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GENFIT Announces Publication in *Nature Medicine* Confirming the Performance of its NASH Diagnostic Technology

Lille (France); Cambridge (Massachusetts, United States); Zurich (Switzerland); September 26, 2023 - **GENFIT (Nasdaq and Euronext: GNFT)**, a late-stage biopharmaceutical company dedicated to improving the lives of patients with rare and severe liver diseases, today announced the publication of data demonstrating the effectiveness of its non-alcoholic steatohepatitis (NASH)[1] diagnostic technology NIS4® by the FNIH's [2] NIMBLE [3] project in the scientific journal, *Nature Medicine*[4].

NIMBLE, part of the FNIH Biomarkers Consortium, is a public-private partnership that brings together U.S. government agencies, academic researchers and industry partners to study the diagnostic performance of non-invasive biomarkers to assess liver disease. The recent study evaluated five blood-based panels[5], which included NIS4®, NIS2+™'s predecessor.

The study aims to confirm the diagnostic performances of existing biomarker panels and determine their advantage over commonly used laboratory tests (ALT and FIB-4). Such studies conducted provide necessary data for the regulatory approval of biomarkers for the diagnosis of at-risk NASH and is a crucial step in moving the field closer to having qualified Non-Invasive Tests, such as NIS4® or now NIS2+™, that can be used for widespread clinical use.

The findings, published in the scientific journal *Nature Medicine*, concluded that NIS4® achieved an AUROC [6] of 0.815 for its intended use of diagnosing at-risk NASH, demonstrating significant superiority over common clinical-laboratory tools. It also confirmed that NIS4® was the only panel efficient for the diagnosis of the composite phenotype of at-risk NASH. Regarding the detection of NASH and significant fibrosis (F≥2) independently, NIS4®'s performance was superior to the other biomarker panels tested, achieving AUROC values of 0.832 and 0.874, respectively.

These findings represent an important milestone in NIS4® technology's path to regulatory approval by the U.S Food and Drug Administration. NIS2+™, the newly published and optimized version of

[1] At the EASL Congress in June 2023, it was announced that NASH would now be referred to as Metabolic dysfunction-associated steatohepatitis (MASH).
[2] Foundation for the National Institutes of Health
[3] Non-invasive Biomarkers of Metabolic Liver Disease
[4] https://doi.org/10.1038/s41591-023-02527-w
[5] NIS4®, OWLiver, PROC3, ELF™ and FibroMeter VCTE
[6] Area under the receiver operating characteristic curve

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NIS4®, is currently in the process of being independently evaluated through the NIMBLE consortium.

Arun J Sanyal, M.D., Director of the Stravitz-Sanyal Institute for Liver Disease and Metabolic Health at Virginia Commonwealth University and Chair of the NIMBLE Consortium, commented: "*Such findings will bring us a step closer towards a fully approved biomarker panel which can be made available for widespread clinical use and potentially alleviate the major barrier to care and drug development access. NIS4®'s utility as an effective technology to diagnose at-risk NASH is clearly demonstrated in these findings and we look forward to evaluating NIS4®'s more advanced version, NIS2+™, in the near future*."

ABOUT GENFIT'S NASH DIAGNOSTIC TECHNOLOGY

NIS2+™ is a blood-based diagnostic technology specifically designed to detect at-risk NASH among patients with metabolic risk factors based on an independent 2-biomarker panel. It is an optimization of the NIS4® technology and was developed and validated by GENFIT as a robust technology across characteristics of interest such as type-2 diabetes, age and sex, allowing large-scale implementation in clinical practice. GENFIT continues to explore the possibility of obtaining regulatory approval and CE Certificates of Conformity, with a development and commercial partner, to release an IVD test powered by NIS2+™ technology on the US and European markets.

NIS4® technology, NIS2+™'s predecessor, is being commercialized by Labcorp in the US and Canada as a Laboratory Developed Test. Since May 2021, Labcorp has been commercializing NASHnext®, powered by NIS4® technology, for use in the clinic. For more information, visit: https://nis4.com

ABOUT THE FNIH BIOMARKERS CONSORTIUM

The Foundation for the National Institutes of Health's Biomarkers Consortium (BC) leads cross-sector efforts to validate and qualify biomarkers that accelerate the development of new therapeutics and health technologies. The core operations of the BC are supported through its contributing membership program, which includes organizations representing private industry and not-for-profit organizations.

ABOUT THE FNIH

The Foundation for the National Institutes of Health (FNIH) builds public-private partnerships that connect leading biomedical scientists at the National Institutes of Health (NIH), life sciences companies, foundations, academia, and regulatory agencies, including the Food and Drug Administration and European Medicines Agency. Through team science, the FNIH solves complex

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health challenges and accelerate breakthroughs for patients, regardless of who they are or what health challenges they face. The FNIH accelerates new therapies, diagnostics, and potential cures; advances global health and equity in care; and celebrates and helps train the next generations of scientists. Established by Congress in 1990 to support the mission of the NIH, the FNIH is a not-for-profit 501(c)(3) charitable organization. For more information about the FNIH, please visit fnih.org

ABOUT GENFIT

GENFIT is a late-stage biopharmaceutical company dedicated to improving the lives of patients with rare and severe liver diseases characterized by high unmet medical needs. GENFIT is a pioneer in liver disease research and development with a rich history and strong scientific heritage spanning more than two decades. Its capacity to develop high potential assets, from early-stages to late development and pre-commercialization stages, is illustrated through the successful 52-week readout of its Phase 3 trial (ELATIVE®) evaluating elafibranor in Primary Biliary Cholangitis (PBC). Today, GENFIT has a diversified R&D pipeline covering several therapeutic areas: five programs in acute on chronic liver failure (ACLF) are in clinical stages (Phase 2) and pre-clinical stages, including hepatic encephalopathy (HE), one of the main complications of ACLF; a Phase 2 clinical program targeting cholangiocarcinoma; and a preclinical program targeting urea cycle disorders (UCD) and organic acidemias (OA). GENFIT's pipeline also includes a diagnostic franchise focused on Metabolic dysfunction-associated steatohepatitis (MASH, formerly known as nonalcoholic steatohepatitis or NASH) and ammonia. GENFIT has facilities in Lille and Paris (France), Zurich (Switzerland) and Cambridge, MA (USA). 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). In 2021, IPSEN became one of GENFIT's largest shareholders and holds 8% of the company's share capital. For more information, visit www.genfit.com

FORWARD LOOKING STATEMENTS

This press release contains certain forward-looking statements with respect to GENFIT, including those within the meaning of the Private Securities Litigation Reform Act of 1995 in relation to the clinical performance of NIS4® and NIS2+™ in NASH and its potential for regulatory approval and utility in the clinical setting. The use of certain words, including "believe", "potential," "expect", "target", "may" 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

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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 in relation to safety of drug candidates, cost of, progression of, and results from, our ongoing and planned clinical trials, review and approvals by regulatory authorities in the United States, Europe and worldwide, of our drug and diagnostic candidates, potential commercial success of elafibranor if approved, exchange rate fluctuations, our continued ability to raise capital to fund our development, as well as those risks and uncertainties discussed or identified in the Company's public filings with the AMF, including those listed in Chapter 2 "Main Risks and Uncertainties" of the Company's 2022 Universal Registration Document filed with the AMF on April 18, 2023, which is available on the Company'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 2022 Annual Report on Form 20-F filed with the SEC on April 18, 2023 and subsequent filings and reports filed with the AMF or SEC, including the Half-Year Business and Financial Report at June 30, 2023 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.

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