



GENFIT: New EASL-EASD-EASO Clinical Practice Guidelines for MASLD Include NIS2+® as Key Tool for Detecting At-Risk MASH

Date Published: Monday, 17 Jun 2024

DETAILED NEWS

Lille (France), Cambridge (Massachusetts, United States), Zurich (Switzerland), June 17, 2024 - GENFIT (Nasdaq and Euronext: GNFT), a late-stage biopharmaceutical company dedicated to improving the lives of patients with rare and life-threatening liver diseases, today announced the inclusion of NIS2+® as a key tool for detecting at-risk MASH1 in the European Clinical Practice Guidelines on the management of metabolic dysfunction-associated steatotic liver disease (MASLD). The guidelines were developed as a joint effort by the European Association for the Study of the Liver (EASL), the European Association for the Study of Diabetes (EASD), and the European Association for the Study of Obesity (EASO), and provide healthcare providers an update on prevention, screening, diagnosis, follow-up and treatment for MASLD.

The new guidelines were presented during the EASL congress 2024, and were released in the Journal of Hepatology2. "The inclusion of NIS2+® in the EASL-EASD-EASO clinical guidelines is a major scientific recognition based on solid evidence that NIS2+® could play an important role in identifying patients that may benefit from emerging treatments for MASH," commented Dean Hum, Chief Scientific Officer at GENFIT.

"Additionally, GENFIT's diagnostic technology featured as a monitoring treatment response in a Phase 2 study on tirzepatide's safety and efficacy for MASH, and was recently presented during the Late Breaking session at EASL and jointly published in the New England Journal of Medicine3," he added. In the new guidelines, NIS2+® is included for the first time as a non-invasive tool to detect at-risk MASH, and is the only blood-based panel mentioned for this condition.

With the recent U.S Food and Drug Administration approval of resmetirom in the US, and given that liver biopsy will be used sparingly in routine clinical practice due to its invasiveness and procedure-related limitations, alternative non-invasive panels with high predictive value validated for the detection of at-risk MASH such as NIS2+®, could play an important role in selecting individuals able to benefit from pharmacotherapy. The new Clinical Practice Guidelines on the management of MASLD can be found at: [https://www.journal-of-hepatology.eu/article/S0168-8278\(24\)00329-5/fulltext](https://www.journal-of-hepatology.eu/article/S0168-8278(24)00329-5/fulltext) ABOUT MASH MASH is a liver disease characterized by an accumulation of fat (lipid droplets), along with inflammation and degeneration of hepatocytes.

↪ The disease is associated with an increased risk of cardiovascular disease along with long-term risk for progression to cirrhosis, leading to liver insufficiency and potential progression to liver cancer.

↪ MASH is a serious disease that often carries no symptoms in its early stages, but if left untreated can result in cirrhosis, cancer, and the need for liver transplant.

↪ The prevalence of MASH is rapidly increasing as a result of the growing obesity and diabetes epidemics and is believed to affect as much as 12 percent of people in the U.S. and six percent worldwide. ABOUT NIS2+® NIS2+® is a blood-based diagnostic technology specifically designed to detect at-risk MASH 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, for the widespread use of an IVD test powered by NIS2+® technology in both the United States and Europe. ABOUT GENFIT GENFIT is a late-stage 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 has built up a diversified and rapidly expanding R&D portfolio of programs at various stages of development.

↪ The Company focuses on Acute-on-Chronic Liver Failure (ACLF).

↪ Its ACLF franchise includes five assets under development: VS-01, NTZ, SRT-015, CLM-022 and VS-02-HE, based on complementary mechanisms of action using different routes of administration.

↪ Other assets target other serious diseases, such as cholangiocarcinoma (CCA), urea cycle disorder (UCD) and organic acidemia (OA).

↪ GENFIT's expertise in the development of high-potential molecules from early to advanced stages, and in pre-commercialization, was demonstrated in the FDA's accelerated approval of Iqirvo® (elafibranor) for Primary Biliary Cholangitis (PBC).

↪ Beyond therapies, GENFIT also has a diagnostic franchise including NIS2+® in Metabolic dysfunction-associated steatohepatitis (MASH, formerly known as NASH for non-alcoholic steatohepatitis) and TS-01 focusing on blood ammonia levels.

↪ GENFIT is headquartered in Lille, France and has offices in Paris (France), Zurich (Switzerland) and Cambridge, MA (USA).

↪ The Company is listed on the Nasdaq Global Select Market and on the Euronext regulated market in Paris, Compartment B (Nasdaq and 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, including those within the meaning of the Private Securities Litigation Reform Act of 1995 with respect to GENFIT, including, but not limited to statements about the potential for NIS2+® to play an important role in identifying patients that may benefit from emerging treatments for MASH.

The use of certain words, such as "believe", "potential", "expect", "target", "may", "will", "should", "could", "if" 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 others, 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, and 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 "Risk Factors and Internal Control" of the Company's 2023 Universal Registration Document filed on April 5, 2024 (no.

D.24-0246) 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 the public documents and reports filed with the U.S. Securities and Exchange Commission ("SEC"), including the Company's 2023 Annual Report on Form 20-F filed with the SEC on April 5, 2024 and subsequent filings and reports filed with the AMF or SEC 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 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. CONTACT GENFIT | Investors Tel: +33 3 3 2016 4000 | investors@genfit.com GENFIT | Media Stephanie Boyer – Press relations | Tel: +333 2016 4000 | stephanie.boyer@genfit.com GENFIT | 885 Avenue Eugène Avinée, 59120 Loos - FRANCE | +333 2016 4000 | www.genfit.com 1 Metabolic dysfunction-associated steatohepatitis 2 DOI: <https://doi.org/10.1016/j.jhep.2024.04.031> DOI: <https://doi.org/10.1056/NEJMoa2401943> 4 Elafibranor will be marketed and commercialized by Ipsen under the trademark Iqirvo and may be prescribed immediately in the U.S. for eligible patients. Attachment GENFIT: New EASL-EASD-EASO Clinical Practice Guidelines for MASLD Include NIS2+® as Key Tool for Detecting At-Risk MASH

GENFIT, a biopharmaceutical company specializing in rare and life-threatening liver diseases, announced the inclusion of NIS2+® in the European Clinical Practice Guidelines for the management of metabolic dysfunction-associated steatotic liver disease (MASLD).

This inclusion is a major scientific recognition of the potential role of NIS2+® in identifying patients who may benefit from emerging treatments for MASH.

The guidelines, developed by the European Association for the Study of the Liver (EASL), the European Association for the Study of Diabetes (EASD), and the European Association for the Study of Obesity (EASO), provide updates on prevention, screening, diagnosis, follow-up, and treatment for MASLD.

These guidelines were presented at the EASL congress 2024 and published in the Journal of Hepatology.

NIS2+® is included in the guidelines as a non-invasive tool to detect at-risk MASH.

It is the only blood-based panel mentioned for this condition.

With the recent U.S Food and Drug Administration approval of resmetirom, alternative non-invasive panels like NIS2+® could play a significant role in selecting individuals for pharmacotherapy.

MASH is a liver disease associated with an increased risk of cardiovascular disease, cirrhosis, and liver cancer.

MASH's prevalence is rapidly increasing because of the growing obesity and diabetes epidemics, affecting up to 12 percent of people in the U.S. and six percent worldwide.

GENFIT continues to explore the possibility of obtaining regulatory approval and CE Certificates of Conformity for the widespread use of an IVD test powered by NIS2+® technology in both the United States and Europe.

The company is also known for its expertise in the development of high-potential molecules from early to advanced stages and in pre-commercialization.