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# GENFIT Announces First Patient First Visit for the Evaluation of NTZ in Subjects with Hepatic Impairment as part of its ACLF Program

**Lille, France; Cambridge, MA; November 09, 2021** - **GENFIT (Nasdaq and Euronext: GNFT)**, a late-stage biopharmaceutical company dedicated to improving the lives of patients with metabolic and chronic liver diseases, today announced the first patient first visit for the evaluation of NTZ in subjects with hepatic impairment as part of its ACLF program.

The open-label, non-randomized, 2-center, repeated-dose, parallel-group study will provide preliminary insight into NTZ pharmacokinetics (PK) and safety in the setting of hepatic impairment and will inform the potential need for dose adjustment in future studies to be conducted in patients with cirrhosis and hepatic impairment. In this study, adult subjects with moderate and severe hepatic impairment will be given NTZ 500mg twice daily for 7 days, and the PK of NTZ will be compared with the PK in volunteers without hepatic impairment.

In a dedicated pre-clinical program, NTZ demonstrated the potential to favorably act at multiple levels of pathological processes possibly leading to acute on chronic liver failure (ACLF) and death.

The initiation of this Phase 1 trial represents a key milestone in the Company's pipeline development and, upon completion, would enable GENFIT to move forward into a proof of concept study in patients with acute decompensated cirrhosis (AD) and ACLF.

ACLF is a life-threatening condition associated with chronic liver diseases. It is defined by an acute episode of hepatic decompensation that may progress to one or more extrahepatic organ failures, including the brain, kidneys, heart and/or lungs. There are currently no approved drugs<sup>1</sup> to prevent further complications and death in patients with AD or ACLF. The only therapeutic option that exists today is liver transplantation. In May 2021, GENFIT announced the launch of its new clinical program in ACLF, a therapeutic area with a high unmet medical need.

Data for this Phase 1 study will be available as early as the third quarter 2022.

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<sup>1</sup> Allen, A. Kim, WR. Moriarty, JP. Shah, ND. Larson, JJ. Kamath, PS. Time trends in the health care burden and mortality of ACLF in the US. *Hepatology*. 2016. Dec.64(6):2165-2172

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**Dr Jacqueline O’Leary, MD at the UT Southwestern Medical Center, Dallas, TX**, commented: *“ACLF is a serious condition for which the only therapeutic option is liver transplantation. There is, no doubt, a strong need for the development of a promising therapy to reduce the morbidity and mortality in these patients, as well as to provide healthcare professionals with non-surgical therapeutic options. The existing body of evidence with NTZ is encouraging. Preclinical data derived from different models of ACLF suggest a benefit on systemic inflammation and hepatic and renal function. The favorable data from these studies in disease models are supportive of investigating the potential clinical effects of NTZ in patients with AD and ACLF, and this Phase 1 study is an important first step in understanding whether NTZ can decrease systemic inflammation and prevent organ dysfunction and ACLF.”*

**Pascal Prigent, CEO of GENFIT**, stated: *“In May 2021, we announced the launch of our new clinical program in ACLF, a therapeutic area with a high unmet medical need, and today we’re excited to be starting the first trial in this new indication with NTZ. In the US only, the target population in need of treatment options corresponds to 10-30% of cirrhotic patients hospitalized<sup>2</sup>. There is currently no non-surgical therapeutic option available to them, and we hope that this first set of safety data will allow us to accelerate clinical development with a much larger trial to further evaluate efficacy.”*

### ABOUT ACLF

ACLF is a serious syndrome associated with chronic liver diseases and is defined by an acute episode of hepatic decompensation that may progress to one or more extrahepatic organ failures, including the brain, kidneys, heart and/or lungs.

ACLF is a life-threatening condition that may occur in patients with cirrhosis, which may be due to excessive alcohol consumption, viral hepatitis (B and C), Non-Alcoholic-Steatohepatitis (NASH) or a chronic cholestatic disease (e.g Primary Biliary Cholangitis or Primary Sclerosing Cholangitis).

GENFIT has long-standing expertise in drug development for severe liver diseases, from discovery to late clinical development, and is committed to the discovery of new therapies for conditions such as ACLF that have significant unmet needs and for which no approved therapies are currently available.

