

UNITED STATES SECURITIES  
AND EXCHANGE COMMISSION  
Washington, D.C. 20549

**FORM 6-K**

REPORT OF FOREIGN PRIVATE ISSUER  
PURSUANT TO RULE 13a-16 OR 15d-16  
UNDER THE SECURITIES EXCHANGE ACT OF 1934

Date of report: April 15, 2019

Commission File Number: 001-38844

**GENFIT S.A.**

(Translation of registrant's name into English)

---

Pare Eurasante  
885, avenue Eugene Avinee  
59120 Loos, France  
+33 3 20 16 4000  
(Address of principal executive office)

---

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F  Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule IOI(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

---

EXHIBIT LIST

**Exhibit**

**Description**

99.1

[Press Release dated April 13, 2019.](#)



**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: April 15, 2019

**GENFITS.A.**

By: /s/ JEAN-FRANCOIS MOUNEY

Name: Jean-Francois Mouney

Title: Chairman and Chief

Executive Officer

A handwritten signature in black ink, consisting of a stylized 'J' followed by a horizontal line that extends to the right and ends in a small hook.

**GENFIT to Present Additional Data from the Positive Phase 2  
Clinical Trial Evaluating Elafibranor in Primary Biliary  
Cholangitis at the International Liver Congress™ 2019**

- Further analysis shows significant improvements in PBC cholestatic markers such as GGT (-39% for 80mg and -40% for 120mg), significant reduction on immuno/inflammation markers (eg. IgM, hsCRP), decrease in bile acid precursors (C4), and improvement in metabolic markers (total cholesterol, LDL, triglycerides)
- New data also suggest an improvement in pruritus – a major symptom of PBC – with a median change in VAS of -24% (80mg) and -49% (120mg) vs. -7% (placebo)
- This new dataset further supports elafibranor’s potential for improved efficacy and tolerability compared to existing PBC therapies, and favorably complements previously disclosed top line data showing significant reductions in ALP of -52% (80mg) and -44% (120mg) when compared to placebo ( $p < 0.001$ ), and a substantial response rate on a composite endpoint used for regulatory approval, with 67% (80 mg) ( $p = 0.002$ ) and 79% (120 mg) ( $p \leq 0.001$ ) responders vs. 6.7% for placebo.

Lille (France), Cambridge (Massachusetts, United States), April 13, 2019 – GENFIT (Nasdaq and 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 it will present additional in depth analyses of data from its Phase 2 clinical trial evaluating elafibranor in PBC at the International Liver Congress™ (ILC) 2019. Elafibranor is GENFIT’s lead compound currently under evaluation in RESOLVE-IT, a Phase 3 clinical trial in NASH, and following the positive Phase 2 results in PBC, will be evaluated in a Phase 3 clinical trial for PBC, expected to initiate in 2019. The abstract describing Phase 2 PBC data was selected as “Best of ILC 2019” at this year’s conference.

A press conference to present abstracts selected as Best of Late Breaking Abstracts will be hosted on Saturday, April 13, 2:30pm to 3:30pm CET (room Lehar).

Dr. Velimir A. Luketic, MD, Division of Gastroenterology, Hepatology and Nutrition Virginia Commonwealth University School of Medicine, Richmond, VA (USA), will present the late breaker abstract “*Elafibranor, a peroxisome proliferator-activated receptor alpha and delta agonist demonstrates favourable efficacy and safety in patients with primary biliary cholangitis and inadequate response to ursodeoxycholic acid treatment*” on Saturday, April 13, from 4:15pm to 4:30pm CET (Main Plenary).



## PRESS RELEASE

The anti-cholestatic effects of elafibranor were evaluated in a 12-week double-blind randomized placebo-controlled Phase 2 trial of non-cirrhotic patients with PBC and with inadequate response to ursodeoxycholic acid (UDCA) defined as an alkaline phosphatase (ALP) level > 1.67x upper limit of normal (ULN). Patients were randomly assigned to receive elafibranor 80 mg/day, 120 mg/day or placebo (15 patients per group; 43 women and 2 men; mean age 59 years). UDCA was continued in all patients. The primary endpoint was ALP percentage change from baseline to week 12.

Patients receiving both elafibranor doses achieved a significant decrease in their mean ALP: -48% for the 80 mg dose, and -41% for 120 mg dose, compared to a mean 3% increase in ALP for patients receiving placebo, resulting in a highly significant treatment effect versus placebo: -52% (95% CI: [-62.5;-41.5]) (p<0.001) for 80mg and -44% (95% CI: [-55.7;-32.1]) (p< 0.001) for 120mg. A composite endpoint composed of ALP < 1.67xULN and ALP decrease >15% and total bilirubin < ULN, was achieved in 67% patients at 80 mg and 79% of patients at the 120 mg dose (p= 0.002 and p< 0.001, respectively) as compared to 6.7% patients on placebo.

In addition to significant reductions in ALP, patients, in both elafibranor-treated groups, showed improvements in other PBC markers. The effect on gamma-glutamyl transferase (GGT) was highly significant as compared to placebo: -39% (80mg) and -40% (120mg), (p=0.001 and p=0.002 respectively). Improvements in lipid markers including total cholesterol, low-density lipoprotein and triglycerides, as well as reduction of anti-inflammatory markers (such as IgM, CRP, haptoglobin and fibrinogen); and a decrease in C4, an intermediate of bile acid synthesis, were also noted. By self-reported visual analogue scale (VAS) in patients with pruritus at baseline (10/group), the VAS median percentage change from baseline to week 12 was -24%, -49% and -7% in the 80mg, 120 mg and Pbo groups, respectively. Treatment with both doses of elafibranor were generally well-tolerated, and will be further evaluated for safety and efficacy in a Phase 3 study to be initiated in 2019.

