



PRESS RELEASE

GENFIT: Significant Milestones Achieved under a New Qualification Program of Proprietary miRNAs and Algorithms for a Non-invasive NASH Diagnostic

- **Launch of a large scale qualification program for a proprietary non-invasive NASH diagnostic based on miRNAs, with a first collaboration agreement signed with Pr. Sven Francque from the Antwerp University Hospital**
- **Validation, with the independent cohort of Pr. Francque, of miRNAs discovered in H2 2015 using the GOLDEN-505 cohort**
- **Discovery, at the same time, of a new set of highly predictive miRNAs (detailed results will be presented by the end of 2016)**

Lille (France), Cambridge (Massachusetts, United States), September 20, 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 launch of a large scale validation and qualification program for non-invasive NASH diagnostic and longitudinal patient follow-up based on proprietary miRNAs and algorithms.

MicroRNAs (miRNAs) represent a class of small non-coding RNAs whose principal role is to control essential biological functions by modulating expression of target genes. They are emerging players in the understanding of the development of chronic diseases. Their differential expression in disease states and their stability in biological fluids make them ideal candidates in the search of circulating biomarkers of NASH.

As part of a newly launched qualification program dedicated to proprietary miRNAs and associated algorithms for a non-invasive diagnostic of NASH, GENFIT announced the signature of a long-term collaboration with Pr. Sven Francque, MD, PhD, Professor of Hepatology, Head of the Department of Gastroenterology and Hepatology, Antwerp University Hospital, Belgium.

This first agreement is the initial milestone of a large program that will involve multiple expert hepatology clinics across Europe and in the USA. Ultimately, the level of circulating miRNAs will be measured in thousands of NAFLD patients (NASH and non-NASH), and their performance in the diagnosis of liver lesions – as well as their evolution – will be qualified in different medical and operational contexts.

Under the agreement with the Antwerp University Hospital, GENFIT has access to a new cohort of obese patients with associated liver biopsies and blood samples. First analyses have validated the predictive value of miRNAs previously identified by GENFIT as biomarkers of NASH.



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In parallel, GENFIT has identified a new set of miRNAs with high predictive value for identification of NASH patients to be treated. Validation of these new miRNAs in the Antwerp cohort should be obtained by the end of 2016.

Together, these milestones demonstrate the ability of GENFIT to develop a non-invasive diagnostic test. The ultimate purpose of this approach is to facilitate the identification of NASH patients to be treated. From a commercial perspective, these discoveries are intended to unlock the NASH market potential.

About the Antwerp University Hospital cohort

The Antwerp University cohort includes obese patients (NASH and non-NASH). Some patients have undergone bariatric surgery (stomach and/or intestines) in order to limit food absorption and consequently diminish daily caloric intake. For all patients, a liver biopsy was made and blood samples were collected and stored. For some patients, a second liver biopsy and new blood tests were made a year later, in order to evaluate changes in liver histology.

Under the agreement, GENFIT will not only have access to samples for miRNA quantification, but also to all patient-related information: anthropometry, medical history, clinical and biochemical exams, histologic scores for NASH (steatosis, inflammation, ballooning) and fibrosis, at the time of surgery as well as a year later.

As required by regulations, all patients have given prior consent, and all information provided to GENFIT is anonymized.

Jean-François Mouney, CEO, Co-founder, and Chairman of the board of GENFIT, commented: *“MiRNAs quantification methods developed by GENFIT and applied to GOLDEN samples have demonstrated the superiority of circulating miRNAs for diagnosing NASH, in comparison with other more conventional biomarkers. We now enter into an essential large scale validation and qualification phase for proprietary miRNAs and algorithms. Tools we develop will ultimately allow us to quickly identify patients who need to be treated, without any invasive liver biopsy.”*

Pr. Sven Francque, MD, PhD, Professor of Hepatology, Head of the Department of Gastroenterology and Hepatology, Antwerp University Hospital, Antwerp, Belgium commented: *“The strong prevalence of NASH, especially in the U.S. and in Europe, is closely related to the obesity epidemic. Banked samples from morbidly obese patient cohorts are therefore extremely useful to search and validate new diagnostic biomarkers for NASH. They also allow the validation of these biomarkers for monitoring the evolution of the disease.”*



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About Elafibranor

Elafibranor (GFT505) 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 to treat 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 (GFT505), completed a Phase 2b study in NASH and is currently in a Phase 3 study. With facilities in Lille, France, and Cambridge, MA (USA), the Company has approximately 100 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, results of clinical data from the RESOLVE-IT trial, 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 indications, and biomarkers, the success of any inlicensing



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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 4 "Risk Factors" ("Facteurs de Risque") of the Company's 2015 Registration Document registered with the French market authority (AMF) on June 29, 2016 under n° R.16-062, 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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