

**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 26, 2024

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

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## INCORPORATION BY REFERENCE

The contents of this report on Form 6-K (including Exhibit 99.1) are hereby incorporated by reference into the registrant's registration statement on Form F-3 (File No. 333-271312) and registration statement on Form S-8 (File No. 333-271311) and related prospectuses, as such registration statements and prospectuses may be amended from time to time, and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished. Information contained on, or that can be accessed through, any website included in Exhibit 99.1 is expressly not incorporated by reference.

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EXHIBIT LIST

<u>Exhibit</u>	<u>Description</u>
<a href="#">99.1</a>	<a href="#">Press Release dated July 26, 2024.</a>

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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: July 26, 2024

By: /s/ Pascal PRIGENT

Name: Pascal PRIGENT

Title: Chief Executive Officer



## **GENFIT: Positive Opinion from EMA Committee for Ipsen's Iqirvo® (elafibranor) in Primary Biliary Cholangitis**

**Lille (France), Cambridge (Massachusetts, United States), Zurich (Switzerland), July 26, 2024** - GENFIT (Nasdaq and Euronext: GNFT), a late-stage biopharmaceutical company dedicated to improving the lives of patients with rare and life-threatening liver diseases, today announced the positive opinion issued by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency's (EMA) for Ipsen's Iqirvo® (elafibranor) for the treatment of Primary Biliary Cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA or as a monotherapy in patients unable to tolerate UDCA.

Elafibranor, a 'first-in-class' molecule marketed and commercialized in the United States by Ipsen under the trademark Iqirvo® since June 2024, was developed by GENFIT, from initial discovery to the conclusion of a 52-week Phase 3 clinical study. Ipsen licensed the exclusive worldwide rights (except China, Hong Kong, Taiwan and Macau) to elafibranor from GENFIT in 2021.

The European Commission will now consider the CHMP recommendations, and a final decision on marketing authorization for Iqirvo® is anticipated in the second half of 2024.

Further details can be found [here](#).

**ENDS**

### **ABOUT GENFIT**

GENFIT is a late-stage biopharmaceutical company committed to improving the lives of patients with rare, life-threatening liver diseases whose medical needs remain largely unmet. GENFIT is a pioneer in liver disease research and development with a rich history and a solid scientific heritage spanning more than two decades. Today, GENFIT has built up a diversified and rapidly expanding R&D portfolio of programs at various stages of development. The Company focuses on Acute-on- Chronic Liver Failure (ACLF). Its ACLF franchise includes five assets under development: VS-01, NTZ, SRT-015, CLM-022 and VS-02-HE, based on complementary mechanisms of action using different routes of administration. Other assets target other serious diseases, such as cholangiocarcinoma (CCA), urea cycle disorder (UCD) and organic acidemia (OA). GENFIT's expertise in the development of high-potential molecules from early to advanced stages, and in pre-commercialization, was demonstrated with the success of the 52-week Phase 3 ELATIVE® study evaluating elafibranor in Primary Biliary Cholangitis (PBC). Elafibranor, a 'first-in-class' molecule developed by GENFIT from

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initial discovery to the conclusion of a 52-week Phase 3 study, is now marketed and commercialized in the United States by Ipsen under the trademark Iqirvo® since June 2024.

Beyond therapies, GENFIT also has a diagnostic franchise, including NIS2+® in Metabolic dysfunction-associated steatohepatitis (MASH, formerly known as NASH for non-alcoholic steatohepatitis) and TS-01 focusing on blood ammonia levels. GENFIT is headquartered in Lille, France and has offices in Paris (France), Zurich (Switzerland) and Cambridge, MA (USA). The Company is listed on the Nasdaq Global Select Market and on the Euronext regulated market in Paris, Compartment B (Nasdaq and Euronext: GNFT). In 2021, Ipsen became one of GENFIT's largest shareholders, acquiring an 8% stake in the Company's capital. [www.genfit.com](http://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, but not limited to statements regarding the timeline for the European Commission to consider the CHMP recommendations, and a final decision on marketing authorization for Iqirvo® in Europe. The use of certain words, such as "believe", "potential", "expect", "target", "may", "will", "should", "could", "if" 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 others, the uncertainties inherent in research and development, including in relation to safety of drug candidates, cost of, progression of, and results from, our ongoing and planned clinical trials, review and approvals by regulatory authorities in the United States, Europe and worldwide, of our drug and diagnostic candidates, potential commercial success of elafibranor if approved, exchange rate fluctuations, and our continued ability to raise capital to fund our 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 "Risk Factors and Internal Control" of the Company's 2023 Universal Registration Document filed on April 5, 2024 (no. D.24-0246) with the *Autorité des marchés financiers* ("AMF"), which is available on GENFIT's website ([www.genfit.fr](http://www.genfit.fr)) and the AMF's website ([www.amf.org](http://www.amf.org)), and those discussed in the public documents and reports filed with the U.S. Securities and Exchange Commission ("SEC"), including the Company's 2023 Annual Report on Form 20-F filed with the SEC on April 5, 2024 and subsequent filings and reports filed with the AMF or SEC or otherwise made public, by the Company. In addition, even if the results, performance, financial position and liquidity of the Company 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

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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**

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