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Press release

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GENFIT ANNOUNCES POSITIVE RESULTS FROM PROPRIETARY NASH BIOMARKER PROGRAM

- **GENFIT has designed a diagnostic tool – as an alternative to invasive liver biopsy – to identify NASH patients that deserve to be treated, according to the consensual definition agreed between experts and regulatory agencies.**

- **The diagnostic tool requires a simple blood sample and is based on algorithms including a new type of NASH biomarkers: circulating miRNAs.**

- **GENFIT has filed new patents and is building up a partnering program to make a diagnosis kit available at the time of commercialization of anti-NASH drugs.**

Lille (France), Boston (Massachusetts, United States), September 15th, 2015 – 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 announces the development of a new reliable and non-invasive diagnostic method, based on the measurement of a novel type of blood biomarker: small non-coding RNA, or miRNA. The algorithm developed enables the identification of NASH patients that should be treated with Elafibranor (GFT505) or any other appropriate drug.

In terms of public health, the management of the NASH epidemic is a priority. However, NASH is currently under-diagnosed since: i) NASH is a silent, asymptomatic disease, ii) NASH diagnosis necessitates an invasive procedure, the liver biopsy, that can only be performed by an experienced person, iii) there is currently no approved medicine for this indication.

The efficient management of the NASH patient population thus requires new, non-invasive, diagnostic tools, that are simple, rapid, reliable, and can be widely distributed, in order to screen and detect NASH patients that should be treated.

GENFIT has launched an R&D initiative in the field of NASH diagnosis biomarkers based on its expertise in transcriptomics applied to small circulating non-coding RNAs, in particular miRNA.

GENFIT has constituted a large bank of plasma samples from NASH patients with a liver biopsy. This patient cohort is extremely well-characterized (complete anthropometric and biochemical data, centralized biopsy reading), and covers a wide spectrum of NASH disease activity and severity.

After developing and validating a reliable method for the systematic measurement of different miRNAs in the plasma, GENFIT has introduced these measurements into the data set and challenged their diagnostic values versus over 70 variables using two independent biostatistical approaches. Two methods were used to generate thousands of cohorts from the initial patient population in order to mimic real-life NASH variability and assure the translatability of the results to the global NAFLD/NASH population. These parallel approaches independently identified the same two specific miRNA species within the top 3 most powerful diagnostic markers of NASH. The two resulting algorithms combine the identified miRNAs and known markers of liver damage. A comparative study demonstrates that these algorithms are more powerful than existing scoring systems for the identification of NASH patients that deserve to be treated. New patent applications have been filed for the use of the technologies developed by GENFIT for the diagnosis of NASH.

A new proprietary diagnostic tool will be used in the Phase 3 trial for Elafibranor. Moreover, GENFIT has established international scientific collaborations to widen its use in multiple cohorts of NASH patients. Finally, GENFIT is open to partnerships with NASH and/or diagnostic stakeholder companies with the objective of providing an FDA/EMA-approved NASH diagnosis kit available at the time of drug commercialization.

Jean-François Mouney, Chairman and Chief Executive Officer of GENFIT, declared: «*For several years now, GENFIT has established an integrated R&D strategy in NASH based on the parallel development of a non-invasive diagnostic test and on the development of Elafibranor as a first-line medicine. After the recent demonstration of the efficacy of Elafibranor for NASH treatment, today we are announcing a new success in the NASH diagnostics field. We are thus ideally positioned to meet the future medical and public health challenges linked to the identification and management of millions of NASH patients.*»

Professor Arun Sanyal, Division of Gastroenterology, Hepatology and Nutrition, Virginia Commonwealth University School of Medicine, Richmond, VA, commented: «*Circulating miRNAs undeniably represent a new research domain for the development of novel diagnostic methods in numerous chronic diseases and cancers. GENFIT's algorithmic approach combining the levels of specific miRNAs with other known markers of liver damage is extremely promising. The results provide the proof of the added value of miRNAs as diagnostic markers in NASH. They open the way to the development of a new type of non-invasive diagnostic test for NASH.*»

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Professor Sven Francque, Division of Gastroenterology and Hepatology, University Hospital of Antwerp, Belgium, added: «*In parallel with the growing awareness of the major public health problem associated with the NASH epidemic, we see an increasing number of NASH patients in our Gastroenterology and Hepatology department. However, these patients only represent a small fraction of the sick population with NASH that is in need of medical care and follow-up. It is clear that there is an urgent need for a simple, reliable, non-invasive test to be made available to the entire medical profession, to enable the detection of NASH patients in at-risk populations (diabetes, obesity, or metabolic syndrome). There is no doubt that the data obtained by GENFIT raises the hope of rapidly obtaining such a diagnostic tool.*»

About GENFIT:

GENFIT is a biopharmaceutical company focused on the Discovery and Development of drug candidates in fields of high medical need due to a lack of suitable treatment and an increasing number of patients worldwide. GENFIT's R&D efforts are focused on contributing to bringing new medicines to market for patients with metabolic, inflammatory, autoimmune and fibrotic diseases, that affect the liver (such as NASH - Nonalcoholic steatohepatitis) or the bowel (such as the inflammatory bowel disease). GENFIT implements mutually beneficial approaches that combine novel treatments and biomarkers; its research programs have resulted in the creation of a rich and diversified pipeline of drug candidates, including GENFIT's lead proprietary compound, GFT505/Elafibranor, that has completed a positive Phase 2b study in NASH and is currently launching a Phase 3 study. With facilities in Lille, France, and Boston, MA (USA), the Company has approximately 90 employees. GENFIT is a public company listed in compartment B of Euronext's regulated market in Paris (Euronext: GNFT; ISIN: FR0004163111). www.genfit.com

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 anticipated. For a discussion of risks and uncertainties which could cause the Company's actual results, financial condition, performance or achievements to differ from those contained in the forward-looking statements, please refer to the Risk Factors ("Facteurs de Risque") section of the Listing Prospectus upon the admission of Company's shares for trading on the regulated market Euronext of Euronext Paris filed with the AMF, which is available on the AMF website (www.amf-france.org) or on GENFIT's website (www.genfit.com).
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