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GENFIT: FNIH NIMBLE Study Demonstrates NIS4® Technology's Unique Performance in Identifying Patients with "at-risk" NASH

Lille, France; Cambridge, MA; November 18, 2021 - **GENFIT (Nasdaq and Euronext: GNFT)**, a late-stage biopharmaceutical company dedicated to improving the lives of patients with metabolic and chronic liver diseases, is proud to announce that NIS4® technology's utility has been recognized in a Stage 1 study[1] undertaken by the Non-Invasive Biomarkers of Metabolic Liver Disease (NIMBLE) initiative of the Foundation for the National Institutes of Health's Biomarkers Consortium as demonstrating a unique performance in identifying patients with "at-risk" Non-Alcoholic Steatohepatitis (NASH).

The late-breaking oral presentation "LO1: PRIMARY RESULTS OF THE NIMBLE STAGE 1-NASH CRN STUDY OF CIRCULATING BIOMARKERS FOR NONALCOHOLIC STEATOHEPATITIS AND ITS ACTIVITY AND FIBROSIS STAGE" at The Liver Meeting 2021 highlighted the importance for the diagnosis of "at risk" NASH patients (defined as NASH + NAS ≥4 and fibrosis ≥2) as a subpopulation at greater risk of liver-related outcomes. Of the five blood-based biomarker panels which were assessed in this study, only NIS4® technology produced results showing the capacity to identify these "at-risk" NASH patients.

The study also provided evidence that NIS4® technology – with a sensitivity of 82.3 and a specificity of 79.9 – had the best results for the diagnosis of fibrosis stage ≥ 2, a critical component of "at-risk" NASH.

The presentation concluded that NIS4® technology met the *a priori* criteria established for Stage 1 NIMBLE by the NIMBLE Circulating Biomarkers Workstream (CWS) for:

- Diagnosis of NASH
- Diagnosis of NAS≥4
- Fibrosis stage 2 or higher

Arun J Sanyal, MD, FAASLD, stated: *"The ability to rigorously diagnose at-risk NASH with non-invasive tests is critical to preventing disease progression before it becomes too late for patients. It has important implications for the evolving standard of care for patients and for drug development. NIMBLE's initial data results offer a potential path for companies developing new therapies for NASH to enrich clinical trial populations and accelerate drug development."*

[1] https://fnih.org/sites/default/files/2021-11/CWS_NIMBLE_Abstract.pdf

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Pascal Prigent, CEO of GENFIT, added: *"NIS4® technology was conceived and developed to identify at-risk NASH, and we are thrilled today to see that its performance and utility have been recognized by a large biomarker consortium of well-respected experts using an independent approach and a robust methodology. This FNIH study is a critical milestone for us as it confirms our previous findings. And with NIS4® technology already powering a commercially available test in the US and Canada as a Laboratory Developed Test, we believe that these findings will have a strong utility for the whole NASH field and for all practitioners. Moreover, they will hopefully pave the way for regulatory qualification for non-invasive tests in NASH."*

ABOUT THE FNIH

The Foundation for the National Institutes of Health (FNIH) creates and manages alliances with public and private Institutions in support of the mission of the NIH, the world's premier medical research agency. The Foundation, also known as the FNIH, works with its partners to accelerate biomedical research and strategies against diseases and health concerns in the United States and across the globe. The FNIH organizes and administers research projects; supports education and training of new researchers; organizes educational events and symposia; and administers a series of funds supporting a wide range of health issues. Established by Congress in 1990, the FNIH is a not-for-profit 501(c)(3) charitable organization.

ABOUT NIMBLE

The NIMBLE consortium is a comprehensive multi-year pre-competitive, public-private partnership collaboration conducted under the auspices of the Foundation for the NIH (FNIH) Biomarkers Consortium. The NIMBLE project is supported by multiple entities including AbbVie, Amgen Inc., AstraZeneca, Boehringer Ingelheim, Bristol Myers Squibb, Echosens, GE Healthcare, Genentech, Inc., Gilead Sciences, Inc., Intercept Pharmaceuticals, Inc., Novo Nordisk A/S, Pfizer Inc, Regeneron Pharmaceuticals Inc, and Takeda Development Center Americas Inc. Additionally, many companies have donated their assays, equipment, and services to the NIMBLE consortium, including AMRA Medical, Canon Medical Systems USA, Inc, Echosens, GENFIT SA, GE Healthcare, Nordic Bioscience A/S, OWL Metabolomics, Philips Ultrasound, Inc., P-Value, LLC, Hologic SuperSonic Imagine, Siemens Healthineers, and Siemens Medical Solutions USA, Inc.

