, promoting cardiovascular protection, and reducing the risk of HCC development.

The effect of elafibranor on liver tumor development was investigated in proof of concept studies in different NASH disease models. The number of neoplastic nodules that developed in mice exposed for several months to a NASH-inducing diet was significantly attenuated in mice that received elafibranor. Furthermore, elafibranor administration in mice that are primed to develop NASH and hepatic tumors, including HCC, prevented the appearance of liver tumors that are characterized by a complete loss of natural liver architecture.

In addition to these *in vivo* studies, elafibranor has previously shown a direct cytostatic effect in 22 human tumor cell lines with a maximum inhibition effect comprised between 41% and 90%.

Sven Francque, MD, PhD, Head of Department, Gastroenterology and Hepatology Antwerp University Hospital, Antwerp, Belgium, commented: "*HCC is a real concern for NASH patients, as it can develop even at pre-cirrhotic stages of the disease. Rates of hepatocellular carcinoma in the U.S. are believed to grow exponentially, which may be – in some cases – attributable to an increasing number of NASH cirrhotoses, but there is also evidence suggesting that NAFLD could lead to hepatic carcinogenesis via an independent mechanism. The annual incidence rate of developing HCC in patients with NASH-related cirrhosis is not clearly understood, with a*



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mean estimated rate of 2.6% but rates up to 12.8% have been reported. Hence it is clear that it is crucial to find drugs addressing this high unmet need.”

Dean Hum, Deputy CEO and Chief Scientific Officer of GENFIT, added: *“These results open new perspectives to evaluate elafibranor in the context of reducing risk of developing HCC liver cancer while concomitantly treating NASH. Although NAFLD/NASH cirrhosis is an independent risk factor for the development of HCC, patients with non-cirrhotic NASH also have elevated risk for the development of HCC as compared to patients with NAFL, or isolated steatosis.”*

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 HCC

Hepatocellular carcinoma (HCC) is the most common primary liver cancer with high fatality rate. Patients with NAFLD/NASH are at an increased risk for HCC and the prevalence of NAFLD/NASH-related HCC is increasing worldwide following the trend of the NAFLD/NASH epidemic. Currently, hepatitis C is the most common risk factor for HCC in the Western world. However, NAFLD/NASH is projected to become the most common risk factor for HCC globally, surpassing viral hepatitis.

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 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 gastrointestinal 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

FORWARD LOOKING STATEMENT / DISCLAIMER



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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 and the trial of elafibranor in PBC, 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 drug candidates in other indications and biomarkers candidates, 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 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) 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.

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