



PRESS RELEASE

GENFIT Initiates Paediatric NAFLD/NASH Program in Europe Further to the Approval of elafibranor's Paediatric Investigation Plan by the EMA

- › **Elafibranor's Pediatric Investigation Plan (PIP) approved by the European Medicine Agency (EMA) for the Treatment of non-alcoholic fatty liver disease (NAFLD) including non-alcoholic steatohepatitis (NASH)**
- › **First studies started further to the opinion formulated by the Paediatric Committee of the EMA**
- › **No concerns on potential long term safety/efficacy issues in relation to paediatric use in children from 2 to 18 years of age**

Lille (France), Cambridge (Massachusetts, United States), November 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 that the company has initiated its program in paediatric NAFLD/NASH.

This key step follows the approval by the European Medicine Agency (EMA) of elafibranor's Pediatric Investigation Plan (PIP).

Due to its good safety/efficacy profile demonstrated in adults in Phase2b, elafibranor presents a promising potential to treat children from 2 to 18 years of age.

Dr. Joel Lavine, MD, PhD, Co-Chair NASH CRN (NIDDK), Professor & Vice-Chair (Research), Department of Pediatrics Chief, Pediatric GI/Hepatology/Nutrition, Columbia University, NY, USA commented: *"Pediatric NAFLD is an alcohol-like disease of the liver that develops in children who drink no or little alcohol. Prevalence is quite high in general, with boys, obese, and patients of certain Hispanic origins being particularly affected. In addition to the higher prevalence associated with age, there is also a strong association between metabolic syndrome and liver histologic severity among children with NAFLD. It's very exciting to see elafibranor being given a green light by the European regulatory agency to proceed further with trials in this critical space. The efficacy and safety profile renders this drug a very promising therapy."*

Sophie Mégniën, Chief Medical Officer (CMO) of GENFIT commented: *"We are very pleased today to develop a plan for children requiring treatment of their NAFLD/NASH. Juvenile toxicology studies are ongoing and we all look forward to similar steps in the US, given the encouraging results seen in adults in the Phase 2b trial. Due to the very good tolerability and safety profile of elafibranor, and given the efficacy it has demonstrated in adults earlier, we are confident in the potential of the molecule to address key unmet needs in children and teenagers."*



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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). 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 7 "Main Risks and Uncertainties" of the Company's Half Year



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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.

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