ABOUT THE BIOMARKERS CONSORTIUM

The Biomarkers Consortium (BC) embraces government, industry, patient advocacy groups, and not-for-profit organizations each of which has a stake in the identification, development, and the seeking of regulatory approval for biomarkers. The BC addresses one of the most pressing needs

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in the diagnosis and treatment of disease: the development and the seeking of regulatory approval for disease biomarkers and surrogates. The core operations of The Biomarkers Consortium are supported through the contributing membership program. Organizations representing private industry (including the pharmaceutical, biotechnology, diagnostics, and information technology industries) and not-for-profit organizations (including associations, advocacy groups, trade organizations, and philanthropic organizations) that wish to support biomarkers development are eligible to become contributing members.

ABOUT NIS4® TECHNOLOGY

NIS4® is GENFIT's non-invasive, blood-based diagnostic technology, developed to identify patients with NASH and significant to advanced fibrosis (F≥2), also referred to as at-risk NASH. In January 2019, GENFIT signed a licensing agreement with Labcorp® to make NIS4® technology available for use in clinical research through their drug development subsidiary, Covance. In September 2020, GENFIT signed another licensing agreement with Labcorp® to commercialize NIS4® in the US and Canada as a Laboratory Developed Test. Since May 2021, Labcorp® has commercialized NASHnext®, powered by NIS4® technology, for use in the clinic. GENFIT also continues to explore opportunities to obtain formal marketing authorization of an in vitro diagnostic (IVD) test. For more information, please visit: https://nis4.com.

ABOUT GENFIT

GENFIT is a late-stage biopharmaceutical company dedicated to improving the lives of patients with severe chronic 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.

Today, GENFIT has a robust and diversified pipeline, using different compounds and technologies evaluated at different development stages and in different liver diseases.

Leveraging its internal assets and in-house expertise, GENFIT's R&D is focused on cholestatic diseases and Acute on Chronic Liver Failure (ACLF): two therapeutic areas with significant unmet medical needs. Currently, the ELATIVE™ Phase 3 clinical trial evaluating elafibranor (elafibranor is an investigational compound that has not been reviewed nor been approved by a regulatory authority) in patients with Primary Biliary Cholangitis (PBC) is being conducted following a successful Phase 2 clinical trial. Patient enrolment is anticipated to be completed in the first quarter of 2022 and topline data is expected to be announced between the end of the first quarter and the end of the second quarter 2023. A Phase 2 clinical development program is also underway with

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elafibranor in Primary Sclerosing Cholangitis (PSC), and a Phase 1 clinical program with nitazoxanide in ACLF has been initiated.

GENFIT has facilities in Lille and Paris, France, 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). www.genfit.com

GENFIT 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, including statements regarding NIS4® technology's performance compared to other non-invasive tests, its suitability for use in clinical trials for treatments for NASH and regulatory approval of such non-invasive tests including NIS4®. The use of certain words, including "consider", "contemplate", "think", "aim", "expect", "understand", "should", "aspire", "estimate", "believe", "wish", "may", "could", "allow", "seek", "encourage" or "have confidence" or (as the case may be) the negative forms of such terms or any other variant of such terms or other terms similar to them in meaning is intended to identify forward-looking statements. Although the Company believes its projections are based on reasonable expectations and 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 in relation 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, impact of the ongoing COVID-19 pandemic, exchange rate fluctuations 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 Chapter 2 "Main Risks and Uncertainties" of the Company's 2020 Universal Registration Document filed with the AMF on 23 April 2021 under n° D.21-0350, 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 2020 Annual Report on Form 20-F filed with the SEC on April 23, 2021 and subsequent filings and reports filed with the AMF or SEC, 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

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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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