

GENFIT
TOWARDS BETTER MEDICINE

PRESS RELEASE

GENFIT Highlights Data from Clinical Studies of Nangibotide, Supporting Its Advancement into ACLF with Phase 2 Data Expected in 2027

- **Comprehensive clinical and scientific data supporting Phase 2 development of nangibotide in ACLF unveiled to leading experts during AASLD The Liver Meeting®**
- **Strong biological rationale in ACLF: TREM-1 modulation is designed to dampen excessive inflammatory amplification without directly targeting immune recognition**
- **Prior Phase 2 clinical evidence demonstrated a well-characterized safety profile, efficacy signals in a subgroup of patients from septic shock trial, improved clinical status and lower mortality in patients with severe COVID-19**
- **UPWARD Phase 2a proof-of-concept trial expected to be initiated by end of 2026, data expected second half of 2027**

Lille (France), Cambridge (Massachusetts, United States), November 9, 2026 - **GENFIT (Euronext: GNFT)**, a biopharmaceutical company dedicated to improving the lives of patients with rare and life-threatening liver diseases, yesterday unveiled an in-depth review of nangibotide, its new lead asset in acute-on-chronic liver failure (ACLF), during a scientific event gathering leading ACLF experts in Denver during AASLD The Liver Meeting®.

Professor Jennifer C. Lai, MD, MBA, Transplant Hepatologist, Endowed Professor of Liver Health & Transplantation, University of California, San Francisco (UCSF) commented: *"The unmet need in ACLF remains tremendous, particularly for patients in the ICU who can rapidly progress to multi-organ failure. What is especially exciting about nangibotide is that we are not starting from scratch: the program already benefits from substantial Phase 2 clinical experience and proof-of-concept in acute inflammatory conditions characterized by organ dysfunction. This gives us a rare opportunity to bring an already extensively studied clinical-stage candidate into ACLF and explore whether those signals can translate into meaningful benefit for these critically ill patients."*

Strong biological rationale for TREM-1 modulation in ACLF

ACLF presents a major therapeutic challenge: controlling excessive systemic inflammation, a key driver of organ failure, without further compromising an already dysfunctional immune response. By modulating TREM-1, an amplifier of inflammation, nangibotide is designed to dampen excessive inflammatory amplification without directly targeting immune recognition itself.



GENFIT
TOWARDS BETTER MEDICINE

PRESS RELEASE

This mechanism provides a strong biological rationale for nangibotide in ACLF, where TREM-1 pathway activation has been reported as patients progress from acute decompensation to acute-on-chronic liver failure, and has been associated with disease severity and adverse outcomes.

Prior Phase 2 clinical data highlight a favorable safety profile and encouraging efficacy signals

Nangibotide has generated substantial clinical experience across 416 exposed subjects, including three Phase 2 studies in septic shock and COVID-19, with an overall safety profile similar to placebo and no safety signal identified.

Efficacy signals were observed across both indications. In a subgroup of 118 septic shock patients with elevated levels of soluble TREM-1 (sTREM-1), nangibotide showed a 2.5-point greater reduction in SOFA[1] score versus placebo at Day 5, with statistically significant improvements in respiratory, cardiovascular and renal components, as well as favorable trends in Day 28 mortality and other clinical outcomes. In 219 patients with COVID-19, nangibotide was associated with improved clinical status and lower Day 28 mortality.

Together, this favorable safety profile and Phase 2 efficacy data provide clinical validation of the therapeutic rationale across acute inflammatory conditions characterized by organ dysfunction and support the development of nangibotide in ACLF, where systemic inflammation and multi-organ dysfunction are central features.

Advancing nangibotide into the UPWARD Phase 2 study in ACLF

The planned Phase 2a proof-of-concept trial is a placebo-controlled, randomized study designed to evaluate the safety of nangibotide in patients with ACLF grade 2 and a bacterial infection. Patients will be randomized to receive nangibotide or placebo (according to a 2:1 ratio), each administered as a continuous intravenous infusion for 3 to 7 days in addition to the standard of care. The primary endpoint of the trial is safety. The secondary endpoints will be pharmacokinetics. Exploratory endpoints will assess signals of efficacy.

The UPWARD trial is expected to initiate by the end of 2026, subject to regulatory approval, and initial data are expected in the second half of 2027.

END

[1] Sequential Organ Failure Assessment



GENFIT
TOWARDS BETTER MEDICINE

PRESS RELEASE

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 (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 second-line treatment of Primary Biliary Cholangitis (PBC). Iqirvo® is now marketed in several countries.[2] 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) 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 development and potential therapeutic profile of nangibotide, the potential role of TREM-1 in Acute-on-Chronic Liver Failure (ACLF), the initiation, design, conduct, timing and results of future clinical trials, including the planned Phase 2a proof-of-concept study in ACLF, the potential clinical benefits, safety profile and therapeutic value of nangibotide, the potential relevance on future clinical investigations of efficacy signals and safety data observed in prior clinical studies conducted in other indications, the expected timing of data readouts, regulatory interactions and future development activities, as well as the Company's strategic plans and objectives. 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

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



GENFIT
TOWARDS BETTER MEDICINE

PRESS RELEASE

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 relating to the successful integration and development of nangibotide following its acquisition by the Company; the ability to initiate and complete clinical trials within anticipated timelines; uncertainties associated with patient enrollment, site activation and trial execution; the possibility that clinical trial results may not support further development of nangibotide; safety findings that may emerge during future studies and; regulatory requirements, interactions and decisions and manufacturing and supply considerations. No assurance can be given that the planned Phase 2a study will demonstrate efficacy, safety, or clinical benefit, nor that nangibotide will ultimately receive regulatory approval for any indication. Those risks and uncertainties also include those 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 2025 Universal Registration Document filed on April 3, 2026 (no. 26-0221) 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 reports filed with the AMF or otherwise made public, by the Company, including the 2026 Half-Year Business and Financial Report. 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

Kevin Gardner – Life Science Advisors | kgardner@lifesciadvisors.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