
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: May 9, 2023

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

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be amended from time to time, and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.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.

EXHIBIT LIST

<u>Exhibit</u>	<u>Description</u>
99.1	Press Release dated May 9, 2023.

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: May 9, 2023

By: /s/ PASCAL PRIGENT
Pascal Prigent
Chief Executive Officer



GENFIT Presents Phase 1 Clinical Data Evaluating NTZ at Digestive Disease Week® as part of its ACLF Program

Lille (France); Cambridge (Massachusetts, United States); Zurich (Switzerland); May 9, 2023 - GENFIT (Nasdaq and Euronext: GNFT), a late-stage biopharmaceutical company dedicated to improving the lives of patients with rare and severe liver diseases, today announced that it is presenting Phase 1 clinical data evaluating NTZ as part of its Acute-on-Chronic Liver Failure (ACLF) Program at Digestive Disease Week®, taking place from May 6-9, 2023 in Chicago, Illinois (USA).

The Phase 1, open-label clinical study was conducted to evaluate the safety, tolerability and pharmacokinetics (PK) of nitazoxanide (NTZ) in subjects with hepatic impairment (HI), as part of GENFIT's NTZ in ACLF program.

For the study, subjects between 18 and 75 years of age with HI received repeated oral dose administration of NTZ 500 mg twice a day for 7 days.

NTZ was generally well tolerated, with a favorable safety profile, in subjects with moderate and severe HI.

Preliminary data from a similar Phase 1 study conducted in subjects with renal impairment also support a favorable safety and tolerability profile. Taken together, safety and pharmacokinetic results, as well as exploratory pharmacodynamic data, support further clinical development of NTZ in patients with ACLF.

A Phase 2a proof of concept study with NTZ in patients with ACLF grades 1 and 2 is currently under discussion with the FDA.

Dr. Carol Addy, CMO at GENFIT commented:

"We are pleased with the encouraging data and outcome of this Phase 1 study as it supports the potential of NTZ in ACLF and the rationale for further exploration of this drug in this indication. ACLF is an underserved medical condition given its high short-term mortality and that no drugs are currently approved for this indication. We hope that the Phase 2 study, expected to be launched in the second half of 2023, will replicate these encouraging results and support the potential for NTZ as a novel therapeutic option for patients with ACLF."



PRESS RELEASE

POSTER PRESENTATION

Presentation title: Pharmacokinetics and safety of nitazoxanide in subjects with hepatic impairment

Session type: Poster session

Session title: AASLD Acute on Chronic Liver Failure - Acute on Chronic Liver Failure

Session Date & Time: May 9, 2023 from 12.30PM to 1.30PM CDT

Poster number: Tu1503

Authors: Carol Addy et al

ABOUT DIGESTIVE DISEASE WEEK® (DDW)

Digestive Disease Week® (DDW) is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases (AASLD), the American Gastroenterological Association (AGA) Institute, the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Surgery of the Alimentary Tract (SSAT), DDW takes place May 6-9, 2023 in Chicago, Illinois (USA). The meeting showcases more than 3,100 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. More information can be found at www.ddw.org.

ABOUT GENFIT

GENFIT is a late-stage biopharmaceutical company dedicated to improving the lives of patients with rare and severe 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 pipeline covers six therapeutic areas via six programs which explore the potential of differentiated mechanisms of action, across a variety of development stages (pre-clinical, Phase 1, Phase 2, Phase 3). These diseases are acute on-chronic liver failure (ACLF), hepatic encephalopathy (HE), cholangiocarcinoma (CCA), urea cycle disorder (UCD), organic acidemias (OA) and primary biliary cholangitis (PBC). Beyond therapeutics, GENFIT's pipeline also includes a diagnostic franchise focused on NASH and ACLF.

GENFIT | 885 Avenue Eugène Avinée, 59120 Loos - FRANCE | +333 2016 4000 | www.genfit.com



PRESS RELEASE

GENFIT has facilities in Lille and Paris (France), Zurich (Switzerland) 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

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 in relation to the potential of NTZ as a therapeutic option for patients with ACLF and expectations regarding the timeline for the launch and the results of the Phase 2 study. The use of certain words, including "consider", "contemplate", "think", "aim", "expect", "understand", "should", "aspire", "estimate", "targeted", "anticipated", "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, cost of, progression of, and results from, its ongoing and planned clinical trials, review and approvals by regulatory authorities in the United States, Europe and worldwide, of our drug and diagnostic candidates, exchange rate fluctuations, potential synergies related to the acquisition of Versantis, our capacity to integrate its assets, develop its programs 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 "Main Risks and Uncertainties" of the Company's 2022 Universal Registration Document filed with the AMF on April 18, 2023, 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 2022 Annual Report on Form 20-F filed with the SEC on April 18, 2023. 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

Tel: +33 3 2016 4000 | investors@genfit.com

PRESS RELATIONS | Media

Stephanie Boyer – Press relations | Tel: +33 3 2016 4000 | stephanie.boyer@genfit.com

GENFIT | 885 Avenue Eugène Avinée, 59120 Loos - FRANCE | +333 2016 4000 | www.genfit.com