# 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: June 24, 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): $\Box$			
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): $\Box$			

## EXHIBIT LIST

Exhibit	Description		
99.1	Press Release dated June 24, 2019.		

## **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.

Date: June 24, 2019

## **GENFIT S.A.**

By: /s/ Jean-François Mouney

Name: Jean-François Mouney

Title: Chairman and Chief Executive Officer









# GENFIT and Terns Pharmaceuticals Announce \$228MM Strategic Partnership to Develop and Commercialize Elafibranor in Greater China

Lille (France), Cambridge (Massachusetts, United States), June 24, 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 signing of a licensing and collaboration agreement with Terns Pharmaceuticals, a global biopharmaceutical company based in the U.S. and China with a focus on developing novel and combination therapies to treat liver disease. Under the agreement, Terns will have the rights to develop and commercialize elafibranor, GENFIT's proprietary compound, in Greater China, for the treatment of non-alcoholic steatohepatitis (NASH) and primary biliary cholangitis (PBC).

Under the terms of the licensing agreement, GENFIT will receive an upfront payment from Terns of \$35 million and will be eligible to receive up to \$193 million in potential clinical, regulatory and commercial milestone payments. Terns obtains the exclusive rights to develop, register and market elafibranor in mainland China, Hong Kong, Macau and Taiwan ("Greater China") for both NASH and PBC. Upon commercial launch of elafibranor for the treatment of NASH in Greater China, GENFIT will be entitled to receive mid-teen percentage royalties from Terns based on sales in the territory.

As part of the deal, GENFIT and Terns will also undertake joint R&D projects in liver disease, including the development of elafibranor in combination with Terns' proprietary compounds.

Backed by experienced investors in the pharmaceutical industry, including Orbimed, Lilly Asia Ventures, Vivo Capital and Decheng Capital, Terns has extensive clinical development capabilities in China and a robust pipeline of early-stage candidates that present promising opportunities for potential combination therapy with elafibranor.

GENFIT believes that, with a strong presence in China, a seasoned leadership team, and roots in the San Francisco Bay Area biotechnology hub, Terns is well-positioned to maximize elafibranor's value in China. Terns' large footprint in both geographies provides an advantage in navigating the development and regulatory processes required to obtain approvals in Greater China territories, while also ensuring the preparation for a strong commercial launch and long-term sales growth. New regulations currently being implemented in China are expected to accelerate and facilitate the approval of innovative therapies developed by both domestic and international companies.



**Pascal Prigent, Executive Vice President Marketing and Commercial Development of GENFIT** said: "The Terns management team has a strong track record at global pharma and biotech companies, combined with a good understanding of key scientific, regulatory and commercial challenges in China, which gives us a strong level of confidence as to what we can achieve in China through this strategic partnership. We believe mutual alignment on upcoming strategic development steps and priorities paves the way for a bright future together."

Weidong Zhong, PhD., President and CEO of Terns Pharmaceuticals, added: "Since our founding, we have been focused on taking a comprehensive approach to treating liver disease and NASH, and have been working hard to identify compounds with strong, complementary mechanisms of action to add to our portfolio. In addition to its appealing mechanism of action, elafibranor is well positioned in an ongoing Phase 3 program to demonstrate NASH resolution as defined by global regulatory authorities and to provide meaningful benefit for patients living with NASH and PBC. We are excited to work with GENFIT to advance elafibranor as the leading treatment for NASH and PBC in the Greater China region and as the basis for building future combination NASH therapies. We value the experience and accomplishments of GENFIT on disease awareness and non-invasive diagnosis which are essential for the management of NASH patients in all markets and look forward to a productive partnership between our two companies as we seek to improve treatment options for patients living with chronic liver disease."

#### 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 by the U.S. Food and Drug Administration (FDA). 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 PBC by the FDA.

#### **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 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 160 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). <a href="https://www.genfit.com">www.genfit.com</a>



#### **ABOUT TERNS**

Terns Pharmaceuticals, Inc. is a clinical-stage pharmaceutical company that is focused on the discovery and development of medicines for chronic liver disease and cancer. Based in China and the United States, the company is advancing a pipeline of drug candidates for the treatment of non- alcoholic steatohepatitis (NASH) and cancer, across multiple modalities. Terns leverages world class expertise in disease biology, medicinal chemistry, and clinical development in order to bring promising new therapies to patients in China and other global markets. <a href="https://www.ternspharma.com">www.ternspharma.com</a>

#### 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 the potential to and success of commercialization of elafibranor in Greater China and the effect of new regulations in China to accelerate and facilitate drug approvals. 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) 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 final prospectus dated March 26, 2019, and subsequent filings and reports filed with the AMF or SEC, or otherwise made public, by the Company.

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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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