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GENFIT Highlights Long-Term Commercial Opportunity for its MASH Diagnostics Technology

- **Simple, reliable and scalable blood-based testing could identify patients with at-risk MASH among nearly 90 million U.S. individuals receiving medical attention due to MASLD-related risk factors**
- **IQVIA estimates U.S peak sales of products based on NIS™ Technology could exceed USD 1.5 billion by 2033, creating the potential for a meaningful long-term royalty-based stream for GENFIT**
- **The foundations for broader adoption of GENFIT's NIS™ Technology will progressively strengthen in the coming months, with expanding reimbursement, increasing incorporation into clinical guidelines, and growing disease awareness supported by pharmaceutical companies commercializing MASH therapies**
- **Diagnostics use is expected to accelerate significantly from 2028 as additional MASH therapies further drive physician education, patient identification, and disease-monitoring need**
- **GENFIT will host an English-language webcast today at 4:00 p.m. CET / 10:00 a.m. ET, featuring Prof. Vlad Ratziu, MD, PhD**

Lille (France), Cambridge (Massachusetts, United States), September 9, 2026 - **GENFIT (Euronext: GNFT)**, a biopharmaceutical company dedicated to improving the lives of patients with rare and life-threatening liver diseases, today highlights the long-term commercial opportunity associated with NIS4® and next-generation NIS2+®, its proprietary non-invasive NIS™ diagnostic technologies aimed to identify patients with “at-risk MASH”.

The Unmet Need

A Major Inflection Point for MASLD/MASH – The field is undergoing a significant transformation with the U.S. Food and Drug Administration (FDA) approval and launch of two treatments for MASH (Metabolic dysfunction-Associated SteatoHepatitis) in 2025, and additional late-stage programs are expected to further expand therapeutic options in the coming years, if approved. As new therapies enter the market, the key challenge is shifting from treatment availability to patient identification, disease stratification and long-term management. **Prof. Vlad Ratziu, MD, PhD, Professor of Hepatology at Sorbonne University, Hepatologist at AP-HP Pitié-Salpêtrière Hospital, and Researcher at the Institute of Cardiometabolism and Nutrition (IHU ICAN), Paris, France**, said: "*We cannot treat patients that we cannot correctly identify, and we cannot continue to rely on invasive and painful procedures such as liver biopsy or on imprecise non-invasive approaches,*

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as the gateway to care for millions of individuals. As treatments become increasingly available, patient management requires reliable, simple and scalable serum-based tools that can identify patients with active fibrotic MASLD while also supporting disease monitoring and clinical decision-making over time."

Millions Remain Undiagnosed – Evidence-based market research conducted by IQVIA highlights the magnitude of the unmet need in MASH diagnostics in the United States. By 2033, 86 million Americans already closely managed in the care system for elevated enzymes or steatosis may benefit from non-invasive, blood-based testing approaches designed to identify patients with at-risk MASH through the assessment of both disease activity and fibrosis, two key determinants of disease progression and patient management. As awareness of MASLD and MASH grows among healthcare professionals, payers and policymakers, patient management is expanding beyond hepatologists and gastroenterologists. Given the strong links with obesity, type 2 diabetes and other metabolic disorders, primary care physicians (PCPs) and endocrinologists are also expected to become instrumental throughout the patient care journey.

The Commercial Opportunity for GENFIT

Highlights on U.S. Market Potential – Based on intention-to-diagnose data collected across key specialties, increasing disease prevalence, and a staged commercialization strategy spanning Laboratory Developed Tests (LDTs) and In Vitro Diagnostics (IVDs)[1], IQVIA estimates U.S peak sales of products using GENFIT's technology could exceed USD 1.5 billion by 2033, with annual testing volume in the United States reaching more than 7 million tests. **Pascal Prigent, Chief Executive Officer of GENFIT**, commented: *"IQVIA's analysis highlights the scale of the opportunity emerging in MASH diagnostics. The projected figures suggest a commercial potential that could be comparable in scale to, if not substantially larger than, our current PBC business, and potentially approaching the size of today's HbA1c testing market."*

Beyond the United States – In Europe and Asia, GENFIT expects its IVD[2] strategy to play a key role in the future commercialization of its NIS™ Technology. Supported by the anticipated expansion of the MASH therapeutic market and the broader accessibility enabled by IVD products, international markets could represent a meaningful additional revenue opportunity over time.

GENFIT's NIS™ Technology Adoption Expected to Build Over Time, through Multiple Drivers

Reimbursement and market access – In August 2026, Medicare reimbursement of Labcorp's NASHnext® test (based on GENFIT's NIS™ Technology) became effective under the Clinical

[1] Regulatory authorization through the applicable local approval process is required for in vitro (IVD) products and has not yet been obtained.

[2] Regulatory authorization through the applicable local approval process is still required and has not yet been obtained

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Laboratory Fee Schedule for patients meeting coverage criteria. GENFIT believes broader reimbursement coverage across geographies, as well as potential reimbursement by private payers, if obtained, could support accelerated adoption of its technology over time. Further market expansion could also be supported by a potential future IVD launch, which may facilitate deployment across a wider range of healthcare settings.

Scientific recognition and clinical guidelines inclusion – The LITMUS and NIMBLE consortia highlighted in recent publications the unique ability of NIS™ Technology to assess both disease activity and fibrosis, a key differentiator for identifying patients with at-risk MASH and supporting clinical decision-making. This has translated into the NIS™ Technology becoming incorporated into key clinical practice guidelines from major U.S., European and Asian hepatology, gastroenterology and diabetology societies, with additional guideline inclusion expected over time.

