PRESS RELEASE

# GENFIT Reaches a Critical Milestone towards the Development of a Non-Invasive In Vitro Diagnostic (IVD) Test for NASH

- **Completion of the NASH biomarker program feasibility phase, after confirmation of the competitive performance of an miRNA-based signature using independent patient data from the Phase 3 RESOLVE-IT trial**

- **Launch of the next phase, for the development of a new non-invasive In Vitro Diagnostic (IVD) test aimed at identifying NASH patients eligible for treatment**

- **Expansion of a collaboration program for validation of diagnostic solutions in different intended uses**

**Lille (France), Cambridge (Massachusetts, United States), June 23, 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 announced that having successfully completed the critical feasibility milestone in its NASH diagnostics program using biomarkers, it will be moving into the next industrial development phase with its in vitro diagnostic (IVD) test, the goal being to develop an FDA-cleared and CE-marked IVD solution for NASH.

Using a pretreatment dataset of the Phase 3 RESOLVE-IT study, after the screening of the first 500 patients, new results confirm the diagnostic potential of circulating microRNAs and the relevance of GENFIT's signature to identify patients with active NASH (NAS≥4) and significant fibrosis (F≥2), i.e. patients who should be treated:

- A new Next Generation Sequencing (NGS) experiment validates the diagnostic value of 13 circulating microRNAs, previously identified in GOLDEN-505 cohort and in a cohort of obese patients (Professor Sven Francque, LB 535, EASL 2017), in the Phase 3 RESOLVE-IT serum samples.

- A bioinformatics analysis confirms that a previously described signature combining miR-34a, alpha-2 macroglobulin, HbA1c and YKL-40 (Professor Stephan A. Harrison, LB 534, EASL 2017) has a significantly better diagnostic performance than other main scores described in the current literature, when tested in both GOLDEN-Diag and RESOLVE-IT cohorts (see table below):

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***DIAGNOSTIC PERFORMANCES OF GENFIT SIGNATURE IN GOLDEN AND RESOLVE-IT COHORTS FOR IDENTIFICATION OF PATIENTS WITH NAS≥4 and F≥2 AND COMPARISON WITH EXISTING SCORES***

| Scores | AUROC(2) | Accuracy (%) |
|---|---|---|
| **GENFIT signature in GOLDEN-Diag cohort** | **0.82** | **76** |
| **GENFIT signature in RESOLVE-IT(1) cohort** | **0.84** | **82** |
| *Fibrometre-S ™* | *0.73* | *64* |
| *FIB-4* | *0.72* | *59* |
| *APRI* | *0.72* | *67* |
| *ELF ™* | *0.70* | *45* |
| *NAFLD Fibrosis Score* | *0.67* | *56* |
| *FibroTest ™* | *0.68* | *67* |
| *BARD* | *0.64* | *60* |

*(1) Intermediate results, completion foreseen at the end of the screening period of RESOLVE-IT Phase 3 trial;*
*(2) AUROC=Area Under Receiver Operating Characteristic curve (theoretical best value =1);*
*Existing score performances measured in GOLDEN-Diag cohort*

**Professor Stephen A. Harrison, Pinnacle Clinical Research, San Antonio, TX, USA, and Member of the international steering committee of the Phase 3 RESOLVE-IT study in NASH** commented: *"A single biomarker likely cannot provide a universal solution for the diagnosis of a multifactorial disease like NASH and a combination of discriminating biomarkers are necessary to obtain a clinically useful diagnostic response. The test might be ultimately used by the medical community for screening patients at risk of NASH, diagnosing NASH and/or liver fibrosis, identifying NASH patient who should be treated, monitoring NASH activity and/or fibrosis evolutions".*

The feasibility phase suggests that the GENFIT signature can answer different medical needs, at different steps of the patient journey, allowing general practitioners, endocrinologists, diabetologists and hepatologists to support their diagnosis including decision to treat a patient with an anti-NASH drug.

As part of the industrial phase for the development of a new In Vitro Diagnostic (IVD) test, GENFIT intends to partner with a major diagnostic company with particular expertise in microRNA application to IVD, which would also include the development of the test within IVD regulatory requirements, as well as the manufacturing of the kits.

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A regulatory and reimbursement strategy is currently being set up and coordinated at GENFIT in the U.S. and Europe, to ensure a swift registration process and timely market release. A pre-submission meeting with the FDA is anticipated before the end of 2017, and similar approaches will be conducted at European level. Concurrently, contact with U.S. payers will be initiated to discuss and demonstrate clinical utility.

Finally, GENFIT is widening its research collaboration program on NASH biomarkers and announces the signing of an agreement with the University Hospital Center Angers (France). This collaboration with Professor Jérôme Boursier and Professor Paul Calès will provide access to an additional independent cohort of NASH and non-NASH patients. In the coming months, GENFIT expects to sign other collaborations to obtain access to new prospective longitudinal cohorts for further validation of GENFIT diagnostic test in future intended uses.

**Professor Quentin Anstee (Newcastle University, UK)** added: *"There are high hopes for having new drugs for treating NASH and/or liver fibrosis in the near future. However, it will not be possible to effectively manage the NASH epidemic without reliable, cost effective and readily accessible non-invasive tests that can be used by doctors in their routine practice. The rigorous validation of potentially useful new in vitro diagnostic tests is urgently needed to improve the medical care of millions of individuals with NASH and fibrosis."*

**Jean François Mouney, Chairman and CEO of GENFIT,** concluded: "As *planned, we expect our diagnostic test to be available around the same time as the marketing authorization for elafibranor in NASH based on successful results from our RESOLVE-IT study. We are excited about the substantial potential of our non-invasive IVD test to significantly facilitate the identification of NASH patients eligible for treatment. Our global clinical management approach to NASH, including both diagnostic and treatment, has the potential to provide an important benefit for NASH patients."*

## ABOUT NASH DIAGNOSIS

"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. Currently it is estimated that NASH affects about 60 millions of people in US and Europe and about 18 millions are at risk major liver outcomes and CV events due to an active disease (NAS≥4) and presence of significant fibrosis (F≥2) at histological examination of a liver biopsy. To date, liver biopsy remains the only procedure to establish diagnosis of NASH, to evaluate level of disease activity and to measure extent of liver fibrosis. A generalized use of liver biopsy for management of millions of NASH patients is not feasible due to its invasiveness and high costs. Thus, there is an urgent need for cost effective, non-invasive alternatives to biopsy which can be routinely used by medical providers to screen, diagnose and follow up millions of NAFLD/NASH patients.

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## 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 and Paris, France, and Cambridge, MA (USA), the Company has approximately 130 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 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 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 "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) 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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