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### **GENFIT: Contributing Significantly to the European LITMUS Initiative on NASH Biomarkers**

- GENFIT significantly contributes to LITMUS (The “Liver Investigation: Testing Marker Utility in Steatohepatitis” consortium), by the provision of its high value phase 3 clinical trial samples in NASH
- GENFIT will co-lead working groups in two of the predefined work packages, starting at the LITMUS consortium kickoff on November 28-29. GENFIT will also serve as a member of the LITMUS Project Executive Committee.
- Participation in LITMUS offers GENFIT the potential to collaborate in scientific publications, increasing the visibility of its biomarker program (in development phase since June 2017)
- LITMUS is a key partner for GENFIT to further explore a broader list of key questions, leveraging data from a large number of patient cohorts

**Lille (France), Cambridge (Massachusetts, United States), November 27, 2017** – 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 disclosed details on the role it will play in the €34 million European LITMUS initiative funded by the European Innovative Medicines Initiative 2 (IMI2) Joint Undertaking.

LITMUS (The Liver Investigation: Testing Marker Utility in Steatohepatitis) is a European consortium that brings together clinicians and scientists from prominent academic centers across Europe with companies from the European Federation of Pharmaceutical Industries and Associations (EFPIA) that are working in the field of the NAFLD/NASH diagnosis. The aim of this pioneering European research project is to lead to new diagnostic tests to assess patients with Non-Alcoholic Fatty Liver Disease (NAFLD) and identify those most at risk for developing severe inflammation and liver scarring. The common goals of the 47 international research partners included in LITMUS are developing, validating and qualifying better biomarkers for testing NAFLD.

#### **GENFIT at the forefront of biomarker discovery**

As a major player in NASH, committed to the development of a comprehensive approach to clinical management of NASH patients, GENFIT already leads an ambitious discovery and development program aimed at providing patients and physicians with a non-invasive and easy-to-access blood-based test for the diagnosis of NASH. This *In Vitro* Diagnostic test entered into development phase in June 2017, and is expected to be in the market in 2020/2021.



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Non-invasive and blood-based, this diagnostic test will avoid known risks and limitations of biopsy in addition to giving access for diagnostic of NASH at risk of progression to the vast majority of patients, up to primary care level.

Based on a discovery program identifying circulating miRNAs as potential biomarker for NASH and fibrosis in two independent cohorts of patients (Professor Sven Francque, LBP-535, EASL 2017) GENFIT has recently presented data on the identification of a simple diagnostic score to identify NASH patients to be treated (Professor Stephen A. Harrison, LBP- 534, EASL 2017).

The unique signature and calculated score combining miR-34a and 3 independent biomarkers has been identified using advanced biostatistics approaches and validated, in samples from different cohorts, including patients screened for enrollment in RESOLVE-IT Phase 3 study.

Based on this data, GENFIT is confident to translate in the coming years this diagnostic score into an FDA-cleared, CE-marked IVD test to answer different medical needs, at different steps of the patient journey, allowing healthcare professionals to support their diagnosis.

### **GENFIT in LITMUS**

Although already engaged in one of the most advanced industrial program in the field of NASH biomarkers, GENFIT recognizes the value of pan-industry approaches to widen its research scope and expand its collaboration programs. GENFIT also wishes to share its experience, for the benefit of the whole space, especially patients and physicians.

GENFIT will therefore bring a unique contribution by providing LITMUS its RESOLVE-IT drug clinical trial samples.

GENFIT will also be the co-lead in two predefined LITMUS work-packages:

- **Patient Cohorts & Bioresources**, with a special focus on **Recruitment/Registry**
- **Specialized Biomarker Assays**, with a special focus on **Genetics/miRNA**

and will be a member of the LITMUS Project Executive Committee.

Importantly, LITMUS, particularly with its large longitudinal cohorts, will be an extraordinary opportunity to further demonstrate clinical performance of GENFIT diagnostic solution, accelerating clinical adoption by the medical community through production of scientific publications and increased visibility.

**Professor Quentin Anstee, of the Institute of Cellular Medicine, Newcastle University, UK is coordinator of the LITMUS consortium;** he commented: *"NAFLD/NASH is considered as one of the biggest epidemics of the 21<sup>st</sup> century. However, no easy nor accurate test is available at this point in time to diagnose NASH patients at risk of developing the most severe forms of the disease. LITMUS is uniting clinicians, academic experts and leading pharmaceutical companies to tackle the challenge of NAFLD diagnostics. With their Phase 3 clinical trial in NASH (RESOLVE-IT) actively recruiting, GENFIT have one of the more advanced drug development programs in the field so, I'm*



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*thrilled to have the company participating in this initiative. GENFIT will contribute to our work by sharing its experience as well as its key clinical samples and data, which will help the LITMUS consortium to progress.”*

**Jean-François Mouney, Chairman & CEO of GENFIT**, added: *“Thanks to its outstanding position within the LITMUS initiative, GENFIT will reinforce its leadership as one of the most advanced biopharma company in the field of NASH diagnosis. As an active contributor to the LITMUS initiative, GENFIT will be able to ideally prepare for future discussions with the FDA and regulatory bodies for clearance of new IVD tools and with payers for reimbursement.”*

### **ABOUT LITMUS AND THE INNOVATIVE MEDICINES INITIATIVE (IMI)**

Liver Investigation: Testing Marker Utility in Steatohepatitis (LITMUS) is funded by the European Innovative Medicines Initiative 2 Joint Undertaking (Grant Agreement No.777377) and is a public-private partnership between the European Union and the European pharmaceutical industry (via the EFPIA). This Joint Undertaking receives support from the European Union’s Horizon 2020 research and innovation programme and EFPIA. For more information please visit the IMI website: [www.imi.europa.eu](http://www.imi.europa.eu).

### **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 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



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public company listed in compartment B of Euronext's regulated market in Paris (Euronext: GNFT - ISIN: FR0004163111). [www.genfit.com](http://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 in-licensing 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 Chapter 7 of the 2017 Half Year Business and Financial Report and under Section 4 "Main Risks and Uncertainties" of the Company's 2016 Registration Document registered with the French Autorité des Marchés Financiers on April 28, 2017 under n° R.17-034, which is available on GENFIT's website ([www.genfit.com](http://www.genfit.com)) and on the website of the AMF ([www.amf-france.org](http://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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