



PRESS RELEASE

GENFIT Launches *The NASH Education Program™* to Increase Disease Awareness around NASH

- › **Endowment fund created by GENFIT to develop disease awareness activities around NASH and address unmet information needs across a large set of stakeholders in the disease**
- › **Public health initiative allowing GENFIT to play an active educational role via the production and the dissemination of medical and scientific knowledge, under the supervision of a scientific committee led by Pr. Sven Francque**
- › **Inaugural event planned in Q1 2017**

Lille (France), Cambridge (Massachusetts, United States), December 14, 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 creation of ***The NASH Education Program™***, a not-for-profit endowment fund aimed at developing and funding disease awareness activities around NASH.

The NASH Education Program™ is a public health initiative led by GENFIT, with the ambition to significantly contribute to the global effort that must be engaged to increase NASH disease awareness:

- Across the **medical community**, in order to make sure hepatologists, endocrinologists, diabetologists, cardiologists and general practitioners are informed about and up-to-date on all essential clinical features of this emerging disease, including its causes, risk factors, and consequences, as well as about latest diagnostic and treatment options available;
- Within the **general public**, and in particular children, teenagers and their families who are increasingly at risk for developing the disease, due to the expanding prevalence of co-morbidities such as diabetes or obesity, and/or to predisposing factors such as an unfavorable genotype profile.

Operating under the guidance of a Scientific Committee led by Pr. Sven Francque, MD, PhD, Head of Department, Gastroenterology and Hepatology Antwerp University Hospital, Antwerp, Belgium, ***The NASH Education Program™*** will design, fund, and support collaborative approaches involving partners from different background such as academic, corporate, or regulatory, and with the potential to create valuable synergies in the NASH space. Volunteers will also have the opportunity to contribute to various initiatives.

With ***The NASH Education Program™***, GENFIT expands its presence in the NASH space and reinforces its leadership on diagnostic and treatment for NASH. Elafibranor – its lead compound on this pathology – is evaluated in the international Phase 3 clinical trial RESOLVE-IT, through an



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accelerated approval procedure (*Subpart H* with the FDA, et *Conditional approval* with the EMA), and with a first cohort of 1,000 patients expected to be fully enrolled by mid-2017 approximately.

An inaugural event will be organized by **The NASH Education Program™** in Q1 2017, in order to present activities that will be driven by this fund, starting in 2017 and beyond.

An online portal is already available at: www.the-nash-education-program.com/en

Pr. Sven Francque, MD, PhD, Professor of Hepatology, Head of Department, Gastroenterology and Hepatology, Antwerp University Hospital, Antwerp, Belgium, and President of the Scientific Committee of The NASH Education program™ commented:

"NASH is a still emerging disease and a completely new field for the large majority of physicians. As such, it requires significant work if we collectively want to ensure this disease is well understood by all specialties involved, i.e. well diagnosed, and well managed. To give you concrete examples: not only should hepatologists be educated on the cardiometabolic dimension of the disease, but endocrinologists, diabetologists, cardiologists and general practitioners should also be made aware of the risks their patients face if they don't monitor their liver properly. In addition to this obvious challenge directly related to the medical community, another priority is to reach the general public by producing and distributing relevant and easy-to-understand material. Take teenagers for instance: today, we see more and more young patients with advanced liver disease, caused by inappropriate lifestyles that are not the result of excess of alcohol, but of sugar and fat, as well as of sedentarism! This really alarming trend is one of the reasons why I'm extremely pleased and excited to be given the chance to take a leadership role for The NASH Education Program™."

Jean-François Mouney, Chairman & CEO of GENFIT, and President of The NASH Education Program™ added: *"The launch of The NASH Education Program™ is an important step taken in the field of NASH as well as for GENFIT: it indeed becomes our legal entity in charge of coordinating all disease awareness activities in collaboration with our partners. It will oversee the control and steering of all these activities, in a consistent way with those of GENFIT and GENFIT Corp. To give some examples: educational activity during congresses, dedicated training sessions for healthcare providers, or production and dissemination of informative material for doctors, patients, and families, will all be centrally coordinated via this foundation. The set-up and funding of patient registries aimed at increasing the understanding of the disease, or projects aimed at structuring patient referral process between key physician specialties, will also fall into the perimeter covered by The NASH Education Program™."*

Sophie Mégnien, Chief Medical Officer (CMO) of GENFIT noted: *"I meet healthcare providers everyday, and despite a growing interest for NASH – quite obvious if you consider the number of NAFLD/NASH-related presentations that have been held during the last Liver Meeting (organized by the AASLD in Boston) – there is still some effort to be made to ensure NASH gets managed in an optimal way once the first innovative drugs come on the market. Pragmatically-speaking, spreading knowledge across the different physician specialties that will be on the front lines of diagnosis and*



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treatment of NASH patients on a regular basis is definitely the right way to proceed. Then, gathering Real World Evidence data is also a good approach to increase the overall level of knowledge, and will probably represent an important part of the work that will be carried out through The NASH Education Program™. Last, childhood obesity will be a specific focus area. The recent launch of our pediatric study in Europe indeed clearly indicates regulators' interest for addressing unmet needs in young patients. The NASH Education Program™ set-up with Pr. Francque, which will also involve other KOLs, will likely play a positive role and will trigger constructive discussions. I believe this work will ultimately lead to real progress in patient care."

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 110 employees. GENFIT is a public company listed in compartment B of Euronext's regulated market in Paris (Euronext: GNFT - ISIN: FR0004163111).

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, including patient recruitment, and results of clinical data from, the RESOLVE-IT trial, review and approvals by regulatory authorities, such as the FDA



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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 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.

CONTACT

GENFIT | Jean-François Mouney – Chairman & CEO | Ph. +333 2016 4000

MILESTONES – Press Relations | Bruno Arabian | Ph. +331 8362 3484 / +336 8788 4726 – barabian@milestones.fr

GENFIT | 885 Avenue Eugène Avinée, 59120 Loos - FRANCE | +333 2016 4000 | www.genfit.com