



PRESS RELEASE

GENFIT: Major Milestone for the RESOLVE-IT Phase 3 Trial on the Recruitment of the Interim Analysis Cohort

- **Recruitment of the patient cohort for accelerated approval has been reached**
- **Interim baseline data on the first 1,000 randomized patients shows good distribution of patient recruitment worldwide**

Lille (France), Cambridge (Massachusetts, United States), April 11, 2018 – 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 RESOLVE-IT trial in NASH and fibrosis has reached the target recruitment for the interim cohort analysis.

GENFIT's phase 3 registration trial RESOLVE-IT is an international study evaluating the efficacy and safety of elafibranor 120mg once daily in patients with NASH and fibrosis. The primary endpoint is the resolution of NASH without worsening of fibrosis after 72 weeks of treatment.

The recruitment of the patients needed for this analysis has been completed.

The analysis of this histological endpoint will serve as the basis for accelerated approval under Subpart H in the US and international market approval. The phase 3 will continue to enroll the full cohort for long term clinical benefit analysis, based on progression to cirrhosis, mortality, and liver-related outcomes.

The recruitment has also been achieved for the exploratory arm of patients with F1 stage fibrosis.

As initially announced, focus has been made on the balanced distribution of treatments across all sites and countries, based on stratification according to gender, diabetes, and disease severity. In the international setting, patients have been enrolled in more than 250 sites across North America, Europe, Australia, Latin America, Turkey and South Africa.

Interim baseline data on the first 1,000 randomized patients show that these NASH patients have metabolic co-morbidities, with 48% having type 2 diabetes, 59% having hypertension, and 51% having dyslipidemia. The average BMI is 34. Hispanics represent 25% of the study population. The baseline characteristics of the study population are in line with the expected associated risk factors for NASH and fibrosis.



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All these factors will contribute to the robustness of the results, as the study encompasses data from various regions, and allows for a good representation of ethnicities.

Jean-François Mouney, Chairman & CEO of GENFIT, commented: *“We are very pleased to announce that the RESOLVE-IT study has achieved the recruitment goal for the interim cohort. We paid particular attention to having the correct balance in the recruitment and treatment allocation of patients, in order to comply with the approved protocol design. We are confident that this phase 3 registration study has a great foundation for delivering robust data, and in accordance with a real-life setting.”*

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.

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 gastro-intestinal 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



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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 biomarkers, progression of, and results of clinical data from, the RESOLVE-IT trial and the trial of elafibranor in PBC, 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 drug candidates in other indications and biomarkers candidates, 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 in Chapter 7 of the 2017 Half Year Business and Financial Report and 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) and on the website of the AMF (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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