**Dr. Velimir A. Luketic, MD, Division of Gastroenterology, Hepatology and Nutrition Virginia Commonwealth University School of Medicine, Richmond, VA (USA),** commented *“This clinical trial evaluating a 12 week course of elafibranor showed the substantial anticholestatic effects of the compound in patients with PBC and inadequate response to UDCA. Since this was also associated with anti-inflammatory and potential antipruritic effects, elafibranor is certainly a promising novel treatment candidate which could potentially bring a new solution to a significant proportion of PBC patients.”*

**Dean Hum, COO of GENFIT,** added: *“This positive Phase 2 dataset on elafibranor in PBC is very promising. A large proportion of patients have an inadequate response to existing treatments. The data from our trial brings hope to the medical community, patients and their families, potentially offering a safe and efficacious therapy. We plan to further evaluate elafibranor in a Phase 3 trial expected to initiate later this year.”*



## PRESS RELEASE

For more information please visit the EASL Annual Meeting website or please contact GENFIT Investor and Media departments.

### **ABOUT ELAFIBRANOR**

Elafibranor is GENFIT's lead pipeline product candidate. Elafibranor is an oral, once-daily, first-in-class drug acting via dual peroxisome proliferator-activated alpha/delta pathways developed to treat, in particular, nonalcoholic steatohepatitis (NASH). GENFIT believes, based on clinical results to date, that elafibranor has the potential to address multiple facets of NASH, including inflammation, insulin sensitivity, lipid/metabolic profile, and liver markers. Phase 2 clinical trial results have also shown that elafibranor may be an effective treatment for PBC, a rare liver disease.

### **ABOUT PBC**

"PBC" 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" 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 failure, and also progression to liver cancer.

### **ABOUT GENFIT**

GENFIT is a late-stage biopharmaceutical company dedicated to the discovery and development of innovative therapeutic and diagnostic solutions in metabolic and liver related diseases where there are considerable unmet medical needs, corresponding to a lack of approved treatments. GENFIT is a leader in the field of nuclear receptor-based drug discovery with a rich history and strong scientific heritage spanning almost two decades. Its most advanced drug candidate, elafibranor, is currently being evaluated in a pivotal Phase 3 clinical trial ("RESOLVE-IT") as a potential treatment for NASH, and GENFIT plans to initiate a Phase 3 clinical trial in PBC later this year following its positive Phase 2 results. As part of GENFIT's comprehensive approach to clinical management of NASH patients, the company is also developing a new, non-invasive and easy-to-access blood-based *in vitro* diagnostic test to identify patients with NASH who may be appropriate candidates for drug therapy. With facilities in Lille and Paris, France, and Cambridge, MA, USA, the Company has approximately 150 employees. GENFIT is a public company listed on the Nasdaq Global Select Market and in compartment B of Euronext's regulated market in Paris (Nasdaq and Euronext: GNFT- ISIN: FR0004163111). [www.genfit.com](http://www.genfit.com)



## PRESS RELEASE

### FORWARD LOOKING STATEMENTS

This press release contains certain forward-looking statements, including those within the meaning of the Private Securities Litigation Reform Act of 1995, with respect to Genfit, including, the progression of our clinical trials in NASH and PBC. The use of certain words, including “believe,” “potential,” “expect” and “will” and similar expressions, is intended to identify forward-looking statements. Although the Company believes its expectations are based on the current expectations and reasonable assumptions of the Company’s management, these forward-looking statements are subject to numerous known and unknown 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, biomarkers, progression of, and results from, its ongoing and planned clinical trials, review and approvals by regulatory authorities of its drug and diagnostic candidates and the Company’s continued ability to raise capital to fund its development, as well as those risks and uncertainties discussed or identified in the Company’s public filings with the French Autorité des marchés financiers (“AMF”), including those listed in Section 4 “Main Risks and Uncertainties” of the Company’s 2018 Registration Document filed with the AMF on February 27, 2019 under n° D.19-0078, 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)) and public filings and reports filed with the U.S. Securities and Exchange Commission (“SEC”), including the Company’s final prospectus dated March 26, 2019, and subsequent filings and reports filed with the AMF or SEC, or otherwise made public, by the Company. In addition, even if the Company’s results, performance, financial condition and liquidity, and the development of the industry in which it operates are consistent with such forward-looking statements, they may not be predictive of results or developments in future periods. These forward-looking statements speak only as of the date of publication of this document. Other than as required by applicable law, the Company does not undertake any obligation to update or revise any forward- looking information or statements, whether as a result of new information, future events or otherwise.

### CONTACT

#### GENFIT | Investors

Naomi EICHENBAUM – Investor Relations | Tel: +1 (617) 714 5252 | [investors@genfit.com](mailto:investors@genfit.com)

#### PRESS RELATIONS | Media

Hélène LAVIN – Press relations | Tel: +333 2016 4000 | [helene.lavin@genfit.com](mailto:helene.lavin@genfit.com)