



PRESS RELEASE

GENFIT: Official Launch of the NASH Pediatric Program, following PIP and PSP Agreement by EMA and FDA

- **FDA (Food and Drug Administration) agrees with elafibranor's initial Pediatric Study Plan (PSP) for the launch of a NASH pediatric clinical trial in the United States**
- **PSP agreement by the FDA consistent with PIP (Pediatric Investigation Plan) agreement by the EMA (European Medicines Agency)**
- **Phase 2b data supportive of elafibranor's potential benefit in NASH pediatric population, based on safety, histology and cardiometabolic efficacy**
- **Dose ranging study to start in the coming weeks, on young NASH patients living in the United States (8-17 years old)**

Lille (France), Cambridge (Massachusetts, United States), January 23, 2018 – 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 official launch of the clinical study of elafibranor in pediatric NASH:

The PSP agreement by the FDA will lead to the launch of the first pediatric trial to evaluate the safety and efficacy of elafibranor in children with NASH. The experts' confidence in elafibranor's potential, initiated with the promising results of the Phase 2b in adult NASH, is confirmed with this important step of regulatory agreement. These Phase 2b results, published in *Gastroenterology*, have indeed shown that elafibranor has a unique potential combining:

- **Efficacy on histology**, *i.e.* "Resolution of NASH without worsening of fibrosis" (as defined in phase 3 clinical trial protocols) in the 52-week trial;
- **Cardiometabolic risk factor reduction** (lipids, insulin resistance, glucose homeostasis, inflammation), an essential benefit for NASH patients who primarily die from cardiovascular diseases;
- **Safety**, a crucial requirement for any chronic condition such as NASH;
- **Good tolerability**, a major advantage in the context of a silent disease like NASH.

The rising global figures of obesity and type 2 diabetes are becoming an important concern for public health. Gastroenterologists and hepatologists are at the front line in managing the consequences of these epidemics, including within the pediatric population.

Fatty liver disease is increasingly diagnosed and is the most common liver abnormality in children (Schwimmer *et al.*, 2006). In children, NAFLD has been associated with insulin resistance and



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hypertriglyceridemia (Schwimmer *et al.*, 2008). NAFLD is considered as the hepatic manifestation of the metabolic syndrome and should be suspected in all overweight or obese children and adolescents (Nobili *et al.*, 2015).

An alarming number of children are developing serious liver conditions as a result of obesity, insulin resistance and overweight, as the following figures show:

- Between 1988 and 2010, the rates of abnormal liver tests in American children and adolescents (raised ALT) have tripled, going from 3.9% to 10.7%¹. Based on elevated ALT, an estimated 10% of American children have NAFLD, of which one third is likely to have NASH, and 17% could have fibrosis².
- A study among obese children has shown that those with metabolic syndrome are three times as likely to develop NAFLD compared to those without metabolic syndrome.³
- A recent study has shown statistically significant differences between NASH and NAFL suggesting an increased CVD risk in children with NASH⁴.

These figures confirm the **unmet need in the pediatric population**, given there is currently no approved pharmacological therapy for NAFLD/NASH, even in adults. The main goal when treating pediatric NAFLD is to stop and reverse liver injury. The ultimate aim is to improve quality of life by reducing long-term morbidity and mortality related to the metabolic consequences of fatty liver disease, as well as impeding progression to cirrhosis and its complications.

Dr. Joel Lavine, MD, PhD, Co-Chair NASH CRN (NIDDK), Chief of Division of Pediatric GI/Hepatology/Nutrition, NY Presbyterian Children's Hospital and Columbia University, NY, USA commented: *"NASH in the pediatric population has become an increasing concern for hepatologists and gastroenterologists around the globe. The dramatic increase in the prevalence of NAFLD is a direct consequence of rising childhood obesity. Obese, pre-diabetic, overweight, insulin-resistant children, and children of certain ethnicities, are particularly predisposed. I look forward to starting the first pediatric clinical trial with elafibranor, as its safety profile and additional cardiometabolic efficacy clearly address the medical need for these children with metabolic dysfunction, who unfortunately progress to advanced fibrosis, type 2 diabetes and cardiovascular disease in the absence of effective treatments. Having the green light from the FDA on the PSP is a key step for us in the United States."*

Dr. Sophie Mégnien, Chief Medical Officer of GENFIT CORP., added: *"We are thrilled by the FDA's agreement on the Pediatric Study Plan for elafibranor. Most importantly, it allows us to proceed further with a pediatric clinical trial in the US. Many children and teenagers with NASH are in need for a therapeutic solution, so generating new data on elafibranor in a pediatric setting is of utmost importance, and we hope to obtain clear evidence of the drug's potential to address unmet needs in that very specific population."*

¹ Welsh *et al.* Increasing prevalence of nonalcoholic fatty liver disease among United States adolescents, 1988-1994 to 2007-2010, *J Pediatr.* 2013

² Africa *et al.*, In Children With Nonalcoholic Fatty Liver Disease, Zone 1 Steatosis Is Associated With Advanced Fibrosis. *Clin Gastroenterol Hepatol.* 2017.

³ Papandreou *et al.*, Obese Children with Metabolic Syndrome Have 3 Times Higher Risk to Have Nonalcoholic Fatty Liver Disease Compared with Those without Metabolic Syndrome, *Int J Endocrinol.*, 2017.

⁴ AASLD, Poster 20-96, Konomi *et al.*, 2017, NASH CRN, Vos, 2017.



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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 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 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 and the trial of elafibranor in PBC, 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 drug candidates in other indications and biomarkers candidates, 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 in Chapter 7 of the 2017 Half Year Business and Financial Report and 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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