Concurrent with this Phase 1 assessment of NTZ, elafibranor (a dual PPAR  $\alpha/\delta$  agonist) and GFT1575 (a pan-PPAR agonist) are being evaluated in two distinct ACLF related preclinical programs. Evaluations are based on a growing body of evidence linking dysregulated energy homeostasis and development of organ failures in ACLF.

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<sup>2</sup> Hernaez et al. J. of Hepatol. 2019

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### ABOUT GENFIT

GENFIT is a late-stage biopharmaceutical company dedicated to improving the lives of patients with severe chronic liver diseases. GENFIT is a pioneer in the field of nuclear receptor-based drug discovery, with a rich history and strong scientific heritage spanning more than two decades.

Today, GENFIT has a robust and diversified pipeline, using different compounds and technologies evaluated at different development stages and in different liver diseases.

Leveraging its internal assets and in-house expertise, GENFIT's R&D is focused on cholestatic diseases and ACLF: two therapeutic areas with significant unmet medical needs. Currently, the ELATIVE™ Phase 3 clinical trial evaluating elafibranor (elafibranor is an investigational compound that has not been reviewed nor has received approval by any regulatory authority) in patients with Primary Biliary Cholangitis (PBC) is being conducted following [a successful Phase 2 clinical trial](#). Patient enrolment is anticipated to be completed in the first quarter of 2022 and topline data is expected to be announced between the end of the first quarter and the end of the second quarter 2023. A Phase 2 clinical development program is also underway with elafibranor in Primary Sclerosing Cholangitis (PSC), and a Phase 1 clinical program with nitazoxanide in ACLF has been initiated.

As part of GENFIT's comprehensive approach to clinical management of patients with liver diseases, the Company is also developing NIS4®, a new non-invasive blood-based diagnostic technology, which could enable easier identification of patients with at-risk NASH. Since May 2021, Labcorp® has commercialized NASHnext®, powered by NIS4®, for use in the clinic. GENFIT also continues to explore opportunities to obtain formal marketing authorization of an in vitro diagnostic (IVD) test.

GENFIT has facilities in Lille and Paris, France, and Cambridge, MA, USA. GENFIT is a publicly traded company listed on the Nasdaq Global Select Market and on compartment B of Euronext's regulated market in Paris (Nasdaq and Euronext: GNFT). [www.genfit.com](http://www.genfit.com)

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### GENFIT FORWARD LOOKING STATEMENTS

This press release contains certain forward-looking statements with respect to GENFIT, including those within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the pharmacokinetics, safety and tolerability of NTZ in subjects with moderate and severe hepatic impairment and healthy volunteers, the potential need for dose adjustment in future studies in cirrhotic and hepatic impaired patients, the potential clinical effects of NTZ in patients with AD and ACLF, the potential of this first set of safety data to lead us to the next clinical development stage in our ACLF program and the timelines for the data readout of the Phase 1 study in ACLF. The use of certain words, including “consider”, “contemplate”, “think”, “aim”, “expect”, “understand”, “should”, “aspire”, “estimate”, “believe”, “wish”, “may”, “could”, “allow”, “seek”, “encourage” or “have confidence” or (as the case may be) the negative forms of such terms or any other variant of such terms or other terms similar to them in meaning is intended to identify forward-looking statements. Although the Company believes its projections are based on reasonable expectations and 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 other things, the uncertainties inherent in research and development, including in relation to safety, biomarkers, progression of, and results from, its ongoing and planned clinical trials, review and approvals by regulatory authorities of its drug and diagnostic candidates, impact of the ongoing COVID-19 pandemic, exchange rate fluctuations and the Company’s continued ability to raise capital to fund its development, as well as those risks and uncertainties discussed or identified in the Company’s public filings with the French *Autorité des Marchés Financiers* (“AMF”), including those listed in Chapter 2 “Main Risks and Uncertainties” of the Company’s 2020 Universal Registration Document filed with the AMF on 23 April 2021 under n° D.21-0350, which is available on the Company’s website ([www.genfit.com](http://www.genfit.com)) and on the website of the AMF ([www.amf-france.org](http://www.amf-france.org)) and public filings and reports filed with the U.S. Securities and Exchange Commission (“SEC”) including the Company’s 2020 Annual Report on Form 20-F filed with the SEC on April 23, 2021 and subsequent filings and reports filed with the AMF or SEC, or otherwise made public by the Company. In addition, even if the Company’s results, performance, financial condition and liquidity, 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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