

## PRESS RELEASE

### **GENFIT Presents Promising New Preclinical Data on NTZ/G1090N for the Treatment of ACLF at The Liver Meeting® 2025**

- **Preclinical studies demonstrated significant efficacy on systemic inflammation and organ function in ACLF disease models**
- **Safety data from Phase 1 on healthy volunteers and initial efficacy signals from *ex-vivo* functional assays expected by year-end 2025**

**Lille (France), Cambridge (Massachusetts, United States), Zurich (Switzerland), November 10, 2025** - **GENFIT (Nasdaq and Euronext: GNFT)**, a biopharmaceutical company dedicated to improving the lives of patients with rare and life-threatening liver diseases, today presents promising new preclinical data in ACLF at The Liver Meeting® 2025 with nitazoxanide (NTZ). GENFIT is advancing NTZ through a novel formulation, investigational drug G1090N, which serves as the cornerstone of our ACLF pipeline and reflects our commitment to addressing critical unmet needs in liver disease. G1090N was designed to optimize dose-response and permit sufficient dosing flexibility in patients with ACLF, who are known to have varying degrees of renal or hepatic impairment or failure.

**Dr. Jonel Trebicka, MD, PHD, Head of Department and Professor of Medicine, University of Münster, Germany**, commented: *"These preclinical findings demonstrate beneficial effects on systemic inflammation and organ failure in ACLF disease models and add to a growing body of evidence for this therapy. We eagerly await the upcoming safety data from G1090N in healthy volunteers, along with potential efficacy signals on key biomarkers from ex-vivo approaches. Positive results at the end of this year could pave the way to further clinical development."*

ACLF presents as a syndrome defined by a combination of hepatic and extrahepatic organ dysfunctions and failures and a uniformly poor prognosis. In patients with liver cirrhosis and acute hepatic decompensation, ACLF can be triggered by a precipitating event (e.g. an infection) that leads to a progressive functional deterioration of multiple organs with high short-term mortality (23% to 74% mortality at 28 days<sup>1</sup>).

Poster #4165 *Efficacy of Nitazoxanide (NTZ) on systemic inflammation and organ function in disease models of acute-on-chronic liver failure (ACLF) when administered post-ACLF trigger* highlights NTZ's demonstrated efficacy on systemic inflammation and organ function in disease models of ACLF

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<sup>1</sup> Arroyo V et al., Nat. Rev. Dis. Primers 2 (2016)

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when administered post-ACLF trigger. NTZ was shown to reduce LPS-induced inflammatory cytokines levels both *vitro* and *in vivo*. Moreover, a rapid restoration of hepatic and renal functions was observed upon a single dose of NTZ administration in a disease model of ACLF.

These preclinical findings further support the development of investigational drug G1090N as a new therapeutic approach for ACLF.

A Phase 1 First-in-Human study in healthy volunteers is currently underway with safety data expected at the end of this year. Early signals of efficacy from *ex-vivo* functional assays are also expected at the same time.

**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. GENFIT has built up a diversified and rapidly expanding R&D portfolio of programs at various stages of development. The Company focuses on a broad spectrum of conditions that patients with ACLF (Acute-on-Chronic Liver Failure) may experience, including Acute Decompensation (AD) or Hepatic Encephalopathy (HE), with several assets based on complementary mechanisms of action using different routes of administration. GENFIT also targets 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 accelerated approval of Iqirvo® (elafibranor) by the U.S. Food and Drug Administration, the European Medicines Agency and the Medicines and Healthcare Regulatory Agency in the UK for Primary Biliary Cholangitis (PBC). Iqirvo® is currently commercially launched in several countries.<sup>2</sup> Beyond therapies, GENFIT also has a diagnostic franchise including NIS2+® in Metabolic dysfunction-associated steatohepatitis (MASH, formerly known as NASH for non-alcoholic steatohepatitis). 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<sup>3</sup> and on the Euronext regulated market in Paris, Compartment B (Nasdaq and Euronext: GNFT). In 2021, Ipsen became

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<sup>2</sup> Elafibranor is marketed and commercialized, notably in the U.S and Europe, by Ipsen under the trademark Iqirvo®

<sup>3</sup> On October 30, 2025 [GENFIT announced its intention to voluntarily delist its American Depositary Shares from The Nasdaq Global Select Market](#)

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one of GENFIT's largest shareholders, acquiring an 8% stake in the Company's capital.  
[www.genfit.com](http://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 related to GENFIT's expectations regarding the availability of safety data from the ongoing Phase 1 study and initial efficacy signals from ex-vivo assays by year-end 2025; the potential initiation of a Phase 2 proof-of-concept study in the first half of 2026; the anticipated impact of positive results on the progression of clinical development; and the continued development of investigational drug G1090N as a new therapeutic approach for ACLF. 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, 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](http://www.genfit.fr)) and the AMF's website ([www.amf.org](http://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 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,

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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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