



PRESS RELEASE

GENFIT: New data to be presented at 2018 AASLD meeting, ahead of key results expected in 2018 and 2019

- **KOL event to be held ahead of expected data release with elafibranor in PBC by end of 2018 (Phase 2) and in NASH end of 2019 (Phase 3)**
- **Confirmation of the diagnostic performance of NIS4 algorithm in identifying NASH patients eligible to therapeutic intervention**
- **Elafibranor's potential as cornerstone drug in combination therapies for NASH confirmed with new data**
- **New data indicating elafibranor's potential in treating hepatic cancer (HCC)**
- **Bioinformatics approaches based on deep learning methods paving the way for automatization of histological NASH diagnosis**

Lille (France), Cambridge (Massachusetts, United States), October 2, 2018 – GENFIT (Euronext: GNFT - ISIN: FR0004163111), 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 today announces its participation in *The Liver Meeting*[®], the annual meeting of the American Association for the Study of Liver Diseases (AASLD) in San Francisco, November 9-13, 2018. Abstracts are available on the meeting's website. *The Liver Meeting*[®] is one of the most important congresses organized for the medical and scientific community specializing in hepatology worldwide. It brings together more than 10,000 scientists, gastroenterologists and hepatologists.

Update on NASH landscape

The 2018 edition of AASLD comes after the recent publication of a number of early-stage clinical study results, and importantly ahead of 2019, expected to bring significant catalysts in the NASH space. To date, only three programs globally have finalized the enrollment of their Phase 3 cohorts in NASH (Subpart H), paving the way for first late stage data readouts in 2019. GENFIT's elafibranor is one of the aforementioned programs having the potential to be part of a first set of marketing approvals to offer clinicians the first therapeutic solutions for treating NASH (other molecules may follow only a few years later). It is also ideally positioned to potentially cover the widest spectrum of NASH patients, based on compelling Phase 2 data (*Ratziu et al., Gastroenterology, 2016*) that have shown elafibranor's potential to combine:



PRESS RELEASE

- Efficacy on “NASH resolution without worsening of fibrosis” (26% vs 5%; p-value 0,02), the biopsy-based regulatory endpoint for market approval that addresses the underlying cause of disease progression;
- Beneficial cardiovascular profile (LDL, TG, HDL, insulin resistance), known to be crucial for NASH patients;
- Clean safety and tolerability, essential for a chronic and silent condition like NASH.

Ahead of next year’s data readout in NASH with elafibranor, GENFIT is expected to make several announcements over the next few months in the field of PBC, NASH and fibrosis:

- Elafibranor Phase 2 data readout in PBC by year end 2018;
- Launch of a Phase 2 proof of concept study of nitazoxanide in NASH fibrosis;
- Enrollment of the first pediatric NASH patient: elafibranor is the first and only molecule to be evaluated in pediatric NASH after having shown safety and efficacy in a Phase 2 trial on adult NASH patients;
- Regulatory and commercial development milestones of the In Vitro Diagnostic test aimed at identifying NASH patients to be considered for treatment.

Events during AASLD

Prior to the new Phase 2 clinical data for elafibranor in PBC by year end 2018, GENFIT will hold a NASH/PBC *KOL Meeting* during AASLD, providing financial analysts and institutional investors a unique opportunity to understand how medical and scientific opinion leaders approach the challenges posed by these diseases and how they evaluate the potential of diagnostic and therapeutic solutions currently under development.

GENFIT will continue to engage with key stakeholders in order to move forward with the set up of its first Market Access Advisory Board that will be held in January next year. Early payer research already points to the strong differentiation of elafibranor.

Following the success of the 1st International NASH Day, GENFIT will host the first steering committee aimed at preparing the 2019 edition. It will be organized together with learned societies and patients associations who are expected to play an increasingly important leadership role. Feedback from the satisfaction survey run over the summer will help further increase the scale of the next edition.

From November 10 to 12, GENFIT will be present at the “Moscone North and South Convention Center” exhibition hall, allowing all scientific and medical staff attending the event to keep informed on the ongoing R&D programs. The institutional booth #635 and The NASH Education Program booth #244 will welcome meeting attendees.

New data presented during the Liver Meeting:

- **NASH Diagnostic: oral presentation, Sunday, November 11**

The NIS-4 algorithm – non-invasive score combining circulating levels of miR-34a, Alpha2-macroglobulin, YKL-40 and HBA1c – is confirmed as a powerful NASH diagnostic tool to identify patients with active NASH (NAS \geq 4) and significant fibrosis (F \geq 2) irrespective of patient sex, age, obesity or type of diabetes.



PRESS RELEASE

"NIS4 for the detection of active NASH (NAS \geq 4) and significant fibrosis (F \geq 2) in 714 patients at risk of NASH: diagnostic metrics are not affected by age, sex, presence of type 2 diabetes or obesity", R. Hanf et al. (Abstract 142)

- **Treatment with elafibranor: "Poster of distinction" and poster, Friday, November 9**

New anti-NASH treatment combinations, using elafibranor – "first-in-class" PPAR alpha and delta receptor agonist – as backbone, were studied in *in vitro* and *in vivo* NASH models, associating it with an acetyl-CoA carboxylase inhibitor. A complementary and synergistic action was observed on fatty acid catabolism accompanied by resolution of liver steatosis. In addition, elafibranor counteracted the ACC inhibitor-induced hypertriglyceridemia.

"Elafibranor synergizes with ACC inhibitors to enhance fatty acid catabolism and reduce steatosis in the liver of a NASH model", V. Legry et al. (Abstract 732)

As NASH is projected to become the most common risk factor for HCC, this *in vivo* study has shown that preneoplastic lesion development was prevented to a significant extent upon elafibranor treatment in rodent model. In addition, elafibranor directly reduced tumor cell proliferation.

"Elafibranor administration prevents liver tumor development in mouse models of NASH", P. Parroche et al. (Abstract 737)

- **NASH diagnosis through deep learning: Poster, Saturday, November 10**

The study has shown that scoring systems based on deep-learning methods showed similar results as with human evaluation which could facilitate the analysis of preclinical and, in the future, clinical NASH patients' biopsies. GENFIT's technology could also assist experts in better interpreting certain specific regions of cells in histological samples that are difficult to interpret.

"A rapid and reproducible quantification of ballooning and inflammation using a deep-learning approach and comparison with manual scoring", E. Perspicace et al. (Abstract 1298)

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) and Primary Biliary Cholangitis (PBC). Elafibranor is believed to address multiple facets of NASH, including inflammation, insulin sensitivity, lipid/metabolic profile, and liver markers. Elafibranor also presents a particularly interesting profile to potentially treat PBC, a rare liver disease.

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.



PRESS RELEASE

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 discovering and developing drug candidates and diagnostic solutions targeting liver diseases, in particular those of metabolic origin, and hepatobiliary diseases. GENFIT’s concentrates its R&D efforts in areas of high unmet medical needs corresponding to a lack of approved treatments. GENFIT’s lead proprietary compound, 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. It is also 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 an ambitious discovery and development program aimed at providing patients and physicians with a blood-based test for the diagnosis of NASH, i.e. non-invasive and easy-to-access. 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

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) 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



PRESS RELEASE

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 | +333 2016 4000

PRESS RELATIONS | Bruno Arabian – Ulysse Communication | +336 8788 4726