PRESS RELEASE

GENFIT Receives FDA Orphan Drug Designation for NTZ for the treatment of ACLF

- **FDA grants Orphan Drug Designation (ODD) for NTZ for ACLF, a severe condition with no approved therapies**
- **NTZ is being advanced in ACLF through its G1090N reformulation, designed to unlock its clinical potential for patients facing this life-threatening condition**
- **This regulatory milestone follows favorable Phase 1 safety results and strong anti-inflammatory activity observed in ex vivo assays on samples from healthy volunteers and cirrhotic donors**

Lille (France), Cambridge (Massachusetts, United States), Zurich (Switzerland), March 9, 2026 - **GENFIT (Euronext: GNFT)**, a biopharmaceutical company dedicated to improving the lives of patients with rare and life-threatening liver diseases, today announces that the U.S. Food and Drug Administration (FDA) has granted ODD to NTZ (nitazoxanide), its investigational small-molecule drug candidate developed as a new formulation for the treatment of Acute-on-Chronic Liver Failure (ACLF).

G1090N is GENFIT's lead investigational program within the ACLF segment of its pipeline. The FDA's ODD recognizes the potential of G1090N's active substance to address this severe, rare condition characterized by rapid deterioration, systemic inflammation, and high short-term mortality.

This designation follows recent Phase 1 data demonstrating a favorable safety and tolerability profile in healthy volunteers, as well as compelling anti-inflammatory activity across ex vivo models, providing a solid foundation for advancing the program toward initiation of Phase 2 clinical development, targeted for the second half of 2026. ODD also provides development incentives, including FDA regulatory guidance, certain user fee reductions, and eligibility for seven-year U.S. market exclusivity for the designated indication upon FDA approval.

END

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

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(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 the treatment of Primary Biliary Cholangitis (PBC). Iqirvo® is now marketed in several countries.[1] 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 therapeutic potential of G1090N, the significance and implications of the U.S. Food and Drug Administration's Orphan Drug Designation, the expected benefits associated with such designation, including regulatory incentives and potential market exclusivity, the advancement of G1090N into further clinical development, the anticipated initiation and timing of a Phase 2 clinical trial, and GENFIT's overall development strategy and prospects in Acute-on-Chronic Liver Failure. 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 non-clinical and pre-clinical programs, reproducibility of preclinical results, the translation of animal model data to human biology, in relation to safety of drug candidates, cost of, progression of, and results from, our ongoing and planned clinical trials, patient recruitment, review and approvals by regulatory authorities in the United States, Europe and worldwide, of our drug and diagnostic candidates, pricing, approval and commercial success of elafibranor in the relevant jurisdictions, 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 2024 Universal Registration Document filed on April 29, 2025 (no. 25-0331) 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

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

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U.S. Securities and Exchange Commission ("SEC"), including the Company's 2024 Annual Report on Form 20-F filed with the SEC on April 29, 2025 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 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.

CONTACTS

GENFIT | Investors
Jean-Christophe Marcoux – Chief Corporate Affairs Officer | Tel: +33 3 2016 4000 |
jean-christophe.marcoux@genfit.com

GENFIT | Media
Bruno ARABIAN – Agence Maarc | Tel : 06 87 88 47 26 | bruno.arabian@maarc.fr

Stephanie Boyer – Press relations | Tel: +333 2016 4000 | stephanie.boyer@genfit.com