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PRESS RELEASE

GENFIT: Positive 30-month DSMB Recommendation for Continuation of Phase 3 RESOLVE-IT Study of Elafibranor in NASH

- **Data Safety Monitoring Board (DSMB) recommended the continuation of RESOLVE-IT without any modifications, based on the pre-planned review of safety data, including adverse events and laboratory data**
- **Positive recommendation consistent with previous observations supporting the favorable safety profile of elafibranor**
- **Top line data expected by the end of 2019**

Lille (France), Cambridge (Massachusetts, United States), December 17, 2018 – GENFIT (Euronext: GNFT - ISIN: FR0004163111), 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 DSMB issued a new positive recommendation for the continuation of the RESOLVE-IT Phase 3 trial evaluating elafibranor in nonalcoholic steatohepatitis (NASH) without any modification. This new pre-planned review of the DSMB did not identify any safety concerns.

As NASH is considered a chronic condition, safety is crucial for any drug candidate that aims to address the unmet clinical needs related to this pathology.

The positive DSMB safety review enables GENFIT to move forward as planned, with the RESOLVE-IT study. The Phase 3 trial has already completed recruitment of the cohort needed for the interim analysis. GENFIT expects to report top line data by the end of 2019, a year expected to be pivotal for the NASH space. These results, if positive, would support accelerated approval from the U.S. Food and Drug Administration, or FDA, and conditional approval from the European Medicines Agency, or EMA, as early as 2020. Elafibranor has received fast track designation from the FDA for the treatment of NASH.

Dr Pascal Birman, Deputy Chief Medical Officer of GENFIT, commented: "*NASH is considered a chronic condition and therefore a favorable safety profile is crucial for any drug candidate aiming to address the unmet clinical needs related to this pathology. Safety is indeed an essential requirement*



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for regulatory authorities like the FDA and EMA, and will also be scrutinized by payers. This positive DSMB review gives us confidence as we move toward completion of the first treatment period."

ABOUT ELAFIBRANOR

Elafibranor is GENFIT's lead pipeline product. Elafibranor is being developed as an oral once-daily treatment, and a first-in-class drug acting via dual peroxisome proliferator-activated alpha/delta pathways developed to treat, in particular, nonalcoholic steatohepatitis (NASH). Elafibranor is believed to address multiple facets of NASH, including inflammation, insulin sensitivity, lipid/metabolic profile, and liver markers. Elafibranor also presents a particularly interesting profile to potentially treat PBC, a serious chronic 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", or nonalcoholic steatohepatitis, 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 - state where liver function is diminished, leading to liver insufficiency - and to liver cancer. Patients are also exposed to an aggravated cardiovascular risk, and CVD is the leading cause of death in this population.

ABOUT GENFIT

GENFIT is a biopharmaceutical company focused on discovering and developing drug candidates and diagnostic solutions targeting liver diseases, in particular those of metabolic origin, and hepatobiliary diseases. GENFIT concentrates its R&D efforts in areas of high unmet medical needs corresponding to a lack of approved treatments. GENFIT's lead proprietary compound, elafibranor, is a drug candidate currently being evaluated in one of the most advanced Phase 3 studies worldwide ("RESOLVE-IT") in nonalcoholic steatohepatitis (NASH), considered by regulatory authorities as a medical emergency because it is silent, with potentially severe



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consequences, and with a prevalence on the rise. Elafibranor has also obtained positive results in a Phase 2 clinical trial in Primary Biliary Cholangitis (PBC), a chronic liver disease. As part of its comprehensive approach to clinical management of NASH patients, GENFIT is conducting an ambitious discovery and development program aimed at providing patients and physicians with a blood-based test for the diagnosis of NASH, i.e. non-invasive and easy-to-access. With facilities in Lille and Paris, France, and Cambridge, MA (USA), the Company has approximately 150 employees. GENFIT is a public company listed in compartment B of Euronext's regulated market in Paris (Euronext: GNFT - ISIN: FR0004163111). www.genfit.com

FORWARD-LOOKING STATEMENT/DISCLAIMER

This press release contains certain forward-looking statements. Although the Company believes its expectations are based on reasonable assumptions, these forward-looking statements are subject to numerous 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, including its RESOLVE-IT Phase 3 trial, review and approvals by regulatory authorities, such as the FDA or the EMA, of its drug and diagnostic candidates, the success of any in-licensing strategies, the Company's continued ability to raise capital to fund its development, as well as those discussed or identified in the Company's public filings with the AMF, including those listed in Section 4 "Main Risks and Uncertainties" of the Company's 2017 Registration Document registered with the French Autorité des marchés financiers on April 27, 2018 under n° R.18-032, which is available on GENFIT's website (www.genfit.com) and on the website of the AMF (www.amf-france.org) and as updated by the 2018 Half Year Business and Financial Report and available on the Investors page of GENFIT's website. Other than as required by applicable law, the Company does not undertake any obligation to update or revise any forward-looking information or statements. This press release and the information contained herein do not constitute an offer to sell or a solicitation of an offer to buy or subscribe to shares in GENFIT in any country. This press release has been prepared in both French and English. In the event of any differences between the two texts, the French language version shall supersede.

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