

**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: February 9, 2021**

**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):

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EXHIBIT LIST

**Exhibit**

**Description**

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[99.1](#)

[Press Release dated February 9, 2021](#)

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**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: February 9, 2021

By: /s/ Pascal PRIGENT

Name: Pascal PRIGENT

Title: Chief Executive Officer

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## GENFIT Announces Publication of Positive Results from the Phase 2 Clinical Trial Evaluating Elafibranor in Patients with PBC in the *Journal of Hepatology*

**Lille, France; Cambridge, MA; February 09, 2021** - GENFIT (Nasdaq and Euronext: GNFT), a late-stage biopharmaceutical company dedicated to improving the lives of patients with metabolic and liver diseases, today announced that the positive results from the Phase 2 clinical trial evaluating elafibranor in patients with Primary Biliary Cholangitis (PBC) with incomplete response to ursodeoxycholic acid (UDCA) have been published in the *Journal of Hepatology*.

**Dr. Carol Addy, CMO at GENFIT**, commented: *“These data support the potential for elafibranor as novel treatment in PBC and confirm the rationale of evaluating our compound in this disease in a pivotal Phase 3 trial. PBC remains a disease with significant unmet medical needs, mostly because a substantial number of patients have insufficient response or cannot benefit from existing therapies. This publication reminds us that research can give patients and healthcare professionals hope for new therapeutic options. We seek to replicate the Phase 2 efficacy and safety results in ELATIVE™, our Phase 3 clinical trial in PBC, in the hope that we may improve the prospect of new treatment for patients.”*

These data show a clinically relevant improvement on the primary and composite biochemical endpoints, a positive trend on pruritus improvement, while maintaining a favorable tolerability profile, all of which are supportive of the conduct of ELATIVE™, a longer term, larger scale pivotal Phase 3 study to evaluate elafibranor in patients with PBC.

**Dr. Jörn Schattenberg, Director Metabolic Liver Research Program, University Medical Center, Mainz, Germany** added: *“These promising findings along with existing safety data derived from past clinical trials suggest elafibranor is a promising development candidate as a potential novel treatment for patients with PBC. Regulatory authorities know the disease well and there remains an important unmet need to be addressed as many patients at present remain without a long-term therapeutic option.”*

Based upon the Phase 2 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). In September 2020, GENFIT initiated enrollment of patients in ELATIVE™, a global pivotal Phase 3 clinical trial to evaluate the efficacy and safety of elafibranor in patients with PBC and an inadequate response to UDCA. The randomized study (2:1, elafibranor: placebo) will evaluate approximately 150 patients following 52 weeks of treatment. Topline data are expected in Q1 2023.

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## PRESS RELEASE

**Dr. Kris V. Kowdley, Director, Liver Institute Northwest, Clinical Professor Elson S. Floyd College of Medicine, Washington State University** added: *“These encouraging Phase 2 data are particularly exciting as they highlight a favorable trend in pruritus, which is a debilitating symptom of PBC and one that significantly affects patients’ quality of life. These data suggest that elafibranor is a promising drug candidate, and I’m eager to see whether this trend becomes more significant following longer-term administration, while maintaining the favorable safety/tolerability profile we have seen in the Phase 2 trial.”*

### ABOUT GENFIT

GENFIT is a late-stage biopharmaceutical company dedicated to improving the lives of patients with cholestatic and metabolic chronic 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 is currently enrolling in ELATIVE™, a Phase 3 clinical trial evaluating elafibranor in patients with Primary Biliary Cholangitis (PBC). Elafibranor is an investigational compound that has not been reviewed and has not received approval by any regulatory authority. 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 could enable easier identification of patients with at-risk NASH. NIS4™ technology has been licensed to LabCorp in the U.S. and Canada for the development and commercialization of a blood-based molecular diagnostic test powered by NIS4™ technology. GENFIT has facilities in Lille and Paris, France, and Cambridge, MA, USA. 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](http://www.genfit.com)

### FORWARD LOOKING STATEMENTS

This press release contains certain forward-looking statements with respect to GENFIT, including those within the meaning of the Private Securities Litigation Reform Act of 1995, with respect to GENFIT, including statements regarding the ability to reproduce the Phase 2 PBC trial efficacy and safety results in the ELATIVE Phase 3 clinical trial and expectations regarding timing of the publication of topline data from the ELATIVE Phase 3 trial. The use of certain words, including “consider”, “contemplate”, “think”, “aim”, “expect”, “understand”, “should”, “aspire”, “estimate”, “believe”, “wish”, “may”, “could”, “allow”, “seek”, “encourage” or “have confidence” or (as the case may be) the negative forms of such terms or any other variant of such terms or other terms similar to them in meaning is intended to identify forward-looking statements. Although the Company believes its projections are based on reasonable expectations and 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 in relation 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, exchange rate fluctuations 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 AMF, including those listed in Chapter 2 “Main Risks and Uncertainties” of the Company’s 2019 Universal Registration Document filed with the AMF on 27 May 2020 under n° D.20-0503 and in Section 2 “Risk Factors” of the Company’s Amendment to the Universal Registration Document filed with the AMF on 22 December 2020 under n° D.20-0503-A01, which are available on the Company’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 2019 Annual Report on Form 20-F filed with the SEC on 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.

### CONTACT

#### GENFIT | Investors

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