



PRESS RELEASE

GENFIT announces the acceptance of two new abstracts, including one to be presented in an oral session at the 2016 AASLD meeting

- › **Two new late-breaking abstracts accepted by AASLD**
- › **Two new data sets (i) validating importance of miRNAs as relevant targets for diagnosis of NASH patients eligible for treatment and (ii) demonstrating high correlation between histological activity of NASH and progression of fibrosis**
- › **Organization of a scientific advisory board on fibrotic diseases, with the support of international experts in the field**

Lille (France), Cambridge (Massachusetts, United States), October 20th, 2016 – 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 the acceptance of two new abstracts at the annual AASLD meeting (“The Liver Meeting” Boston, November 11-15, 2016), through an oral abstract presentation and a poster, respectively. GENFIT also announced, in addition to the analyst and investor event in which four international experts will participate, that it will organize a scientific advisory board on fibrotic diseases presided by Dr. Scott Friedman, Chief of the Division of Liver Diseases at Mount Sinai School of Medicine and widely viewed as one of the leading experts in fibrotic disease in the world.

The Liver Meeting organized by the AASLD is one of the most important meetings organized by – and for – the scientific and medical community specialized in hepatology worldwide. It brings together more than 10,000 scientists, gastroenterologists and hepatologists.

The AASLD has accepted two additional late-breaking GENFIT abstracts. One abstract will be presented in an oral session and will showcase the importance of biomarkers as relevant targets for the diagnosis of NASH patients eligible for treatment, in particular through the predictive power of miRNA-34a and miRNA-122. A second abstract, presented as a poster, will highlight the importance of treating the histological parameters of NASH, and more precisely necro-inflammation (ballooning and inflammation), in the regression of fibrosis. A total of five abstracts were proposed by GENFIT and accepted by the AASLD committee.

- **Poster: Sunday, November 13**
“Improvement in NASH histological activity highly correlates with fibrosis regression”, V. Ratziu *et al.* (Abstract LB-37)
- **Oral session: Monday, November 14, 3:15pm -3:30pm**



PRESS RELEASE

“Validation of mir-34a, mir-122 and mir-200a as biomarkers for identification of NASH patients eligible for treatment”, S. Francque *et al.* (Abstract LB-2)

As a reminder, three other posters were accepted by the AASLD and will be presented during the meeting:

- **Friday, November 11**

“Assessment of serum levels of Chitinase-3-like protein 1 (CHI3L1) improves identification of the NASH patients at risk who should be treated”, A. Sanyal *et al.* (Abstract 658)

- **Saturday, November 12**

“ALT as a non-invasive biomarker of histological response to pharmacotherapy in NASH patients: insights from the elafibranor GOLDEN-505 trial”, V. Ratziu *et al.* (Abstract 1154)

- **Sunday, November 13**

“Comparison of liver pathology in three rodent NASH models to that observed in human NASH patients”, F. Texier *et al.* (Abstract 1598)

Update on GENFIT participation at the 2016 AASLD Annual Meeting:

Elafibranor is currently being evaluated in the RESOLVE-IT Phase 3 clinical study, but the annual meeting of the AASLD will provide an opportunity to shed some light on new data derived from the GOLDEN-505 Phase 2 trial. It will also highlight the potential of promising non-invasive biomarkers identified by GENFIT to improve the identification of NASH patients eligible for treatment.

On this occasion, GENFIT will host three events:

- An analyst and investor event, with the participation of four international experts:
 - o Dr. Vlad Ratziu, France, and Stephen A. Harrison, USA, members of the international steering committee of the RESOLVE-IT Phase 3 clinical study in NASH
 - o Dr. Joe Levine, USA, international expert in pediatric NASH
 - o Dr. Velimir Luketic, USA, international expert in PBC (Primary Biliary Cholangitis)
- A scientific advisory board dedicated to biomarkers in NASH. The purpose of this meeting of experts will be to understand and define the current and future medical needs in diagnosis and screening. This includes laying the groundwork for better treatment of at-risk patients, allowing, for example, the identification of the best registration paths to bring GENFIT’s proprietary diagnostic tools, based on measurement of levels of circulating miRNAs, to market.
- A scientific advisory board on fibrosis with Dr. Scott L. Friedman to continue the strategic discussions already engaged on preclinical and clinical development of the anti-fibrotic drug candidates in GENFIT’s pipeline



PRESS RELEASE

In addition,

- GENFIT will host a booth (#335) in the exhibitor hall of the John B. Hynes Veterans Memorial Convention Center; and
- Sophie Mégnien, CMO of GENFIT, will co-chair a working group of the Liver Forum, which aims to optimize drug development for the treatment of NASH patients in collaboration with regulatory agencies, learned societies, as well as academic and industry stakeholders.

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 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 gastro-intestinal 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, France, and Cambridge, MA (USA), the Company has approximately 110 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



PRESS RELEASE

trial, review and approvals by regulatory authorities, such as the FDA or the EMA, regarding in particular, elafibanor in NASH and PBC, as well as other indications, and biomarkers, 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 under Section 7 "Main Risks and Uncertainties" of the Company's Half Year 2016 Business and Financial Report, 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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