

**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: September 24, 2020

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

<u>Exhibit</u>	<u>Description</u>
99.1	Press Release dated September 24, 2020.

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: September 24, 2020

By: /s/ Pascal PRIGENT

Name: Pascal PRIGENT

Title: Chief Executive Officer



GENFIT Announces First Patient First Visit for ELATIVE Phase 3 Study Evaluating Elafibranor in PBC

Lille, France; Cambridge, M.A.; September 24, 2020 - GENFIT (Nasdaq and Euronext: GNFT), a late-stage biopharmaceutical company dedicated to improving the lives of patients with metabolic and liver diseases, today announced the first patient first visit for ELATIVE, the global, pivotal, Phase 3 study evaluating elafibranor in Primary Biliary Cholangitis (PBC).

ELATIVE is a randomized, double blind, placebo-controlled, global multicenter Phase 3 study evaluating the efficacy and safety of elafibranor, a dual PPAR alpha and delta agonist, in PBC. The primary endpoint will evaluate the response to treatment defined by alkaline phosphatase (ALP) $< 1.67 \times$ upper limit of normal (ULN), total bilirubin (TB) \leq ULN and ALP decrease $\geq 15\%$. Key secondary endpoints will include the effect of elafibranor on normalization of ALP and change in pruritus from baseline. The randomized study (2:1, elafibranor:placebo) will evaluate approximately 150 patients with inadequate response to ursodeoxycholic acid (UDCA) following 52 weeks of treatment.

PBC is a severe cholestatic liver disease that impacts and gradually destroys the bile ducts, leading to inflammation and scarring in the liver. This condition, if left untreated, can lead to cirrhosis, liver failure and may ultimately require liver transplantation. There is no existing cure for PBC, and current therapies are only able to potentially slow the progression of the disease. Approximately half of patients with PBC are unable to benefit from existing therapies due to lack of response or intolerable side effects.

Kris V. Kowdley, MD, Director at Liver Institute Northwest, Seattle, WA, and Clinical Professor at the Elson S. Floyd College of Medicine, Washington State University, commented:

“A significant percentage of patients with PBC are in need of additional therapies and face a reduced quality of life due to the debilitating disease symptoms and treatment side effects, including pruritus. This leaves healthcare professionals with limited therapeutic options and ongoing need for new therapies, given that in the absence of treatment the median survival for some patients presenting with symptoms may be as short as seven to eight years.² The development of a new promising therapy with the potential to address both cholestasis and pruritus provides hope for patients and healthcare providers in treating the PBC population.”

¹ Shah RA, Kowdley KV. Current and potential treatments for primary biliary cholangitis. *Lancet Gastroenterol Hepatol.* 2020 Mar;5(3):306-315. doi: 10.1016/S2468-1253(19)30343-7. Epub 2019 Dec 2. PMID: 31806572.

² Lindor et al. *Hepatology* 2019.



PRESS RELEASE

In 2018, GENFIT announced positive Phase 2 data in PBC, where elafibranor showed a clinically relevant improvement on the primary and composite biochemical endpoints providing early confirmation of efficacy, a positive trend on pruritus improvement, while maintaining a favorable tolerability profile. Based upon these data, elafibranor was granted Breakthrough Therapy designation by the Food and Drug Administration (FDA), as well as Orphan Drug designation by the FDA and the European Medicines Agency (EMA).

Pascal Prigent, CEO at GENFIT, added: *“I am proud of the GENFIT team, who have worked hard to achieve the first patient first visit for ELATIVE amidst the ongoing challenges presented by the COVID-19 global pandemic. This is a significant milestone and it means that we are now a step closer to hopefully bringing patients and caregivers a promising option to treat this debilitating disease and its symptoms. We see an important potential for elafibranor in PBC and will provide further information at the upcoming Corporate Update on September 30.”*

ABOUT PBC

Primary biliary cholangitis (PBC) is a chronic, autoimmune 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, currently in a phase 3 clinical trial for PBC (ELATIVE), has shown promising results for the treatment of PBC in a Phase 2 clinical trial, and was granted Breakthrough Therapy designation by the FDA and Orphan Drug designation by the FDA and EMA in this condition.

ABOUT GENFIT

GENFIT is a late-stage biopharmaceutical company dedicated to improving the lives of patients with metabolic and liver diseases. GENFIT is a pioneer in the field of nuclear receptor-based drug discovery, with a rich history and strong scientific heritage spanning more than two decades. GENFIT has initiated a Phase 3 clinical trial of elafibranor in patients with PBC. As part of GENFIT’s comprehensive approach to clinical management of patients with liver disease, the Company is also developing NIS4™, a new, non-invasive blood-based diagnostic technology which, if approved, could enable easier identification of patients with at-risk NASH. With facilities in Lille and Paris, France, and Cambridge, MA, USA, the Company has approximately 200 employees. GENFIT is a publicly traded company listed on the Nasdaq Global Select Market and on compartment B of Euronext’s regulated market in Paris (Nasdaq and Euronext: GNFT). 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 statements regarding the potential 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 2.1 “Main Risks and Uncertainties” of the Company’s 2019 Universal Registration Document filed with the AMF on May 27, 2020 under n° D.20-0503, 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 20-F dated May 27, 2020. 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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