



## PRESS RELEASE

### **GENFIT: Major Milestone achieved with full recruitment of the Phase 2 trial evaluating elafibranor in PBC**

- **Final patient randomized in a Phase 2a clinical trial evaluating efficacy and safety of elafibranor in PBC (Primary Biliary Cholangitis), a rare liver disease with unmet needs**
- **Top line results of the 12 week proof-of-concept study expected by end-of-year**

**Lille (France), Cambridge (Massachusetts, United States), August 28, 2018** – GENFIT (Euronext: GNFT - ISIN: FR0004163111), 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 today announces the completion of enrolment in the Phase 2a trial evaluating elafibranor in PBC (Primary Biliary Cholangitis), a rare liver disease. GENFIT anticipates the release of top line data by end-of-year.

The 45<sup>th</sup> (and last) patient was enrolled in July, and a number of patients have already finished the 12-week treatment period.

This trial is a multicenter, double-blind, randomized, placebo-controlled, Phase 2a study to evaluate the efficacy and safety of elafibranor in adult patients with PBC and inadequate response to ursodeoxycholic acid. The trial is designed as follows:

- 3 arms (80mg, 120mg, placebo)
- 45 patients (15 patients per arm)
- 12-week treatment
- Clinical centers in the U.S. and in Europe

The primary objective is to determine the effect of daily oral administration of elafibranor on serum alkaline phosphatase (ALP) in these patients.

Secondary endpoints will include safety and tolerability of elafibranor, notably on pruritus, and Quality of Life assessment.

PBC is a rare autoimmune disease characterized by the progressive damage of bile ducts in the liver, which may lead to cirrhosis and even liver failure. Unfortunately, many patients are either not responsive to existing therapies or have exacerbated side effects such as pruritus upon initiation of these medications. As such, additional therapeutic options are still needed.

**Dr. Velimir A. Luketic, MD, Division of Gastroenterology, Hepatology and Nutrition Virginia Commonwealth University School of Medicine, Richmond, VA (USA)**, commented: "*A substantial number of patients do not benefit from the currently available therapies – UDCA or OCA – either because of lack of response or intolerable side*



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*effects. This represents a major unmet need for this population. In the literature, targeting PPAR receptors has shown that it reduces the synthesis of bile acids and to improve detoxification of bile in the bile ducts. In clinical trials, PPAR-targeting drugs have shown significant decrease in ALP, and improved biochemical profiles and pruritus in PBC patients. As an investigator in this trial, I am very thrilled that we have completed enrollment and I eagerly await the results which should become available later this year."*

**Sophie Mégnien, Chief Medical Officer of GENFIT, added:** *"We are thrilled to have the last randomized PBC patient in this Phase 2 trial and are enthusiastically awaiting top line results by the end of the year. Elafibranor, a dual PPAR alpha & delta agonist, is an attractive candidate for PBC patients due to its impact on lowering alkaline phosphatase levels, as shown consistently in previous clinical studies, on other populations. This attribute, along with what PPAR agonists have demonstrated on ALP reduction, provides a strong rationale for elafibranor in PBC. Recent clinical data has shown that PPAR alpha may also have a positive impact on pruritus, which further differentiates the dual mechanistic action of elafibranor to not only improve liver biochemistry (delta) but also alleviate pruritus (alpha) in this rare disease. In such a rare disease, finalizing patient recruitment is a key milestone. We are confident in elafibranor's potential to provide a meaningful benefit to patients, and to ultimately address the unmet need. We thank all of the patients, patient families, and investigators of the Phase 2a trial for their dedication."*

### 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) and Primary Biliary Cholangitis (PBC). Elafibranor is believed to address multiple facets of NASH, including inflammation, insulin sensitivity, lipid/metabolic profile, and liver markers. Elafibranor also presents a particularly interesting profile to potentially treat PBC, a rare liver disease.

### ABOUT PBC

"PBC", or Primary Biliary Cholangitis, is a chronic disease in which bile ducts in the liver are gradually destroyed. The damage to bile ducts can inhibit the liver's ability to rid the body of toxins, and can lead to scarring of liver tissue known as cirrhosis.

### 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 discovering and developing drug candidates and diagnostic solutions targeting liver diseases, in particular those of metabolic origin, and



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hepatobiliary diseases. GENFIT's 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 studies worldwide ("RESOLVE-IT") in nonalcoholic steatohepatitis (NASH), considered by regulatory authorities as a medical emergency because it is silent, with potentially severe consequences, and with a prevalence on the rise. It is also evaluated in a Phase 2 study in Primary Biliary Cholangitis (PBC), a rare 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 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](http://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 Section 4 "Main Risks and Uncertainties" of the Company's 2017 Registration Document registered with the French Autorité des marchés financiers on April 27, 2018 under n° R.18-032, which is available on GENFIT's website ([www.genfit.com](http://www.genfit.com)) and on the website of the AMF ([www.amf-france.org](http://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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