

**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 23, 2019**

**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

<u>Exhibit</u>	<u>Description</u>
<a href="#">99.1</a>	<a href="#">Press Release dated May 23, 2019.</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: May 23, 2019

By: /s/ Jean-François Mouney

Name: Jean-François Mouney

Title: Chairman and Chief Executive Officer



## GENFIT Launches a Combination Therapy Clinical Program in NASH

- GENFIT has identified multiple therapeutic compounds synergistic with its lead asset, elafibranor (PPAR alpha/delta), for the treatment of NASH
- Combined metabolic mechanisms could offer optimal benefits by addressing the underlying drivers of NASH disease progression and its downstream consequence, fibrosis, through complementary pathways
- A proof of concept study will initiate in 2H19 to evaluate safety, tolerability and exploratory markers of efficacy of a GLP-1 receptor agonist or an SGLT2 inhibitor in combination with elafibranor as backbone therapy
- This program will leverage non-invasive diagnostic tools, including GENFIT's NIS4, an innovative diagnostic blood test for NASH identification and monitoring

**Lille (France), Cambridge (Massachusetts, United States), May 23, 2019** – GENFIT (Nasdaq and Euronext: GNFT), a late-stage biopharmaceutical company dedicated to the discovery and development of innovative therapeutic and diagnostic solutions in metabolic and liver related diseases, today announced the launch of a combination program to identify new treatment options for NASH, using elafibranor as backbone therapy.

Elafibranor, a PPAR alpha/delta agonist and GENFIT's lead compound, is currently the only therapy in an advanced Phase 3 trial targeting "NASH resolution without worsening of fibrosis" (RESOLVE-IT clinical study). As such, elafibranor could be the first monotherapy to be approved by regulatory agencies for resolving NASH, the underlying cause of disease progression potentially leading to cirrhosis or cancer. Compelling Phase 2b data published in *Gastroenterology*, by Ratziu, in May 2016, have shown elafibranor's unique potential to combine:

- Efficacy on "NASH resolution without worsening of fibrosis", the FDA/EMA regulatory endpoint that addresses the underlying cause of disease progression;
- Improvement of the cardiometabolic risk profile (reduction of LDL and TG, increase of HDL, and improvement of insulin sensitivity), crucial for NASH patients;
- Favorable safety and tolerability profile, which is essential for a pharmacological treatment targeting a chronic and silent condition like NASH.



## PRESS RELEASE

Based on these positive Phase 2b data, GENFIT plans to expand its pipeline with an ambitious combination program and will start to evaluate synergies between elafibranor and a GLP-1 receptor agonist, and elafibranor in combination with an SGLT2 inhibitor. The anticipated clinical trial will be a proof of concept study evaluating safety, tolerability and exploratory markers of efficacy in both combinations for the treatment of NASH.

The study will also utilize non-invasive diagnostic tools, including NIS4, GENFIT's innovative diagnostic blood test for NASH patient identification and monitoring. Starting in 2H19, this will be the first clinical trial in the field to evaluate a Phase 3 compound in development for NASH in combination with anti-diabetic drugs.

### Trial Design

- Study to assess safety, tolerability and exploratory markers of efficacy of elafibranor (120mg) in combination with a GLP1 analogue or in combination with an SGLT2 inhibitor;
- Study will enroll and monitor patients with suspected NASH and significant to advanced fibrosis, through the use of non-invasive technologies;
- U.S. multi-center study with 24-week trial duration.

This combination program complements GENFIT's growing foothold as an industry leader in the field of NASH, with a pipeline currently including two pharmacologic assets in development (elafibranor and nitazoxanide) and NIS4, a diagnostic blood test for NASH and fibrosis.

**Dean Hum, Chief Operating Officer and Chief Scientific Officer at GENFIT** said: *"NASH is a multifaceted cardio-metabolic disease affecting the liver, the cardiovascular system, and a driver of systemic decline. Like in diabetes, over time, optimal treatments will likely combine several molecules with already proven efficacy and clean safety as stand-alone therapies. Consequently, we believe combining multiple potentially synergistic mechanisms that target the underlying pathways of NASH will be a relevant way to optimize clinical management of NASH patients."*

**Dr. Stephen Harrison, Medical Director of Pinnacle Clinical Research, San Antonio, TX, USA**, added: *"NASH and cardiometabolic diseases are closely associated with one another, which is why it is very exciting to evaluate whether some drugs acting on complementary pathways can provide additional benefit when combined to elafibranor, which has already demonstrated in a Phase 2b its potential as a monotherapy to resolve NASH."*



## PRESS RELEASE

### ABOUT ELAFIBRANOR

Elafibranor is GENFIT's lead pipeline product candidate. Elafibranor is an oral, once-daily, first-in-class drug acting via dual peroxisome proliferator-activated alpha/delta pathways developed to treat, in particular, nonalcoholic steatohepatitis (NASH), for which it has been granted Fast Track Designation. GENFIT believes, based on clinical results to date, that elafibranor has the potential to address multiple facets of NASH, including inflammation, insulin sensitivity, lipid/metabolic profile, and liver markers. Phase 2 clinical trial results have also shown that elafibranor may be an effective treatment for PBC, a severe liver disease. Elafibranor was granted a Breakthrough Therapy Designation in this indication.

### ABOUT NASH

NASH is a liver disease characterized by an accumulation of fat (lipid droplets), along with inflammation and degeneration of hepatocytes. The disease is associated with long term risk of progression to cirrhosis, a state where liver function is diminished, leading to liver failure, and also progression to liver cancer.

### ABOUT GENFIT

GENFIT is a late-stage biopharmaceutical company dedicated to the discovery and development of innovative therapeutic and diagnostic solutions in metabolic and liver related diseases where there are considerable unmet medical needs, corresponding to a lack of approved treatments. GENFIT is a leader in the field of nuclear receptor-based drug discovery with a rich history and strong scientific heritage spanning almost two decades. Its most advanced drug candidate, elafibranor, is currently being evaluated in a pivotal Phase 3 clinical trial ("RESOLVE-IT") as a potential treatment for NASH, and GENFIT plans to initiate a Phase 3 clinical trial in PBC later this year following its positive Phase 2 results. As part of GENFIT's comprehensive approach to clinical management of NASH patients, the company is also developing a new, non-invasive and easy-to-access blood-based *in vitro* diagnostic test to identify patients with NASH who may be appropriate candidates for drug therapy. With facilities in Lille and Paris, France, and Cambridge, MA, USA, the Company has approximately 150 employees. GENFIT is a public company listed on the Nasdaq Global Select Market and in 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, including those within the meaning of the Private Securities Litigation Reform Act of 1995, with respect to GENFIT, including



## PRESS RELEASE

the potential benefits of combination therapy with elafibranor in addressing NASH and fibrosis, the timing of the start of a proof of concept study in combination with elafibranor and the approval of elafibranor in NASH and the timing thereof by regulatory authorities. 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 4 “Main Risks and Uncertainties” of the Company’s 2018 Registration Document filed with the AMF on February 27, 2019 under n° D.19-0078, which is available on GENFIT’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 final prospectus dated March 26, 2019, and subsequent filings and reports filed with the AMF or SEC, or otherwise made public, by the Company. 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

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