PRESS RELEASE

GENFIT: Favorable Phase 1 Safety Profile and Strong Anti-Inflammatory Activity for ACLF Lead Asset G1090N

- **Phase 1 results confirm investigational drug-candidate G1090N has a favorable safety and tolerability profile, supporting further clinical evaluation**
- **Compelling anti-inflammatory activity of G1090N was evidenced through functional ex vivo assays on blood samples from study participants and cirrhotic donors, showing inhibition of pro-inflammatory pathway**
- **Findings provide a solid foundation for advancing G1090N into Phase 2 proof-of-concept studies across the ACLF continuum**

Lille (France), Cambridge (Massachusetts, United States), Zurich (Switzerland), January 6, 2026 - **GENFIT (Euronext: GNFT)**, a biopharmaceutical company dedicated to improving the lives of patients with rare and life-threatening liver diseases, today announced that G1090N – a small molecule and the Company's lead investigational drug candidate for Acute-On-Chronic Liver Failure (ACLF) – demonstrated a favorable Phase 1 safety profile, and a strong anti-inflammatory activity in ex-vivo studies.

Dr. Jacqueline O'Leary, MD at the UT Southwestern Medical Center, Dallas, TX (USA), commented: *"The safety profile observed in Phase 1 and the consistent biological activity evidenced in ex vivo assays represent a meaningful step in development. These findings position G1090N as a promising candidate for patients with acute decompensation and for patients with ACLF, a life-threatening condition with no approved therapies and significant unmet medical need. We are eager to see more patient data as the program moves forward, to confirm G1090N's safety and strengthen the case for its activity in patients with organ failure."*

Phase 1

The Phase 1, open-label trial assessed the safety, tolerability and pharmacokinetics (PK) of G1090N in healthy volunteers following a Single Ascending Dose administration (SAD) phase, and a Multiple Ascending Dose administration (MAD) phase. 13 healthy volunteers were enrolled in each segment, with a total of 76 participants. G1090N's safety profile observed in healthy volunteers supports continued evaluation.

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Ex vivo studies

GENFIT evaluated the modulation of inflammation-related signaling pathways in ex vivo pharmacodynamic and proof-of-efficacy assays:

- G1090N demonstrated robust biological activity in peripheral blood mononuclear cells (PBMC) assays from healthy volunteers using blood samples from Phase 1 study participants, on LPS-induced IL-6 and TNFα cytokines production, with up to 76% statistically significant inhibition ($p<0.0001$);
- The bioactive metabolite of G1090N confirmed its anti-inflammatory potential on ex vivo assays performed on blood collected from cirrhotic donors.

These findings indicate that G1090N:

- Displays strong anti-inflammatory activity at the doses tested in the first-in-human study
- Effectively engages its target mechanism of action in circulating immune cells
- Modulates key pathways driving systemic inflammation, a major contributor to acute decompensated cirrhosis with or without ACLF.

Next steps

These results support further clinical development of G1090N. GENFIT will engage with regulatory authorities, including the U.S. Food and Drug Administration, to determine the best approach for progressing to Phase 2 proof-of-concept in inflammatory conditions such as ACLF where systemic immune dysregulation is a critical driver of disease progression.

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.

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PRESS RELEASE

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 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 about the future development of G1090N, including plans to advance into Phase 2 proof-of-concept studies, anticipated regulatory interactions, potential therapeutic benefits in ACLF and related conditions, and the expected progression of GENFIT's research and development programs. 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

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

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TOWARDS BETTER MEDICINE

PRESS RELEASE

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 (bdif.amf-france.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, including the Half-Year Business and Financial Report at June 30, 2025, 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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