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GENFIT: positive late-breaking Phase 2 data for elafibranor in Primary Sclerosing Cholangitis (PSC) to be presented by Ipsen at EASL Congress 2025

Lille (France), Cambridge (Massachusetts, United States), Zurich (Switzerland), April 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 that Ipsen will be presenting data from its late-breaking abstract on elafibranor, highlighting favorable safety profile and significant efficacy in Primary Sclerosing Cholangitis (PSC), at the European Association for the Study of the Liver (EASL) on May 10, 2025 at 11.15 CET.

Efficacy results of Ipsen's Phase 2 ELMWOOD trial (LB25222/OS089) showed that patients on elafibranor had significant dose-dependent reductions in alkaline phosphatase (ALP), with patients on elafibranor 80 mg and 120 mg having significant reductions at week 12 versus placebo (−103.2 U/L and −171.1 U/L vs +32.1 U/L; $p < 0.0001$), and improvements observed as early as week 4. Similar findings were seen in other biochemical liver parameters, including alanine aminotransferase (ALT) and gamma-glutamyl transferase (GGT), which are important biochemical markers of disease progression. Patients on elafibranor also had stabilization in Enhanced Liver Fibrosis (ELF), a non-invasive marker of liver fibrosis, versus patients on placebo at week 12. Additionally, patients on elafibranor 120 mg experienced improvements in pruritus compared with patients on placebo according to the Worst Itch Numeric Rating Scale (WI NRS) score (-0.96 vs -0.28; $p<0.05$).[1]

Elafibranor, a 'first-in-class' molecule marketed and commercialized in the United States, the European Union and the UK by Ipsen under the trademark Iqirvo® since June 2024 for the treatment of Primary Biliary Cholangitis (PBC), was developed by GENFIT, from initial discovery to the conclusion of a 52-week Phase 3 clinical study. Ipsen licensed the exclusive worldwide rights (except China, Hong Kong, Taiwan and Macau) to elafibranor from GENFIT in 2021.

Pascal Prigent, CEO of GENFIT, commented: *"We continue to be very pleased with Ipsen's commitment to developing elafibranor, and the results from the ELMWOOD Phase 2 trial further reinforce our belief in elafibranor's potential to address serious liver diseases."*

[1] Levy. C. et al. Elafibranor for primary sclerosing cholangitis: The ELMWOOD phase II randomized controlled trial. European Association for the Study of the Liver (EASL) Congress, 2025. Abstract LB25222

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For more information on the press release, click on the following link : Late-breaking elafibranor primary sclerosing cholangitis (PSC) data demonstrates favorable safety profile and significant efficacy in second potential rare liver disease indication

ABOUT PSC

PSC is a rare, chronic liver disease characterized by inflammation and scarring of the bile ducts, which can lead to liver damage and eventually liver failure. The exact cause of PSC is unknown, but it is often associated with other autoimmune conditions, such as inflammatory bowel disease. Symptoms of PSC can include itching, fatigue, jaundice, and abdominal pain. Over time, PSC can result in complications like bile duct infections, liver cirrhosis, and an increased risk of liver cancer. Currently, there are no U.S Food and Drug Administration (FDA) or European Medicines Agency (EMA) approved therapies for the treatment of PSC.

ABOUT ELAFIBRANOR

Elafibranor is an oral peroxisome proliferator-activated receptor (PPAR) agonist, which exerts an effect on PPARα and PPARδ. Activation of PPARα and PPARδ decreases bile toxicity and improves cholestasis by modulating bile acid synthesis, detoxification and transporters. Activation of PPARα and PPARδ also has anti-inflammatory effects by acting on different pathways. In 2019, elafibranor was granted Breakthrough Therapy Designation by the FDA in adults with PBC who have an inadequate response to ursodeoxycholic acid (UDCA) the existing first-line therapy for PBC. Elafibranor under the brand name IQIRVO®[2] was granted FDA accelerated approval in June 2024, EU conditional approval by the European Commission (EC) in September 2024 and UK Medicines and Healthcare products Regulatory Agency (MHRA) approval in October 2024, for the treatment of PBC in combination with ursodeoxycholic acid (UDCA) in adults who have an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA. The FDA, EC and MHRA approvals are contingent on the further verification of clinical benefit. Elafibranor was developed by GENFIT. Ipsen licensed the exclusive worldwide rights (except China, Hong Kong, Taiwan and Macau) to elafibranor from GENFIT in 2021.

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 has built up a diversified and rapidly expanding R&D

[2] Iqirvo®, and NIS2+® are registered trademarks of GENFIT SA

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portfolio of programs at various stages of development. The Company focuses on Acute-on-Chronic Liver Failure (ACLF). Its ACLF franchise includes five assets under development: VS-01, G1090N, SRT-015, CLM-022 and VS-02-HE, based on complementary mechanisms of action using different routes of administration. Other assets target 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[3]) by the FDA, the EMA and the MHRA in the UK for PBC. Beyond therapies, GENFIT also has a diagnostic franchise including NIS2+® in Metabolic dysfunction-associated steatohepatitis (MASH, formerly known as NASH for non-alcoholic steatohepatitis) and TS-01 focusing on blood ammonia levels. 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. 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 the potential of elafibranor in PSC. 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, 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 2023 Universal Registration Document filed on April 5, 2024 (no. D.24-0246) 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

[3] Elafibranor is marketed and commercialized in the U.S by Ipsen under the trademark Iqirvo®.

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public documents and reports filed with the U.S. Securities and Exchange Commission ("SEC"), including the Company's 2023 Annual Report on Form 20-F filed with the SEC on April 5, 2024, the Half-Year Business and Financial Report dated September 19, 2024 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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