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: July 30, 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 July 29, 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: July 30, 2019

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

EXHIBIT 99.1

GENFIT: FDA and EMA Grant GENFIT's Elafibranor Orphan Drug Designation for Primary Biliary Cholangitis (PBC)

FDA and EMA Grant GENFIT's Elafibranor Orphan Drug Designation for Primary Biliary Cholangitis (PBC)

Lille (France), Cambridge (Massachusetts, United States), July 29, 2019 – GENFIT (Nasdaq and Euronext: GNFT), 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 the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have both granted Orphan Drug Designation to elafibranor, a PPAR alpha/delta agonist, for the treatment of PBC.

PBC is a cholestatic liver disease, wherein bile ducts become damaged leading to scarring of liver tissue or cirrhosis. The causes are still unknown. This disease mainly affects women, and many patients cannot benefit from existing therapies, representing a significant unmet medical need.

Elafibranor, in a Phase 2 placebo-controlled trial in PBC patients with inadequate response to UDCA, clearly showed statistical significance on achieving the primary endpoint of reducing ALP versus placebo. Beneficial effects in patients also included improvements in cholestatic markers (GGT, 5'), lipid markers (total cholesterol, LDL, and triglycerides) and anti-inflammatory markers (IgM, CRP, haptoglobin and fibrinogen). These improvements are consistent with the results from the Phase 2b clinical trial evaluating elafibranor in NASH, and essential when treating a cholestatic disease such as PBC, or when treating NASH which is considered as the liver manifestation of the metabolic syndrome.

In this trial, elafibranor also met the composite endpoint used for drug registration in PBC, providing further evidence about its strong potential to treat this pathology and robust insights confirming its highly competitive profile.

Earlier this year, elafibranor received Breakthrough Therapy Designation from the FDA for the treatment of PBC, following the detailed presentation of this positive Phase 2 data during EASL 2019.

Dr. Velimir A. Luketic, MD, Division of Gastroenterology, Hepatology and Nutrition, Virginia Commonwealth University School of Medicine, Richmond, VA (USA), commented: *"Elafibranor has shown over the course of just 12 weeks a substantial anti-cholestatic impact in PBC patients with inadequate response to UDCA. The magnitude of the effect observed in markers of liver dysfunction and inflammation provides us with strong confidence in elafibranor's ability to address the medical need of patients suffering from this severe condition. Aside from the clinical benefits, elafibranor also demonstrated a positive safety and tolerability profile, potentially providing an antipruritic effect, which further addresses the symptoms of PBC."*

Dr Pascal Birman, Deputy Chief Medical Officer of GENFIT, added: "*PBC is a devastating disease with very few treatment options, and of those that do exist, often they do not ensure an adequate patient response. This is why new therapies are urgently needed, and also one of the reasons why we have support from both the U.S. and E.U. regulatory agencies. The compelling Phase 2 PBC data provide hope for patients and their families. We expect to launch the Phase 3 trial later this year and further demonstrate the safety and efficacy of elafibranor in PBC."*

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), for which it has been granted Fast Track Designation. 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 severe liver disease. Elafibranor was granted a Breakthrough Therapy Designation in this indication.

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. Elafibranor has shown promising results for the treatment of PBC in a Phase 2 clinical trial, and was granted the Breakthrough Therapy Designation by the FDA in this indication.

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 160 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). 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 the timing of the launch of a Phase 3 trial of elafibranor in 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) 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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Attachment

- 2019.07.29 - PR - FDA Orphan designation for PBC (https://ml-eu.globenewswire.com/Resource/Download/ae30536c-70e6-48ff-a4da-9a7eaf92ea0f)