



## PRESS RELEASE

### **GENFIT: Positive Outcome from the 1-year Pre-Planned Safety Review by the DSMB, in RESOLVE-IT Phase 3 Clinical Trial with Elafibranor**

- › **Safety data, including adverse events and laboratory data, were reviewed by the Data Safety Monitoring Board (DSMB) which recommended the continuation of the trial without any modifications**

**Lille (France), Cambridge (Massachusetts, United States), June 1, 2017** – GENFIT (Euronext: GNFT - ISIN: FR0004163111), a biopharmaceutical company at the forefront of developing therapeutic and diagnostic solutions in metabolic and inflammatory diseases, that notably affect the liver or the gastrointestinal system, today announced that the Data Safety Monitoring Board (DSMB) issued a positive recommendation for the continuation of the RESOLVE-IT Phase 3 trial in NASH without any modifications.

**Dean Hum, Chief Scientific Officer of GENFIT**, commented: *"We are pleased that the DSMB has found no safety concern that would require modifying the study. We consider this recommendation as a positive sign for the on-going Phase 3 RESOLVE-IT clinical trial. NASH is indeed a chronic condition, which means that safety is crucial for any molecule aiming to address the unmet clinical needs related to this disease. The positive outcome of this safety review by the DSMB allows us to actively pursue our effort in enrolling patients."*

#### **ABOUT ELAFIBRANOR**

Elafibranor is GENFIT's lead pipeline product. Elafibranor is an oral once-daily administered molecule, and a first-in-class compound 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.

#### **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, a state where liver function is diminished, leading to liver insufficiency, and also progression to liver cancer.



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### ABOUT GENFIT

GENFIT is a biopharmaceutical company focused on the discovery and development of drug candidates in areas of high unmet medical needs corresponding to a lack of suitable treatment and an increasing number of patients worldwide. GENFIT's R&D efforts are focused on bringing new medicines to market for patients with metabolic, inflammatory, autoimmune and fibrotic diseases, that affect the liver (such as NASH – Nonalcoholic steatohepatitis) and more generally the gastrointestinal arena. GENFIT's approach combines novel treatments and biomarkers. Its lead proprietary compound, elafibranor, is currently in a Phase 3 study. With facilities in Lille and Paris, France, and Cambridge, MA (USA), the Company has approximately 130 employees. GENFIT is a public company listed in compartment B of Euronext's regulated market in Paris (Euronext: GNFT - ISIN: FR0004163111). [www.genfit.com](http://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 biomarkers, progression of, and results of clinical data from, the RESOLVE-IT trial, review and approvals by regulatory authorities, such as the FDA or the EMA, regarding in particular, elafibranor in NASH and PBC, as well as other indications, and biomarkers, the success of any inlicensing 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 under Section 4 "Main Risks and Uncertainties" of the Company's 2016 Registration Document registered with the French Autorité des marchés financiers on April 28, 2017 under n° R.17-034, 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)). 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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