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TOWARDS BETTER MEDICINE

PRESS RELEASE

GENFIT: Ipsen's Iqirvo® (Elafibranor) Receives EU Approval as a First-in-Class Treatment for Primary Biliary Cholangitis following U.S. FDA Accelerated Approval

Lille (France), Cambridge (Massachusetts, United States), Zurich (Switzerland), September 23, 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 that the European Commission has conditionally approved Iqirvo®[1] (elafibranor) 80mg tablets for the treatment of Primary Biliary Cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA or as a monotherapy in patients unable to tolerate UDCA. This follows the positive opinion issued by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) on July 26, 2024 and the U.S. FDA Accelerated Approval on June, 10, 2024 .

Pascal Prigent, CEO of GENFIT, commented: *"The approval of Iqirvo in the EU is another landmark moment for GENFIT. Iqirvo's EU approval provides further validation of our scientific and clinical capabilities, demonstrating how we are capable of taking a drug candidate all the way from discovery to the end of a Phase 3, with Iqirvo now becoming a new treatment option for patients. The expected €26.5 million milestone payment upon Iqirvo's pricing and reimbursement approval in three European countries, will enable us to drive forward with our robust pipeline for other severe liver diseases with high unmet need, including Acute On-Chronic Liver Failure."*

Elafibranor, a 'first-in-class' molecule marketed and commercialized in the United States by Ipsen under the trademark Iqirvo since June 2024, was developed by GENFIT, from initial discovery to the conclusion of a 52-week Phase 3 clinical study. Ipsen licensed the exclusive worldwide rights (except China, Hong Kong, Taiwan and Macau) to elafibranor from GENFIT in 2021.

Further details can be found here.

EU SUMMARY OF PRODUCT CHARACTERISTICS

Important safety information and recommendations for the use of Iqirvo are detailed in the Summary of Product Characteristics (SmPC), published in the European public assessment report

[1] Iqirvo is a registered trademark by GENFIT SA

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(EPAR) and available in all official EU languages. The full SmPC can be found at: Iqirvo, INN-elafibranor (europa.eu).

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, including pre-commercialization, was demonstrated in the FDA's accelerated approval of Iqirvo® (elafibranor[2]) 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. 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,

[2] Elafibranor is marketed and commercialized in the U.S by Ipsen under the trademark Iqirvo

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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.

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