Pharmaceutical industry effort – Pharmaceutical companies commercializing MASH therapies are expected to invest heavily in physician education, disease awareness and patient identification initiatives, further supporting adoption across the patient care pathway. NIS™ Technology is already incorporated into, or evaluated in connection with, more than 20 large-scale clinical studies conducted by leading companies developing therapies for MASH, including Novo Nordisk, Eli Lilly, AstraZeneca, Akero and others. GENFIT continues to generate scientific evidence supporting NIS™ technology, to allow its broader incorporation in routine practice, and advance the development of partnerships intended to broaden patient access to testing.

Engaging the broad ecosystem – Recognizing that the growing burden of MASLD/MASH represents a major public health challenge requiring coordinated action across stakeholders, GENFIT and the Global Liver Institute (GLI) are in the process of establishing a non-partisan coalition dedicated to advancing awareness, earlier patient identification and improved care pathways. **Larry R. Holden, Chief Executive Officer of the GLI**, a leading patient advocacy organization dedicated to improving liver health worldwide, said: *"For many years, the major challenge in MASH was the absence of approved therapies. Today, that is no longer the case. The challenge is rapidly becoming one of patient identification and management. Building a broad coalition around earlier identification and better patient pathways will be essential to ensure that advances in treatment translate into meaningful benefits for the millions of people affected by MASLD and MASH, while also helping healthcare systems and payers address the growing burden of liver disease."*

Link to the English-language webcast to be held today at 4:00 p.m. CET / 10:00 a.m. ET, featuring Prof. Vlad Ratziu: https://lifescievents.com/event/yj29ot7/

These announcements are expected to coincide with GENFIT's presentations at the **Liver Forum** (September 9) and the **Paris MASH Meeting** (September 10-11), two major international gatherings of regulators, healthcare professionals, patient advocates, industry leaders and other stakeholders involved in liver disease and MASH.

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ABOUT GENFIT

GENFIT is a biopharmaceutical company committed to improving the lives of patients with rare, life-threatening liver diseases whose medical needs remain largely unmet. GENFIT is a pioneer in liver disease research and development with a rich history and a solid scientific heritage spanning more than two decades. Today, GENFIT focuses on Acute on-chronic Liver Failure (ACLF) and associated conditions such as acute decompensation (AD) and hepatic encephalopathy (HE). It develops therapeutic assets which have complementary mechanisms of action, selected to address key pathophysiological pathways. GENFIT also targets other serious diseases, such as cholangiocarcinoma (CCA), urea cycle disorders (UCD) and organic acidemia (OA). Its R&D portfolio, covering several stages of development, ensures a constant news flow. GENFIT's expertise in developing high-potential molecules – from early to advanced pre-commercialization stages – culminated in 2024 with the accelerated approval of Iqirvo® (elafibranor) by the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA) and the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom for second-line treatment of Primary Biliary Cholangitis (PBC). Iqirvo® is now marketed in several countries.[3] Beyond therapies, GENFIT also has a diagnostic franchise including NIS2+® for the detection of Metabolic dysfunction-associated steatohepatitis (MASH, formerly known as NASH for non-alcoholic steatohepatitis). GENFIT, a BCorp™ certified company since 2025, is headquartered in Lille, France and has offices in Paris (France), Zurich (Switzerland) and Cambridge, MA (USA). The Company is listed on the Euronext regulated market in Paris, Compartment B (Euronext: GNFT). In 2021, Ipsen became one of GENFIT's largest shareholders, acquiring an 8% stake in the Company's capital. www.genfit.com

FORWARD LOOKING STATEMENTS

This press release contains certain forward-looking statements with respect to GENFIT, including, but not limited to, statements regarding the potential market opportunity for products based on GENFIT's NIS® technology, the future adoption, commercialization and reimbursement of such products, and the impact of the development of the therapeutic MASH market on the diagnostics market, potential royalty streams and other revenues that could be generated therefrom, the future development of the MASH diagnostics market, guideline inclusion, market access, and expected demand for non-invasive diagnostic testing. The use of certain words, such as "believe",

[3] Elafibranor is marketed and commercialized, notably in the U.S and Europe, by Ipsen under the trademark Iqirvo®

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"potential", "expect", “target”, “may”, “will”, "should", "could", "if" and similar expressions, is intended to identify forward-looking statements. Certain statements included in this press release are based on market analyses and projections prepared by IQVIA and commissioned by GENFIT. Such analyses are based on numerous assumptions, including assumptions regarding patient identification, disease prevalence, treatment adoption, reimbursement coverage, physician behavior, testing frequency, market penetration and other market factors. The projections described in this press release do not constitute forecasts of GENFIT's future revenues, financial performance or royalty income. Actual market adoption, testing volumes, product sales and economic outcomes may differ materially from those projected. 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 others, uncertainties relating to the development, validation, regulatory acceptance and commercialization of diagnostic products, the timing and scope of reimbursement decisions and payer coverage, inclusion in clinical practice guidelines, physician adoption and testing practices, the availability and uptake of therapies for MASH, regulatory developments, the ability to establish and maintain commercial partnerships, evolving competition in the MASH diagnostics field, market acceptance of competing technologies 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 "Risk Factors and Internal Control" of the Company's 2025 Universal Registration Document filed on April 3, 2026 (no. 26-0221) with the Autorité des marchés financiers ("AMF"), which is available on GENFIT's website (www.genfit.fr) and the AMF's website (www.amf.org), and those discussed in reports filed with the AMF or otherwise made public, by the Company. In addition, even if the results, performance, financial position and liquidity of the Company 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 press release. 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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