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 13, 2022

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 September 13, 2022.

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 13, 2022

By: /s/ Pascal PRIGENT
Name: Pascal PRIGENT
Title: Chief Executive Officer

FDA Grants GENFIT's GNS561 Orphan Drug Designation for the Treatment of Cholangiocarcinoma

Lille (France), Cambridge (Massachusetts, United States), September 13, 2022 – GENFIT (Nasdaq and Euronext: GNFT), a late-stage biopharmaceutical company dedicated to improving the lives of patients with severe chronic liver diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to GNS5611 (ezurpimtrostat), a novel clinical-stage autophagy/PPT1 inhibitor, for the treatment of cholangiocarcinoma.

Cholangiocarcinoma is a rare liver malignancy with high mortality and limited treatment options. It occurs mostly in people over the age of 50.

GNS561 (ezurpimtrostat) is a PPT-1 (Palmitoyl Protein Thioesterase-1) inhibitor that blocks autophagy. Autophagy is activated in tumor cells in response to certain conditions, due to a tumor cell growth in advanced cancers. GNS561 has completed pre-clinical studies and a Phase 1b trial confirming the rationale for targeting cholangiocarcinoma. A Phase 2 trial is expected to start in the fourth quarter 2022, with a first patient visit expected in the first quarter 2023.

Dr Mark Yarchoan, **Associate Professor of Oncology at John Hopkins Medicine (Baltimore, MD)** commented: "*Cholangiocarcinoma is a rare cancer with a high mortality rate. Patients have limited treatment options, particularly following first line therapy. This is why new therapies are urgently needed and is one of the reasons that GNS561 was granted Orphan Drug Designation by the FDA. There is a real path forward for new options for second line treatment in cholangiocarcinoma, and GNS561 represents a strong second-line therapy candidate and hope to patients.*"

ABOUT GNS561

GNS561 is a PPT-1 (Palmitoyl Protein Thioesterase-1) inhibitor that blocks autophagy. Autophagy is activated in tumor cells in response to certain conditions, due to a tumor cell growth in advanced cancers. One of the key cellular organs implicated in the autophagy process is the lysosome. By entering the lysosomes and binding to its target, GNS561 has an important inhibiting activity on late-stage autophagy, which leads to tumor cell death.

ABOUT CHOLANGIOCARCINOMA

Cholangiocarcinoma is a type of cancer that forms in the slender tubes (bile ducts) that carry the digestive fluid bile. Cholangiocarcinoma occurs mostly in people over the age of 50. Cholangiocarcinoma is divided into intrahepatic and extrahepatic types based on where the

disease occurs in the bile ducts. Cholangiocarcinoma is often diagnosed when it is advanced, making successful treatment difficult to achieve. Several risk factors of chronic inflammatory damage and increased cellular turnover have been established, such as primary sclerosing cholangitis (a cholestatic liver disease), liver flukes, biliary tract cysts, hepatolithiasis and toxins. Treatment options for cholangiocarcinoma are limited and associated with high rates of tumor recurrence, and short survival times.

ABOUT GENFIT

GENFIT is a late-stage biopharmaceutical company dedicated to improving the lives of patients with severe chronic liver diseases characterized by high unmet medical needs. GENFIT is a pioneer in liver disease research and development with a rich history and strong scientific heritage spanning more than two decades. Thanks to its expertise in bringing early-stage assets with high potential to late development and pre-commercialization stages, today GENFIT boasts a growing and diversified pipeline of innovative therapeutic and diagnostic solutions.

Its R&D is focused on three franchises: cholestatic diseases, Acute on Chronic Liver Failure (ACLF) and NASH diagnostics. In its cholestatic diseases franchise, ELATIVE™, a Phase 3 global trial evaluating elafibranor[1] in patients with Primary Biliary Cholangitis (PBC) is well underway following a successful Phase 2 clinical trial (https://pubmed.ncbi.nlm.nih.gov/33484775/). Topline data is expected to be announced in the second quarter 2023. In 2021, GENFIT signed an exclusive licensing agreement with IPSEN to develop, manufacture and commercialize elafibranor in PBC and other indications. [2] GENFIT is also developing GNS561[1] in cholangiocarcinoma following the acquisition of exclusive rights in this indication from Genoscience Pharma in 2021[3]. In ACLF, a Phase 1 clinical program with nitazoxanide has been initiated with data expected as early as the third quarter 2022. As part of its diagnostic solutions franchise, the Company entered into an agreement with Labcorp in 2021 to commercialize NASHnext®, powered by GENFIT's proprietary diagnostic technology NIS4® in identifying at-risk NASH.

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). In 2021, IPSEN became one of GENFIT's largest shareholders and holds 8% of the company's share capital. www.genfit.com

[1] Elafibranor and GNS561 are investigational compounds that have not been reviewed nor been approved by a regulatory authority
[2] With the exception of China, Hong Kong, Taiwan, and Macau where Terns Pharmaceuticals holds the exclusive license to develop and commercialize elafibranor
[3] Agreement includes commercialization and development in the United States, Canada and Europe, including the United Kingdom and Switzerland

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, including statements regarding the timelines to start a Phase 2 study of GNS561 in cholangiocarcinoma, the expected timeline for first patient enrollment and the probability of success of GNS561's mechanism of action to address the unmet medical need related to cholangiocarcinoma. 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, the impact of the COVID-19 pandemic, 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 2021 Universal Registration Document filed with the AMF on 29 April 2022 under n° D.22-0400, which is available on the Company'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 2021 Annual Report on Form 20-F filed with the SEC on April 29, 2022. 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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