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FOR IMMEDIATE RELEASE

GENFIT Announces FDA Protocol Clearance for Phase 2 Clinical Trial of Elafibranor in Pediatric NASH

- **FDA accepts study protocol, providing green light for GENFIT to initiate Phase 2 clinical trial in pediatric NASH**
- **Elafibranor, the first molecule with positive results on registrational endpoint in Phase 2b clinical trial in adult NASH to be evaluated in pediatric NASH**
- **12-week randomized trial of 20 pediatric patients to be initiated at U.S. clinical centers specializing in NASH pediatrics**

Lille (France), Cambridge (Massachusetts, United States), March 11, 2019 – GENFIT (Euronext: GNFT - ISIN: FR0004163111), a late-stage biopharmaceutical company dedicated to the discovery and development of innovative therapeutic and diagnostic solutions in metabolic and liver related diseases, today announced protocol clearance by the FDA for a Phase 2 trial evaluating elafibranor in children and adolescents with non-alcoholic steatohepatitis (NASH).

The first NASH pediatric trial based on compelling Phase 2 clinical data in adults

Elafibranor is ideally positioned to be evaluated in children and adolescents with NASH, based on its compelling Phase 2 data in adult NASH[1]:

- Efficacy on "NASH resolution without worsening of fibrosis" (26% elafibranor vs. 5% placebo; p-value 0.02), the biopsy-based regulatory endpoint for marketing approval that addresses the underlying cause of disease progression;
- Beneficial cardiovascular profile (reduction of LDL, TG, HDL, and improved insulin sensitivity), known to be important for NASH patients;
- No safety and no tolerability concerns observed, essential in a chronic and silent condition like NASH.

Based on this clinical evidence, GENFIT had already obtained the PSP (Pediatric Study Plan) agreement by the FDA as well as the PIP (Pediatric Investigation Plan) agreement by the EMA

[1] Ratziu, et al. (2016). Elafibranor, an Agonist of the Peroxisome Proliferator–Activated Receptor–α and –δ, Induces Resolution of Nonalcoholic Steatohepatitis Without Fibrosis Worsening. *Gastroenterology*, 150(5), pp.1147-1159.e5.

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(European Medicines Agency), supporting the initiation of this first-of-its-kind clinical trial. Randomization of the first group of patients is expected in the upcoming weeks.

Trial design

- Study to assess the pharmacokinetic and pharmacodynamic profile and the safety and tolerability of two dose levels of elafibranor (80 mg and 120 mg);
- 20 patients between 8 to 17 years of age, with NASH;
- 12-week trial duration;
- Open-label study;
- Randomized across two arms;
- U.S. multicenter study.

The burden of NASH in the pediatric population

Non-Alcoholic Fatty Liver Disease, or NAFLD, has become the most common liver abnormality diagnosed in children and adolescents[2], and is associated with insulin resistance and hypertriglyceridemia[3]. NAFLD is considered as the hepatic manifestation of the metabolic syndrome and should be suspected in all overweight or obese children and adolescents[4].

Recent alarming figures, collected between 1988 and 2010 in more than 8000 American children and adolescents (NHANES participants), have shown a tripling in the rates of NAFLD from 3.3% to 10.1%, and a prevalence of NASH with an almost five-fold increase from 0.7% to 3.4% over the same period, resulting in serious liver conditions[5].

In addition, studies have shown that 17% of American children with NAFLD are likely to have fibrosis[6]. Among obese children, those with metabolic syndrome are three times as likely to develop NAFLD compared to those without metabolic syndrome[7]. Statistically significant differences between NASH and NAFLD suggest an increased cardiovascular disease risk in children with NASH[8].

Dr. Joel Lavine, MD, PhD, Co-Chair NASH CRN (NIDDK), Professor and Chief of Pediatric GI/Hepatology/Nutrition, Columbia University, NY, USA, commented: "*Childhood obesity is a problematic diagnosis for children, their families and the medical community at large. The prevalence*

