



# **GENFIT Announces New Data to be Presented at AASLD Liver Meeting 2019**

- Presentations include new data on NIS4's<sup>1</sup> diagnostic performance in the diabetic population and synergies between elafibranor<sup>2</sup> and nitazoxanide (NTZ), and a GLP1
- Engaging with KOLs via a PBC Investigator meeting and an Advisory Board on NIS4,
  GENFIT's investigational blood based diagnostic test
- Analyst and Investor KOL luncheon scheduled at AASLD

**Lille (France), Cambridge (Massachusetts, United States), October 31, 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 multiple upcoming presentations at *The Liver Meeting*®, the annual meeting of the American Association for the Study of Liver Diseases (AASLD) to be convened in Boston, MA, November 8 -12, 2019.

The Liver Meeting® is one of the most important hepatology congresses for the medical and scientific community. It brings together more than 10,000 scientists, gastroenterologists and hepatologists from around the world.

#### **Posters and Presentations**

Presentations will include a poster on NIS4, GENFIT's innovative, non-invasive diagnostic blood test to identify individuals with NASH and fibrosis ( $F \ge 2$ ; NAS  $\ge 4$ ), specifically on test performance in the diabetic population. In addition, two posters will be presented demonstrating synergistic efficacy of elafibranor in combination with nitazoxanide (NTZ) and in combination with semaglutide.

**Title:** Type 2 diabetes as a risk factor for NASH and fibrosis in a cohort of 2363 patients with suspicion of NAFLD: use of NIS4 for identification of at-risk NASH in diabetic patients

**Poster:** # 1757

**Author/s:** R. Hanf et al.

**Display:** Sunday November 10 – all day **Presentation:** From 12:30pm to 1:30 pm

<sup>&</sup>lt;sup>1</sup> NIS4 is not currently approved as an *in vitro* diagnostic test (IVD). NIS4 has been licensed to LabCorp for use as a laboratory developed test (LDT) for patients in clinical trials.

<sup>&</sup>lt;sup>2</sup> Elafibranor is currently investigational and not approved for any indication.





Title: Elafibranor and nitazoxanide have complementary actions to protect against oxidative stress in

NASH

**Poster:** # 2227

Author/s: C. Foucart et al.

**Display:** Monday November 11 – all day **Presentation:** From 12:30pm to 1:30 pm

Title: Elafibranor synergizes with semaglutide to reduce liver steatosis in a model of NASH

**Poster:** #2198

Author/s: V. Legry et al.

**Display:** Monday November 11 – all day **Presentation:** From 12:30pm to 1:30 pm

Abstracts are available on the meeting's website.

#### **Key events**

November 11, 2019: GENFIT will host an **investor and analyst luncheon** discussing the medical community's approach to challenges in NASH and PBC, with a focus on both therapeutics and diagnosis. Key speakers will include Dr Stephen Harrison, MD, Hepatologist, Medical Director of Pinnacle Clinical Research, San Antonio, TX, (USA) and Dr. Jörn Schattenberg, MD, Division of Gastroenterology and Hepatology, University Medical Center, Mainz (Germany). New insights on the NASH market opportunity, derived from independent market research conducted by IQVIA in 2019 will also be shared by Andy Wong, Senior Principal at IQVIA. The investor and analyst luncheon will be available via **webcast**. Institutional investors and analysts may RSVP to genfit@troutgroup.com.

Throughout the congress, GENFIT will also engage with key medical stakeholders to continue driving the strategic development of GENFIT's programs:

- A **NIS4 Advisory Board** will be conducted to gain valuable insights through dialog and debate on the future of NASH diagnosis with a diverse panel of clinical experts in the field. NIS4 is a validated diagnostic test not yet approved by the FDA, and it is available only for use in clinical research at this time through a partnership with Covance, a subsidiary of LabCorp®. GENFIT expects to file for regulatory approval in 2020, with the objective of providing a simple, non-invasive and cost-effective diagnostic tool to healthcare providers involved in the clinical management of patients with NASH.
- A PBC Investigator Meeting will be chaired by Dr. Jörn Schattenberg, MD, Division of Gastroenterology and Hepatology, University Medical Center, Mainz (Germany), and Dr. Kris V. Kowdley, MD Director, Liver Care Network and Organ Care Research, Swedish Medical Center, Seattle, WA, ahead of the Phase 3 study, which is expected to start early next year.

#### **Booth**





From November 9 to 11, GENFIT team members will be available for further information regarding the ongoing R&D programs. Two booths will co-exist in the Hynes Convention Center – Hall C: **#209** (Genfit Corporate) and **#114** (NIS4 Diagnostic Test).

For more information please visit the AASLD Annual Meeting website (<a href="https://www.aasld.org/event/liver-meeting">https://www.aasld.org/event/liver-meeting</a>) or please contact GENFIT Investor and Media departments.

#### **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 by FDA. 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 an effective treatment for PBC, a chronic liver disease. Elafibranor was granted a Breakthrough Therapy Designation by FDA in this indication.

#### **ABOUT NIS4**

GENFIT is developing an *in vitro* diagnostic (IVD) test to identify patients with NASH and fibrosis  $(F \ge 2, NAS \ge 4)$ , who are the focus of current NASH clinical trials. The NIS4 program is based on the inhouse discovery of a 4-biomarker algorithm and is currently pursuing commercialization of this test which aims to be a validated alternative to the liver biopsy. In January, 2019, GENFIT signed a licensing agreement with LabCorp® to roll out the diagnostic kit in the clinical research field, and plans to file NIS4 for formal marketing approval with the FDA in 2020.

#### **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 insufficiency, and also potential progression to liver cancer.

#### **ABOUT PBC**

Primary biliary cholangitis (PBC) is a chronic, autoimmune 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. Elafibranor has shown promising results for the treatment of PBC in a Phase 2 clinical trial and was granted the Breakthrough Therapy Designation by the FDA in this indication.

#### **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 next year following its positive Phase 2 results. As part of GENFIT's comprehensive approach to clinical management of patients with NASH, 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 200 employees. GENFIT is a publically traded 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 statements about the company's expectations for NIS4 regulatory filing submission and potential to provide a simple, non-invasive and cost-effective diagnostic tool to all healthcare providers involved in the clinical management of NASH patients, as well as the timing of the start of the Phase 3 trial of elafibranor in PBC. 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 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 no 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.

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