



# GENFIT Announces Advances Across its ACLF Pipeline at AASLD The Liver Meeting® 2025

- Several posters and presentations featuring new data on three ACLF programs, including G1090N (NTZ reformulation) disease model data, new real-world data and biomarker insights in cirrhosis
- New Iqirvo® PBC and PSC data to be presented by partner Ipsen, underscoring its potential in rare cholestatic liver diseases

**Lille (France), Cambridge (Massachusetts, United States), Zurich (Switzerland), October 28, 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 participation at the upcoming American Association for the Study of Liver Diseases (AASLD) The Liver Meeting® 2025 in Washington, D.C., November 7-11, 2025.

GENFIT will present new data highlighting the potential of its pipeline in Acute on-Chronic Liver Failure (ACLF):

**G1090N** (reformulation of nitazoxanide) – **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* 

Authors: Bobowski-Gerard, M. *et al* Session: Acute-on-Chronic Liver Failure

Date & Time: November 10, 2025 (8.00 am - 5.00 pm)

G1090N is the lead program in GENFIT's ACLF pipeline. Clinical safety data and markers of early efficacy are expected at the end of the year.

**SRT-015** – **Poster** #**4171**: ASK1 inhibitor SRT-015 reduces systemic inflammation while promoting immune host defense mechanisms in preclinical in vitro and in vivo models related to ACLF

Authors: Legry, V. et al

Session: Acute-on-Chronic Liver Failure

Date & Time: November 10, 2025 (8.00 am – 5.00 pm)

**CLM-022** – **Poster #4565**: Efficacy of CLM-022, an inhibitor of the NLRP3 inflammasome, in vivo and in vitro Pathogen-Associated Molecular Patterns (PAMPs)-induced disease models Authors: Vidal, G. et al





Session: Inflammation and Immunobiology

Date & Time: November 10, 2025 (8.00 am - 5.00 pm)

A poster on the *Effect of VS-01 on systemic inflammation and liver injury in a rat model of endotoxemia* will also be presented by GENFIT. While VS-01 has been discontinued in ACLF, pre-clinical studies continue in Urea Cycle Disorder (UCD).

Other posters and oral presentations covering ACLF management and diagnostic and prognostic biomarkers in cirrhosis will be presented:

#### Real-World Evidence

**Oral presentation #0086**: A RWE-based characterization of patients admitted in US hospital for an event of acute decompensation highlights differences in the management of inpatients

Presenters: Trebicka, J. et al

Session: Emerging Determinants and Outcomes in Liver Disease: From Population Trends

to Patient-Centered Insights

Date & Time: November 10, 2025 (9.15 am – 9.30 am)

**Poster #2325**: Impact of bacterial infection on clinical outcomes in patients with acute decompensation: real-world evidence insights

Authors: Fernández, J. et al

Session: Portal Hypertension and Other Complications of Cirrhosis

Date & Time: November 8, 2025 (8.00 am - 5.00 pm)

#### Patient journey

**Poster (distinction) & Oral presentation #4127**: Systemic challenges in managing Acute-on-Chronic Liver Failure (ACLF) in the U.S.: diagnostic delays, referral barriers, and fragmented post-discharge care

Authors: Karvellas, J. C. et al

Session: Acute on-Chronic Liver Failure Special Interest Group

Date & Time: November 7, 2025 (3.45 pm - 4.15 pm)

#### Diagnostic and prognostic biomarkers in cirrhosis

**Poster (distinction) #2022**: Single circulating biomarkers sVCAM-1 and TSP2 achieved effective prognostic performances for the detection of fibrosis progression to cirrhosis

Authors: Ratziu, V. et al

Date: November 8, 2025 (8.00 am - 5.00 pm)





**Poster #2050**: Combining sVCAM-1 or TSP2 with FIB-4 for an improved detection of patients with

cirrhosis

Authors: Francque, S. et al

Date & Time: November 8, 2025 (8.00 am - 5.00 pm)

#### New data presented by Ipsen in PBC and PSC

The set of data to be presented underscores Iqirvo®'s potential to address both disease progression and symptom burden across rare cholestatic liver diseases.

- Ipsen will be presenting six abstracts<sup>1</sup> from the ongoing Iqirvo® (elafibranor) ELATIVE® study in **Primary Biliary Cholangitis** (PBC), including two late-breaking presentations and one abstract in Primary Sclerosing Cholangitis (PSC).
- Data in PBC continue to support Iqirvo®'s efficacy and safety profile towards modifying disease progression while improving multiple key symptoms including fatigue and pruritus (itch), in patients living with PBC.
- Data in Primary Sclerosing Cholangitis (PSC) from the elafibranor ELMWOOD Phase 2 study provide insights into the sustained efficacy and tolerability profile of elafibranor 120mg in patients with PSC.

GENFIT will also organize two events focusing on ACLF:

- ACLF Insights (November 7, 2025)
- ACLF Patient Advocacy Council (November 9, 2025)

**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

<sup>&</sup>lt;sup>1</sup> https://www.ipsen.com/statement/ipsen-to-present-data-across-five-rare-liver-diseases-at-aasld-2025-3163092/





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 precommercialization 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.<sup>2</sup>

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 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 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. <a href="https://www.genfit.com">www.genfit.com</a>

#### ABOUT AMERICAN ASSOCIATION FOR THE STUDY OF LIVER DISEASES (AASLD)

AASLD is the leading organization of scientists and health care professionals committed to preventing and curing liver disease. They foster research that leads to improved treatment options for millions of liver disease patients, and advance the science and practice of hepatology through educational conferences, training programs, professional publications, and partnerships with government agencies and sister societies. Every year AASLD organizes The Liver Meeting® where the global hepatology community comes together. With access to the latest breakthroughs in liver disease research, practical tools for patient care, and a powerful network of experts shaping the future of hepatology, the program offers something for everyone committed to improving liver health.

#### FORWARD LOOKING STATEMENTS

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





This press release contains certain forward-looking statements, including those within the meaning of the Private Securities Litigation Reform Act of 1995. 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, 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 (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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