[2] Schwimmer, et al. (2006). Prevalence of Fatty Liver in Children and Adolescents. Pediatrics, 118(4), pp.1388-1393.
[3] Schwimmer, J., Pardee, P., Lavine, J., Blumkin, A. and Cook, S. (2008). Cardiovascular Risk Factors and the Metabolic Syndrome in Pediatric Nonalcoholic Fatty Liver Disease. Circulation, 118(3), pp.277-283.
[4] Nobili, V., et al. (2015). Nonalcoholic Fatty Liver Disease. JAMA Pediatrics, 169/2: 170.
[5] Selvakumar, et al. (2016). Reduced lysosomal acid lipase activity – A potential role in the pathogenesis of non alcoholic fatty liver disease in pediatric patients. *Digestive and Liver Disease*, 48/8: 909-913.
[6] Africa et al., In Children With Nonalcoholic Fatty Liver Disease, Zone 1 Steatosis Is Associated With Advanced Fibrosis. Clin Gastroenterol Hepatol, 2017.
[7] Papandreou, D., Karavetian, M., Karabouta, Z., & Andreou, E. (2017). Obese Children with Metabolic Syndrome Have 3 Times Higher Risk to Have Nonalcoholic Fatty Liver Disease Compared with Those without Metabolic Syndrome. International Journal of Endocrinology, 2017: 1-5.
[8] AASLD, Poster 20-96, Konomi et al., 2017, NASH CRN, Vos, 2017.

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of NASH in children is rapidly rising - the direct consequence of modern lifestyles, unhealthy eating habits, and limited exercise - becoming a major concern for hepatologists, gastroenterologists and diabetologists around the world. The trial evaluating elafibranor for pediatric NASH is the first study of its kind and a key milestone for the NASH community. The scientific rationale, based on adult Phase 2 clinical evidence, is sound. Elafibranor's neutral safety profile coupled with cardiometabolic efficacy may address the major medical needs faced by these children. Children demonstrating metabolic dysfunction are at risk to progress to advanced fibrosis, type 2 diabetes and cardiovascular disease in the absence of effective interventions. Thus, the scientific community eagerly awaits the clinical readout of elafibranor in this NASH population."

Dean Hum, Ph.D, Chief Operating Officer of GENFIT, added: *"The initiation of a Phase 2 trial of elafibranor in pediatric NASH is a landmark study, as to our knowledge there has been no other molecule that has shown clinical evidence in a Phase 2b adult NASH trial and then progressed to clinical evaluation in the pediatric NASH setting. Given the substantial number of children from 8 to 17 years old with NASH, GENFIT is enthusiastic to explore the potential to provide children and adolescents with a treatment option in the near future. Beyond the clinical usage of elafibranor, we believe the scientific data generated throughout the trial will be highly beneficial for physicians tackling this disease and impactful for the still immature field of pediatric NASH."*

ABOUT GENFIT

GENFIT is a biopharmaceutical company focused on discovering and developing drug candidates and diagnostic solutions targeting liver diseases, in particular those of metabolic origin, and hepatobiliary diseases. GENFIT concentrates its R&D efforts in areas of high unmet medical needs corresponding to a lack of approved treatments. GENFIT's lead proprietary compound, elafibranor, is a drug candidate currently being evaluated in one of the most advanced Phase 3 clinical trials worldwide ("RESOLVE-IT") in nonalcoholic steatohepatitis (NASH), considered by regulatory authorities as a medical emergency because it is often silent, with potentially severe consequences, and with a prevalence on the rise. Elafibranor has also obtained positive preliminary results in a Phase 2 clinical trial in primary biliary cholangitis (PBC), a severe chronic liver disease. As part of its comprehensive approach to clinical management of NASH patients, GENFIT is conducting an ambitious discovery and development program aimed at providing patients and physicians with a blood-based test for the diagnosis of NASH, i.e. non-invasive and easy-to-access. With facilities in Lille and Paris, France, and Cambridge, MA (USA), the Company has approximately 150 employees. GENFIT is a public company listed in compartment B of Euronext's regulated market in Paris (Euronext: GNFT - ISIN: FR0004163111).

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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 safety, progression of, and results from, its ongoing and planned clinical trials, including its anticipated pediatric clinical trial of elafibranor and its RESOLVE-IT Phase 3 trial of elafibranor, the potential for elafibranor to produce similar results in a pediatric population as it has in adult populations, review and approvals by regulatory authorities, such as the FDA or the EMA, of its drug and diagnostic candidates, as well as those discussed or identified in the Company's public filings with the AMF, including those listed in Section 4 "Main Risks and Uncertainties" of the Company's 2018 Registration Document filed with the French Autorité des marchés financiers on February 27, 2019 under n° D.19-0078, 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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