
PRESS RELEASE

GENFIT: Positive 36-month DSMB Recommendation for Continuation of Phase 3 RESOLVE-IT Study of Elafibranor in NASH

- **Data Safety Monitoring Board (DSMB) recommends the continuation of the RESOLVE-IT clinical trial without any modifications, based on the pre-planned review of safety data**
- **Positive recommendation consistent with previous guidance, supporting favorable safety profile of Elafibranor**

Lille (France), Cambridge (Massachusetts, United States), May 14, 2019 – **GENFIT (Euronext: GNFT – Nasdaq: 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 that the Data Safety Monitoring Board (DSMB) issued a new positive recommendation for the continuation, without any modifications, of the RESOLVE-IT Phase 3 trial evaluating elafibranor in NASH. This sixth planned review by the DSMB reiterates previous positive guidance and saw no safety concerns.

The 36-month positive DSMB safety review supports GENFIT's positive momentum in continuing the RESOLVE-IT study. Top-line interim results, based on the primary endpoint of "NASH resolution without worsening of fibrosis", are expected to be announced at the end of 2019. If positive, the interim data would support accelerated approval (Subpart H) from the U.S. Food and Drug Administration (FDA), and conditional approval from the European Medicines Agency (EMA), as early as 2020. Elafibranor is currently the only late-stage, Phase 3 therapy undergoing investigation for "NASH resolution without the worsening of fibrosis". As such, elafibranor could be the first available therapy able to eliminate the underlying cause of NASH disease progression. Elafibranor has received fast track designation from the FDA for the treatment of NASH.

Dr Pascal Birman, Deputy Chief Medical Officer of GENFIT, commented: *"This sixth positive DSMB review continues to support GENFIT's development of elafibranor in NASH. NASH is considered a chronic condition and therefore a clean safety profile is crucial for any drug candidate aiming to address the unmet clinical needs related to this pathology. In addition, the safety profile gives us further confidence as we explore elafibranor in the clinical setting, specifically for pediatric NASH – a naïve patient population and a trial we expect to begin enrolling shortly – and PBC, a program we plan to move into a Phase 3 clinical trial later this year."*

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). 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 rare liver disease.

ABOUT RESOLVE-IT

RESOLVE-IT is a phase 3 study evaluating the efficacy and safety of elafibranor 120mg versus placebo in patients with nonalcoholic steatohepatitis (NASH) and fibrosis. It is a multicenter, randomized, double-blind, placebo-controlled study with 2 arms. It is conducted under Subpart H (FDA) and conditional approval (EMA). Treatment duration until interim analysis for accelerated approval is 72 weeks.

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 insufficiency, 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

PRESS RELEASE

the Nasdaq Global Select Market and in compartment B of Euronext's regulated market in Paris (Nasdaq and Euronext: GNFT). 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 the continuation of its clinical trials in NASH. 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. 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

Naomi EICHENBAUM – Investor Relations | Tel: +1 (617) 714 5252 | investors@genfit.com

PRESS RELEASE

PRESS RELATIONS | Media

Hélène LAVIN - Press relations | Tel: +333 2016 4000 | helene.lavin@genfit.com