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GENFIT Announces Discontinuation of its VS-01 Program in ACLF: VS-01 Development Refocused on UCD

Lille (France), Cambridge (Massachusetts, United States), Zurich (Switzerland), September 19, 2025 - **GENFIT (Nasdaq and Euronext: GNFT)**, a biopharmaceutical company dedicated to improving the lives of patients with rare and life-threatening liver diseases, today announced its decision to discontinue its VS-01 program in ACLF (Acute-on-Chronic Liver Failure), and reprioritize the development of VS-01 on UCD (Urea Cycle Disorder).

GENFIT's decision follows the occurrence of a peritonitis case reported as Serious Adverse Event (SAE) in the UNVEIL-IT® clinical trial evaluating VS-01 in patients with ACLF grades 1, 2 or 3a and ascites and subsequent review and feedback from the independent Data Monitoring Committee (iDMC). The committee concluded that the trial could continue but required additional data and monitoring. Despite the possibility to move ahead with the study, GENFIT decided – after considering the target population's clinical profile as well as the implications of this type of safety signal for the benefit/risk ratio of VS-01 in this indication – to discontinue both UNVEIL-IT® and the proof-of-concept study evaluating VS-01 in patients with Hepatic Encephalopathy (HE) grades 2 to 4 in the presence of Acute Decompensation (AD) or ACLF grade 1 and ascites. GENFIT would like to thank patients, families, as well as investigators and their teams involved in these two trials.

GENFIT will continue the preclinical evaluation of VS-01 in UCD, a genetically driven disorder characterized by acute hyperammonemic crisis (HAC). The condition, patients and drug administration set-up will be very different from what they were in ACLF. There is a significant unmet medical need in this indication, and based on ammonia clearance data, we believe VS-01 has the potential to be a useful therapeutic option for children affected by this disease.

GENFIT remains fully committed to ACLF and associated conditions such as Acute Decompensation (AD) or Hepatic Encephalopathy (HE). ACLF is characterized by a critical unmet medical need, with no approved treatment options for patients facing poor prognosis and life-threatening risks. Since we embarked in this therapeutic area, we have engaged in multiple KOL interactions and observed growing interest in this indication, together with clear support for our clinical strategy. This feedback reinforces our confidence in our plan and validates our positioning. In this context, we ambition to accelerate the development of the four other assets currently under development in ACLF, which are all based on different mechanisms of action and use different routes of administration. We hope to deliver positive results, as we move forward, starting with safety data and early markers of efficacy on healthy volunteers with G1090N, expected at the end of this year. Other programs in the ACLF pipeline are SRT-015, CLM-022 and VS-02-HE.

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By year-end, we also aim to share Phase 1b data in another life-threatening indication, cholangiocarcinoma (CCA). CCA is a rare type of biliary tract cancer with high mortality and limited treatment options, and GNS561 is a novel autophagy/PPT1 inhibitor currently evaluated in combination with a MEK inhibitor in CCA with KRAS mutation.

Following the discontinuation of our VS-01 program in ACLF, we anticipate a substantial reduction in our operating expenses. This will provide strategic flexibility, either as an opportunity to extend projected cash runway by at least a year versus previous guidance, i.e. beyond 2028[1], or as a means to explore new mechanistic approaches through business development initiatives aiming to tackle the multiple dimensions of the urgent gaps in ACLF care.

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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[2]) 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. 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

[1] We expect that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements beyond the end of 2028. This is based on current assumptions and programs and does not include exceptional events. This estimation assumes (i) our expectation to receive significant future commercial milestone revenue pursuant to the license agreement with Ipsen and Ipsen meeting its sales-based thresholds, (ii) drawing down all additional installments under the Royalty Financing, and (iii) the reimbursement at maturity in October 2025 of any OCEANEs not converted or repurchased and cancelled.
[2] Elafibranor is marketed and commercialized in the U.S by Ipsen under the trademark Iqirvo®.

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 GENFIT's corporate strategy and objectives, our achievement of key milestones enabling us to receive payments under our license agreement with Ipsen, the potential of Iqirvo® (elafibranor) to receive marketing authorization and successful launch and commercialization in countries other than those in which it is currently approved and commercialized, our achievement of the necessary objectives to obtain the future €55 million in additional payments under the royalty financing agreement signed with HCRx (Royalty Financing), anticipated timing for study enrollment and data readouts, in particular regarding our development programs for G1090N in the prevention and/or treatment of ACLF and for GNS561 in CCA, our ability to accelerate and continue development of our other pipeline programs, in particular those related to SRT-015, CLM-022 and VS-02 HE in ACLF, and VS-01 in UCD, as well as our financial outlook including cash flow and cash burn projections as updated following the termination of our VS-01 in ACLF research program. 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"),

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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 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.

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