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## PRESS RELEASE

### **GENFIT: Provides Initial Update on Corporate Strategy**

- **Termination of the RESOLVE-IT Phase 3 clinical trial evaluating elafibranor in nonalcoholic steatohepatitis (NASH) with fibrosis**
- **Prioritization of elafibranor in Primary Biliary Cholangitis (PBC) and of NIS4™, GENFIT's non-invasive technology to identify patients with at-risk NASH**
- **Complete corporate strategy update to be announced end of September 2020**

**Lille (France), Cambridge (Massachusetts, United States), July 22, 2020** – **GENFIT (Nasdaq and Euronext: GNFT)**, a late-stage biopharmaceutical company dedicated to improving the lives of patients with metabolic and liver diseases, today announced the discontinuation of the RESOLVE-IT Phase 3 clinical trial of elafibranor in adults with non-alcoholic steatohepatitis (NASH) and fibrosis.

On May 11, 2020, GENFIT announced the results from the interim analysis of the RESOLVE-IT Phase 3 trial, which did not meet the predefined primary surrogate efficacy endpoint of NASH resolution without worsening of fibrosis in the ITT population of 1,070 patients.

Following the detailed review of the full RESOLVE-IT interim efficacy dataset, which involved several experts in the NASH field, GENFIT determined that the investment needed to continue the trial was not justified, as it was unlikely to provide results that would be sufficient to support elafibranor for registration in NASH in the USA and Europe.

GENFIT will now engage with the RESOLVE-IT investigators to expedite the trial termination process. GENFIT will also meet with regulatory agencies to share key learnings, including upcoming results from the second reading of liver biopsies that will help better understand inter-reader variability and its impact. GENFIT is committed to finalizing this process, considering that insights gained from such a large international Phase 3 trial will provide valuable and beneficial information for the whole of the NASH community.

This decision is the first step of the new corporate strategy and allows GENFIT to accelerate its cost-saving plan, and to focus its efforts on developing its two major programs: elafibranor development in PBC, and the commercial growth of NIS4™, for NASH diagnostics.

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PBC is an exciting opportunity with the market for second line therapy estimated to potentially reach \$1.5 billion by 2035<sup>1</sup>, and remains an indication with a high unmet medical need. Elafibranor demonstrated promising results in a Phase 2 clinical trial for PBC and GENFIT's clinical team is now fully focused on the initiation of the Phase 3 clinical trial.

Increased ease of NASH diagnosis and treatment efficacy evaluation are critical both for patients and healthcare professionals, but also for regulatory authorities and payers. With the NIS4™ program, GENFIT plans to develop efficient and cost-effective non-invasive solutions, to address this growing need.

**Pascal Prigent, CEO of GENFIT**, noted: *"We believe the early termination of RESOLVE-IT is the appropriate decision from an ethical and clinical perspective, and this decision will contribute to accelerating cost savings and to focusing our efforts on our two top priorities: the PBC program and NIS4™, the technology to support a non-invasive diagnostic program in NASH. We are currently evaluating potential strategic partnerships that could maximize these opportunities and we will present our latest developments and complete corporate strategy at the end of September."*

### ABOUT PBC

Primary biliary cholangitis (PBC) is a chronic, autoimmune disease in which bile ducts in the liver are gradually destroyed. The damage to bile ducts can inhibit the liver's ability to rid the body of toxins, and can lead to scarring of liver tissue, known as cirrhosis. Elafibranor has shown promising results for the treatment of PBC in a Phase 2 clinical trial, and was granted the Breakthrough Therapy Designation by the FDA in this indication.

### ABOUT NIS4™

NIS4™ GENFIT's non-invasive, blood-based diagnostic technology, is developed to identify patients with at-risk non-alcoholic steatohepatitis (NASH) and significant fibrosis (F<sub>≥2</sub>). GENFIT is currently pursuing commercialization of this technology, which aims to be a validated alternative to the liver biopsy. In January 2019, GENFIT signed a licensing agreement with LabCorp® to make the NIS4™ diagnostic kit available in the clinical research field, and GENFIT plans to file an application with the FDA for approval of NIS4™ as an *in vitro diagnostic* (IVD).

### ABOUT GENFIT

GENFIT is a late-stage biopharmaceutical company dedicated to improving the lives of patients with metabolic and liver diseases. GENFIT is a pioneer in the field of nuclear receptor-based drug discovery, with a rich history and strong scientific heritage spanning more than two decades.

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<sup>1</sup> Third Party Market Research

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GENFIT plans to initiate a Phase 3 clinical trial of elafibranor in patients with PBC. As part of GENFIT's comprehensive approach to clinical management of patients with liver disease, the Company is also developing NIS4™, a new, non-invasive blood-based diagnostic technology which, if approved, could enable easier identification of patients with at-risk NASH. With facilities in Lille and Paris, France, and Cambridge, MA, USA, the Company has approximately 200 employees. GENFIT is a publicly traded company listed on the Nasdaq Global Select Market and on compartment B of Euronext's regulated market in Paris (Nasdaq and Euronext: GNFT). [www.genfit.com](http://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 statements about the value and benefit of insights from analysis of the RESOLVE-IT interim efficacy dataset and second reading of liver biopsies, the impact of the termination of the RESOLVE-IT trial on cost savings, potential strategic partnerships, and the ability of NIS4™ to address the growing NASH epidemic. 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 2.1 "Main Risks and Uncertainties" of the Company's 2019 Universal Registration Document filed with the AMF on May 27, 2020 under n° D.20-0503, 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)) and public filings and reports filed with the U.S. Securities and Exchange Commission ("SEC"), including the Company's 20-F dated May 27, 2020. 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

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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.

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