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 18, 2019

Commission File Number: 001-38844

GENFIT S.A.

(Translation of registrant's name into English)

Parc Eurasanté
885, avenue Eugène Avinée
59120 Loos, France

(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 101(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 18, 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.

GENFIT S.A.

Date: April 18, 2019

By: /s/ Jean-François Mouney
Name: Jean-François Mouney
Title: Chairman and Chief Executive Officer

GENFIT Announces FDA Grant of Breakthrough Therapy Designation to Elafibranor for the Treatment of PBC

- **FDA grants elafibranor Breakthrough Therapy Designation, based on Phase 2 data, for treatment of PBC (Primary Biliary Cholangitis) in adults with inadequate response to UDCA**

- **Breakthrough Therapy Designation follows Late Breaker presentation of additional data from positive Phase 2 placebo-controlled trial evaluating elafibranor in PBC at EASL International Liver Congress™ 2019, selected as "Best of ILC" 2019**

Lille (France), Cambridge (Massachusetts, United States), April 18, 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 that its lead product candidate elafibranor was granted Breakthrough Therapy Designation by the U.S. Food and Drug Administration (FDA) for the treatment of Primary Biliary Cholangitis (PBC) in adults with inadequate response to ursodeoxycholic acid (UDCA). Elafibranor is a first-in-class double peroxisome proliferator-activated receptor alpha and delta (PPAR alpha/delta) agonist which has produced positive results in a Phase 2 clinical trial evaluating its safety and efficacy in adults with PBC and inadequate response to UDCA. Elafibranor is also currently evaluated in a Phase 3 clinical trial in nonalcoholic steatohepatitis (NASH).

Breakthrough Therapy Designation is granted by the FDA to expedite the development and review of drugs designed to treat serious conditions for which preliminary data and evidence indicate that the product candidate may demonstrate substantial improvements over existing therapies on one or more clinically significant endpoints.

GENFIT presented detailed results from its positive Phase 2 clinical trial evaluating elafibranor in PBC during the European Association for the Study of the Liver (EASL) annual International Liver Congress™ (ILC). In a 12-week double-blind randomized placebo-controlled Phase 2 trial of non-cirrhotic patients with PBC and with inadequate response to UDCA, elafibranor showed a significant decrease of alkaline phosphatase (ALP) levels, resulting in significant treatment effects versus placebo on the primary endpoint, whilst also meeting the composite endpoint used for drug registration. In addition to significant reductions in ALP, patients, in both elafibranor-treated groups, showed improvements in other PBC markers, including gamma-glutamyl transferase (GGT), lipid markers (total cholesterol, LDL and triglycerides), and anti-inflammatory

markers (IgM, CRP, haptoglobin and fibrinogen). The improvement in GGT, lipid and – anti-inflammatory markers is consistent with what was observed in our Phase 2 clinical trial in NASH, and is essential both for treating PBC and for treating a metabolic disease like NASH. Treatment with both doses of elafibranor was generally well-tolerated, and will be further evaluated for safety and efficacy in a Phase 3 clinical trial expected to be initiated in 2019.

Pascal Birman, Deputy Chief Medical Officer of GENFIT, commented: *"PBC is a severe liver disease that can lead to cirrhosis and liver failure, and is commonly associated with debilitating symptoms such as pruritus, that affect patients' quality of life. Approximately 50% of patients have an inadequate response to existing therapies, either because they do not respond to treatment or because they experience intolerable side effects like aggravated pruritus (itching) or hepatic toxicity. Elafibranor has shown promising anticholestatic effects in a Phase 2 clinical trial, while showing a trend in reducing pruritus. The FDA's decision to grant elafibranor the Breakthrough Therapy Designation on the basis of our Phase 2 data, is of course a milestone that will allow us to accelerate elafibranor's development, and further confirms our strong belief that elafibranor could potentially address this significant unmet medical need."*

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 insufficiency, 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

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 statements related to the development timeline for elafibranor, the belief that elafibranor may be a safe and effective treatment for NASH and PBC, timelines for the commencement of clinical trials and the expected regulatory pathway for elafibranor. 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) and on the website of the AMF (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.

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